Reference B
PAPER 1 of 2

THE HAEMOPHILIA SOCIETY

Response to the Scottish investigation into hepatitis C infection via contaminated blood within the haemophilia community

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The Haemophilia Society
Chesterfield House
385 Euston Road
LONDON
NW1 3AU
Tel: 020 7380 0600
Fax: 020 7387 8220
Email: GRO-C@haemophilia.org.uk
or GRO-C@haemophilia.org.uk

1. Introduction

1.1 The Haemophilia Society welcomes the opportunity to contribute to the investigation called by Susan Deacon, Minister for Health and Community Care, into the circumstances surrounding the infection of people with haemophilia by contaminated blood products used in their NHS treatment in Scotland. Since Society representatives met with Ms Deacon on 14 September 1999, we have consulted widely with our 333 members in Scotland and we have drawn on their views and concerns in preparing this submission.

1.2 The information in this submission should be viewed in conjunction with the material already submitted to Susan Deacon and officials at our meeting in September. The Society is happy to provide further details or discuss any queries arising from our submission.

1.3 **Recent actions by the Society in Scotland**
At the suggestion of Ms Deacon, we have also met with representatives of the Scottish National Blood Transfusion Service (SNBTS) in November. The information presented by SNBTS at that meeting confirmed our original concern that Scots manufactured blood products were not inactivated against hepatitis C until well after those manufactured in England. On the basis of the new information shared with our representatives at the meeting it now appears that the time lag between Scotland and England was still longer than we had first thought, as HCV inactivated product only became available in Scotland in 1987 (not 1986 as previously thought).

1.4 This has come as a considerable shock to the haemophilia community in Scotland: until recently people with haemophilia had been led to believe that 1985 was the cut off point after which blood products were supposed to have been safe from HCV. **In Scotland, we have now been told that home produced blood products were not inactivated against HCV until 1987, and were not fully in use until 1988.**

1.5 Since meeting with Ms Deacon, the Society has been consulting widely with the haemophilia community in Scotland and with Members of the Scottish Parliament in order to sound out opinions, views and experiences on the issue. We organised a meeting on the hepatitis C situation with our Scottish members held in Edinburgh in November, attended by over 60 people, which demonstrated the considerable strength of feeling within the haemophilia community. Also present at that meeting were a number of solicitors who are engaged in legal actions on behalf of people with haemophilia who were infected with HCV.

1.6 We have also met with MSPs who have affected constituents and with members of the Health Committee of the Scottish Parliament.

2. The need for an independent inquiry

2.1 The fact that vital and significant information is only coming to light and being made known to people with haemophilia more than ten years after the event, confirms the Society's very strong view that a full independent inquiry into how people with haemophilia were infected with HIV and HCV is essential. **The information we have been offered to date provides only partial answers to the many questions which arise about the use of contaminated blood products in Scotland; by their own admission SNBTS representatives were unable to give answers on many key points raised during our meeting.**

2.2 As was made clear from the questions that could not be answered at that meeting with SNBTS, the process of gathering full information on all relevant aspects of the contaminated blood tragedy must examine the actions of a number of other bodies beyond the SNBTS. This should include the various committees with responsibility for blood safety in the UK and Scotland, and the haemophilia clinicians' organisation. **In this submission we have outlined below the questions which require answers and the scope of the inquiries needed to uncover the full picture.**

2.3 There is a very strong wish for a full independent inquiry among people with haemophilia in Scotland who have suffered as a result of contaminated blood products, many of whom have now petitioned the Scottish Parliament with this request. It should be recognised that despite the scale of this adverse outcome in haemophilia treatment, there has been no official report or apology to those affected, and this in itself is a source of considerable anger and distress within the patient group.

2.4 We would bring to the Minister's attention also that doctors and nurses in the haemophilia field have also supported the call for an inquiry, as evidenced by the petition submitted to the Scottish Parliament .

2.5 Over 48 MSPs of all political parties have already signed a motion (SIM 323) to the Scottish Parliament calling for an independent inquiry.

2.6 The principles of independence and transparency are critical to an effective and meaningful inquiry. Whilst questions remain about possible past negligence and liability we fear there may be a conflict of interest for Government in investigating the use of contaminated blood products in the NHS. **We believe therefore that the investigation and inquiry must be undertaken by another body or group, and cannot be conducted solely by officials of the Scottish Executive.** The Society is deeply concerned that the investigation currently being undertaken by the Scottish Executive at the behest of the Minister may be seen as a PR exercise which does not deliver the independence required.

2.7 The official inquiries already being undertaken in other countries into the contaminated blood tragedy, notably the Republic of Ireland, provide much valuable experience on which to draw in formulating a process appropriate for Scotland. We would draw attention particularly to the terms of reference agreed by the Irish Government for their inquiry into the impact of contaminated blood products within the haemophilia community [attached Appendix 1]. This example is interesting not least because the haemophilia populations in Scotland and Ireland are of comparable size, and also because the Irish inquiry will be gathering information relating to the UK and international situation which could feed into a parallel process being undertaken in Scotland.

2.8 The Society proposes two approaches which we would hope to see taken forward by government in Scotland . First, we believe the Health Committee of the Scottish Parliament should be asked to investigate and report on the impact of contaminated blood products within the haemophilia community and to make recommendations for action from the NHS, Government and other bodies. This remit would enable the Committee to gather evidence from the infected patient group and their carers.

2.9 Second, we want to see the establishment of an independent, expert task force to carry forward the investigation in Scotland, which should include a number of patient representatives, as well as medical and scientific experts. The issues and themes, which would need to be covered, are outlined in the next sections of this document, in which we indicate the very serious questions, which remain unanswered for the patient group.

3. Concerning the issues raised by Susan Deacon

A. The introduction of HCV viral inactivation for factor VIII

- **Were patients with haemophilia in Scotland exposed to the risks of HCV for longer than they should have been?**

3.1 The question of whether patients in Scotland were exposed to risks for longer than they should have been is very complex, and requires information on the actions taken during the 1970s and 1980s by a number of bodies, some UK wide and some with responsibilities for Scotland only. Largely because no official investigation and report have been produced, the information required to put together and assess this complex picture has not been gathered and debated in the public domain.

3.2 **The process of investigation initiated by Susan Deacon is for the patient group the first and only time that we have had an opportunity to engage in any form of retrospective inquiry which might begin to answer this question. In order to establish the full picture, we believe the following key questions of crucial concern to patients must be investigated in Scotland.**

- Why was Scottish blood product not made safe from hepatitis C until two years after that being produced in England?
- Why were more active steps not taken to protect the haemophilia patient group from the risks of hepatitis during an era when blood products were well known to be carrying the virus?
- Why did Scotland not follow the practice of other countries, which adopted surrogate testing (ALT testing) ahead of the UK?

- Were financial considerations put ahead of patient safety during this era?

3.3 These key concerns give rise to a host of detailed questions which we have attempted to set out below, bearing in mind that at this stage that the policies and actions of a number of bodies have to be examined to provide the necessary answers. *Among those which must be scrutinised are*

(i) actions of Scottish Office
(ii) actions of SNBTS
(iii) actions of haemophilia clinicians
(iv) UK national policies
(v) International actions/response.

The need for accurate figures

3.4 There is still no official figure for the number of patients with haemophilia in Scotland who were infected with hepatitis C during the 1970s and 1980s. No look back exercise has been undertaken in the UK to ensure that all those who may have been exposed to contaminated blood products have been traced, tested, counselled and treated if appropriate.

3.5 There is no published data on the number of Scots haemophilia patients with HCV, nor on the numbers who have been treated for HCV infection or those who have died from it. We need to know how many of the total infected group has mild, moderate or severe haemophilia; and how many were first treated between 1985 and 1988. An overview of the current state of health of the infected community should be produced showing how many have advanced liver disease.

3.6 **The Society urges that this data should be collected immediately by the haemophilia centres and made available in the public domain. It is essential to know clearly how many have been infected in addition to learning how they were infected and whether this infection was preventable.**

Questions about treatment in the 1970s and 1980s

3.7 s were in use in Scotland in the 1970s and 1980s; both commercial and state produced. The SNBTS have told the Society that it was not their responsibility to decide which products should be imported for haemophilia treatment. Patients therefore wish to know whose responsibility this was and what assessment was made of the safety and efficacy of blood products being imported for use in the NHS in Scotland.

3.8 It is equally important to establish what infections the different products carried and how many Scots haemophilia patients were infected by each product in use at the time.

3.9 The risks of hepatitis as a blood borne virus were well known in the 1970s and before, and warnings about the use of blood products were published in the medical literature (some references are included on page 8). SNBTS representatives explained to the Society that efforts were being directed at eliminating HCV from blood products throughout the 1970s, well before HIV was identified and became the urgent focus in the 1980s.

3.10 This raises many questions about whether effective and timely steps were taken to reduce patients' exposure to these risks. We wish to know what considerations led to the SNBTS/Scottish Office view that Scotland should be self sufficient in blood? When was this policy first stated and what steps were taken to implement it? What warnings were given to patients about the risks of blood products?

3.11 **In the case of people with mild haemophilia who might have required treatment no more than once or twice in a lifetime, alternatives to the use of blood products were available i.e. not to treat or to use DDAVP instead. Why was this strategy not adopted comprehensively in Scotland? And why were many of these patients not informed of the risks of using these products?**

3.12 Given the known viral risks of blood products in the 70s and 80s, we are concerned to learn what guidance was issued to clinicians about their use and particularly on which patients should not be treated with blood products. Such guidance should have included the recommendation not to treat those with mild haemophilia with blood products.

3.13 We understand from the SNBTS meeting that a Coagulation Factor Working party was in existence during the period in question together with an Advisory Committee on the Virological Safety of Blood. What were the responsibilities and remits of these groups as regards ensuring the safety of blood products being used in the treatment of patients with haemophilia in Scotland? What was the role of the MCA or its precursor in this field?

3.14 What were the considerations that influenced the Scottish Office/Scottish haemophilia centre directors/SNBTS in selecting what blood products to import in the days before Scotland was self-sufficient? Were these considerations adequate and timely in trying to ensure that Scottish haemophiliacs were exposed to as few "risks" as possible?

3.15 We need to know far more about the steps taken by the various UK wide and Scottish bodies at the time to ensure that the safest possible blood supplies and treatment products were in use. In this context information is required on the blood donor selection policy used in Scotland in the '70s and '80s (selection, screening, testing)? In particular, since hepatitis transmission via blood products was known to take place, what measures were taken and when (and why) to screen out hepatitis from the blood supply. Were these measures adequate? How did they compare with measures taken internationally?

3.16 Looking at why Scotland took so much longer than England to produce clotting factor products which were safe from hepatitis C, we need to know what viral inactivation procedures were researched and introduced into the manufacture of haemophilia blood products in the '70s and '80s? And what was the rationale behind this research? How did Scottish R & D compare to what was being done internationally?

3.17 Whilst we appreciate that hepatitis C was only formally identified as such in 1989, it was well known as non-A, non-B hepatitis during the 1970s and the risks of hepatitis generally were well understood. In this context we understand that there was a transition phase from 1985 onwards when products inactivated against HCV began to be introduced first in England and later in Scotland.

3.18 Again looking at this from the perspective of how best patients might have been protected from risks, we need to know when products (home and commercial) were known/expected to have probably caused infection, what steps were taken to ensure these products were no longer used/recalled? Were these steps adequate? Were they timely?

3.19 This aspect needs to be considered particularly from the point of view of previously untreated patients (PUPs) i.e. children diagnosed after 1985 and adults with mild haemophilia who may not have required treatment before then. Were these patients given priority to ensure that they received the safest product available as a preventative measure to protect them from the risks of the virus?

3.20 **Follow up to the infection**

The Society has highlighted in a number of reports the fact that no follow up strategy was implemented by Government once it became known that large numbers of haemophilia patients had been infected with HCV. This contrasts with the action taken to follow up patients who might have been infected with HCV via blood transfusions for whom the Chief Medical Officer in 1995 ordered a 'look back exercise.'

3.21 Without a planned follow up strategy nationally any action in response to the infection appears to have been left to the discretion of individual clinicians. At a national level, the Society has produced evidence to show that some patients are still only now being told of their HCV infection, well over a decade since they were probably infected. Others were tested but not told the results. In some centres testing has not been done effectively using the latest PCR tests.

3.22 Clearly if people were not told of their HCV infection they were not given the information necessary to make changes to lifestyle (i.e. cut down on alcohol, practice safer sex) to protect their own health and the health of those close to them.

3.23 These issues have been extensively described in the Society's recent submission to the Health Committee at Westminster (some references are included on page 8) a copy of which has already been provided to Ms Deacon and officials. **This is an area, which requires further investigation in Scotland. Very recently we have learned of an individual in Scotland who has only just been diagnosed with HCV, which leads us to believe that the problems outlined above are not confined solely to the rest of the UK. We have also heard from individuals in Scotland of**

failure by clinicians to inform patients of their diagnosis. In one instance the patient learned of his HCV status by taking a look at his own notes. In others Scottish patients have only become aware of the possibility that they might have HCV infection as a result information provided by the Society.

3.24 We need to know far more about the steps, which were taken in Scotland to follow up the known infection of patients with haemophilia with HCV. Where products were known to have caused, or probably caused, infection what steps were taken to identify and trace patients who were/had been at risk, to inform these patients that they may be/have been at risk and to offer them information, support, testing and counselling? Patients are clearly asking now whether enough was done, and whether it was done soon enough.

3.25 Again we are concerned to know which body was responsible for leading on these matters: the Department of Health, the Scottish Office, the clinicians, the SNBTS?

B. Were patients given enough information about the risks of HCV in the 1980s to enable them to make an informed choice?

3.26 As indicated above and in previous evidence submitted by the Society, patients generally appear to have been given no information about the risks of blood borne viruses in clotting factor treatment. **Even those first treated as late as 1986 state that they were told nothing about the risks.**

3.27 Many patients only became aware of the possibility of HCV infection through information provided to them by the Haemophilia Society. Whilst evidence was accumulating within the medical and scientific community about the risks of blood borne viruses in clotting factor treatment, this information was not shared with patients.

3.28 In this context, the Society wishes to know on behalf of patients how the Scottish authorities responded to the growing weight of evidence about the risks. For instance, the publication of a *Lancet* article in 1975 documenting the hepatitis infection of nine our of 18 haemophilia patients treated at Bournemouth Haemophilia Centre, and the publication in the *Journal of American Medical Association* in 1972 of further research on hepatitis and clotting factor concentrates which recommended avoiding the use of multi-donor products for those with mild haemophilia (Craske et all, 1975, Kasper and Kipnis, 1972).

3.29 The Society wishes to know which body in Scotland was responsible for providing information to patients, and what steps were taken from the 1970s onwards to warn patients and enable them to be able to make informed choices about accepting blood product treatment.

4. Other Concerns

The social and economic impacts of the virus

4.1 The Society has well documented evidence of the social and economic impacts of HCV. We have commissioned two reports nationally (Cheetham, 1996; Roberts, 1999) which provide evidence of the stigma, strains on family and personal relationships, and the loss of income due to declining health.

4.2 The most recent – as yet unpublished – study by Dr Jenny Roberts of the London School of Hygiene and Tropical Medicine aimed to assess the social and economic impacts of the virus. In the course of the study, which involved structured interviews with 25 individuals affected by HCV, the researchers identified many unmet needs with regard to information, support and counselling, again drawing attention to the lack of follow up action targeting the infected haemophilia community.

4.3 The conclusions of that study are included at Appendix 2. It should be noted that this was a small-scale pilot intended to pave the way for a larger study. **The Society recommends that such a study could be carried out within Scotland to gain a full assessment of the social and economic impacts of hepatitis C within the Scottish haemophilia population.**

The case for a financial assistance scheme

4.4 The infection of the haemophilia community with HCV has caused considerable anguish and hardship. Those infected are living with stigma, much uncertainty as to the likely progress of the disease, and in many cases impaired health due to HCV has forced people to give up or cut down on work. In addition to loss of earnings, living with hepatitis adds costs eg. For special dietary requirements and medication costs. As discussed previously, the virus has had serious health, social and economic impacts, particularly in a patient group already suffering a lifelong, disabling medical condition. As the study conducted by Dr Roberts indicated, it is possible to differentiate the impacts of the HCV virus from the effects of haemophilia itself. Especially for those with mild haemophilia, the virus has created far more problems than the haemophilia itself.

4.5 Treatment prospects, whilst improving with the recent introduction of ribavirin/interferon combination therapy, are still not good. The treatment carries very severe side effects, which many cannot tolerate, and success rates range from 40% to as low as 10-20%. Undergoing a six to 12 month course of treatment is very onerous for patients particularly when the chances of success are so uncertain.

4.6 There is a precedent for the provision of financial assistance for members of the haemophilia community infected with HIV through contaminated blood products used in their NHS treatment. The Conservative Government in 1987 accepted a moral responsibility to provide financial assistance for this group, and provided £10 million for the Society to set up the Macfarlane Trust in 1988. The Trust continue to administer both regular payments and one off hardship grants to the HIV survivors in the UK haemophilia patient group.

4.7 This experience, together that of other countries such as Canada, Ireland, Italy, could be used to develop a financial assistance scheme for the Scottish haemophilia community who are suffering the impacts of HCV. **We would recommend the establishment of a hardship fund which could provide financial help for those most seriously affected by the virus. A mix of medical/social criteria could be used to assess eligibility, the system already used by the Macfarlane Trust, with haemophilia centre doctors playing a leading role in assessing health status and need of individuals.**

4.8 In Canada, where financial assistance is being provided for those with HCV contracted from contaminated blood products, a series of graduated trigger points have been developed to determine the level of award depending on the seriousness of the individual's medical condition. These provide another model which could be adapted for Scotland.

4.9 The current situation is highly inequitable in that patients who were infected in the same way at the same time through contaminated blood products used in their NHS treatment are not able to receive financial assistance in the same way. Those infected with HIV, most of whom are co-infected with HCV, are eligible for help from the Macfarlane Trust, whilst those who have HCV alone are not.

4.10 **The Society strongly urges the Scottish Parliament to offer a more equitable and just response to the tragedy the haemophilia community has suffered by establishing a financial assistance scheme/hardship fund for those with HCV to run alongside that available from the Macfarlane Trust to those with HIV. The numbers involved in Scotland are relatively small, and were the fund to be available for those in most serious need as a priority, only a proportion of the total HCV infected haemophilia population would become eligible for help initially.**

Treatment access problems

4.11 The Society is increasingly concerned that the only available treatment regime for those with HCV – ribavirin and/or interferon – is not being provided for patients in some parts of the UK on funding grounds. In effect, a treatment by postcode situation is developing with regard to interferon/ribavirin treatment. We have raised this issue with the Department of Health and have been assured that clinical need should determine the provision of this treatment i.e. it should not be denied on funding grounds alone.

4.12 It now appears that this is a problem in Scotland as well as other parts of the UK. We have evidence that patients in Scotland who have been recommended treatment based on clinical needs are having difficulty securing it because of funding constraints. This is unacceptable: at the very least patients who have been infected with HCV via NHS treatment should be entitled to receive the most effective treatment available for the virus.

4.13 **The Society urges the Health Minister to remind health authorities and trusts in Scotland of this principle, and to ensure that all those HCV infected people with haemophilia who need the treatment are able to receive it.**

References

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