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INFECTED BLOOD INQUIRY

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Summary

In the 1970s and 1980s approximately five hundred Scots with haemophilia were infected with the hepatitis C virus as a result of their NHS treatment.[1] Eighty-seven were also infected with HIV.[2] For the last twenty-five years the Scottish haemophilia community has sought to discover how these infections, described by Lord Robert Winston as 'the worst treatment disaster in the history of the NHS',[3] were allowed to happen.

The victims of this disaster have long suspected that procrastination over the introduction of tighter safety rules compromised the safety of blood products. Why was Scotland slow compared to other developed countries to introduce heat treatment and donor testing? Were the risks of concentrated clotting factors adequately assessed before this treatment was rolled out? Were patients adequately warned about the risks of their treatment? Did the ability of the Scottish National Blood Transfusion Service to operate its facilities under Crown Immunity contribute towards lax safety and hygiene standards? Did delays informing patients that they had contracted viruses lead to partners and spouses being exposed to avoidable risks?

The ethics of medical research are also the cause of ongoing concern. People with haemophilia suspect that, without their knowledge or consent, they were the subjects of various research projects, including studies mapping the progression of the HIV virus. In addition, questions have been raised about whether counselling provisions were adequate given the terrible psychological toll of the contaminated blood disaster. Haemophilia Scotland has heard reports of patients having difficulty accessing treatments such as liver transplants and endoscopies. Interferon-ribavirin treatment for hepatitis C has a low success rate and severe side effects for people with haemophilia.[4]

The Penrose Inquiry is timely. The current debate about donor testing for vCJD has strong echoes of the debate about the introduction of a donor test for non-A, non-B hepatitis, which continued unresolved throughout the 1980s. This shows that lessons still have not been learned. This submission will conclude that many of the infections caused by contaminated blood products could have been avoided if all available precautions had been introduced immediately. Swifter steps should have been taken to improve the safety of blood products, and the use of factor concentrates should have been minimised in the meantime. The Scottish haemophilia community is delighted that these matters are finally being investigated by a formal Inquiry, and hopes that the lessons can now be learned.

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[1] Scottish Parliament Health Committee, Follow Up Submission by the Scottish National Blood Transfusion Service, SP Paper 398, 1 (2001), 3.4.6.
[2] Scottish Parliament Health Committee, Follow Up Submission by the Scottish National Blood Transfusion Service, SP Paper 398, 1 (2001).
[3] BBC News Monday 19th February 2007.
[4] Franchini et al, 'Treatment of Chronic Hepatitis C in Haemophiliac Patients with Interferon and Ribavirin: a Metanalysis', Journal of Antimicrobial Chemotherapy, 19th March 2008, http://jac.oxfordjournals.org/cgi/reprint/dkn119v1; The Side Effects of Interferon/Ribarvirin Combination, MedicineNet.com, http://www.medicinenet.com/script/main/art.asp?articlekey=14529, (both accessed 7th June 2010 – APPENDIX ONE]

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The Manufacture of Blood Products

Factor concentrates, produced from thousands of individual blood donations, emerged as the standard medical treatment for people with haemophilia in the late 1970s. Previously, haemophilia was treated using cryoprecipitate, a product manufactured from between one and six units of blood. While factor concentrates may have been more convenient to administer than cryoprecipitate, the risk of transmitting viruses was instantly multiplied a thousand times.

There are four stages at which the Scottish National Blood Transfusion Service (SNBTS), as manufacturers of the product, could have reduced the risks to patients and wider public health.

1. Improving donor selection, rejecting donations from individuals known to have a statistically high risk of blood-borne viruses. This would include drug users or prisoners.
2. Moving as swiftly as possible to develop the technology to kill any viruses in blood products through heat treatment or pasteurisation.
3. Testing blood donors for known viruses as soon as such tests were available.
4. Minimising the risk of external contamination by processing blood donations in a clean and hygienic environment.

The opening section of this submission will discuss documents which suggest that the Scottish National Blood Transfusion Service failed to introduce these possible safety precautions swiftly and adequately.

1.1 Donor Selection and Prison Blood

Prior to the introduction of heat treatment and donor testing, it was essential to avoid collecting blood donations from high-risk donors. This would include any group of people known to have a high prevalence of blood-borne viruses such hepatitis, including prisoners and intravenous drug users. Although this was a crude way of protecting the safety of the blood supply more reliable alternatives had not yet been developed, which meant that donor selection procedures should have erred on the side of caution.

Why did the Scottish National Blood Transfusion Service continue to collect blood donations from prisons and borstals until at least 1984? By this time, the long-term health implications of non-A, non-B hepatitis were clear and a new virus, which later became known as HIV, had started to claim victims in Scotland.

Moreover, the SNBTS had long been advised to cease collecting blood donations from prisons and borstals. In spring 1982 inspectors reporting on the Dundee and Edinburgh Blood Transfusion Centres explained why they did not consider prisons and borstals to be safe sources of blood donations.

The report gave the following specific reasons why prison blood was considered unsafe:

> *'12 (a) Prison Medical Officers are often not involved in assessing the suitability of donors.*
> *13 (b) The increased risk of infection associated with prison populations and the increased risk of transmitting disease through such donations.*
> *14 (c) The unreliable answers to the pre-donation questionnaire that can occur in such environments as well as the motivation of some of the donors.'* [5]

This recommendation should have been implemented promptly. Instead, the Scottish National Blood Transfusion Service procrastinated. The report was not formally acknowledged until March 1983, a full year after it was written, when it was noted that the 'Medicines Inspector had commented adversely on the practice of collecting blood in prisons and borstal institutions'. [6] The SNBTS decided to ask the Working Party on the Selection and Care of Blood Donors to consider the issue. In September 1983 the SNBTS was still 'unable to reach a consensus', despite being informed that 'the practice was diminishing in all regions in England and Wales.'[7]

It is unclear when, precisely, SNBTS eventually stopped collecting blood donations from prisons and borstals. Since no course of action had been agreed by late 1983, this dangerous practice must have continued until at least 1984, and perhaps beyond. Such irresponsible donor selection policies meant that haemophilia patients were put at significant avoidable risk.

1.2 Donor Testing

Donor selection cannot exclude would-be donors who have picked up a blood-borne virus despite appearing to have a low-risk lifestyle. Further lines of defence are needed. It is therefore best practice to supplement the exclusion of high-risk groups with the individual testing of donors for specific viruses. **Documents reveal that there was significant procrastination over introducing a donor test for non-A, non-B hepatitis** (as hepatitis C was formally known).[8]

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[5] Inspectors' Report following visit to East of Scotland Blood Transfusion Centre, Dundee (Nine Wells), 25 March 1982. [APPENDIX TWO] See also report of inspectors' Visit to Edinburgh and SE Scotland BTS, 10-11 March 1982 and 10-12 May 1982 [APPENDIX THREE].

[6] Scottish National Blood Transfusion Service, Minutes of Directors' Meeting held in SNBTS Headquarters Unit on Tuesday 29 March 1983. [APPENDIX FOUR]

[7] Scottish National Blood Transfusion Service, Minutes of Directors' Meeting held in BTS Headquarters Unit on Tuesday 13 September 1983. [APPENDIX FIVE]

[8] Non-A, Non-B Hepatitis (NANBH) was the old name for hepatitis C. The virus was renamed in 1989 following the discover of the causative virus in 1988.

Prior to its formal identification as hepatitis C in 1988 non-A, non-B hepatitis was diagnosed using 'surrogate tests'.[9] These tests looked for markers such as raised liver enzymes. Surrogate tests could significantly reduce the number of non-A, non-B infected blood donations that reached the blood supply. Adopting the logic that some protection against this deadly virus was better than no protection, the German and Italian blood services introduced ALT testing (a surrogate test) in 1965 and 1970 respectively.

Because awareness of the long-term danger of non-A, non-B hepatitis was high by the mid 1980s, [10] 'surrogate tests' became widely adopted in developed countries. In 1986, France and the USA introduced a combination of ALT testing and anti-HBc testing, the most reliable type of 'surrogate test'. Discussions in the Scottish National Blood Transfusion Service directors' meeting of June 1986 minutes reflected this trend. It was minuted that:

> 'There was increasing evidence that the USA and several European countries were introducing anti-HBc and/or ALT testing of blood donors in an effort to minimise the risks of NANBH transmission through blood and blood products. Dr Cash believed that the SNBTS would soon come under pressure from clinicians to introduce testing.'[11]

In March 1987 the SNBTS directors decided that a surrogate test should be introduced in Scotland. It was resolved:

> 'to recommend to the SHHD that surrogate testing for NANBH should be implemented with effect from 1 April 1988 as a national development requiring strictly new funding. Each Director should let Dr Cash know what funds would be required in his/her region, assuming that both core testing and ALT would be undertaken in the Transfusion Centres.'[12]

Following their decision to introduce a surrogate test, the SNBTS directors took the unusual step of writing to the Lancet in July 1987. They wrote that 'the introduction of surrogate marker testing for NANBH was now virtually inescapable'.[13] They gave three reasons for reaching this conclusion:

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[9] 'Surrogate' tests included ALT testing (which measured liver enzyme levels) and anti-HBc testing, which tested for hepatitis B. Many 'surrogate tests' used a combination of these two tests.

[10] C R M Hay, F E Preston, DR Triger and JCE Underwood, 'Progressive Liver Disease in Heamophilia: An Understated Problem', *The Lancet*, June 29 1985 p 1495. In 1985 four eminent English haematologists published a paper in the Lancet describing worrying biopsy results from an 8-year study of 79 unselected patients with haemophilia. They concluded that 'although few reports of death attributable to liver disease in haemophilia have yet appeared, we predict that this will become more common.' [APPENDIX SIX]

[11] Scottish Blood Transfusion Service, Minutes of a Directors' Meeting held in the HQ unit on 25th June 1986, p5. [APPENDIX SEVEN]

[12] Scottish National Blood Transfusion Service, Minutes of a Directors' Meeting held in the HQ Unit on 3 March 1987, p 6. [APPENDIX EIGHT]

[13] D B L McClelland, J D Cash, R Mitchell, S Urbaniak, E Brookes, W Whitrow and R J Perry, 'Testing Blood Donors for Non-A, Non-B Hepatitis: Irrational, Perhaps, But Inescapable', The Lancet, July 4, 1987, Vol 330, Issue 8549, p36. [APPENDIX NINE]

(1) 'The impending introduction of European legislation introducing strict product liability.' This suggests concern about liability was more important than patients' well being.
(2) 'Even if surrogate marker screening would only modestly reduce the level of infectivity in these products, many would argue that some improvement is better than none.' This argument could have been used many years before.
(3) If standards of blood safety were lower in the UK than in the United States, Germany and France, the 'local NHS blood supplier [would] have trouble shrugging off accusations of providing a second-class product.'[14]

The letter to the Lancet also drew attention to the high cost of treating cirrhosis of the liver. It argued that 'the cost of preventing morbidity by surrogate market testing for NANBH may be no greater, and could be less, than those which are accepted for established screening programmes.' [15] **Given that the SNBTS directors were clearly convinced of the merits of introducing a surrogate test, why was this decision not implemented?** Later justifications that surrogate testing was not introduced because of the number of 'false positives' that it generated are not supported by minutes of SNBTS meetings, or by the letter that was written to the Lancet. In the end, a surrogate test was never introduced, and there was no donor test to protect against non-A, non-B hepatitis or hepatitis C until 1991.

The SNBTS directors were right about the legal consequences of failing to introduce the surrogate test by 1988. In 2001, 114 claimants successfully sued the English National Blood Authority for damage caused by defective blood products using the Consumer Protection Act 1987. He held that 'surrogate testing should have been in place by March 1988 and thus, like France, the United Kingdom would have run the new routine screening alongside the surrogate tests from 1 March 1990 onwards.' [16] NHS Scotland made payments to Scottish people whose circumstances were analogous to those who had benefited from the High Court judgment. Twenty people who had been infected with hepatitis C from blood products administered by NHS Scotland received compensation as a result. Once again, procrastination over introducing new safety measures led to infections that were entirely avoidable.

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[14]D B L McClelland, J D Cash, R Mitchell, S Urbaniak, E Brookes, W Whitrow and R J Perry, 'Testing Blood Donors for Non-A, Non-B Hepatitis: Irrational, Perhaps, But Inescapable', The Lancet, July 4, 1987, 2(8549), pp36-37. [APPENDIX NINE]
[15] D B L McClelland, J D Cash, R Mitchell, S Urbaniak, E Brookes, W Whitrow and R J Perry, 'Testing Blood Donors for Non-A, Non-B Hepatitis: Irrational, Perhaps, But Inescapable', The Lancet, July 4, 1987, 2(8549), pp36-37. [APPENDIX NINE]
[16] A and Others v The National Blood Authority and Others [2001] EWHC QB 446.

1.3 Processing Facilities

Once collected from donors, blood donations are pooled and fractionated to produce concentrated clotting factor. At this stage, sterile conditions and constant refrigeration are essential. Unfortunately, inspectors' reports from the early 1980s demonstrate that basic standards of hygiene were not met.

The 1982 Medicines Inspectors' report into the Edinburgh facilities stated that 'existing facilities are quite inadequate and must rank amongst the worst seen anywhere.'[17] The following comments are a small sample of the concerns raised in the report:

- 'there were problems with 'blunt needles, pin-holed bags, fungally contaminated outers, splits in the rubber segment of the donor tube'.
- 'there is no doubt that the existing facilities for the processing and handling of blood are grossly deficient and would have been quite unacceptable'.
- 'the existing issue facility is most unsatisfactory – it is overcrowded and blood may be left for up to an hour at ambient temperature'.
- the pooling facility was 'most unsatisfactory' because 'there are too many other activities nearby as well as draughts from opening windows'. [18]

Overall, the report into the Edinburgh facility stated that blood products were being processed in conditions that were not sterile. The report concluded that 'even the proposed upgrading will not convert this into a Clean Room environment.' [19] Why, then, were these facilities not shut down following the 1982 inspectors' reports?

In 1981 the Scottish National Blood Transfusion Service's manufacturer's licence was due for renewal. After taking fresh legal advice, the SNBTS decided to use Crown Immunity rather than renewing its manufacturers' licence.[20] This meant that the Medicine Inspectors' reports were only advisory.

The Medicines Inspectors' reports reveal that SNBTS was not an organisation operating at the forefront of practice. At this time, there was no enforceable system to ensure high standards of processing.

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[17] Inspectors' Report, Visit to Edinburgh and SE Scotland BTS, 10-11 March 1982 and 10-12 May 1982, Mr D R S Warburton and Mr D Haythornthwaite. [APPENDIX THREE]
[18] Inspectors' Report, Visit to Edinburgh and SE Scotland BTS, 10-11 March 1982 and 10-12 May 1982, Mr D R S Warburton and Mr D Haythornthwaite. [APPENDIX THREE]
[19] Inspectors' Report, Visit to Edinburgh and SE Scotland BTS, 10-11 March 1982 and 10-12 May 1982, Mr D R S Warburton and Mr D Haythornthwaite. [APPENDIX THREE]
[20] Oral Evidence of Dr Peter R Foster to the Archer Inquiry, Wednesday 19th September 2007, p28 lines 12-20.

1.4 The Introduction of Heat Treatment

Since the early 1980s, perhaps the most powerful tool in the fight against viruses in blood products has been heat treatment. Unfortunately, records demonstrate that SNBTS was late introducing heat treatment, both at a level that would kill the HIV virus (68° centigrade for 24 hours) and at a heat that would kill non-A, non-B hepatitis (80° for 72 hours).

A confidential memorandum in November 1985 noted with concern that patients were still seroconverting to HTLV III (later known as HIV) despite receiving heat-treated blood. The memorandum raised concerns that the level of heat treatment at the Liberton plant was inadequate. The memorandum stated that:

> 'Certain heat-treated products are not being subjected to sufficient inactivation. There is considerable variation between the methods used by commercial firms and in particular the Protein Fractionation Laboratory in Liberton in Scotland introduced on a short-term basis a very quick method which they thought might inactivate the virus at the beginning of the year. I believe that it is this latter which may be implicated in the information that I have received' [about the continued seroconversion of patients receiving heat-treated blood]. [21]

This memorandum raised concerns that people with haemophilia were continuing to contract HIV from their NHS treatment because SNBTS blood was insufficiently heated. Therefore, although SNBTS claims that Scotland was the first country in the world to move over completely to heat treated factor VIII,[22] its heat treatment was insufficient.

By late 1985 SNBTS blood was being heat treated to a level that would kill the HIV virus. Unfortunately, previous investigations have confirmed that the Scottish National Blood Transfusion Service was also eighteen months behind the Blood Products Laboratory in Elstree in supplying blood products heated to a temperature that would kill the non-A non-B hepatitis virus.[23] By November 1985 the Blood Products Laboratory was convinced that 'there is good evidence that the prolonged and high temperature treatment [...] is inactivating the non-A non-B agent.' However, this innovation (heat-treating blood at 80° C for 72 hours) was not adopted in Scotland until 1987.

In relation to both heat treatment for HIV and non-A non-B hepatitis, there is worrying evidence that SNBTS was not operating at anywhere near the cutting edge of technology. Questions remain about whether all available avenues of cooperation between SNBTS and BPL were explored. Did the SNBTS take every possible step to replicate successful heat treatment techniques discovered by BPL as quickly as possible? If it was not possible to replicate these technological advances immediately, could SNBTS have arranged for its blood products to be processed at the BPL plant? Every delay meant more lives ruined by HIV and hepatitis C infections that could have been avoided.

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[21] Memorandum 'In Confidence', 28th November 1985. [APPENDIX NINE A)

[22] Oral Evidence of Dr Peter R Foster to the Archer Inquiry, Wednesday 19th September 2007, p49, lines 23-25.

[23] Scottish Executive Health Department, *Hepatitis C and Heat Treatment of Blood Products for Haemophiliacs in the Mid-1980s*, October 2000, p1.

1.5 Summary of Delays Introducing Safety Measures

Official documents and minutes reveal that the Scottish National Blood Transfusion Service was operating far from the cutting edge of technology. Inspectors' reports show that processing facilities were unhygienic, and that appropriate refrigeration was not used. The same reports also show that blood donations were actively collected from prisons until at least 1984, a full two years after inspectors recommended that this practice should cease.

Minutes of SNBTS directors' meetings tell us that a decision was made to introduce a surrogate test for non-A, non-B hepatitis in spring 1987. However, no surrogate test was introduced, and recipients of blood and blood products were denied the safeguard of a donor test for this virus until 1991.

Previous investigations have established that SNBTS was eighteen months behind the Blood Products Laboratory in Elstree introducing sufficient heat treatment to kill the non-A, non-B hepatitis virus. However, a confidential memorandum reveals that there were also delays introducing heat treatment at a level sufficient to de-activate the HIV virus.

The replacement of cryoprecipitate with factor concentrates as the standard treatment for haemophilia meant vastly-increased risks of virus infection for people with haemophilia. Without improved safety precautions to compensate for this extra risk, the mass infection of this patient group was a disaster waiting to happen. No concrete steps were taken to improve the safety of concentrated blood products until the mid 1980s, by which time almost every Scottish haemophilia patient was infected with non-A, non-B hepatitis and many were also infected with HIV.

2

Risk Management and Patient Choice

Factor concentrates are often described as a 'life-saving' treatment. This is true only in a very limited number of cases because this treatment was not reserved solely for life-threatening situations. From the 1970s onwards, concentrated clotting factors were increasingly used on a 'prophylactic' basis, focussing on the prevention rather than the treatment of bleeds. In the short term this meant that people with haemophilia could lead much more normal lives than when they were being treated with cryoprecipitate. For example, they could now play a wide variety of sports. However, the increased frequency of treatment meant that patients were now exposed to the untreated blood of thousands of donors every week. The extent to which this vastly increased risk was justified by improved quality of life in the short term is highly questionable.

Dr Jack Melling, a member of the Committee on Safety of Medicines at the time of the contaminated blood disaster, raised this issue succinctly with the Archer Inquiry:

> "How much effort was made to say: okay, we see some risk with this material, therefore it will only be given to people with a life-threatening condition? Now 'life threatening' again is a somewhat subjective judgment, but it could eliminate a significant proportion [of infections]."[24]

Patients were rarely (if ever) consulted about achieving a balance between short-term improvements in quality of life and increased longer-term risks of virus transmission. People with severe haemophilia know their bodies well, and can often tell which bleeds are dangerous and which are resolvable with rest: it would have been entirely possible to have saved the high-risk factor concentrates for the most serious bleeds. Alternative treatments were available for children and adults with mild to moderate haemophilia. This section will consider whether available options were considered fully and weighed appropriately.

[24] Dr Jack Melling, Oral Evidence to the Archer Inquiry, 19th September 2007

2.1 Risk Assessment

Although factor concentrates carried a high risk of transmission of blood-borne viruses because of their very large donor pool, there is no evidence that a comprehensive risk assessment was carried out before they became commonly prescribed in non-emergency situations. Nor is there any evidence that their use was reassessed when the theoretical risk of a dangerous new blood-borne virus became a reality.

In January 1983, the New England Journal of Medicine carried an article warning that people with haemophilia were at a high risk of contracting AIDS due to the large size of donor pools used in the manufacture of clotting factor. The article urged doctors to consider this risk before prescribing factor concentrates:

> 'Unfortunately, the data are consistent with a greater potential for AIDS in the population treated with concentrate. Physicians involved in the care of hemophiliacs must now be alert to this risk. Preventing the complications of present treatment may have to take precedence over preventing the complications of hemophilia.'[25]

Still, no changes were made to haemophilia treatment in Scotland.

By mid-1983 it was increasingly obvious that clotting factors were a 'highly beneficial product [that] could actually have potentially horrendous consequences.'[26] At this point, the United Kingdom Haemophilia Centre Directors' Organisation and the World Federation of Haemophilia recommended the reduced use of factor concentrates.

Still, no changes were made to haemophilia treatment in Scotland.

The options for reducing the risks of haemophilia treatment

Alternative treatment options for young children: it was possible to avoid administering high-risk factor concentrates to small children by returning to the old, pre-factor VIII treatment, cryoprecipitate. Although much less convenient than concentrated clotting factor, cryoprecipitate was usually made from the blood of a single donor, and therefore carried a much lower risk of virus transmission. In July 1983 the UKHCDO recommended that children under four should be treated with cryoprecipitate rather than clotting factor.

Alternative treatment options for adults with mild to moderate haemophilia: Instead of using factor concentrates, it was possible to treat patients with mild to moderate haemophilia with DDAVP, an analogue of the natural brain hormone desmopressin. This treatment raises the patient's level of Factor VIII into the normal range for three to five days. In July 1983 it was recommended that doctors treating mildly affected patients should use DDAVP rather than factor concentrates.[27]

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[25] Jane F Desforges, M.D, 'AIDS and Preventative Treatment in Hemophilia', [1983] Jan 308(2) pp 94-95.
[26] Dr Jack Melling, Oral Evidence to the Archer Inquiry, Wednesday 19th September 2007, p13 lines 4 and 5. [APPENDIX TEN]
[27] Dr Mark Winter, Oral Evidence to the Archer Inquiry, 29th August 2007, p 73.

Reducing the virus exposure of adults with severe haemophilia: Although alternative treatment options were more limited for adults with severe haemophilia, the long-term exposure to numerous batches made it all the more important that patients were involved in balancing the risk of their treatment against the benefits. In these circumstances, the first consideration should have been whether each treatment was absolutely necessary. People with haemophilia can reduce the risk of bleeds occurring by avoiding physical activities such as sport. Elective surgery could also be postponed. It was also possible to reduce the risk of treatment with factor concentrates by minimising the number of batches that each patient was exposed to. In February 1984 it was finally decided that 'efforts could be made to reduce the number of batch exposures per patient per year.'[28] This tardy decision was never implemented.

Despite the increasing knowledge about the risks of factor concentrates, and the availability of alternative treatments, clinicians seemed reluctant to consider that the risks of prophylactic treatment with factor concentrates might outweigh the benefits. The minutes of the SNBTS and Haemophilia Directors in January 1983 show that SNBTS managers and haemophilia directors were increasingly aware of the risks that concentrated clotting factors posed,[29] but the only action taken as a result was a questionnaire to haemophilia directors.'[30] Even by December 1983, when the British Medical Journal contained the stark warning that 'there is no evidence that any product, commercial or volunteer, is free from risk of transmitting AIDS,'[31] there was no change in their advice to patients about how to manage haemophilia. By February 1984 it was acknowledged that AIDS was a threat to the safety of the Scottish blood supply. [32]

There is no evidence that clinicians scaled back the use of prophylactic treatment as the contaminated blood disaster unfolded, or advised patients of the increased risk that they now faced. Infection rates could have been significantly reduced if clinicians had restricted the use of concentrated clotting factors to life-threatening situations.

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[28] Minutes of the Meeting of Directors of the Scottish National Blood Transfusion Service and Haemophilia Directors held in St Andrew's House on Thursday 2 February 1984. [APPENDIX ELEVEN]

[29] Minutes of the Meeting of Directors of the Scottish National Blood Transfusion Service and Haemophilia Directors, held in St Andrew's House, Friday 21 January 1983, p7. [APPENDIX TWELVE[

[30] Minutes of the Meeting of Directors of the Scottish National Blood Transfusion Service and Haemophilia Directors held in St Andrew's House on Friday 21 January 1983, item 6, page 7.

[31] British Medical Journal, 10 December 1983. [APPENDIX THIRTEEN]

[32] Minutes of the Meeting of Directors of the Scottish National Blood Transfusion Service and Haemophilia Directors held in St Andrew's House on Thursday 2 February 1984. [APPENDIX FOURTEEN]

2.2 The Use of Imported Blood Products in Scotland

Despite Scotland's apparent self-sufficiency in blood and blood products, the Scottish National Blood Transfusion Service estimates that 67 of the 87 people with haemophilia and HIV in Scotland contracted HIV from commercial concentrates.[33] The 'Edinburgh Cohort' infections, caused by Scottish National Blood Transfusion Service blood, are well documented. Less is known about the other significant cluster of HIV infections in Scotland, which occurred at Yorkhill Children's Hospital, Glasgow. Here, imported commercial blood products were routinely used. A number of young children were infected with HIV as a result.

Even before the AIDS threat emerged, it was commonly believed in the medical community that locally produced blood products were safer than commercial alternatives. This was based on the fact that the SNBTS relied on voluntary donations while commercial products were manufactured using blood collected from paid donors. Although the use of prison blood and the lack of screening meant that Scottish blood products carried an almost 100% risk of hepatitis C, Scotland was several years behind the USA in relation to the developing AIDS epidemic. It is therefore troubling that high-risk imported blood products were used by Yorkhill Hospital to treat children when the lower-risk SNBTS products were freely available. A significant number of the Scottish HIV infections through contaminated blood could have been avoided if commercial products had not been used.

2.3 Informed Consent to the Risk of Treatment

In May 1983 the World Federation of Hemophilia issued guidance that 'the patient and physician must weigh up and balance the type and intensity of treatment against potential risks/problems as opposed to medical and psychologic benefits.'[34] This meant that the doctor and patient should work together to agree a course of treatment that would maintain a satisfactory level of factor replacement while minimising exposure to blood products. The Penrose Inquiry will hear evidence from individual patients that they were given little information about the risks of their treatment or alternative treatment options, and were not consulted about the management of their haemophilia or how to reduce their risk of bleeds by altering their lifestyle.

Given the risk of transmission of serious viruses via blood products, patients had the right to expect that the risks of their treatment should have been communicated to them explicitly, person to person, by their clinician, as part of a wider discussion of the risks and benefits of various treatment options. Indeed, in the A and Others v National Blood Supply and Others case, Mr Justice Burton concluded that, in order for patients to be aware of the risk of transfusions, there would probably be a need for 'express warnings'[35] to individual patients, rather than assuming that patients would seek out generalised information about the risks of their treatment.

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[33] Evidence of Dr Peter Foster to the Archer Inquiry, Wednesday 19th September 2007, pp 58-59.
[34] World Federation of Hemophilia Guidance, May 19 1983. [APPENDIX FIFTEEN]
[35] A and Others v The National Blood Authority and Others [2001] EWHC QB 446.

The Scottish Executive's report 'Hepatitis C and Heat Treatment of Blood Products for Haemophiliacs in the Mid-1980s' cites the existence of Haemophilia Society publications and meetings as evidence that patients were adequately informed about the risks of their treatment. This only serves to highlight the paucity of first-hand information made available to patients at the point of treatment. The Haemophilia Society is a small patients' group that strives to make information available to members on a very limited budget. Its contact with patients is limited and it can only ever play a supplementary role in making information available. Its staff members have never been suitably qualified to offer detailed advice on medical treatment. It has never had contact details for the majority of people affected by a bleeding disorder. People with mild or moderate haemophilia often do not know that they have a bleeding disorder until they arrive in hospital following a major trauma.

There can be no substitute for a comprehensive discussion of the risks and benefits of treatment at the time that it is administered. In addition, patients should have been given the opportunity to opt out of sports and other physical activities in order to minimise their exposure to blood products. It was the responsibility of individual physicians to discuss the risks and benefits of treatment with each individual patient.

2.4 Summary of Risk Management Failures

Increasing the donor pool of each in individual clotting factor treatment posed not only a serious threat to people with haemophilia but also to the wider public health. Introducing no extra safety precautions to lower this risk and, at the same time, increasing the frequency of treatment was a tragedy on a mass scale waiting to happen.

Minutes of meetings held by haemophilia doctors suggest a number of failures to adequately account for the infection risk posed by factor concentrates. Firstly, when factor concentrates were rolled out in the 1970s, haemophilia doctors entirely failed to account for the vastly increased infection risk posed by each dose because of the massive donor pool. Secondly, as evidence mounted in the early 1980s that the worst-case scenario was fast becoming a reality, there was still no review of whether the use of factors should be limited to genuinely life-threatening situations. Thirdly, individual patients were not consulted about how they wished to balance the infection threat of factor concentrates against the risks and inconveniences of limiting this treatment.

3

The Ethics of Medical Research

People with haemophilia worry a great deal about the ethics of medical research. Although our community understands that medical research is vital for improving existing treatments and developing new treatments, reliance on medical treatment puts people in a vulnerable position. Patients have to be able to trust their doctor to give them full information about the treatments that they are taking, to keep them informed about the state of their health, and to gain their explicit consent for treating them with any experimental or unlicensed products. There is a strong suspicion amongst patients with haemophilia that this has not always been the case.

Particular concern surrounds research that was carried out in the mid 1980s. The emergence of a new killer virus, and the urgent need to develop safer treatments in response to this, led to a massive expansion in research. The ethics of some of this research were highly suspect. This section will discuss three specific research projects where there is documentary evidence that patients were used for research which they claim was carried out without their knowledge or consent. These are: the 'Edinburgh cohort' (a group of Edinburgh Royal Infirmary patients infected with HIV as a result of treatment with a single batch of factor VIII); infectivity research into the spouses and partners of those infected with HIV; and patients in Edinburgh and Glasgow hospitals who received early experimental batches of heat-treated factor VIII.

3.1 The 'Edinburgh Cohort'

The 'Edinburgh Cohort' was 'a unique group of haemophiliacs that became infected [with HIV] in the spring of 1984 by transfusion with a single batch of factor VIII concentrate.'[36] Research into this group of patients began in 1983, and was said to be particularly valuable because its members were 'uniquely homogenous' having all been infected with HIV as the result of a single infected batch of factor VIII. Its members were said to be perfect subjects for research because they had been 'assessed immunologically before exposure to HIV and have participated in detailed follow-up studies at regular intervals'.[37] Articles about the progression of HIV within the 'Edinburgh Cohort' appeared in major medical journals between 1984 and 1991. The long list of published research cited below gives an idea of the

[36] Medical Research Council News, September 1990, No 48, p13. [APPENDIX SIXTEEN]
[37] R J Cuthbert, CA Ludlam, J Tucker, CM Steel, D Beatson, S Rebus, JF Peutherer, 'Five Year Prospective Study of HIV Infection in the Edinburgh Haemophiliac Cohort', *British Medical Journal (Clinical Research Edition)* [1990] Dec 15, 301(6765): 1395-6. [APPENDIX SEVENTEEN]

scale of the research carried out into this group of patients, and the length of time for which they were being observed.[38]

An application to the Ethics of Medical Research Sub-Committee for Medicine and Clinical Oncology stated that 'patients and controls are very well informed about our studies' and that the patients' consent would be 'written in case notes'. However, members of this cohort insist that their consent to this research was neither sought nor recorded. The fact that this group of patients with haemophilia became 'one of the most extensively studied groups of HIV infected individuals in the world' is a cause of great upset and discomfort to patients who were observed for years without their knowledge.

Questions have also been raised about exactly when members of the 'Edinburgh Cohort' were informed of their HIV-positive status. Some patients say that several years passed before they were finally told,[39] despite their illness being reported in the *Lancet* as early as 1985. This put partners and spouses of patients at unnecessary risk, and further contributed to a breakdown in trust between patients and their clinician. Members of the 'Edinburgh Cohort' have also raised concerns that entire pages of their medical files are missing.

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[38] R Carr, SE Veitch, E Edmond, JF Peutherer, RJ Prescott, CM Steel, CA Ludlam, 'Abnormalities of Circulating Lymphocyte Subsets in Haemophiliacs in an AIDS-free Population', *Lancet* [1984], Jun 30; 1 (8392): 1431-4; CA Ludlam, J Tucker, CM Steel, RS Tedder, R Cheingsong-Popov, RA Weiss, DB McClelland, I Philip, RJ Prescott, 'Human T-Lymphotropic Virus Type III (HTLV-III) Infection in Seronegative Haemophiliacs after Transfusion with Factor VIII, *Lancet* [1985], Aug 3 2(8449): 233-6; P Simmonds, FA Lainson, R Cuthbert, CM Steel, JF Peutherer, CA Ludlam, 'HIV Antigen and Antibody Detection: Variable Responses to Infection in the Edinburgh Haemophiliac Cohort', *British Medical Journal* [1988] Feb 27, 296(6622): 593-8; CM Steel, CA Ludlam, D Beatson, JF Peutherer, RJ Cuthbert, P Simmonds, H Morrison, M Jones, 'HLA Haplotype A1 D8 DR3 as a Risk Factor for HIV-related disease', *Lancet* [1988] May 28, 1(8596): 1185-8; CA Ludlum, 'Effects of Alloantigens in Blood Products on Immunity', *Seminars in Hematology*, [1988] Apr 25(2) Suppl 1:3-7; RJ Cuthbert, CA Ludlam, S Rebus, JF Peutherer, DW Aw, D Beatson, CM Steel and B Reynolds, 'Human Immunodeficiency Virus Detection: Correlation with Clinical Progression in the Edinburgh Haemophiliac Cohort', *British Journal of Haematology* [1989] Jul 72(3): 387-90; R J Cuthbert, CA Ludlum, J Tucker, CM Steel, D Beatson, S Rebus, JF Peutherer, 'Five Year Prospective Study of HIV Infection in the Edinburgh Haemophiliac Cohort', *British Medical Journal (Clinical Research Edition)* [1990] Dec 15, 301(6765): 1395-6; GM Smith, BA McVerry, EH Cooper, 'HIV Infection in the Edinburgh Haemophiliac Cohort', *British Medical Journal (Clinical Research Edition)* [1990] Dec 15; 301(6765): 1395-6; P Simmonds, D Beatson, RJ Cuthbert, H Watson, B Reynolds, JF Peutherer, JV Parry, CA Ludlam, CM Steel, 'Determinants of HIV Disease Progression: Six-Year Longitudinal Study in the Edinburgh Haemophilia/HIV Cohort', *Lancet* [1991] Nov 9, 338(8776): 1159-63. [APPENDIX EIGHTEEN]

[39] In oral evidence given to Lord Archer's Independent Public Inquiry into Contaminated Blood and Blood Products on 24th May 2007, Robert Mackie, a patient in the 'Edinburgh Cohort', stated that, "I was continually asking both my consultant and doctors at my haemophilia centre about any risks from factor VIII from mid 1983 when I was continually being told there was nothing to worry about. At no time was I ever informed of being treated for AIDS, HTLVIII or HIV. The first I knew of being tested was in 1987 when I was told I had been infected with HIV for several years."

3.2 Research into the Sexual Transmission of HIV

As the AIDS virus continued to spread, the need to discover more about routes of transmission grew. Because the virus was thought to be transmissible through heterosexual intercourse, a proposal to monitor the health of spouses of people with haemophilia was discussed at a UKHCDO meeting.[40] One of the Scottish centre directors presented the others with a form to gather information about whether partners of people with haemophilia were showing symptoms of AIDS. This form caused some controversy, with one Centre Director describing the study as 'insensitive, unscientific and unethical'.[41]

Some patients recall that their clinicians used to regularly inquire after the health of their wives during this period.[42] At the same time, many patients were not even told that they were HIV positive, let alone advised to start taking precautions against sexual transmission. These patients are understandably resentful that they were not immediately advised to avoid unprotected sexual intercourse during this period. Again, trust between clinicians and patients was undermined because patients now believe that their doctors were observing the health of their spouses while, at the same time, failing to pass on information that was essential to protect the health of their spouses.

3.3 Research into the Efficacy of Heat-Treated Products

By 1983 the SNBTS was developing new, heat-treated factor VIII concentrates. These were urgently needed, and had to be tested, but again concerns have been raised about the ethics of the testing that occurred.

The SNBTS asked haemophilia doctors to find five subjects for this research. Two patients from Edinburgh and three patients from Glasgow[43] were used as subjects in research that began in 1983. On 11th January 1984 a letter from a clinician to the SNBTS described an adverse reaction that a patients had to the new, heat-treated factor VIII, describing that:

> 'On the first [infusion] the recipient had a short episode of diarrhoea beginning within an hour of the infusion. On the second and third occasion he felt ill towards the end of each infusion. He developed transient central chest pain, pallor and

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[40] Minutes of the 16th Meeting of UK Haemophilia Centre Directors held in Oxford on Monday 21st October 1985, Item 9, p6. [APPENDIX NINETEEN]

[41] Minutes of the 16th Meeting of UK Haemophilia Centre Directors held in Oxford on Monday 21st October 1985, Item 9, p6.

[42] Evidence of Alice Mackie to the Archer Inquiry, 24th May 2007, p208: 'When we went up to the centre, what did they ask? "Oh, how is your wife keeping?" or, "How's your girlfriend keeping?" How's the children?" This is how they kept an eye on you. If you turned round and said to them, "Oh, my wife's got a sore throat that won't clear up", which was one of the ways that they knew about serocoversion, then they knew without a doubt that their partner was probably infected. The thing is, when that happened, did they consider even informing the haemophiliac or the spouse then? No, they just left it and waited a year and a half later when they started telling the haemophiliacs themselves. And then they said, "Well maybe your wife could have it."'

[43] Letter from National Medical Director, Dr John D Cash, to Consultant Physician Dr C D Forbes, 6th January 1983. [APPENDIX TWENTY]

> wretching. There was no change in his pulse, BP or temperature. To ascertain whether this was likely to be an organic reaction to the concentrate we gave him a 'placebo' infusion of ordinary SNBTS factor VIII. He was told that it was the heated material and the infusion protocol was identical. He had no adverse reaction to the standard product. I therefore have to conclude that this batch of material genuinely gave rise to significant and unacceptably adverse reactions in the patient. I hope this information is helpful to you in the further development of hepatitis reduced factor VIII concentrates.' [44]

Three months later, further patient trials were proposed. A letter from the SNBTS to a haemophilia doctor stated that:

> 'I am now beginning to plan ahead with regard to getting our product put into SHS 'virgin' haemophilia A patients and to this end intend to put up, in due course, a proposal for consideration by the Scottish Haemophilia Centre/Transfusion Centre Directors' Working Party.' [45]

This exchange of letters raises two major concerns. Firstly, it is clear from the letter dated 11th January 1984 that the patient described had been misled about the treatment administered to him. The patient was given a 'placebo' infusion of ordinary SNBTS factor VIII but was told that it was the heated material. Secondly, there are substantial ethical problems with carrying out trials on 'virgin' patients', which were almost always children or people with mild haemophilia. According to UKHCDO guidelines, neither of these groups should have been treated with factor VIII concentrates in 1984. One consultant haematologist wrote to SNBTS to express that he believed 'very strongly that children should **not** by used in this situation.'

3.4 Summary of Ethical Failures

Even in situations where there is a race against time to improve knowledge of a virus and develop safer treatments, vulnerable patients still have a fundamental human right not to be the subjects of research without consent. The 'Edinburgh Cohort' became the most observed group of HIV infected individuals in the world, but patients claim they were unaware that they were infected with HIV. Rather than telling their patients to avoid unprotected intercourse with their spouses and partners, doctors observed the health of spouses and partners to see if they showed any symptoms of HIV. Doctors worked with the SNBTS towards the testing of new heat-treated blood products on virgin patients, despite the fact that 'virgin patients' should not have been treated with concentrated blood products during this period. It is hardly any wonder that, in addition to the physical impact of the contaminated blood disaster, the breakdown in trust between clinicians and patients has heightened the impact of this disaster on patients' mental health. It is absolutely imperative that the circumstances of this research are investigated in order that trust can begin to be rebuilt.

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[44] Letter from Dr C A Ludlam, Consultant Haematologist, to Dr J D Cash, Blood Transfusion Service, 11th January 1984. [APPENDIX TWENTY]

[45] Letter from Dr J D Cash to Dr C D Forbes, 28th March 1984. [APPENDIX TWENTY]

Conclusion

The documents summarised in this submission reveal that the Scottish National Blood Transfusion Service was not operating at the forefront of good practice, and that there were serious failures to correctly assess the risk posed by concentrated clotting factors.

Opportunities were missed to minimise the risk of infecting whole batches of blood products at the point of collection and manufacture. The introduction of both heat treatment and donor testing was tardy. The continued collection of blood donations from prisons and borstals increased the risk of introducing infected blood into batches. Blood products were manufactured on premises that were strongly criticised by inspectors.

At the point of clinical treatment no allowance was made for the extra risk posed by the vast number of donors that contributed to factor concentrates. After prophylactic treatment was rolled out, patients were routinely being exposed to the untreated blood of thousands of donors *every week*. Patients were not involved in decisions about balancing the risks and benefits of treatment, or advised of ways in which they could reduce their risk of bleeds, thus lessening their need for treatment.

The death toll of the contaminated blood disaster could have been substantially reduced if *either* factor concentrates had been reserved for genuinely life-threatening situations *or* measures to improve the safety of concentrated clotting factors had been implemented more swiftly.

This submission also detailed three examples of medical research, conducted by clinicians apparently without their patients' consent, which raise further concerns about the lack of patient involvement in their treatment. The ethical issues about when patients should be told that they have illnesses if those illnesses are untreatable have continuing relevance today, currently reflected in the debate about when to introduce a donor test for vCJD, and whether people who test positive for vCJD should, or should not, be told of the result.

The haemophilia community would like to thank Lord Penrose and his team for reading this submission. We look forward to receiving some answers to many of the questions that have been pressing on the minds of the victims of this tragedy for over twenty-five years. We would also like to thank those who have campaigned for so many years to keep the injustices experienced by the haemophilia community in the public eye, and those who have supplied documents and other evidence that have contributed to this report.