



Haemophilia Society

Submission

to the

Archer Independent Public Inquiry

into the

“circumstances surrounding the supply to patients of contaminated NHS blood and blood products; its consequences for the haemophilia community and others afflicted; and further steps to address both their problems and needs and those of bereaved families.”

Executive Resume

Thousands of people contracted deadly viruses as a result of being treated with contaminated blood products between the late 1970s and the mid-1980s.

By the time heat treatment was introduced in 1985 (1987 in Scotland) 4,670 people with haemophilia had been infected with hepatitis C. Of those, 1,200 were also infected with HIV. 1,757 people with one or both of these viruses have since died.

Continuously since 1988 the haemophilia community has campaigned for a public inquiry to unravel all the facts of this worst ever treatment disaster in the NHS.

Successive governments have maintained that screening, testing and heat treatment of blood products were introduced as soon as practicable. The haemophilia community has found evidence of a catalogue of life-threatening delays. This submission will show that:

- Despite the announcement of a policy of self-sufficiency, a decade was wasted before the Government finally invested in the Blood Products Laboratory. This meant a prolonged dependence on less-safe commercial blood products from the USA;
- The UK was one of the last countries in Western Europe to introduce HIV testing of donors and the heat treatment of blood products;
- The UK was one of the last countries in the developed world to introduce testing of blood donors for hepatitis C;
- Heat treatment to the required temperature to kill the hepatitis C virus was delayed in Scotland by eighteen months without explanation;
- Delays in testing, and in informing patients of the results of tests, led to the largely avoidable infection of 63 intimate relatives;¹
- A further decade was wasted before the full roll-out of recombinant treatment, putting further lives at risk and proving that lessons had not been learned; and
- Many key documents held by the Department of Health relating to contaminated blood and blood products have been unaccountably destroyed.

This submission will also show the effect that the contaminated NHS blood disaster has had on the haemophilia community as a whole. As well as poor health, people have suffered psychological damage. They have experienced stigma, uncertainty about their health prospects and multiple bereavements, as exemplified by the case of the Murphy family, represented by Mrs Maureen Murphy, her son and daughter at the Inquiry's first hearing of witnesses. The haemophilia community has suffered financially, both from loss of earnings and lack of access to financial products. Their family lives have also been affected: many relationships have failed to withstand the strain and 'normal' family life has been made impossible.

This disaster would have been difficult to come to terms with in any circumstances. However, the psychological trauma has been deepened by widespread suspicion of a 'cover up'. The Haemophilia Society would like to thank The Rt Hon The Lord Morris of Manchester for his tireless work. We hope that the inquiry he has created will now bring full and final closure to a dispute that should have been settled long ago. Afflicted and bereaved people have been and are being called to give evidence of their personal experiences. This submission will therefore concentrate on the impact of HIV, hepatitis C and vCJD on the haemophilia community as a whole; and in a second submission I will point the way forward to what we would regard as an acceptable financial settlement.

¹ Macfarlane Trust

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What is haemophilia?

Haemophilia is a hereditary condition characterised by low levels of clotting factor in the blood. People with severe haemophilia have virtually no clotting factor, which can be very debilitating without treatment. However, people with mild haemophilia have some clotting factor, and may only become aware of their condition after an accident or tooth extraction.

Contrary to common belief, internal bleeding, rather than profuse bleeding from cuts, is the main concern for people with haemophilia with cerebral bleeding most likely to prove fatal.

There are two main types of haemophilia. Haemophilia A is caused by a deficiency of factor VIII in the blood, while haemophilia B, which is less common, is caused by a lack of factor IX. Von Willebrand's is a similar condition which is caused by a von Willebrand's factor deficiency. This submission will use the term 'people with haemophilia' to describe people with haemophilia A, haemophilia B, von Willebrand's and other related bleeding disorders.

What is the Haemophilia Society?

The Haemophilia Society is a charity which works for people with haemophilia, von Willebrand's and related bleeding disorders, and their families. Our objectives are to relieve the suffering of people with haemophilia and improve public education into the nature and causes of haemophilia.

We aim to secure the best possible care, treatment and support for people with these conditions. We work to assist people with haemophilia and related disorders by providing information and support, by representing the interests of people with haemophilia and related bleeding disorders and their families, and by raising awareness of bleeding disorders amongst the public and with health professionals.

The Society was established in 1950 and is the national charity in the UK for people with bleeding disorders. The Society provides support and campaigning for people with blood disorders. We have 4113 members and registered supporters, and a network of 17 local groups throughout the UK. Half of all people with severe haemophilia are members or registered supporters of the Society. 12,000 people a year use the Haemophilia Society website and 2,000 people call the helpline for advice every year. The Society has twelve trustees; ten are elected and two are co-opted.

We provide services for all people with haemophilia. Our information resources include advice on HIV issues, HIV and hepatitis C co-infection, all hepatitis viruses, vCJD, pain management, orthopaedics, all bleeding disorders and welfare and benefits.

Related Organisations

Macfarlane Trust

The Macfarlane Trust (named after Professor Gwyn Macfarlane, founder of the Oxford Haemophilia Centre) was set up in 1988 to administer funds made available by the government for people with haemophilia infected with HIV through treatment with contaminated blood products. The Trust was established as a result of intensive lobbying by the Haemophilia Society and other campaigners.

The Trust aims to provide appropriate help for:

- anyone suffering from haemophilia who, as a result of receiving infected blood products in the United Kingdom, is suffering from AIDS or HIV, and who is in need of assistance;
- the spouses, parents, children and other dependants of infected persons;
- the spouses, parents, children and other dependants of infected persons who have died.

The Trust is governed by twelve trustees, four appointed by the Haemophilia Society, four appointed by the Secretary of State for Health and four appointed by the Board.

The Haemophilia Society works closely with the Macfarlane Trust. However, we are concerned that its funding has not been reviewed to take into account the changing requirements of its registrants. The prognosis for those affected has changed greatly since the Trust was established, but the help and support that it is able to provide has not. We were disappointed that the Macfarlane Trust's well-argued business case for improved funding was turned down by the Department of Health, leaving the Trust unable to fully address the needs of its registrants.

Skipton Fund

The Skipton Fund is a UK-wide ex-gratia payment scheme established in 2004 to make payments to certain people who were infected with hepatitis C through NHS blood or blood products prior to September 1991, and other persons eligible for payment in accordance with the scheme's provisions. The Fund was established as a result of intensive lobbying by the Haemophilia Society and other campaigners.

A first stage payment of £20,000 is available to all those who are eligible to join the scheme. For those whose hepatitis C infection has led to advanced liver disease there is a second stage payment payable of £25,000.

The Haemophilia Society has three main concerns about these payments:

1. They are too low, and do not reflect financial and other personal repercussions of infection with hepatitis C.
2. They unfairly exclude bereaved partners whose loved ones died before August 2003.
3. The illogical exclusion of payments to people with chronic hepatitis B, which has similar symptoms to hepatitis C, and people who have cleared hepatitis C naturally.

Eileen Trust

The Eileen Trust was set up to support people who have become HIV positive because of NHS treatment, for example, following transfusions or a needlestick injury. It provides financial support in the form of small regular payments or one off payments to affected individuals. A lump sum settlement payment from the Government varying from £41,500 to £80,500 is available, according to age and family circumstances. The Eileen Trust also provides advice and information on benefits, housing, health and employment problems, amongst other issues.

Treatment for haemophilia

Fifty years ago bed rest was the only treatment available for people with haemophilia. The discovery of cryoprecipitate in the 1960s revolutionised treatment, although it could not be self-administered. The introduction of freeze-dried plasma-derived factor VIII and factor IX concentrates in the 1970s transformed the lives of people with severe haemophilia, allowing them to be active and treat themselves at home.

Unfortunately, lack of effective screening and viral inactivation procedures meant blood-borne viruses, such as hepatitis C and HIV, were present in some products. All people with haemophilia who were treated with commercial factor concentrates during the 1970s and early 80s have been exposed to infection with the hepatitis viruses B and C. Many were also exposed to HIV. By the time viral inactivation processes were introduced in 1985 (1987 in Scotland), some 4,670 people with haemophilia had been infected with hepatitis C and 1,200 also with HIV. Of those, 1757 have since died. Approximately eighty percent of people with haemophilia during the late 1970s and early 1980s were infected with one or both of these viruses.

Recombinant clotting factors were licensed for use in 1993. These are made from genetically engineered clotting protein and are considered to be much safer than human blood products. Third generation recombinant treatments are entirely synthetic, and eliminate the pathogen risk associated with the use of animal and human-derived plasma protein additives. These were not made available to every adult across the UK until 2006, causing further unnecessary exposure to vCJD.

Infection

Hepatitis C

Hepatitis means swelling or inflammation of the liver. Hepatitis C (also known as Hep C or HCV) is a blood borne virus infection which is spread when blood from an infected person infiltrates the bloodstream of another.

Hepatitis C infection varies in its severity: some people with the virus are asymptomatic while others experience extreme tiredness and can feel very unwell. Reported symptoms include fatigue, weight loss, nausea, 'flu like symptoms, lack of concentration, abdominal pain and jaundice.

It is estimated that 15% of infected people clear their infections naturally within the first six months of infection. For the remainder, hepatitis C is a chronic condition that, without treatment, is assumed to be life-long. Recent data suggests that among untreated patients, 20% will develop liver cirrhosis in less than 20 years. Almost a third will experience cirrhosis within 30 years. Of those, 3-4% will develop hepatocellular

carcinoma, which is a type of cancer specific to this infection. The progression to cirrhosis is significantly swifter for those co-infected with HIV.

Hepatitis C is also associated with sicca syndrome, thrombocytopenia, lichen planus, diabetes mellitus and with B-cell lymphoproliferative disorders. Infection confers a 20 to 30% increased risk of non-Hodgkin lymphoma.²

Current treatment is a combination of pegylated interferon alpha³ and the antiviral drug ribavirin for a period of 24 or 48 weeks, depending on genotype. This treatment has a limited success rate of around 40% for people with genotype 1, which is the most common strain of the virus affecting people with haemophilia. It is unpleasant to take. Side effects range from a 'flu-like' syndrome (the most common, experienced for a few days after the weekly injection of interferon) to severe adverse reactions including anaemia, cardiovascular events and psychiatric problems such as depression or even suicide. Between ten and fifteen percent of sufferers have to stop the course of treatment because of the severity of the side effects.⁴

HIV

HIV (human immunodeficiency virus) attacks and infects cells in the body which are part of the immune system, especially CD4 cells (sometimes called T4 or T-helper cells) which help the body to fight infection. When a person's immune system breaks down, he or she becomes susceptible to other illnesses, especially infections (e.g. tuberculosis and pneumonia) and cancers, many of which are not normally a threat to a healthy person. At that severe stage of infection the person is often diagnosed as having AIDS (Acquired Immunodeficiency Syndrome).

The current treatment for HIV infection is highly active antiretroviral therapy (HAART). This has been highly beneficial to many HIV-infected individuals since its introduction in 1996, when the protease inhibitor-based HAART initially became available. However, side effects include lipodystrophy, dyslipidaemia, insulin resistance, an increase in cardiovascular risks and birth defects.

Drug resistance is also a major concern. Over time, the HIV virus in the body changes to include fewer drug sensitive strains and more resistant ones. It is thought that anti-HIV drugs may therefore only have limited or short term usefulness. It is not clear how developing resistance will affect the risk of future illness. For the time being, any reduction in viral load is associated with a benefit in terms of improved health and survival.⁵

Hepatitis C and HIV Co-infection

Almost everyone who was infected with HIV through blood products was also infected with hepatitis C. Living with a bleeding disorder, HIV and hepatitis C is extremely challenging. It has been demonstrated in clinical studies that HIV infection causes a more rapid progression of chronic hepatitis C to cirrhosis and liver failure. Following

² Risk of Non-Hodgkin Lymphoma and Lymphoproliferative Precursor Diseases in US Veterans with the Hepatitis C Virus, *Journal of the American Medical Association*, Vol. 297 No. 18, May 9 2007 (appendix 1)

³ Recommended by the National Institute for Clinical Excellence, October 2000

⁴ Professor Geoffrey Dusheiko, *Review of Side Effects of Interferon Alpha in Viral Hepatitis*, Hepatitis Central website www.hepatitis-central.com/hcv/ifn/sideeffects (appendix 2)

⁵ www.aidsmap.com/cms1032052.asp

significant advances in HIV treatment, liver failure due to hepatitis C is now one of the most common causes of death in the co-infected group.

Conversely, drug treatments for hepatitis C may have an impact on the course of HIV infection. Interferon (one of the drugs used to treat hepatitis C) has been shown to lower CD4 counts, which is a particular problem for those who are HIV positive.

Care must be taken to ensure that drug interactions are avoided. There is considerable geographic variation in treatment. Some trusts integrate HIV and hepatitis C treatment with haemophilia treatment, while others involve one or two other departments (typically GUM and hepatology) in addition to haemophilia. This multiplicity of hospital appointments can be unnecessarily stressful, tiring and time consuming for the patient.

vCJD

Creutzfeldt-Jakob Disease (CJD) is a rare and ultimately fatal progressive degenerative brain disease. It is one of a group of diseases called Transmissible Spongiform Encephalopathies (TSEs) that affect humans and animals. TSEs are thought to be caused by the build up in the brain of an abnormal form of the naturally occurring 'prion' protein.

CJD was initially described in its classical, or sporadic, form in 1920. A new classification, known as variant CJD (vCJD), was first identified in 1996. Variant CJD is strongly linked to exposure, probably through food, to a TSE of cattle called Bovine Spongiform Encephalopathy (BSE).

Early symptoms of vCJD are often psychiatric, including anxiety, withdrawal, behavioural changes and depression. Persistent pain and odd sensations in the face and limbs are other early indicators. More obvious neurological symptoms, such as unsteady gait and sudden, jerky movements then develop, along with progressive dementia. All movement and speech is eventually lost and the patient will require 24 hour nursing care. Death occurs within an average of 14 months after the first onset of symptoms. The incubation period is unknown.

Many people with haemophilia have received letters informing them that they have received treatment made in part from the plasma of people who have subsequently developed vCJD. In addition, haemophilia centres wrote to patients in 2004 to inform them of a universal risk status if they had been treated with British-source plasma concentrate between 1980 and 2001.⁶ This letter, which appeared without warning and contained no offer of support or counselling, brought back painful memories for many haemophilia patients. It also triggered new fears about potential health risks, which still cannot be quantified. This concern is exacerbated by the fact that there is still no test or treatment for vCJD.

A prototype commercial scale blood test has recently been developed by a Canadian company.⁷ The Government should urgently consider using this to screen blood products in order to prevent the possibility of vCJD transmission.

⁶ Letter dated 20th September 2004 (appendix 3)

⁷ http://www.amorfix.com/2007_02_12_CHI_Conf_2007.pdf (appendix 4)

Other pathogens

Parvovirus B19

Parvovirus B19 causes a rash, joint pain and swelling. Symptoms usually last only a week or two, but may last several months. People with immune deficiencies such as HIV are at risk of serious illness from parvovirus B19 infection.

Hepatitis A and B

Many people with haemophilia were also exposed to hepatitis A and B in the 1970s. People with hepatitis B usually clear the virus naturally, but 5% develop a chronic infection which can lead to liver cirrhosis and cancer. Hepatitis B is more infectious than hepatitis C, and can be passed on by sexual contact and vertical transmission. Hepatitis A is more infectious than hepatitis B or C, but does not develop into a chronic illness.

Unknown Pathogens

People with haemophilia are understandably anxious that any products derived from human blood may contain new, or currently unknown, blood borne pathogens.

Section 1: The Impact of the Infections

'Both illnesses can be – and are – debilitating. All those who suffer face the worry of passing the disease to a loved one or to an unborn child. All face difficulties in education and employment. All face the impossibility of long-term financial commitments. All face the impossibility of gaining life insurance, unless it is offered at a totally prohibitive cost.'⁸

'Patients with these viruses are frightened about their marital relationships. They are concerned about having sex. At the same time, paradoxically and ironically, they suffer a loss of libido. They feel sick, have no appetite and lose weight. The end is a mixture of decline, mental confusion and finally coma.'⁹

Physical Health and Access to Treatment

'One cannot escape the fact that death by liver failure or liver cancer is a particularly horrible end.'¹⁰

'I lost four stone. I was lucky if I got an hour's sleep a day...It was like I was somebody else. It was the worst six months of my life'¹¹

HIV, Hepatitis C and Co-infection

The Archer Inquiry has already heard many personal testimonies to the physical effects of hepatitis C and HIV, which demonstrate how devastating infection with the two viruses can be.

Although treatments for HIV have improved in recent years, they still involve a punishing array of medication and medical appointments. Hepatitis C continues to grow as a problem, with current medical opinion suggesting that after 20-40 years of infection, most people with hepatitis C will have some degree of liver damage. Since people with haemophilia have now been infected for over 20 years, almost half are now experiencing severe liver problems, including cirrhosis.¹²

Treatment for both viruses has improved considerably in recent years, but the haemophilia community has consistently found it necessary to campaign to gain and maintain access to the most effective treatments. Local NHS Trusts can be reluctant to prescribe new treatments because of the cost. It took considerable lobbying to ensure consistent access across the UK to Interferon after it was licensed to treat hepatitis C.

Access to treatment for hepatitis C and HIV varies across the country. Some people need to travel for up to three or four hours to access a comprehensive care centre.¹³ We have long been concerned about the 'postcode lottery', where the standard of treatment and availability of specific medication has varied widely across the UK.

vCJD

⁸ Mr George Mudie MP (Leeds East), House of Commons Hansard, 14th December 1995 (appendix 48)

⁹ Lord Robert Winston, House of Lords Hansard, 5th June 1998 (appendix 44)

¹⁰ Lord Robert Winston, House of Lords Hansard, 5th June 1998 (appendix 44)

¹¹ Living Stories – description of interferon/rivavirin treatment

¹² Sue Rocks and John Morris, *Oxford and Sheffield Survey of People with Hepatitis C and Haemophilia*, The Haemophilia Society, 22 February 2002 (appendix 5)

¹³ Gary Streeter MP (South West Devon), House of Commons Hansard 20th November 2001 (appendix 48)

'We have seen three generations now of patients affected [by infected blood] and in the face of all this our Government, both the Conservatives and the Labour party, have refused to endorse the unanimous opinion of the Haemophilia Centre directors that recombinant factor VIII and now factor IX is probably safer than plasma products and therefore must be the treatment of choice for people with severe haemophilia.'¹⁴

Given the background of vCJD, it was particularly unacceptable that it took the haemophilia community almost a decade of campaigning to secure universal access to recombinant clotting factor as a treatment for adults with haemophilia across the UK. Some people with haemophilia went on plasma 'treatment strike' because they were so concerned about the possibility of contracting new viruses or prions.

Most people with haemophilia have now been classified as 'at risk' of developing vCJD. Evidence is mounting that this is leading to difficulty in accessing health and dental care. Shortly after people with haemophilia were advised of their 'at risk' status, concerns were raised in the House of Lords that:

*'An interesting incident arose when [a] haemophiliac patient needed a gastroscopy and biopsy of his stomach a month ago. It was performed immediately by the gastroenterologist, who was then told that the brand-new video endoscope, worth about £35,000, must go immediately into indefinite quarantine.'*¹⁵

There is anecdotal evidence that hospitals, reluctant to have expensive equipment impounded, are seeking to postpone or avoid treating patients deemed to be a high vCJD risk. In April 2007 the Department of Health wrote to dentists to inform them that, where root canal treatment was performed on those 'at risk', single use instruments must be used.¹⁶ There are fears that this will compromise dental care for people who already find it difficult to access dentistry because of their bleeding disorder.

This is at odds with reassurances provided by the Department of Health in 2004 that 'care should not be compromised in any way'.¹⁷

Given that some of the people deemed to be 'at risk' were babies when they were treated with implicated clotting factor, and that this status may stay with them for the rest of their lives, there is a strong argument for some people with haemophilia to be individually risk assessed. There is a wide variation in the number of potentially infected treatments people with haemophilia could have received, which means that not all will have been exposed to the same level of risk.

Recommendations

The Haemophilia Society is concerned about these ongoing difficulties with treatment provision, and calls for the haemophilia community to be given formal representation on statutory bodies making decisions about health care for people with haemophilia.

¹⁴ Haemophilia: Recent History of Clinical Management, The transcript of a Witness Seminar held at the Wellcome Institute for the History of Modern Medicine, London, on 10 February 1998. Edited by D A Christie and E M Tansey, p65 (appendix 6)

¹⁵ Baroness Gardner of Parkes, House of Lords Hansard, 1st December 2004 (appendix 44)

¹⁶ Letter from the Department of Health to all dentists, April 2007 (appendix 7)

¹⁷ Letter from the Department of Health sent to all patients, 'Variant Creutzfeldt-Jakob Disease and Plasma Products, Information for Patients', 7th September 2004 (appendix 8)

Psychological Health

'Psychologically it affects one's mind in various aspects. How long do I have to live? How long can I carry on walking? What additional suffering am I going to go through as well as coping with my haemophilia and severe arthritis? The keyword is uncertainty.'¹⁸

'I feel I should carry a bell around my neck saying 'unclean, unclean'. I feel there is no future and I certainly don't want to live like this. I'm existing, not living and just feel so alone at times. I have panic attacks, very weepy days and find that everyday living is difficult. I can't see a future and sometimes feel there is no point in continuing. HCV has totally devastated my life.'¹⁹

'In my haemophilia centre I witnessed the infection of so many friends and fellow patients with viruses, resulting in terrible long term illness and in most cases eventual death. This of course had an enormous psychological impact on me, to such an extent that I had to ask for outside support to try and come to terms with what had happened.'

Almost half of people with haemophilia and HIV are unhappy, and one in five is very unhappy.²⁰ In contrast, 10% of the general population suffer from depression at any one time.²¹

Three quarters of people with hepatitis C say the virus has adversely affected their family and social life in a variety of different ways.²²

One of the major problems for those infected is uncertainty. Knowledge about both HIV and hepatitis C is still evolving. It has therefore been difficult for clinicians to provide reliable long-term prognoses for patients with haemophilia, HIV and hepatitis C. Most infected people were told in the mid-1980s that they had between three and five years to live. This prognosis proved accurate for many, but 361 people with haemophilia, HIV and hepatitis C are still alive, often having made life decisions based on the prognosis they were given.

Whilst new treatments for HIV and AIDS might have given infected people hope for the future by the mid-1990s, any optimism was dampened by the emerging impact of hepatitis C.

Understandably, ongoing fear about the safety of blood products is widespread. The haemophilia community was anxious for the speedy roll out of recombinant treatment, but this was only completed last year, despite being approved as the treatment of choice by the UKHCDO eleven years earlier in 1995. This meant avoidable exposure to vCJD. The psychological strain of injecting a potentially contaminated treatment for someone already living with at least one life-threatening virus is enormous.

¹⁸ Oxford and Sheffield Survey of People with Hepatitis C and Haemophilia (appendix 5)

¹⁹ Hep C Impact Study Interim Report (1995) NICE Report (appendix 9)

²⁰ Haemophilia Society Needs Assessment 2003 (appendix 10)

²¹ www.mind.org.uk

²² Report of the Hepatitis C Working Party to the Haemophilia Society, June 2002 (appendix 11)

Stigma

'I was about fifteen, beginning to get seriously involved with a girl and I decided to tell her about my status. She seemed fine, but a couple of weeks later she told me she'd met someone else. It was a real body blow. Took me years to get over.'²³

'Sufferers were also subjected to stigmatism and a whole range of other social problems. There were cases of doors daubed with graffiti, lost jobs and children not allowed to mix with other children at school – in short people were denied a normal family life.'²⁴

A recent opinion poll found that 75% of the British population believe there is still a strong stigma attached to HIV.²⁵ As recently as 2004, the Macfarlane Trust had to help a registrant to move home to escape persecution.²⁶

One fifth of HIV-positive people questioned had recently experienced discrimination and rejection.²⁷ Almost half had experienced problems with self-confidence in the previous twelve months.²⁸ Internalised stigma also contributes to mental health problems, which occurs more frequently in people with HIV than the general population.²⁹

People with HIV have reported experiencing a temporary or even permanent deterioration in their relationships with friends and family after their diagnosis.³⁰ The majority of people with HIV in the UK have not told some or all of their family. One in three Macfarlane registrants said nobody other than the Trust and medical professionals knew their HIV status.³¹ This often includes people with whom they are living, making it difficult to manage treatment or access support.

In some instances, housemates and family members have refused to use the same crockery and cutlery as people they know to be HIV positive, and sheets have been burnt after HIV-positive people have slept in them.³² Given the stigma, it is hardly surprising that many people with HIV keep their diagnosis a secret.

Non disclosure is not without risk. It is now well established that failure to disclose HIV positive status to a sexual partner can lead to criminal prosecution.

Groups representing people with HIV and hepatitis C have repeatedly identified the need for public awareness and education campaigns aimed at providing information about these viruses. Prejudice is usually based on ignorance, and it is hoped that such campaigns would reduce stigma, help overcome discrimination and possibly even aid disclosure.

²³ 'Double Jeopardy article by co-infected person with haemophilia, Positive Nation, September 2001 (appendix 12)

²⁴ Mr Tom Sackville MP, Parliamentary Under-Secretary of State for Health, House of Commons Hansard, 15 June 1995 (appendix 48)

²⁵ 'HIV, Stigma and You', Michael Carter 2006 (appendix 13)

²⁶ Macfarlane Trust Business Case, 2005 (appendix 14)

²⁷ Sigma Report: Living with HIV (appendix 15)

²⁸ Ibid

²⁹ Ibid

³⁰ Ibid

³¹ Macfarlane Trust, Long Term Review: Final Report 2005 (appendix 14)

³² Ibid

There is a widespread feeling in the community that the Government could do much more to educate the general public about HIV and hepatitis C. Although the NHS is currently running a hepatitis C awareness campaign (faCe it), it needs a higher profile.

Impact on Intimate Relations

'My partner [is] more distant and afraid of catching the virus. It has definitely introduced a barrier that was not present previously.'³³

'I feel I can't get close to my family anymore - my partner and my grandchildren. I feel as if I am not clean anymore to kiss and love them like I used to. It is as if there is a dark cloud over you all the time.'³⁴

There is also the worry about household transmission, particularly with hepatitis C which can be passed on through contaminated toothbrushes, razor blades and similar implements.

Most people with HIV and/or hepatitis C worry about infecting their partners even when precautions are being taken. Often sexual contact ceases altogether as a result.³⁵ There were 63 cases of partners becoming infected with HIV.³⁶

Impact on Families

'The last time I saw [my brother] was suffering from lypodistrophy and looked just like a Belsen victim. He kept saying that when he was better he would do an Open University course. As we left he hugged me, the first time he had ever done this, and I knew I would never see him again. Both my mother and his girlfriend were with him when he died. He was 27. Grief does strange things to people.'³⁷

'A second bombshell fell when we were told he had died of liver failure caused by HCV. His body was put into a body bag with a large notice, no viewing or touching, highly infectious. The family were grief-stricken. No-one had been allowed to pay their last respects.'³⁸

Although it is very rare for women to have haemophilia, they suffer from the enormous pressure of guilt associated in passing the condition on through the family. This is compounded by the remorse felt by those who injected their young sons with infected clotting factor and then watched them develop fatal viruses.

The effect on those who care for people with haemophilia, HIV and hepatitis C can be profound. They often have to deal with the untimely death of loved ones, sometimes children, and there is the added trauma of multiple loss within families and communities.

Many bereaved relatives say that the use of body bags in hospitals after the death of their loved ones added to their distress. We have evidence of a case where the body of the deceased was cremated without the knowledge or consent of the family.

³³ Oxford and Sheffield Survey of People with Hepatitis C and Haemophilia (appendix 5)

³⁴ Ibid

³⁵ Pat Latimer, *The Ethical Dilemmas Experienced by Women Carers who have Suffered Haemophilia and HIV bereavement*, August 1997, p68 (appendix 16)

³⁶ Macfarlane Trust Business Case, 2005 (appendix 14)

³⁷ Torch, 2001 (appendix 17)

³⁸ Hepatitis C Impact Study Interim Report, The Haemophilia Society, December 1995 (appendix 9)

The stigma of HIV and hepatitis C means that carers and bereaved relatives often feel they have no-one to turn to for moral or practical support. If their husband has kept his HIV status a secret in life, they often feel that they must keep his secret in death. This causes a lack of social support, which can be very isolating.³⁹

Starting a Family

'There is an uncertainty in what the future holds, and how to raise children with this in mind.'⁴⁰

'As a parent, you don't want to pass anything on to your children. You want them to have perfect health.'⁴¹

The threat of passing on the HIV and hepatitis C viruses to partners and unborn children is a considerable barrier to starting a family. Sperm washing is possible where the male has a virus and the female does not. After sperm washing, the woman must undergo IUI, IVF or ISCI treatment. Multiple cycles are often necessary, and this procedure is not universally available on the NHS. The Macfarlane Trust assists with travel and hotel expenses, but can only provide this for three cycles due to lack of funds.⁴²

The birth rate in the haemophilia community has fallen steadily since the 1980s. As well as the practical difficulties faced by those infected with HIV and hepatitis C, some women carrying the haemophilia gene fear having children after seeing friends and relatives suffer from deadly viruses.

³⁹ Pat Latimer, *The Ethical Dilemmas Experienced by Women Carers who have Suffered Haemophilia and HIV bereavement*, August 1997, pp28-29 (appendix 16)

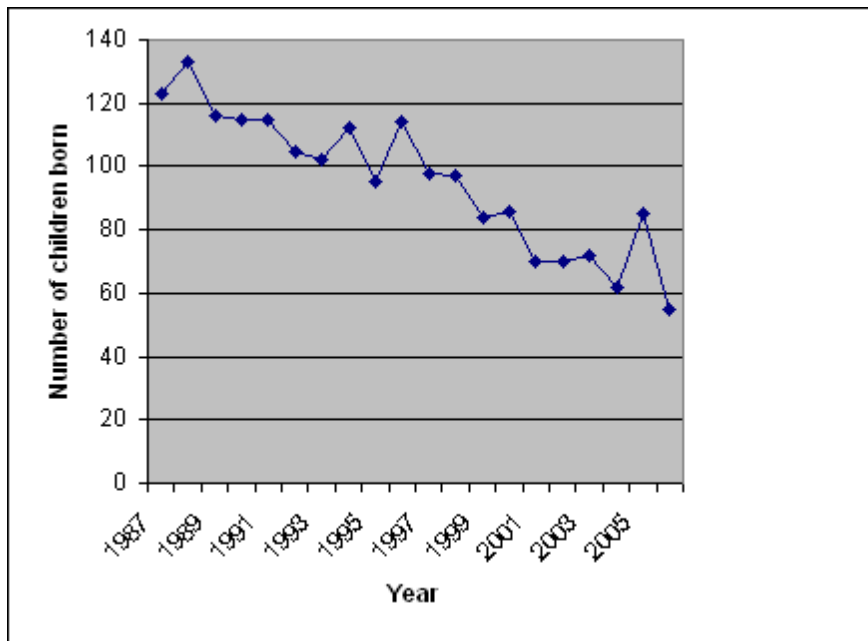
⁴⁰ Ibid

⁴¹ Ibid p37

⁴² Macfarlane Trust Business Case, 2005 (appendix 14)

Number of Children Born with Haemophilia ⁴³

Year	Haemophilia A	Haemophilia B	All haemophilia
1987	97	26	123
1988	113	20	133
1989	97	19	116
1990	95	20	115
1991	104	11	115
1992	90	15	105
1993	85	17	102
1994	92	20	112
1995	81	14	95
1996	98	16	114
1997	85	13	98
1998	84	13	97
1999	71	13	84
2000	69	17	86
2001	60	10	70
2002	63	7	70
2003	61	11	72
2004	47	15	62
2005	73	12	85
2006	47	8	55



⁴³ UKHCDO Birth Rate Statistics (appendix 18)

Financial Circumstances: Employability, Insurability and Mortgages

'The effect on widows and children left behind is shattering both financially and otherwise.'

'A well qualified man with a degree in his early 30s. He has been unemployed for the past four years. Every interview he has, he discloses his antibody status. He is never offered employment.' ⁴⁴

Employment

One in five people with haemophilia and hepatitis C is unable to work due to ill health. This rises to almost two thirds for those who are co-infected.⁴⁵ This compares with an unemployment rate amongst the general population of 5.5%.⁴⁶ Despite receiving limited support from the Macfarlane Trust and state benefits, two thirds of co-infected people have problems with money.

It is not only the illnesses that are debilitating; combination therapy for HIV and interferon/ribavirin treatment for hepatitis C can have extreme side effects which make it difficult or impossible to carry on working. The Haemophilia Society knows of individuals who have postponed accepting interferon treatment because they cannot afford to take the financial risk of being forced to give up work by the side effects of the treatment.

For those who are able to continue working, many have to reduce their hours of work, give up opportunities for promotion, or take a less demanding job. Discrimination and the attitudes of employers also present a barrier to returning to work.

A considerable number of countries require HIV tests for anyone seeking to stay over three months, and some place travel restrictions on those living with HIV even for short stays. Until very recently, it was necessary for people with HIV to obtain a 'waiver' before travelling the USA, even for a short holiday. This further limits opportunities for people with HIV/hepatitis C to pursue 'normal' lives and careers.

The current benefits system is problematic for people with episodic, chronic conditions such as HIV and hepatitis C. Current regulations make it extremely difficult for people with these viruses to try out employment without losing their place in the system if they are unable to continue. Many people with chronic viruses are genuinely unsure of their ability to maintain regular or full time work, and fall into the 'benefits trap'. Complaints have also been made about the attitudes and understanding of benefits staff to people with chronic health problems.

People often require help and support to negotiate the complex benefits system. The Haemophilia Society provides assistance where possible, but we question whether it is fair that people who have been infected by contaminated blood products should have to negotiate this bureaucracy. People who have lived with these viruses, given to them by NHS treatment, are tired of 'holding out the begging bowl'. They should be given the opportunity to be economically independent.

⁴⁴ Haemophilia, HIV, Employment and Discrimination, The Haemophilia Society, March 1989 (appendix 19)

⁴⁵ Report of the Hepatitis C Working Party to the Haemophilia Society (appendix 11)

⁴⁶ www.statistics.gov.uk

Access to financial services

People infected with hepatitis C and/or HIV are also denied access to financial services such as mortgages, pensions and insurance.

If infected with hepatitis C, it is very difficult to get a mortgage. If co-infected with hepatitis C and HIV, it is virtually impossible. Almost all of the Macfarlane Trust registrants survive by claiming state benefits, which automatically limits access to mortgages and pensions. Where there is access to a company pension scheme, the premiums are often so expensive that the majority of those infected are unable to afford them.

Access to life insurance is almost impossible for those infected. Most insurers require those with hepatitis C to have no liver damage. Very few people with hepatitis C are in this position. Again, those who are co-infected are at the biggest disadvantage. Many life insurance companies will not provide cover, and those that do charge prohibitively high premiums.

Debt is a substantial problem in the haemophilia community. Disturbingly, many credit card companies are prepared to lend large amounts of money to people reliant on benefits who have no way of containing or reducing the debt.

The plight of carers

The dependents of those who die from their infections are often the poorest and most disadvantaged sector of the community.

Many recently bereaved partners have been carers for over twenty years. It can be very difficult for them to find employment after their partner dies because, having been out of the labour market for many years, they may lack modern skills or recent experience. They are also often extremely traumatised by their bereavement, and their confidence and self esteem may have suffered.

Welfare benefits such as Disability Living Allowance and Income Support will be withdrawn immediately on their partner's death. If the deceased used a Motability car, that will be reclaimed at once. Any income from the Macfarlane Trust is stopped after fifteen months. The Skipton Fund makes no payment to dependants of people who died of hepatitis C before August 2003.

Even if their partner had managed to get a mortgage, there is no life insurance to pay the mortgage back after death. Bereaved partners are left with large mortgage repayments, and are often forced to sell the family home. For those suffering from viruses, the inability to provide for their family on death is a great source of stress, and causes feelings of inadequacy for those affected.

Recommendations

The current financial provision for people with haemophilia who have contracted viruses through their NHS treatment is woefully inadequate. Compensation must account for loss of earnings, both present and future. The Government must step in to assist with the provision of life insurance, travel insurance and other financial concerns.

Life Expectancy

***'This business case highlights the evidence for re-evaluating earlier assumptions about the funding needs of long-term survivors now coping with prolonged ill health, unremitting personal and social stress, strained family relationships, erosion of capital and savings, falling standards of living, susceptibility to the poverty/benefit/credit traps, burgeoning debt and other financial disadvantage.'*⁴⁷**

The payments made to people with haemophilia and HIV in 1989 and 1991 were based on a life expectancy of three to five years.

Although HIV has been reclassified as a 'chronic manageable condition', this description rarely applies to people with haemophilia and HIV. The presence of a bleeding disorder and the added complication of co-infection with hepatitis C mean that, despite improved treatment, infection with HIV continues to be extremely debilitating. Macfarlane Trust registrants are suffering from more health problems as they live longer, and more are having to give up work and become benefit dependent as they get older.

The statement of intent of the Macfarlane Trust was to provide whatever assistance was necessary to those people damaged by their health treatment. The Trustees feel unable to fully honour this commitment due to lack of funding. In October 2005 they submitted a thorough and well-argued case for their funding to be increased, but this was rejected by the Department of Health.

The Haemophilia Society believes that funding for the Macfarlane Trust should be reassessed in light of the increased life expectancy of survivors. It is simply nonsensical that the Department of Health has failed to significantly reassess funding for the Trust in almost twenty years to reflect the changing needs of the registrants.

⁴⁷ Macfarlane Trust Business Case, 2005 p4 (appendix 14)

Section One: The Effect of HIV and Hepatitis C on the Haemophilia Community Summary

1. People with haemophilia and HIV or hepatitis C have been given life-threatening viruses through infected blood products. Of the 4,670 people infected, 1,757 have since died.
2. Of those that are still alive, many are chronically ill. The available treatments have debilitating side effects. Overall, these viruses have significantly reduced prospects for education and employment amongst the infected community.
3. Infection with these viruses has caused great psychological trauma within the community. Most people have watched friends and relatives become seriously ill and die. They face uncertainty about their own future health, which has been recently compounded by fears of vCJD.
4. Discrimination is commonplace. HIV is particularly stigmatising, and most people feel that they cannot be open about their status. As recently as 2004, a Macfarlane Trust registrant was forced to move house to flee persecution. Other, more subtle, forms of discrimination are commonplace and affect people with both viruses. Access to financial services is problematical, and many experience discrimination in the workplace.
5. Infected people cannot start families without significant risk, challenge and expense. The birth rate in the haemophilia community has plummeted since the 1980s.
6. Many infected people face significant financial hardship as a result of their illness. They face extra expenses related to their health, and two thirds of co-infected people are reliant on state benefits. They worry about the fact that they cannot provide for their dependants after their deaths.
7. Many people with haemophilia are now classed as 'at risk' of contracting vCJD, which leads to difficulties accessing health care and dentistry.

There remains a very real need for services for mono and co-infected people with haemophilia, their carers and relatives. These are specific and unique needs, which are not adequately served by other HIV and hepatitis C charities. This is at a time when the Government is in the process of cutting the Haemophilia Society's funding from £200,000 a year to nil. The Government should commit to future funding to maintain these services.

Section Two: A Duty of Care?

The Government claims to have introduced measures to ensure the safety of clotting products as soon as was practicable. The haemophilia community has uncovered evidence of a litany of delays, each one of which added significantly to the number of people exposed to, and infected by, contaminated blood products.

Self-Sufficiency

'Despite calls from the World Health Organisation in the mid-1970s for countries to be self-sufficient in blood products, all UK efforts failed dismally because of underfunding and lack of political will.'⁴⁸

'The origin of the problem goes back to the 1970s when there was a failure to screen imported blood products. My view is that that demonstrated negligence on the part of the Department of Health. It was known at that time that, in the United States, blood donors were paid for giving blood. Those who feel so hard up that they give pints of blood for money included drug addicts and others whose blood may well have been infected. The Department for Health must have known the risks.'⁴⁹

In 1974 David Owen MP (as he then was), announced as the Minister for Health government funding to move the UK towards becoming self-sufficient in blood products following World Health Organisation recommendations. Funding of £500,000 (half of which was recurring) was set aside to achieve this aim. He repeated this intent in 1976, stating that:

*'In some countries, the screening of blood donors for hepatitis is less rigorous than in the UK. For this reason, the Government's policy of making the UK self-sufficient in the supply of blood products commands wide support.'*⁵⁰

A memo on the Economic Aspects of Blood Production in 1978 stated that:

*'There is plenty factor VIII available from commercial sources, but there is doubt about the circumstances in which the plasma is collected abroad which largely influenced Ministers (so I understand) to enunciate the doctrine of NHS self sufficiency in blood products.'*⁵¹

It is therefore clear that the risk of importing hepatitis in commercial blood products was understood by decision-makers in the 1970s. However, the investment was never made and the situation became worse rather than better.

An inspection of the Blood Products Laboratory in July 1979 resulted in a damning report which concluded that:

'If this were a commercial operation we would have no hesitation in recommending that manufacture should cease until the facility was upgraded to a minimum acceptable level.'

⁴⁸ Rebecca Coombes, *Bad Blood*, British Medical Journal, 28th April 2007, p879 (appendix 20)

⁴⁹ Mr John Marshall MP (Hendon South), 11th December 2006, House of Commons Hansard (appendix 48)

⁵⁰ Department of Health and Social Security Press Release, 29th April 1976 (appendix 21)

⁵¹ Memo from T E Dutton on 'The Economic Aspects of Blood Products Production', 10th July 1978 (appendix 22)

The present facility is totally unsuitable for manufacture of sterile products and incapable of being upgraded to the required standard.’⁵²

The redevelopment of the Blood Products Laboratory was eventually completed in 1987. Had this started in 1974, when David Owen MP first announced an intention to invest, hundreds of HIV infections could have been avoided.

Department of Health Self-Sufficiency Report

‘Why does the [self-sufficiency] report fail to mention Mr Justice Burton’s landmark High Court ruling on the legal duty to provide clean blood?’⁵³

The Department of Health report, *Self-Sufficiency in Blood Products in England and Wales: A Chronology from 1973 to 1991*⁵⁴ has no named author and, despite taking four years to produce, is riddled with inaccuracies.

In our view, the reference list is selective, and does not include many papers which we know to be in existence. We believe that these documents will be made available to the Archer Inquiry, and we expect a different and more accurate version of events to emerge.

Although the Haemophilia Society is mentioned in the document several times, we were not given an opportunity to see or comment on it before it was made publicly available.

The Haemophilia Society wrote a very strongly worded letter to the Head of Blood Policy, the civil servant responsible for this report, to complain about errors and omissions in the report. We stated:

‘The impression given is that public health was somehow the responsibility of the Society, when in fact it was the Government’s. On that point, we cannot find any reference to the Government’s responsibility in relation to contaminated blood products. There is no reference to mistakes made at high levels. There is also, notably, no apology for mistakes made. There are also, unusually we believe, no recommendations about further investigation or future policy. We find this unusual and are frankly incredulous that this is the case.

‘We absolutely refute the impression given in the report that people with haemophilia and parents of children with haemophilia were adequately informed about the risks they took in using blood products or in administering them to their children. This is an outrageous and wicked assertion, for the clear inference is that responsible, caring parents would have knowingly injected their children with potentially life threatening products. There are many people with haemophilia who would be happy to share with you and with Ministers their harrowing personal testimonies. These include absolutely dreadful experiences such as:

- *Not being told about the risks of products*
- *Not being given a diagnosis of HIV and or hepatitis C even when this was known to a doctor and was recorded on the person’s medical file*

⁵² Inspection into the Blood Products Laboratory, 25th July 1979 (appendix 23)

⁵³ Lord Morris of Manchester, House of Lords Hansard, 19th April 2006

⁵⁴ Department of Health, *Self-sufficiency in Blood Products in England and Wales - A Chronology from 1973 to 1991*, 2006 (appendix 24)

- *Being informed of a life-threatening diagnosis 'by accident' by a junior doctor in a totally inappropriate way*
- *Being involved in clinical trials without giving informed consent.'*⁵⁵

We raised the following specific concerns about inaccuracies in the report:

- It is stated that 'the Government pursued the goal of self-sufficiency in factor VIII during the 1970s and most of the 1980s, in line with WHO and Council of Europe recommendations.'⁵⁶ This statement is not backed up by evidence. In fact, the Government took no action at all until the BPL was condemned in 1980, and the redevelopment was not completed until 1987.
- It is not explained why the size of donor pools increased from approximately 200 to 15,000 between 1970 and the mid-1980s, or whether any assessment was made of the added risk that this posed. Nor, crucially, is the high risk background of many paid American donors discussed.
- The report claims that in the 1970s and early 1980s hepatitis C was thought to be a mild infection; documents recently released by the Government paint a different picture. Concerns grew throughout the 1970s about the severity of 'non-A, non-B' hepatitis, and by 1980 it was known to be 'rapidly fatal (particularly when acquired by patients with pre-existing liver disease) or can lead to progressive liver damage.'⁵⁷
- It is stated that there was no reliable test for 'non-A, non-B' hepatitis until 1991. On the contrary, a test was available from 1989 and widely used in other countries, including France, the USA, and Canada, by 1990.⁵⁸ Indeed, West Germany introduced a surrogate test in 1965. In a landmark legal judgement, Mr Justice Burton stated that the Government should have introduced the first generation hepatitis C antibody test in March 1990, and a surrogate test prior to this. Inexcusably the report failed to mention his ruling, which also categorically stated that the Government had 'a legal duty to provide clean blood'.⁵⁹
- The issue of HIV is barely referred to at all. The report incorrectly states that concerns were first raised about the possibility of people with haemophilia contracting AIDS through commercial blood products in 1983. In fact, haemophilia doctors knew that HIV was a problem when the first cases were identified in 1981.⁶⁰ The dangers were conclusively identified after the first UK diagnosis of a person with haemophilia with AIDS in 1982.⁶¹ In January 1983 an article in the *New England Journal of Medicine* stated that people with

⁵⁵ Letter from Chief Executive of the Haemophilia Society to Head of Blood Policy, 28th March 2006. The response is also attached (appendix 25)

⁵⁶ Department of Health, *Self-sufficiency in Blood Products in England and Wales - A Chronology from 1973 to 1991*, 2006

⁵⁷ Letter from Diana Walford to Mr Harley, 15th September 1980 (appendix 26)

⁵⁸ Scottish Parliament Research Note for Health and Community Care Committee, 11th December 2000 (appendix 27)

⁵⁹ *A and Others v the National Blood Authority and Others* [2001]EWHC QB 446 (appendix 28)

⁶⁰ *Haemophilia: Recent History of Clinical Management*, The transcript of a Witness Seminar held at the Wellcome Institute for the History of Modern Medicine, London, on 10 February 1998. Edited by D A Christie and E M Tansey, p65 (appendix 6)

⁶¹ Minutes of the 13th Meeting of UKHCDO, University Hall of Residence, Owens Park, Manchester. Monday 13th September 1982. Page 10, paragraph 3 (appendix 29)

haemophilia were at risk of contracting AIDS through blood products, and it was suggested that clotting factor should be withdrawn in favour of cryoprecipitate.⁶² No assessment is made of whether appropriate precautions were taken to prevent the spread of HIV through blood products at this point.

The Head of Blood Policy refused to answer any of these important questions, responding: 'I do not propose to respond to your individual comments.' Our 'comments' – as he called them - were *questions* not comments and we were very disturbed by his lack of engagement and transparency.

It is widely believed that, had the Government delivered self-sufficiency as promised, hundreds of people with haemophilia would have been spared HIV infection. The Self Sufficiency Report raises more questions than it answers. We hope that this Inquiry will finally provide the thorough investigation that is needed.

⁶² The New England Journal of Medicine, AIDS and preventative treatment of haemophilia, January 1983 (appendix 30)

Delays in Heat Treatment, Testing and Screening

Heat Treatment

'In France, two senior staff members at the National Blood Transfusion Service were sentenced to prison for supplying HIV-infected clotting factors to patients. They were accused of having major roles in the decision not to use heated blood products after 1983, an action purportedly taken because of the belief that the French blood supply was safe.'⁶³

In May 1983 it was discovered that the HIV virus could be destroyed by exposing it to dry heat at 68 degrees centigrade for one hour.⁶⁴ By the summer of 1983, a rudimentary test was developed that could have been used to test each batch of blood products. Despite this, heat-treatment of blood products was not introduced in the UK until 1985. The Government also delayed testing blood donors for HIV from January 1985 to October 1985. The UK was one of the last countries in Western Europe to introduce HIV testing.

The haemophilia community is concerned about the possibility that financial concerns contributed to the delay in introducing heat treated factor product. In July 1983 a Department of Health official wrote to the Regional Transfusion Centre in Manchester:

*'Your comments about the potentially major financial consequences for health authorities, in the event of unjustified demands for this material [heat-treated concentrate] being made, could be used to support the argument for the need for properly controlled clinical trials before such material is introduced in this country.'*⁶⁵

Scottish clotting factor was not heated to a temperature high enough to kill hepatitis C until 1987, eighteen months after England and Wales. This is entirely indefensible. Once again, many infections could have been prevented.

Hepatitis C Screening

'Surrogate testing should have been in place by March 1988. Routine screening ought to have been introduced at the earliest practicable time, which I have concluded to be 1 March 1990.'⁶⁶ Mr Justice Burton

'Donor screening for HIV was introduced in 1985 and donor screening for hepatitis C was introduced in September 1991. Both these microbiological tests were introduced as soon as practicable.'⁶⁷ Caroline Flint MP

⁶³ Legal, Financial and Public Health Consequences of HIV Contamination of Blood and Blood Products in the 1980s and 1990s, Annals of Internal Medicine, Volume 136, Number 4, 19th February 2002 (appendix 33)

⁶⁴ Public Health Service Press Conference re Hyland Heat Process/AIDS, June 17th 1983 (appendix 31)

⁶⁵ Letter from the Department of Health and Social Security, 1 July 1983 (appendix 32)

⁶⁶ Mr Justice Burton, A and Others v National Blood Authority and Others [2001] EWHC QB 446 (appendix 28)

⁶⁷ Caroline Flint MP, Minister for Public Health, Response to Commons Parliamentary Question, 22nd February 2007 (appendix 49)

The UK was one of the last countries in the western world to introduce a test for hepatitis C. Prior to the discovery of a specific test in 1989, many countries used surrogate tests. These tested people for raised ALT (liver enzyme) levels or hepatitis B. Although surrogate tests were crude and showed a high number of false positives, many countries thought it best to err on the side of caution.⁶⁸ West Germany introduced a surrogate test in 1965. Other European countries such as Italy and France followed suit. The USA introduced surrogate tests in September 1986.

Following the discovery of a specific test, routine anti hepatitis C screening was introduced in Japan in November 1989. Australia, the USA and most EEC countries swiftly followed in 1990.⁶⁹ Yet this test was only introduced in the UK in September 1991.

In the 1991 court case *A and Others v National Blood Authority and Others*, Mr Justice Burton held that surrogate testing should have been used prior to the development of a specific test, and that specific hepatitis C testing should have commenced in March 1990.⁷⁰

Once again, valuable time was lost, and more people became preventably infected as a result.

Testing

The Haemophilia Society has evidence of considerable delays in informing patients of their HIV status and testing them for hepatitis C. Many people with haemophilia have reported being tested without their knowledge or consent, and then not being told of the result.

The Haemophilia Reference Centre Directors decided on 10th December 1984 that:

*'Directors would like to test all haemophiliac [sic] patients in order to establish their antibody status. Patients who asked for their HTLV III [AIDS] antibody test results should be informed of them otherwise it is up to individual Directors to decide whether or not they wish to tell patients their results.'*⁷¹

Because they did not know about their viruses, infected people were unable to take appropriate precautions to protect those close to them. Sixty three partners of people with haemophilia and HIV were infected with HIV themselves. Some of these infections could have been avoided. Indeed, we know that physicians had an awareness of the risk of AIDS to spouses of people with haemophilia from as early as October 1983.⁷²

In the case of hepatitis C, cutting out alcohol significantly improves the prognosis. Again, in many cases patients were not given the knowledge necessary to safeguard their own health.

Again, more delays meant more preventable infections.

⁶⁸ Scottish Parliament Research Note for the Health and Community Care Committee, 11th December 2000 (appendix 27)

⁶⁹ *A and Others v National Blood Authority and Others* [2001] EWHC QB 446 (appendix 28)

⁷⁰ *ibid*

⁷¹ Minutes of the Meeting of the Haemophilia Reference Centre Directors – 10 December 1984 (appendix 34)

⁷² Notes of the 14th UKHCD Meeting, Oxford RHA, dated 17th October 1983 (appendix 35)

Risk Assessment

'The fact that haemophiliacs are at risk of AIDS is becoming clear. If the use of cryoprecipitate will minimize the risk, the current home infusion programme needs to be revised.'⁷³

In March 1983 restrictions were introduced excluding high risk blood donors in the USA from giving blood or plasma. However, the UK continued to import plasma which had been collected from paid donors prior to these restrictions being introduced.

From the summer of 1983, the ability existed to test batches of clotting factor for HIV. No assessment was made of whether this would have been appropriate. Likewise, although heat treatment was introduced in the UK in March 1985 (already later than many other countries) old stock was used up and heat-treated plasma was not in common use until September 1985.

The Government decided not to ban the import of potentially contaminated clotting factor because 'to do so would cause a crisis of supply'.⁷⁴ No risk assessment was carried out to assess the dangers of continuing to import blood products, or to ascertain what steps could be taken to reduce those dangers.

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 suggested that a return to treatment with cryoprecipitate should be considered. Although not risk free, this was known to be safer because of the exposure to the blood of much fewer donors.

By July 1983, the Haemophilia Centre Directors Hepatitis Working Party had discussed the risks of people with haemophilia contracting AIDS from contaminated blood.⁷⁵

By that time, guidelines had been introduced stating that:

'It is recommended that cryoprecipitate be used to treat patients in the following groups except where there is an overriding medical indication:

- *New born infants and children under 4;*
- *Newly identified patients never treated with factor VIII concentrate; and*
- *Patients with clinically mild haemophilia who require infrequent treatment.'*⁷⁶

The guidelines went on to recommend that DDAVP (synthetic vasopressin analogue) should be used whenever possible in patients with mild or moderate haemophilia A.

The Haemophilia Society is aware of numerous cases where infants, new patients and people with mild haemophilia were treated with clotting factor between 1983 and 1985, apparently in contravention of treatment guidelines. Many went on to develop HIV, hepatitis C or both. Yet again, many infections could have been avoided had the guidelines been followed

⁷³ The New England Journal of Medicine, AIDS and preventative treatment of haemophilia, January 1983 (appendix 30)

⁷⁴ Letter from The Lord Glenarthur to the Revd Alan Tanner, 28th September 1983 (appendix 36)

⁷⁵ Minutes of the UK Haemophilia Centre Directors Hepatitis Working Party, 11th July 1983 (appendix 37)

⁷⁶ World Federation of Hemophilia guidelines, 18th May 1983 (appendix 38)

It is in our view crucially important that the Inquiry investigates why, when the dangers of AIDS were clear by 1983, steps were not taken to minimise the risks.

Informed Consent

'If I'd known the dangers, I'd never had taken it.'⁷⁷

'I do not accept that the consumer expected, or was entitled to expect, that his bag of blood was defective even if (which I have concluded was not the case) he had any knowledge of the problem. I do not consider...that he was expecting or entitled to expect a form of Russian roulette.'⁷⁸

Successive governments have maintained that it is regrettable but unavoidable that thousands of people with haemophilia contracted viruses while receiving 'life saving' treatment. This 'lesser of two evils' argument ignores that fact that it was not inevitable that people with haemophilia would die without treatment with factor concentrate.

As we have already seen, people with mild and moderate haemophilia did not need to use clotting factor, and should not have been treated with it. Most people with severe haemophilia A used clotting factor as prophylaxis. It offered significant improvements to their quality of life and protection from damaging bleeds, but there was no immediate threat to life. Some patients, particularly those who were older or living in areas that were slower to adopt new treatments, were still using cryoprecipitate in the early 1980s.

Patients with severe haemophilia should have been given the opportunity to make an informed decision whether to use clotting factor or not. Many would have chosen the known dangers of untreated haemophilia, or more inconvenient treatment by cryoprecipitate, to the risk of contracting AIDS.

We are also aware of at least one case where unheated US Factor VIII was administered to a man undergoing a routine operation in September 1985, despite his insistence that he would only accept treatment from an English source.⁷⁹ He consequently became infected with HIV. In such cases there appears to be a clear breach of consent.

Was the haemophilia community used as a research base for HIV and HCV?

'Although immunological abnormalities in patients with haemophilia A are well recognised without HIV infection, information from this uniquely homogenous cohort is of special value because its members were assessed immunologically before exposure to HIV and have participated in detailed follow up studies at regular intervals.'⁸⁰

For over two decades the haemophilia community has been troubled by the suspicion that they may have unknowingly been used as a research base to study the infectivity and progression of HIV and hepatitis C.

⁷⁷ John McAughey, *Inquiry Set to Clear Doctors over Hepatitis C Infections*, Sunday Herald, 9th July 2000

⁷⁸ *A and Others v National Blood Authority and Others* [2001] EWHC QB 446 (appendix 28)

⁷⁹ Letter from Mansell Stevenson Solicitors, 23rd March 1987 (appendix 39)

⁸⁰ RJG Cuthbert, CA Ludlam, J Tucker, CM Steel, D Beatson, S Rebus, and JF Peutherer, *Five year study of HIV infection in the Edinburgh haemophiliac cohort*, BMJ Volume 301, 27 October 1990, p960 (appendix 41)

In common with other campaigning groups, the Haemophilia Society has obtained documents referring to research on people with haemophilia. In January 1982 a memo to haemophilia centre directors requested that colleagues identify 'previously untreated patients' on which to test the 'non-A, non-B' hepatitis infectivity of various concentrates.⁸¹ There is widespread concern that this may explain why infants and people with mild to moderate haemophilia were treated with clotting factor contrary to guidelines.

The following year, once it was apparent that infection with AIDS would be widespread in the haemophilia community, the minutes of the Haemophilia Reference Centre Directors meeting record that:

*'Inconsistencies in the results of the tests reveal that a study of the haemophiliac population [sic] would provide invaluable material to increase our knowledge of the disease. I believe a study of haemophiliac patients could be regarded as a research project now.'*⁸²

One report describes an infectivity test to discover whether one infected donor could infect the whole pool, and therefore all recipients from that pool, with HIV. The report states that:

*'There is a group of previously negative patients, the Edinburgh cohort, who received Factor VIII from a pool containing a single seropositive unit of plasma. The recipients of this pool have been intensively followed by antibody and PCR studies. Thirty-two patients received this lot of Factor VIII, and 18 seroconverted.'*⁸³

Those who suspect that they were involved in these trials are adamant that they did not give consent. Given the potential health risks, one would have thought that no less than fully informed, written consent would be required, and that these forms would be retained for future inspection.

The haemophilia community recognises that no treatment is without risk. Research and development is crucial to improve future treatment, and the testing of innovative treatments on humans will be necessary at a late stage of development. However, the haemophilia community deserves a full and honest explanation of how and why any experiments were carried out, and whether the appropriate level of consent was obtained.

The Haemophilia Society hopes that this Inquiry will investigate whether people with haemophilia were used as a research base for HIV and hepatitis C.

⁸¹ Memo from AL Bloom and CA Rizza, Oxford Haemophilia Centre, to all Haemophilia Centre directors, 11th January 1982 (appendix 40)

⁸² Minutes of the meeting of the Haemophilia Reference Centre Directors, 10 December 1984 (appendix 42)

⁸³ David L Aronson, *Infection of Haemophiliacs with HIV*, Journal of Clinical Apheresis, 8:117-119,1993 (appendix 43)

Section Two: A Duty of Care?

Summary

A full exploration of the Government's policy on blood products from the 1970s onwards reveals a litany of delays, missed opportunities and careless assumptions.

- Failure to work towards self sufficiency in the 1970s condemned the UK to a continuing reliance on imported commercial blood products. The Government was well aware that these products were made from plasma collected from paid donors, including prisoners and other people with high-risk lifestyles.
- Heat treatment of blood products could have been introduced in 1983. This was delayed for two years. Similarly, it became possible to test batches of clotting factor by the summer of 1983. Again, no testing was introduced until late 1985.
- Considerable delays in informing patients of test results contributed to the infection of 63 intimate relations, despite the risk of sexual transmission being known about in 1983.⁸⁴ Without knowledge of their illnesses, those infected with HIV and hepatitis C could not take action to safeguard their own health and that of others.
- There are many apparent cases of failure to observe the guidelines, which recommended that patients with mild or moderate haemophilia and infants should not be treated with clotting factor.
- The UK was one of the last countries in the developed world to introduce hepatitis C screening and testing.
- The introduction of heat treatment to eradicate hepatitis C from Scottish blood products was inexplicably delayed by eighteen months.

Timely action to deal with any one of these issues would have saved lives. Added together, it is clear that thousands of infections could have been prevented.

In addition, we are concerned that there was a failure to secure informed consent to being treated with a high-risk product. As Justice Burton said, patients could not have suspected that they were playing 'Russian roulette' when they accepted treatment. That is exactly how it was.

This summary explains why people with haemophilia suspect that they were used as a research base to study the progression and infectivity of HIV and hepatitis C; and it is very important for the haemophilia community's peace of mind that these concerns are fully investigated by the Inquiry.

Most people with haemophilia have now been classified as 'at risk' of developing vCJD. Evidence is mounting that this is leading to difficulty in accessing health and dental care. In light of the community's ongoing concerns about medical care, the Haemophilia Society must be given representation on statutory bodies.

⁸⁴ Notes of the 14th UKHCD Meeting, Oxford RHA, 17th October 1983 (appendix 35)

Section Three: The Campaign for a Public Inquiry

***'There has been no negligence; it is one of those tragedies. There is no need for a public inquiry.'* – Lord Warner⁸⁵**

***'We are told nobody is to blame for the disaster. But how can this be validated, except by an independent inquiry and how, without one, shall we ever know whether the risk of vCJD would have been reduced had the safer recombinant treatment been available for all haemophilia patients in 1995? Is there not now a compellingly urgent need for a wide-ranging public inquiry into this worst-ever treatment disaster in the history of the NHS?'* – Lord Morris of Manchester⁸⁶**

Parliamentary Activity

For over twenty years the haemophilia community has worked tirelessly with parliamentarians and other decision-makers and supporters to keep the issue of contaminated blood on the political agenda.

In the 1970s the debate centred on self sufficiency. Concerns were raised about the cost of imported blood products, and the threat of their contamination with hepatitis C. The first Parliamentary Question about the possibility of people with haemophilia contracting AIDS from infected blood products was tabled in July 1983.⁸⁷

By 1985 the problem of AIDS was frequently debated. At the time it was thought that the virus would prove rapidly fatal in all cases. A campaign for financial assistance was launched in 1986, and political pressure mounted for urgent payments to be made. The Macfarlane Trust was set up to administer a hardship fund in 1987, and in 1989 paid those affected a lump sum of £20,000 each. A further payment was made in 1991, following legal action which resulted in an out-of-court settlement. This varied from £20,500 to £60,000 depending on family circumstances and marital status.

There was discussion of the effect of social stigma of HIV. In the late 1980s the Haemophilia Society lobbied parliamentarians intensely to tackle employment discrimination based on HIV status; but the Government refused to act.

By the early to mid 1990s, the full extent of the hepatitis C 'time-bomb' was starting to become clear. Campaigners focussed on the need for a tracing exercise to identify and test all patients who may have been infected with hepatitis C. It was apparent now that chronic hepatitis C could be a debilitating and life-threatening illness, and calls were made for financial assistance.

In 2004 it was finally announced that people with haemophilia who had contracted hepatitis C would be entitled to ex-gratia payments. Parliamentarians argued that it was wrong to exclude relatives of those already deceased and those suffering from hepatitis B, but to no effect.

⁸⁵ House of Lords Hansard, 26th May 2005 (appendix 44)

⁸⁶ House of Lords Hansard 28th October 2004 (appendix 44)

⁸⁷ Parliamentary Question by Gwyneth Dunwoody MP, 11th July 1983 (appendix 49)

Recombinant Treatment

By 1993 recombinant treatment started to become available. Although it was officially declared the treatment of choice by the UKHCDO in 1995, roll out was slow. Despite concerns about vCJD, which cast further doubt on the safety of human blood products, the Government did not agree to fund recombinant for all until 2003. Full roll out was only completed in 2006.

For over two decades the haemophilia community has campaigned for a full public inquiry to discover how people with haemophilia came to be treated with contaminated blood products, and to what extent this disaster could have been averted. This call has frequently been repeated in both houses, particularly by Lord Morris of Manchester, who deserves credit for his tireless work.

Parliamentary Questions

House of Lords

'Lord Morris of Manchester asked Her Majesty's Government:

What representations they are considering on the Market Research Bureau's recent finding that the United Kingdom has the lowest availability of recombinant for people with haemophilia in the developed world; and whether they will be taking any action.

'The Parliamentary Under-Secretary of State, Department of Health (Lord Hunt of Kings Heath): These findings have been drawn to the Government's attention by the Haemophilia Society and the All Party Parliamentary Group on Haemophilia.

'In England, all haemophilia patients up to the age of 21 years receive recombinant clotting factors. The Government are considering the case for extending provision to all other haemophilia patients. A decision will be made shortly.'⁸⁸

Between 1989 and 2007 110 questions were asked in the House of Lords about people with haemophilia being treated with contaminated blood. Twenty two questions concerned payments for those affected by hepatitis C, and twenty tackled the subject of the threat of contracting vCJD from the blood supply. The same number of questions was asked about the availability of recombinant treatment, an issue closely linked to increasing concerns about vCJD.

⁸⁸ House of Lord Hansard, 16th January 2003 (appendix 44)

House of Commons

'Jenny Willott: To ask the Secretary of State for Health whether blood taken from people with haemophilia has been used at any time since 1977 to measure the pathogenic potential of the UK blood supply; and if she will make a statement.

'Caroline Flint: We are unaware of such assessments. Donor screening for HIV was introduced in 1985 and donor screening for hepatitis C was introduced in September 1991. Both these microbiological tests were introduced as soon as practicable.'⁸⁹

Between 1989 and 2007 230 questions were asked in the House of Commons about treatment for people with haemophilia. The long campaign for universal access to recombinant treatment is reflected in the fifty questions asked. Sixty two questions were asked about payments for those infected with hepatitis C, and the fact that bereaved partners were excluded from the eventual announcement.

Debates

House of Lords

Lord Warner: 'This was blood given to people when it was a matter of life or death whether they received blood, and we were acting on the best scientific and clinical advice at the time.'⁹⁰

Lord Jenkin of Roding: 'Bearing in mind that the Department [of Health] "inadvertently" as the Minister said in response to me in an earlier Question, destroyed all its own files on contaminated blood products and that much new information has recently come to light in the United States, Canada, Ireland and Scotland, is there not now an unanswerable case for a full and impartial public inquiry into what really has been one of the major medical disasters of the National Health Service.'⁹¹

As well as discussions about hepatitis C payments, vCJD and access to recombinant treatment, Peers have raised questions about the number of documents relating to blood supplies during the late seventies and early eighties that have gone missing while being stored by the Department of Health.

Calls for a full public inquiry into the contaminated blood scandal have been frequently made.

⁸⁹ House of Commons Hansard, 22nd February 2007 (appendix 49)

⁹⁰ Lord Warner, House of Lords Hansard, 24th May 2006 (appendix 44)

⁹¹ Lord Jenkin of Roding, House of Lords Hansard, 19th April 2006 (appendix 44)

House of Commons

*'The Haemophilia Society, with strong support from both sides of the House, is simply calling for parity and has documented in an impressive recent report the appalling effects on families of failure to concede their claim. In none of the campaigns I have been closely involved in here over the years – among them those for the thalidomide victims, for children with dyslexia and autism, for war widows and for haemophiliacs infected with HIV – have I had so strong a sense that no campaigning should be necessary to right such an obvious wrong.'*⁹²

*'The patients we are now discussing received the best possible treatment available in light of the medical knowledge at the time.'*⁹³

In the 1970s, the main theme of House of Commons debates was self sufficiency. This was reprised in 2006, when the Government's *Self Sufficiency Report* met with fierce criticism.

In the mid to late 1980s financial assistance to people with haemophilia who had contracted HIV was frequently discussed. After the Macfarlane Trust was set up, MPs also called for payments to others infected with HIV through blood products.

In the 1990s, pressure grew for assistance to be given to people suffering from hepatitis C. Urgent calls were also made for people with haemophilia to be prescribed recombinant clotting factor, with heavy emphasis on the preventable dangers of not doing so.

Parliamentary calls for a public inquiry have been frequently made over nearly two decades, many of them supported by MPs.

Early Day Motions

32 Early Day Motions indicated support for people with haemophilia between 1989 and 2007. These have featured frequent calls for a public inquiry, and requests for financial assistance for people with haemophilia suffering from HIV and hepatitis C.

One EDM, which gained considerable support in 2002, highlighted the fact that, at the time, the United Kingdom had the lowest provision of recombinant treatment for people with haemophilia in the developed world.

Select Committee on Health

In 1999 the Haemophilia Society gave evidence to the Select Committee on Health, which was considering 'Procedures Relating to Adverse Clinical Incidents and Outcomes in Medical Care'.

The Society called for a full public investigation and appropriate follow up in all cases of a wide-scale adverse outcome. We also asked for the role of relevant professional bodies to be reviewed to ensure that early warning signs of widespread adverse outcomes could be effectively picked up and acted upon more urgently. Rapid reaction

⁹² The Rt Hon Alf Morris MP (as he then was) calling for financial assistance for people with haemophilia infected with hepatitis C, 11th December 1996 (appendix 48)

⁹³ Mr John Horam, Under Secretary of State for Health (appendix 48)

is necessary in such circumstances to minimise the number of people preventably damaged. In our view, it is one of the main lessons to be learned from the disaster experienced by the haemophilia community.

We also pressed for a system of 'no-fault' compensation to be introduced in cases of adverse clinical outcomes.

That our recommendations were not acted upon was a missed opportunity for life-saving lessons to be learned.

Ministerial Contact

***'The Government does not accept that any wrongful practices were employed at the time and does not consider that a public inquiry is justified.'*⁹⁴**

The haemophilia community has maintained contact with successive health ministers from the outset and its parliamentary supporters have engaged them in cross-examination of their policies in both houses.

The response has been that *'patients received the best treatment available in light of the medical knowledge at the time'*.

The Haemophilia Society does not share this view. Without an independent review of its validity, no minister can be sure that the best treatment was given. We are concerned that, at best, the Ministers' responses have been complacent, implying that there are no lessons to be learned.

It is hard to conceive how, other than by an independent review, the circumstances surrounding the infection of 4670 people from a single cause, of whom 1757 have subsequently died, could be properly investigated.

⁹⁴ Letter from Melanie Johnson MP, Parliamentary Under Secretary of State for Public Health, to Lord Morris of Manchester, 29th October 2003, in response to being presented with new evidence that the Government knew of the dangers of non-A, non-B hepatitis in the 1970s (appendix 45)

Missing Documents

The Government has stated that most of the documents relating to blood and blood product supply in the 1970s and 1980s have been ‘destroyed in error’.⁹⁵ The haemophilia community finds it highly coincidental that so many important documents were destroyed ‘inadvertently’ – to use another of the Department of Health’s favoured expressions - so soon after the HIV litigation of the early 1990s. Moreover, substantial anecdotal evidence suggests that the shredded documents included evidence of the Government having delayed the introduction of heat treatment due to the costs involved.

Lord Jenkin and Lord Owen, both former ministers, have also complained that they have been unable to gain full access to their papers retained by the Department of Health after their departure.

When the litigation of the early 1990s was settled out of court, 1429 ‘deeds of undertaking’ (waivers) were said to have been signed. Almost all of these ‘deeds of undertaking’ have been destroyed whilst in the care of the Department of Health.

In the 1980s it was not common practice for medical notes to be made available to patients. Patients now have access to their notes, but many have found that whole sections of notes relating to their medical care during this period are now missing.

The Haemophilia Society has applied, under the Freedom of Information Act, to view a number of documents which we know are relevant and have not been destroyed. We have been refused access to 19 of these documents.⁹⁶

Referrals to the Parliamentary Ombudsman

In 1990 the Rt Hon Alf Morris MP (as he then was) presented to the Parliamentary Ombudsman the case of Gerald Hillary, who died of AIDS related illness aged sixteen in 1989 and whose parents have given evidence to this Inquiry. The Ombudsman refused to investigate the case on the grounds that the Haemophilia Society was engaged in litigation. Alf Morris commented:

‘I am deeply disappointed by the reply since my complaint was one of maladministration that has already taken more than 200 lives and threatens over 1,000 more. The Ombudsman is factually wrong to say that the Haemophilia Society is engaged in litigation. On the contrary, the Society’s main preoccupation is to help victims of the maladministration who have no prospect whatever of seeing redress in the courts. As of now, there is a ‘cover up’ in the Department of Health that bars those litigating from accessing documents that are essential to any proper adjudication of their legal actions. Only the Ombudsman can end the ‘cover up.’⁹⁷

In 2003 Chris Hodgson, who then chaired the Haemophilia Society, made a maladministration complaint on the grounds that the slow roll out of recombinant put the

⁹⁵ Letter from Sir Nigel Crisp KCB to the Rt Hon the Lord Jenkin of Roding, 1st December 2005 Ref CEOP048361 (appendix 46)

⁹⁶ Letter from Caroline Flint MP to the Chair of the Haemophilia Society, 25th January 2007 (appendix 47)

⁹⁷ Press Release, The Haemophilia Society Urges Ombudsman to Think Again, August 30th 1990. See also letter from William Reid, Parliamentary Commissioner for Administration to the Rt Hon Alfred Morris QSO MP, 9th August 1990 (appendix 50)

health of people with haemophilia at risk. The Ombudsman refused to investigate this because 'decisions relating to the provision of recombinant products are matters of policy, not administration'.⁹⁸ Presumably there can be investigations of preventable damage to patients if – as in Chris Hodgson's complaint – the issue is judged to be one of policy, not administration.

Several other complaints of Government maladministration in the treatment of haemophilia patients have been referred to the Ombudsman. None of them have been investigated.

The Scottish Parliament

The campaign was taken to the Scottish Parliament after it was set up in 1999. As well as sharing UK-wide concerns, Scots with haemophilia have sought to discover why full heat treatment of blood products was not introduced there until 1987.

The Ross Report

The Report of the Expert Group on Financial and Other Support (known as the Ross Report) was commissioned by the Scottish Executive and delivered in March 2003. It recommended:

- a) *'an initial lump sum of £10,000 to cover inevitable anxiety, stress and social disadvantage;*
- b) *an additional lump sum of £40,000 to those who develop chronic hepatitis C to cover pain and suffering;*
- c) *in addition, those who subsequently suffer serious deterioration in physical condition because of hepatitis C infection e.g. cirrhosis, liver cancer or other similar serious condition(s), should be entitled to full compensation. This compensation should be calculated on the same basis as common law damages taking account of the payments made under A and B above;*
- d) *where people who would have been beneficiaries of these arrangements are deceased and their deaths were not due to the hepatitis C virus, the above payments should pass to their Executors. Where their death was due to the hepatitis C virus, the compensation should be paid to their Executor and relatives.'*⁹⁹

Lord Ross emphasised the importance of the estates of the deceased being entitled to its recommended payments:

*'While we appreciate the Minister's desire to focus on people who are alive, we also believe that it is manifestly unjust that no payments are proposed for people who are deceased. This, in particular, can only serve to increase the worry and frustration of those who are alive because they might not survive to qualify for the payment. For those who have died, it can only add a feeling of unfairness to the grief of relatives, especially when the delay which cuts off compensation is no fault of the deceased.'*¹⁰⁰

Moreover, the report recommended other helpful measures including access to understandable information on hepatitis C, counselling services, a publicity campaign to

⁹⁸ Letter to Chris Hodgson from Ann Abraham, 12th March 2003 (appendix 51)

⁹⁹ Report of the Expert Group on financial and other support, Commissioned by the Scottish Executive, March 2003, p8 (appendix 52)

¹⁰⁰ Ibid, p23

raise awareness and reduce stigma, advice and assistance in securing appropriate and adequate assurance and insurance.

These recommendations were not implemented, but the Scottish Executive accepted the case for ex-gratia payments. They decided to introduce a standard payment of £20,000 for hepatitis C infection, followed by another £25,000 for those who developed advanced liver disease.

It is plain that the Scottish Executive's decision to make ex-gratia payments to people with hepatitis C added to the pressure on the Westminster government to follow suit, and one payment scheme was eventually established across the UK.

Health Committee

On 31st January 2006 the Scottish Parliament's Health Committee met to consider the case for an inquiry into infection with hepatitis C as a result of NHS treatment. Members of the Scottish haemophilia community gave evidence to the committee and, after requesting further information, the Committee agreed to call for an independent public inquiry. The Scottish Health Minister, Andy Kerr MSP, rejected this request, but the Scottish health sub-committee has refused to change its recommendation.

Legal Routes Explored

In 1986 the haemophilia community launched a campaign for compensation. The following year the Government allocated £10 million to set up a hardship fund. The Macfarlane Trust developed from this, and in 1989 administered an ex-gratia payment of £20,000 to every haemophilia patient infected with HIV.

Whilst this was a welcome step in the right direction, it was clearly insufficient to meet the needs of over a thousand co-infected people. In addition, it was felt that a full public inquiry was necessary to identify the cause of the catastrophe, and ensure that lessons were learned.

National Health Service Act

'Now that the issues have been clarified by the pleadings, I wish to invite the parties to give anxious consideration to the prospects of any compromise of these proceedings.'¹⁰¹

'Physical hardship can be alleviated by medicine, but peace of mind cannot be guaranteed by someone saying, "Let us have a court case to be determined next March, April or June." If we wait for a court case to be determined then a number of victims will not be around to see the verdict. Posthumous justice will not grant them peace of mind; it may help the relatives but it will not help them.'¹⁰²

A class action was held from 1989 to 1991 which was based on an alleged breach of the National Health Service Act 1977. Breaches of common law and the European Convention on Human Rights were also claimed.

¹⁰¹ Justice Ognall's statement of direction, 26th June 1990 (appendix 53)

¹⁰² Mr John Marshall MP, Hendon South, House of Commons Hansard 15th October 1990 (appendix 48)

In June 1990 Mr Justice Ognall made a statement to Chambers in which he invited the parties to the litigation to give 'anxious consideration' to the prospects of a compromise.

In September 1991 leading Counsel were directed that:

'Between now and the summer of 1992 scores of haemophiliacs will die. Whatever the result of the litigation, the costs will be massive, and nearly all will be met by the public as taxpayer. The conclusion is surely compelling. Such monies should be expended as part of the compensation to these innocent victims rather than in legal costs.'

Counsel therefore advised acceptance of a settlement, which meant a withdrawal of Legal Aid from any claimant who refused the offer. Those who wished to continue were faced with overwhelming costs if they wished to pursue the claim. The health of many claimants was also deteriorating rapidly.

The case was settled and ex-gratia payments of between £21,500 and £60,000 (depending on age and family circumstances) were made in 1991. Recipients were asked to sign a waiver¹⁰³ rescinding their right to bring any future legal action 'concerning the spread of human immuno-deficiency virus or hepatitis viruses' through blood products.

This waiver is controversial because many people with haemophilia believe that the Government knew at the time that non-A, non-B hepatitis was widespread in the haemophilia community. Many patients say they were tested in secret in the 1980s but not told of the results for up to a decade.

There is a lingering feeling of disappointment in the haemophilia community that it was not possible to proceed with the case, as this would have allowed a thorough examination of the circumstances surrounding the contamination of blood products.

Individual Cases

Some individual out-of-court settlements have been reached between health authorities and people with mild haemophilia based on the individual circumstances of each case. For example, a settlement was made in a case where a patient with mild haemophilia was administered factor VIII prior to a routine tooth extraction and consequently developed hepatitis C.¹⁰⁴

2001: Consumer Protection Act

'I am satisfied that the public at large was entitled to expect that the blood transfused to them would be free from infection.'¹⁰⁵

The Consumer Protection Act introduced a form of strict liability which removed the requirement for claimants to prove fault. In 2001, 114 claimants sued the National Blood Authority under the Consumer Protection Act 1987 for damage caused by defective blood products.

¹⁰³ Undertaking to be given by an individual not under a disability in accordance with clauses 12, 15, 17, 18 and 20 of the deed of the Macfarlane (Special Payments) (No.2) Trust (appendix 54)

¹⁰⁴ Letter from Browne and Wells Solicitors, 11th July 1988 (appendix 55)

¹⁰⁵ A and Others v the National Blood Authority and Others [2001]EWHC QB 446 (appendix 28)

Mr Justice Burton decided that blood contaminated with hepatitis C was a 'defective product' for the purposes of the Act, and that the English blood services were liable to pay compensation. The Scottish Executive accepted that the judgment also applied to Scotland.

However, claims could only be made for injury that occurred after the Act came into force on 1st March 1988. This excluded people with haemophilia, who were probably infected prior to 1988. Claims also had to be lodged within ten years of treatment. Given delays in testing and diagnosis, some people did not discover that they were infected until they were already time-barred.

This judgement is significant because it rebuts the government's claim that it acted as swiftly as possible to ensure the safety of the blood supply. Justice Burton identified specific measures that the Government should have taken to protect blood products from hepatitis C prior to 1991.

2006-2007: Litigation Against US Pharmaceutical Companies

People with haemophilia from around the world, including some UK citizens, are jointly suing American pharmaceutical companies for failing to take adequate steps to ensure the safety of their product. The Plaintiffs allege that:

- Paid donors were recruited from high-risk populations, including intravenous drug users and prisoners;
- The defendants failed to exclude donors, as mandated by federal law, with a history of viral hepatitis; and
- Defendants fraudulently misrepresented that factor VIII and factor IX were safe to use.

Only those who can prove they were infected by American products can join this class action. The outcome will be followed with interest.

Legal Action in Scotland: Judicial Review

This action was brought by three relatives who had lost loved ones to hepatitis C. They sought a judicial review of why Scotland was eighteen months behind England in fully decontaminating blood products. Because one of the deceased was infected after preventative measures were apparently introduced in 1987, questions were also raised about whether they were fully operational at the time claimed.

A verdict is due imminently.

vCJD Litigation

'No amount of psychotherapy or counselling can obliterate the truth. Each plaintiff remains indefinitely at risk of the disease.'¹⁰⁶

Successful claims have been made that the Department of Health and the Medical Research Council put lives at risk by ignoring warnings about the risk of contracting vCJD through growth hormones. In some cases compensation was awarded following death from vCJD. In others, awards were made for the psychological fear of developing vCJD.

¹⁰⁶ The Hon Mr Justice Morland, Queens Bench Division No 1994 – N – 05806 (appendix 56)

In October 2001 the Government announced a compensation fund of £55 million to provide payments in respect of 250 cases. In addition, £50,000 was awarded to each victim or their family to take account of the legal and other difficulties that the first families had to encounter and the additional pressures they had to bear.

Section Three: The Campaign for a Public Inquiry Summary

The haemophilia community has spent twenty years campaigning to expose the truth about how they came to be infected with contaminated NHS blood products. They have found every door to a public inquiry firmly closed.

The door to a public inquiry has been closed. Legal Aid has been withdrawn. Crucial documents have inexplicably disappeared. The Ombudsman has declined to investigate complaints of maladministration. People suffering from HIV have been asked to sign away their right to future legal action, without their knowing that they were also suffering from hepatitis C.

However, with the help of supportive parliamentarians, the haemophilia community has kept the disaster on the parliamentary agenda.

In 2001 Justice Burton held that people receiving blood products were not 'expecting or entitled to expect a form of Russian roulette'.

Two years later, Lord Ross presented an impressive and well-argued report to the Scottish Parliament, which recommended specific levels of assistance for people suffering from hepatitis C and their families. Although his proposals were for the most part set aside, the Health Committee went on to recommend a Public Inquiry. The Scottish Executive has so far refused, but the pressure has continued to build up throughout the UK.

Successive governments have acted as if there are no lessons to be learned. In spite of mounting evidence to the contrary, they have held the line that the testing, screening and heat treatment of blood products was introduced as soon as practicable. We have shown otherwise.

It is hard to imagine any other circumstance in which the death of over a thousand people from the same cause would be thought not to merit an investigation.

The haemophilia community and its parliamentary supporters should not have had to campaign so relentlessly, and for so long, for a public inquiry. We were delighted by the announcement of this Inquiry which we trust will now spell out the truth.

Section Four: Financial Assistance

The Inadequacy of Current Ex Gratia Payment Schemes

'The Government considers it has responded and shown its concern for haemophiliacs with HIV. We propose to keep the sums available to the Macfarlane Trust and the needs of haemophiliacs under review.'

The Rt Hon Virginia Bottomley MP, Minister for Health, 1990 ¹⁰⁷

'The Government pays lip service to patients' rights, yet patients are treated shamefully when things go wrong. The long drawn-out court struggle that is now being imposed on the haemophiliacs with AIDS shows clearly the need for a no-fault compensation scheme.'

Harriet Harman MP, Shadow Labour Health Minister, 1990 ¹⁰⁸

'Infected with hepatitis C, they were denied life assurance, and the onset of liver disease forced many into early retirement, so impoverishing their families. Where is the natural justice in including widows in the existing ex-gratia scheme for HIV infection, while excluding them from this scheme? And where is the morality in denying parity of treatment to widows in identically the same tragic position?'

Lord Morris of Manchester, 2004 ¹⁰⁹

People infected with HIV and/or hepatitis C have suffered physical pain and mental injury. They have often had to give up the hope of starting a family. They have lost earnings due to inability to work because of illness. Even if they feel well enough to work, they have a handicap in the labour market. They must pay expenses directly related to their condition, including travel to receive treatment, prescription costs and nutrition. They also have difficulty obtaining mortgages, insurance and life assurance. Most find it virtually impossible to provide fully for their dependants.

People with haemophilia affected by these viruses currently face unacceptable financial difficulties, and the current ex-gratia payments are woefully inadequate.

HIV

An infected man who was married with a dependant family in 1991 was awarded £60,000, but it appears that the possibility of affected people starting a family in the future was not considered.

Almost one third of the Macfarlane Trust's registrants contracted HIV as infants. They are now at an age where many have started, or are trying to start, families of their own. A capital payment of £21,500 cannot begin to cover the additional costs of a lifetime living with HIV.

In any case, neither of these payments begins to compensate for the financial loss and physical and psychological harm caused by infection with HIV. The case for a review is compelling.

¹⁰⁷ Letter from Virginia Bottomley MP to Christopher Butler MP, 15th October 1990 (appendix 57)

¹⁰⁸ Press release from Harriet Harman MP, Labour Plan for Compensation for Injury Caused by the NHS, 25th October 1990 (appendix 58)

¹⁰⁹ Lord Morris, House of Lords Hansard, 25th March 2004 (appendix 44)

Hepatitis C

The main injustice of the Skipton Fund is that the dependants of those who have died of hepatitis C are not allowed to claim. Considering that those with hepatitis C will have been seriously hampered in making provision for their dependants due to the lack of availability of life insurance, this is manifestly unjust. The financial hardship and feeling of unfairness only adds to the grief of prematurely losing a loved one.

The Inquiry has already heard of a family of three brothers where two were infected with HIV by NHS treatment and died of AIDS related illnesses. The third was infected with hepatitis C and died of liver failure. The two who died of HIV infection had financial help from the Government. The third brother went to his grave having been refused any help at all. He could make no provision for the future well-being of his family. How could any Government justify accepting moral responsibility for the well-being two of the brothers, but not the third?

In addition, it is inconsistent that payment is made to people who have cleared hepatitis C following treatment, but not those who have cleared it at the acute stage of the illness.

Hepatitis B

There is no compensation for those with chronic hepatitis B, or for people who contract hepatitis C but clear it naturally during the acute phase of the illness. This is a gross anomaly given that the chronic hepatitis B can lead to cirrhosis of the liver in the same way as chronic hepatitis C.

Ex-Gratia Payment Schemes in Other Countries

Many other countries in a similar position to the UK have considerably more generous ex-gratia payment schemes for the victims of contaminated blood.

Republic of Ireland

In the Republic of Ireland, a compensation deal worth €10 million was agreed in 1991, but the Government later recognised that this was inadequate.

Current payments are case-specific and range from €50,000 to €2.5 million. The average payment is approximately €400,000. Payments have also been made separately to spouses, carers and family members under a range of headings including loss of consortium, loss of society, solatium and post traumatic stress disorder.

The Government also agreed to assist people living with haemophilia and viruses with life insurance, mortgage protection insurance and travel insurance. Specific legislation was passed into law to provide for this in 2006. Those infected pay the average premium for a healthy person of their age, and the Government pays the additional premium. It is therefore possible to obtain life insurance up to €525,000 and mortgage or re-mortgage insurance of €475,000. Why can't the Government here consider introducing a similar scheme?

A specific health Amendment Act card was also introduced in 1996 which gives everyone with haemophilia infected with Hepatitis C or HIV access to all medical services for any medical condition free of charge and on a prioritised basis.

Contrary to statements by the Government, it is not accurate to say that the Irish settlement arose in circumstances where the Government admitted responsibility. Neither was it as a result of any public inquiry.¹¹⁰ The settlements were agreed in 1995 without admission of liability and prior to the Finlay and Lindsay Tribunals of Inquiry.

Canada

The Canadian system of compensation for those infected with hepatitis C includes five graded payments of up to Can\$115,000 depending on the severity of liver damage. Compensation payments were made by both central and provincial Government. It is also possible to claim for loss of income and funeral expenses. Families of the deceased can claim 'compensation for the loss of services'.

Italy

Monthly payments ranging from €600 up to €900 for co-infection are provided. In addition, single payments for HIV infection were made by Government in settlement of civil litigation. These payments ranged from €465,000 to €620,000.

Other EU Countries

Compensation for hepatitis C infection has also been paid to people with haemophilia in Sweden, France, Spain, Hungary and New Zealand. In Sweden, New Zealand and Spain, these payments were lump sums. In France the payments are monthly. In Hungary, a single lump sum payment and monthly payments were made.

No Fault Compensation Schemes in the UK

There is a precedent for the Government making payment for damage without admitting liability.

Vaccine Damage Payments

Those who have suffered severe mental and/or physical disability as a result of immunisation receive a one off payment of £100,000.

Criminal Injuries Compensation Scheme

The Government spends £200 million annually assisting victims of violent crime, despite the fact that they are in no way implicated in the cause of the injury. Examples of payments are as follows:

- Infection with HIV/AIDS £22,000
- Seriously disabling disorder £22,000
- Mental illness £27,000
- Loss of fertility £55,000

As well as the above payments, it is possible to claim for loss of earnings and special expenses such as medical care. The maximum claim is £500,000.¹¹¹

¹¹⁰ Letter from Malcolmson Law, 17th February 2005 (appendix 59)

¹¹¹ www.cica.gov.uk

Compensation Offer on Thalidomide

Payments have been made to people who have suffered from disabilities as a result of their mothers being treated with Thalidomide in the late 1950s and 1960s. On the basis of the report of an inquiry appointed by the then Minister for Disabled People (The Rt Honourable Alf Morris MP), a compensation settlement was agreed with Distillers, the company which marketed the drug, and Thalidomide survivors receive annual payments which are currently between £13,000 and £14,000 per year.

Many of those affected now have to make expensive lifestyle changes, such as adaptations to the home, particularly as most are facing renewed challenges due to ageing and retirement. With this in mind, payments have recently been reviewed, and are likely to double by 2022.

Section Four: Financial Assistance Summary

In 1990 the Minister for Health, Virginia Bottomley, promised 'to keep the sums available to the Macfarlane Trust and the needs of haemophiliacs under review'.

This promise has not been kept, and the case for a full review is compelling.

There are clear injustices in the current payment schemes. The most obvious ones are:

- People who contracted HIV as infants received only £21,500, while others who were married with children at the time of infection received £60,000. Those who contracted the infection as infants must deal with almost a whole lifetime of infection, and many are now at an age where they are starting families.
- It is manifestly unjust that the widows of people who have died as a result of hepatitis C prior to August 2003 receive nothing. This cut off date is entirely arbitrary, and financial hardship and feelings of unfairness add profoundly to the grief of prematurely losing a loved one.

Yet, current payments through the Macfarlane Trust, the Eileen Trust and the Skipton Fund simply do not begin to compensate for the years of ill health, loss of earnings and psychological trauma that infected people have suffered. On top of that, they face added costs such as prescription charges, paying for extra laundry and a specific diet, and extortionate insurance bills.

The most similar jurisdiction to the UK's is that of the Republic of Ireland. There, as we have seen, the Government has made payments averaging €400,000 without accepting liability. Assistance is also given to allow infected people to access mortgages and insurance. They also have access to all medical services for any medical condition free of charge and on a prioritised basis.

The Government has accepted the moral case for no-fault compensation in other cases, such as vaccine damage payments and criminal injuries compensation. There is no conceivable justification for treating infected haemophilia patients on a different basis.

The Haemophilia Society will make specific recommendations for appropriate financial recompense in our second submission.

Conclusions

The impact of contaminated blood products on the haemophilia community is impossible to exaggerate.

Delays by successive governments in securing the safety of blood products have caused avoidable deaths, considerable illness and mental health problems, as well as severe financial hardship. And the impact goes wider than people with haemophilia alone. Thousands of partners, children, parents and other relatives are also affected.

The Haemophilia Society believes that successive governments missed numerous opportunities to take steps that, looked at together, would have prevented thousands of infections.

A decade was wasted before redeveloping the Blood Products Laboratory, despite the Government's stated policy of self-sufficiency. Further procrastination meant a year was lost before blood products were tested and heated to protect against HIV. The time taken to test people with haemophilia for HIV and inform them of the results meant that 63 intimate relations were infected. During this period, patients with mild haemophilia and infants were treated with clotting factor when they should have been treated with the safer cryoprecipitate.

Several more years were lost as the Government failed to introduce a surrogate donor test for hepatitis C. Most other countries were testing donors from the mid 1980s. The UK did not test donors until late 1991.

Every day wasted meant further exposure to contaminated blood, increased infection, and more lives lost.

More recently, it took over a decade of campaigning for people with haemophilia to secure universal access to recombinant treatment. The Government demonstrably failed to learn the lessons of the late 70s and early 80s.

Such lessons can only be learned from an open and transparent examination of the facts; but, this has so far been denied to the haemophilia community. Documents have been destroyed and questions have been left unanswered.

The haemophilia community has been denied closure. Suspicions that the community was used as a research base have caused distress and must be investigated. Lessons must be learned so that no other community has to experience a similar trauma in the future.

The Haemophilia Society is grateful to The Rt Hon The Lord Archer of Sandwell QC, and Lord Turnbull and Judith Willets for accepting The Rt Hon The Lord Morris of Manchester's invitations to them to undertake this Independent Public Inquiry. We very much hope the Department of Health and other key decision makers will cooperate in full. If that does not happen, a full independent judicial inquiry may still be required.

Recommendations for the Future

It is crucial now that all the lessons are finally learned from the contaminated blood disaster. Only then will we ensure that such a disaster never happens again.

Consultation

The haemophilia community currently feels that there is no meaningful consultation on the issues concerning them. We believe that the Department of Health and the NHS should adopt a more inclusive approach, and that the Haemophilia Society must have a formal role in setting the policies that affect its members.

Future Treatment

When the full roll-out of recombinant treatment was first announced, albeit ten years late, ring-fenced funding was set aside to pay for it. This situation only lasted for three years, and ring-fenced funding must be reinstated to ensure that future cut backs do not result in inferior clotting concentrate being prescribed.

In addition, concerns abound about the impact of vCJD 'at risk' status on future healthcare. It is already clear that access to some medical procedures, including dentistry, is being affected. The haemophilia community needs a guarantee that affected patients will be entitled full access to health care.

Counselling provision has been woefully inadequate over the years. Top quality physical and psychological care must be guaranteed.

Supporting the Affected Community

Mono or co-infected people with haemophilia require support over and above that which is currently provided by HIV and hepatitis C charities. The plan to phase out the Haemophilia Society's core funding would leave us unable to provide this support. It is essential that the Government recognises the importance of the services we provide to this particular group of our members, and provides us the funding.

Compensation

Current payments are inadequate and the criteria for making payments are inconsistent. Some groups have missed out in an unacceptable way, such as people who contracted HIV as children or single young men, and bereaved families who lost loved ones to hepatitis C prior to 2003. We have shown that the case for reviewing the funding for people who contracted viruses through NHS treatment is compelling.

Financial Services

Mono and co-infected people with haemophilia suffer from considerable discrimination in accessing financial services such as mortgages and insurance. We recommend that the Government should assist with this.

The Haemophilia Society will make a further submission making more detailed recommendations on all these recommendations.