

1 December 2011

PENROSE INQUIRY – COLLECTIVE RESPONSE ON BEHALF OF PAST AND PRESENT HAEMOPHILIA CENTRE STAFF IN SCOTLAND ON TOPIC C5:

C5a) The information given to patients (or their parents) about the risk of non A non B Hepatitis and the severity of the condition before their treatment with blood or blood products;

C5b) the tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products; and

C5c) the information given to patients who might have been infected, or who were found to be infected, and their families.

Methodology

This response has been collated by present and past Haemophilia Centre Directors in Scotland who are still alive and contactable (list at end). It builds on our collective response, asked for by the previous Scottish Executive Health Department Inquiry into Hepatitis C and heat treatment of blood products for haemophiliacs in the mid 1980s (October 2000). We have circulated it to present and past Haemophilia Centre Nurse Specialists in Scotland who are still alive and contactable (list at end) for their input and comments. The response represents the collective memories of Haemophilia Centre medical and nursing staff, supplemented by information leaflets for patients with haemophilia (and their families and partners) published by the UK Haemophilia Society, which we have collated from our Centres' files (and from the Society's files) and other documents.

C5a) THE INFORMATION GIVEN BY NHS SCOTLAND TO PATIENTS (OR THEIR PARENTS) ABOUT THE RISK OF NON A NON B HEPATITIS AND THE SEVERITY OF THE CONDITION BEFORE THEIR TREATMENT WITH BLOOD OR BLOOD PRODUCTS

(1) Information given before referral to Haemophilia Centres.

This is a difficult matter for past and present Haemophilia Centre directors to address. The Inquiry is already aware that:-

(a) Most patients with haemophilia in Scotland who acquired non A non B hepatitis (hepatitis C) would have done so at the time of their first treatment with any multidonor clotting factor concentrate (NHS or commercial) or during their first several treatments with cryoprecipitate/fresh frozen plasma (given current knowledge of the prevalence of hepatitis C in blood donor populations), and

(b) Many patients with haemophilia in Scotland received their first treatment at a hospital without a Haemophilia Centre. Hence what information was given to patients (or their parents) about non A non B hepatitis before their first treatment with blood or blood products (which for blood products would likely have infected them with non A non B hepatitis/hepatitis C) would not be known to Haemophilia Centre directors. As the Inquiry has heard, many patients, particularly in the West of Scotland, were not referred to Haemophilia Centres by their local physicians for some years. Information given to patients or parents before their first treatment would not usually be included in referral letters to Haemophilia Centres from district hospitals, recalled by patients or parents, or available from district hospital records now long destroyed.

Hence, for many patients with haemophilia in Scotland, much of the following summary of information given to patients (or their parents) about non A non B hepatitis by Haemophilia Centre staff would be given after their first exposure to and infection with, non A non B hepatitis (hepatitis C).

It should be emphasised that initially Haemophilia Centres were set up to act as reference centres to deal with difficult clinical problems and also to act as a laboratory reference centre. There was no legislation to ensure haemophilia patients should all be registered at regional Haemophilia Centres.

(2) The role of Haemophilia Centre Multidisciplinary Teams in education of patients, parents and partners.

Once referred to a Haemophilia Centre, children and adults were managed by a multidisciplinary team, with a haemophilia nurse specialist playing a pivotal role in education and counselling. The risks of haemophilia and of its treatment, including hepatitis, were well explained by staff and regularly reinforced by haemophilia nurse specialists and doctors. However, nurse specialists were not available in Aberdeen, Inverness or Dundee in the 1980s.

As with many other chronic or lifelong conditions, haemophilia care at Haemophilia Centres is provided by multidisciplinary teams. As described by Dr. P. Jones (Organization of a Haemophilia Service. In: Bloom AL, Thomas DP, eds., Haemostasis and Thrombosis, 1st edition. Edinburgh: Churchill Livingstone, 1981: pages 389-394; Annex 1), such teams include haematologists, physicians, paediatricians, nursing staff, dental and other surgeons, social workers and counsellors. Information given to patients and their parents and partners about non A non B hepatitis would be given by doctors, nursing staff, and on occasion dentists and social workers/counsellors.

In particular, nurse specialists at Haemophilia Centres play a major role in educating patients, parents and partners about haemophilia and the complications of its treatment with blood and blood products – one of the principal complications being viral hepatitis. Such education started when patients were first referred to a Haemophilia Centre, and continued thereafter, e.g. at emergency attendance for treatment of acute bleeding episodes, clinic reviews, and enquiries by telephone, in writing or in person.

The UK Haemophilia Society's survey of patients and parents in 1985-86 records that nurse specialists played a major role in patient management at Haemophilia Centres in Edinburgh Royal Infirmary, Glasgow Royal Infirmary and Glasgow Royal Hospital for Sick Children (Annex 2).

The paediatric haemophilia nurse specialist played a particular role, because she trained the mothers to venepuncture so that they could administer concentrate at

home and for this reason spent a great deal of time with the mothers and boys. In addition in children:

- Many of the mothers had male relatives with haemophilia and were aware of the risks of hepatitis from them
- At the Centres where they were in post, the families were all introduced to the Haemophilia Social Worker, who encouraged them to join the Haemophilia Society which was a useful source of information on hepatitis for families
- Severely affected boys were on prophylactic home therapy with their mother administering the Factor VIII/IX concentrate. Both mother and child were vaccinated against hepatitis B, and later hepatitis A, and the mother/family were well counselled and educated on the risk of hepatitis, how to handle needle stick injuries and blood spills.
- The children had regular 4 monthly liver function tests, which prior to the identification of, and ability to test for, hepatitis C, was the only way of monitoring non A non B hepatitis. The mothers of boys on prophylactic home treatment would bring these bloods to a clinic visit to prevent an unnecessary venepuncture and would have understood why these bloods were being checked
- The haemophilia nurse specialist carried out school visits to educate staff about haemophilia which included the safe handling of a blood spill because of the risk of transmitting hepatitis.

The long standing customary practise to use cryoprecipitate to reduce the risk of hepatitis was reinforced in 1983 when it was again recommended that boys with haemophilia A who had never received blood product, or who had limited previous exposure, should receive cryoprecipitate rather than pooled concentrate (UKHCDO Guideline June 1983). Although this advice in 1983 was given to reduce the risk of HIV transmission, the guideline makes it clear that, it was already common practise to use cryoprecipitate to reduce the risk of hepatitis transmission.

(3) Information given to patients (or their parents) on the risk of hepatitis before their first treatment with blood or blood products

As noted in (1), information given before their first ever treatment with blood or blood products, at hospitals which were not Haemophilia Centres, is usually not available in Haemophilia Centre records.

Prior to their first treatment with blood or blood products at a Haemophilia Centre, patients (or their parents) would normally be advised of possible complications, including reactions and hepatitis. Hepatitis risk would be reinforced in several ways:

(a) Nursing and medical staff taking precautions to avoid transmission during treatment (e.g. use of disposable gloves evolved, and careful disposal of needles, syringes, intravenous lines and blood or blood product packs).

(b) Educational/information leaflets (e.g. those issued by the UK Haemophilia Society) on haemophilia, its treatment and complications. Some examples are provided in Annex 3.

(c) Patients or parents requesting further information about NHS or commercial clotting factor concentrates would be given the information leaflets provided with such concentrates, which included the possibility that they might transmit hepatitis. (Annex 4).

(d) From the introduction of hepatitis B vaccination in the UK NHS in 1985, patients without natural immunity to hepatitis B were offered vaccination. Information given at that time would include that many patients would be naturally immune following hepatitis B exposure through blood product treatment; and that vaccination was protective only against hepatitis B, and not against hepatitis due to other viruses (including non A non B hepatitis) (Annex 5). Similar information would be given when hepatitis A vaccination was offered to patients from 1992. Parents of children with haemophilia, especially those on home treatment, were also offered vaccination, and advised on the risks of hepatitis from blood spills and needle stick injuries.

(e) From 1983, it was evident that patients receiving clotting factor concentrates (NHS or commercial) for the first time, had a high risk of developing non A non B hepatitis (Fletcher et al 1983). Accordingly, UKHCDO and others recommended that cryoprecipitate be preferred to clotting factor concentrates for patients with factor VIII deficiencies with no, or limited, previous exposure (UKHCDO 1983; Forbes et al 1984; Rizza and Jones 1987), until 1988 (UKHCDO 1988). This practice would be explained to relevant patients (or their parents) during this time period.

(f) From 1988, patients previously not exposed to clotting factor concentrates (or their parents) were given information on, and invited to participate in, a clinical trial of virally-inactivated SNBTS clotting factor concentrates whose aim was to demonstrate that such concentrates had a low risk of non A non B hepatitis/hepatitis C. The information sheet is provided in Annex 6. The results of this study were published in 1992, and confirmed a low risk of non A non B hepatitis and hepatitis C (B. Bennett et al 1993; Annex 7).

(g) Following the licensing of non-human-donor (recombinant) clotting factor concentrates in the UK in 1995, Haemophilia Directors in Scotland successfully lobbied the Scottish Health Department to make these available for treatment of patients with haemophilia in Scotland. The first priority was patients previously not exposed to clotting factor concentrates (Annex 8)

(4) Information given to patients (or their parents) on the severity of non A non B hepatitis before their treatment with blood or blood products

The Inquiry's Preliminary Report has already summarised evidence that prior to 1985 non A non B hepatitis, while common, was generally thought not to be a serious illness either in the acute, symptomatic stage (jaundice) or in the more common chronic, asymptomatic stage. This information would be provided to patients (or their parents) during discussions about the risk of hepatitis. From 1985 it was increasingly realised that the chronic, asymptomatic stage of non A non B hepatitis could progress in severity, initially through research studies of serial liver biopsies, and thereafter through epidemiological studies of clinical complications (cirrhosis and liver cancer). From 1985, however, patients (or their parents) would be informed

that it was hoped that viral inactivation of clotting factor concentrates (NHS and commercial) would reduce, or eliminate, the risk of transmission of non A non B hepatitis. This hope was realised in time.

(5) Information given to patients (or their parents) on alternative treatments to blood or blood products.

Patients and parents were advised that the only alternative treatment to blood or blood products for raising low levels of factor VIII to prevent or treat excessive bleeding was the synthetic drug, desmopressin. This was used from the late 1970s for patients with mild haemophilia A or von Willebrand's disease (factor VIII level at least 10% normal), for example to prevent excessive bleeding after dental extraction or other minor surgery. However, it had several limitations:

- Small and short lived effect
- Repeat injections were followed by a lower response due to exhaustion of stores of factor VIII (tachyphylaxis)
- Common vasodilator effects (e.g. flushing, fainting) so not tolerated by some patients
- Less common serious adverse effects (e.g. water intoxication, thrombosis leading to heart attacks) so contra-indicated in patients at risk.
- Desmopressin was ineffective in most patients with haemophilia A (severe or moderately severe patients) and in all patients with haemophilia B.

Hence most patients had no effective alternatives to treatment with blood or blood products until their replacement with non-human (recombinant) clotting factor concentrates during the 1990s. Faced with the prospect that the only treatment of symptomatic bleeding (for example, the agony of a child screaming with pain from acute bleeding into a major joint; or imminent death from excessive blood loss after injury or surgery) was blood and/or blood products, understandably, few patients or

parents in Scotland or other countries were prepared to refuse such treatment for fear that it could transmit hepatitis.

In his 1981 chapter on "Management of patients with inherited blood coagulation defects", Dr. C.R. Rizza, Director of a leading UK Haemophilia Centre in Oxford, stated: "In the meantime, for the general population of haemophiliacs it would be a backward step to withhold factor replacement therapy for fear of transmitting hepatitis. To the majority of haemophiliacs the consequences of haemorrhage with pain and crippling are much less acceptable than the risk of liver disease, the clinical course of which is still not known and which at present is asymptomatic in most patients". (Annex 9). We think that this statement reflects the views of most Haemophilia Centre staff, their patients and the UK Haemophilia Society during the early 1980s, before the risk of non A non B hepatitis (hepatitis C) was abolished by viral inactivation of clotting factor concentrates.

(6) General information given to patients (or their parents) about hepatitis, BEFORE OR AFTER their treatment with blood or blood products.

Since blood transfusion was introduced in the 1940's, it was generally known that hepatitis (e.g. jaundice) could be acquired from blood and blood products. Individuals with haemophilia would learn about hepatitis from a wide variety of sources, some of which are outlined below.

(a) From the first referral of a newly diagnosed patient with haemophilia to a Haemophilia Centre (usually as a child), patients and relatives would be educated by Centre staff on its complications including hepatitis. It was well known by many with haemophilia that 'jaundice' was a complication of the treatment with blood products, even though only a small proportion developed this manifestation of hepatitis.

(b) In the 1970s and early 1980s, when few patients were on home treatment and the majority attended the Haemophilia Centre for treatment of acute bleeds, patients (and parents) would get to know other patients (and parents) as they were all seen and treated in a single room 'Haemophilia Centre'. They would exchange information while they waited for treatment or while it was being infused. Thus

information spread readily. Furthermore, some individuals had other family members with haemophilia from whom they would have learned about the condition and the complications of treatment, including hepatitis.

(c) The UK Haemophilia Society was very conversant with the risk of hepatitis. Their representatives were invited to the UKHCDO Annual General Meetings and the associated Scientific Meetings, at which the issue of hepatitis was repeatedly discussed, especially in the early 1980's.

This information was disseminated to their members by way of the Haemophilia Society's regular information leaflets (Annex 3) and other publications for patients, relatives and partners (extracts from Dr P Jones book on Home Treatment appended Annex 10), which were displayed to patients attending Haemophilia Centres in Scotland.

Local meetings of the Haemophilia Society were an opportunity for treatment and welfare matters to be discussed. For example, at a meeting of the Society in March 1980 at Glasgow Royal Infirmary, Dr Alistair Parker (Consultant Haematologist) reviewed treatment arrangements in Seattle, which he had recently visited, and the minutes record that hepatitis was discussed (Annex 15). At the same meeting Dr Forbes raised a number of initiatives focussing on welfare issues. Professor Ludlam in Edinburgh remembers an invitation to talk about his research on desmopressin in the early 1980s and at this East of Scotland Haemophilia Society meeting he would have emphasised the hepatitis risk and how this in some patients could be avoided by use of this drug. Also, Professor Lowe recalls an invitation to speak at a meeting of the West of Scotland Haemophilia Society in 1988, where during a review of changes in haemophilia care in the 1970s and 1980s he reviewed the risk of hepatitis, and measures taken to reduce the risk including desmopressin, vaccination, cryoprecipitate and heat treatment of factor concentrates – including the SNBTS clinical trial of their products in previously untreated patients which was about to start (Annexes 6 and 7).

(d) Within the Haemophilia Centre waiting and treatment rooms there were notice boards to advertise Haemophilia Society activities, and copies of the Society's

information leaflets (including information on hepatitis) were available for patients to read and take away.

(e) Books about haemophilia were available to patients and relatives in the late 1970s and 1980s and these discussed what was known about hepatitis. The best known was 'Living with Haemophilia' by Dr Peter Jones (1980) which was widely read by patients and promoted by the Haemophilia Society. It was in great demand and ran to several editions. Sections which gave information on hepatitis are appended (Annex 11).

(f) The leaflets accompanying the bottles of both NHS and commercial concentrate were received by patients (and relatives and partners who often assisted patients with preparing and administering treatment) about the concentrates including the possibility that they might transmit hepatitis (Annex 4).

(g) Patients, relatives and partners received education before, and during, home treatment with factor concentrates (usually from the Haemophilia Centres' nurse specialists). This included education on the risks of hepatitis transmission, and the need to take great care with safe disposal of needles to avoid transmission by needlestick injury. (see attached excerpts from Dr. P Jones' book on Haemophilia Home Treatment, Annex 10). Consent forms used in the late 1970s and 1980s which in some Centres patients signed before starting on home treatment indicated that infections were a risk and that this was understood by the patient (example from Edinburgh Royal Infirmary attached, Annex 12). By signing the patients indicated that they understood and accepted the risk, and consequences, indicated by continuing the treatment.

(h) A study in Edinburgh in 1986 of a possible new test to detect non-A non-B hepatitis sought the help of spouses of those with haemophilia. In the letter seeking agreement to the study, which was sent to the husband, it stated that haemophilia treatment was associated with a risk of hepatitis (Annex 13).

(i) Some patients were generous in helping with undergraduate teaching of students either as in-patients or attending for 'clinical teaching' to a group of

students. The patient would be party to all the clinical presentation which included much about haemophilia and the complications of treatment. Hepatitis would have been discussed on many occasions.

Clearly not all patients helped with clinical teaching. The results of blood tests would be discussed with patients if appropriate, i.e. if there was an unexpected abnormality or the patient enquired. Thus many individuals would get to know about the reason for these investigations and hence the possibility of these complications, particularly development of inhibitors and hepatitis as these are the commonest complications.

(j) During the 1970s and 1980s little was known about the risk of sexual spread of non-A non-B hepatitis although it was not considered a significant risk. Once HCV testing became available in the early 1990s and sexual transmission was studied it was found to be uncommon (especially in the absence of other sexually transmitted diseases). Transmission of hepatitis B to a spouse was a known risk of either the presence of acute hepatitis B infection or from a chronic carrier of the virus – this occurs in about 5% of individuals following acute infection.

(k) By 1985 a hepatitis B vaccine (derived from chronic carriers of hepatitis B infection) was available and licensed. This was offered to patients who were susceptible to hepatitis B, i.e. patients who did not have antibodies to hepatitis B in their blood. In offering this vaccine there would have been a general discussion about different types of hepatitis.

(5b) THE TRACING AND TESTING OF PATIENTS WHO MIGHT HAVE BEEN EXPOSED TO THE VIRUS THROUGH THEIR TREATMENT WITH BLOOD OR BLOOD PRODUCTS

(1) Routine surveillance for hepatitis viruses and liver disease at Haemophilia Centres, prior to hepatitis C testing from 1991 onwards.

As in any other chronic disease, management of haemophilia included regular monitoring (usually annually at clinic reviews) for complications of the disease, and complications of its treatment (including hepatitis). For example, Jones (1981),

reviewing the organisation of a haemophilia service in a Chapter of the standard UK textbook, noted examination for hepatosplenomegaly (enlargement of liver or spleen, which might indicate liver disease due to hepatitis) and routine blood tests (Jones P, in Haemostasis and Thrombosis, edited by A.L. Bloom and D.P. Thomas. Edinburgh: Churchill Livingstone, pages 389-394) (Annex 1). Routine blood tests included –

(a) Full blood count to measure haemoglobin, white count (including an assessment of the different kinds of white cells) and platelet count. This would be principally to make sure the patient was not anaemic due to occult bleeding (or in the early days of factor concentrate use that it had not led to a haemolytic anaemia – anaemia due to the premature removal from the recipient's circulation of red blood cells damaged following factor concentrate infusion).

(b) Assessment of blood chemistry consisting of -

- i.) Liver function tests – to assess possible presence and possible degree of hepatitis
- ii.) Urea and electrolytes to assess kidney function – haemophilia can lead to structural damage of the kidneys. Renal failure of any cause can lead to a bleeding state which would exacerbate the haemorrhagic state of the haemophilia.

(c) Assessment of clotting factor deficiency, e.g. factor VIII level and for presence of an anti-factor VIII inhibitor.

(d) Sample for virology for hepatitis B antibody and antigen.

As discussed by Dr. B. Colvin in his evidence to the Inquiry (8 March 2011) the diagnosis of non A non B hepatitis was difficult during the 1980's, prior to the identification of hepatitis C, for several reasons:

- Elevation of serum transaminases at routine clinic attendances (usually annually) provided an insensitive (weak) estimate of liver disturbance
- Elevation of serum transaminases was highly variable between and within individual patients

- Elevation of serum transaminases was insensitive to progression of liver disease
- Elevation of serum transaminases was nonspecific, reflecting liver disturbance due not only to viral hepatitis, but also to alcohol, other drugs, obesity and other causes; as well as disturbance to other body organs (e.g. skeletal or heart muscle).

Hence, interpretation of those blood “liver function tests” was difficult, as was information and advice given to patients.

The few patients with clinically suspected acute hepatitis (jaundice and/or other symptoms) would be routinely admitted to the local infectious disease unit for investigations, symptomatic management, and follow-up.

The few patients with symptomatic chronic liver disease (cirrhosis) would be referred to the local Gastrointestinal/Liver Disease Clinic for investigation, management, and follow-up.

The few patients who were carriers of hepatitis B were advised of the high risk of transmission by blood or sex; and that special precautions were required to avoid such transmission, including practising safe sex, and informing sexual partners of the risk and that they should practice safe sex and seek medical advice, including testing for carriage of the virus and vaccination. As discussed above, from 1985 all patients with haemophilia who were not immune to hepatitis B were advised to have hepatitis B vaccination, as were those assisting them with home treatment, who were at risk of needlestick injuries.

As discussed above, from 1992 all patients with haemophilia were routinely tested for antibody to hepatitis A, and if not immune were advised to have hepatitis A vaccination.

(2) Advice to patients and sexual partners on sexual transmission of hepatitis viruses at Haemophilia Centres, prior to hepatitis C testing from 1991 onwards

As discussed above, the few patients who were carriers of hepatitis B were advised of the high risk of transmission by blood or sex; and that special precautions were required to avoid such transmission, including practising safe sex, and informing sexual partners of the risk and that they should practice safe sex and seek medical advice, including testing for carriage of the virus and vaccination.

For patients with suspected non A non B hepatitis (usually, asymptomatic intermittent or persistent elevation of serum transaminases) no advice about the risk of sexual transmission, or testing of sexual partners, could be given, prior to the identification of the hepatitis C virus and the introduction of hepatitis C testing in NHS Scotland from 1991. Following however the identification of the risk of AIDS and the identification of the causative HIV virus, from 1985 all patients with haemophilia in Scotland who had received treatment with blood products were advised to discuss sexual transmission of bloodborne viruses with their partners and to practice safe sex (e.g. use of condoms), regardless of their HIV blood test results. (see evidence submitted by Prof Ludlam and Prof Forbes on Penrose B5). This advice continues to this day, and is clearly relevant to the (uncommon) risk of sexual transmission of HCV which was clarified during the 1990s, and also to potential sexual transmission of other pathogens.

Following the identification of the hepatitis C virus and the development of tests for exposure (antibody tests) and carriage (PCR tests), UKHCDO recommended in 1990 and 1991 that testing for hepatitis C be added to established routine surveillance for hepatitis/liver disease in patients with haemophilia (history-taking, clinical examination, liver function tests, hepatitis B testing, and from 1992 hepatitis A testing). UKHCDO and Haemophilia Centre directors were advised by their medical defence societies in 1990 (Annex 16) that hepatitis C testing could be undertaken on the same basis as other LFT's (i.e. HIV type counselling was not necessary).

We note that the Inquiry suggests that patients with positive hepatitis C antibody tests should have been informed "immediately". Clinicians may not have considered this to be appropriate clinical practice for a number of reasons. First, no immediate

clinical action was required. Second, given that the first available antibody tests were unreliable (with false positive and false negative results) it was difficult to explain the significance of these early results to patients, and necessary to repeat antibody tests with more reliable tests such as the RIBA-2 test.

We note that at the meeting of the UK Regional Haemophilia Centre Directors meeting on 4 September 1992, in his Liver Disease Working Party report, Professor Preston stated that from replies to his questionnaire from 65 UK centres, only 46% of centres had discussed HCV antibody results with their patients (Annex 17). We think that this reflects the uncertain significance of the first antibody tests, and supports our belief that "immediately" informing patients was generally considered inappropriate

The first tests for hepatitis C antibody (available in NHS Scotland from September 1991 and used by SNBTS to test blood donors from that date) were unreliable, and were replaced by the more specific RIBA-2 test in 1992. All Haemophilia Centres in Scotland routinely tested all patients who had received blood products attending their Centres with the RIBA-2 test from 1992. From about 1994, testing for carriage of the hepatitis C virus (PCR viral tests) became available in NHS Scotland, and was routinely performed in all patients attending Haemophilia Centres who had received blood products. Haemophilia Centre Directors (in collaboration with UKHCDO) have already provided statistics on results of hepatitis C testing to the Inquiry.

(5c) THE INFORMATION GIVEN TO PATIENTS WHO MIGHT HAVE BEEN INFECTED, OR WHO WERE FOUND TO BE INFECTED, AND THEIR FAMILIES

Most patients (and/or parents of children) with positive hepatitis C antibody tests were informed that they had probably been previously exposed to the hepatitis C virus through treatment with blood or blood products – most likely their first treatment with clotting factor concentrate, or their first several treatments with cryoprecipitate/fresh frozen plasma. As with hepatitis B, positive antibody tests were common in patients treated with blood products, but did not necessarily mean that the patient was a chronic carrier of the hepatitis C virus, or that they would develop

chronic liver disease. They were advised that hepatitis C PCR tests would be required for this purpose. They were advised to avoid excessive alcohol consumption. An example of a local patient information sheet on hepatitis C and its investigation and treatment (given to Edinburgh patients) is attached along with a check list of appropriate investigations (Appendix 18)

Patients (and/or parents of children) with positive hepatitis C PCR tests were informed that they were probably chronic carriers of the hepatitis C virus, and had a risk of developing chronic liver disease (cirrhosis or cancer). They were advised to continue to attend the Haemophilia Centre for regular clinical review and blood liver function tests, for detection of these complications. They were advised to avoid excessive alcohol consumption.

Patients were advised that there was emerging evidence that hepatitis C can be transmitted sexually, although this appeared uncommon, and that they should continue to practice safe sex (e.g. use of condoms), as advised since 1985. They were advised to discuss this risk with sexual partners, who should be advised that hepatitis C testing could be performed (e.g. by their general practitioner, at an infectious disease or sexually transmitted disease clinic, or if they preferred at a Haemophilia Centre).

Patients (and/or parents of children) were also informed that the antiviral drug interferon was being evaluated in clinical trials for treatment of hepatitis C; and that liver transplantation was a possible treatment for serious liver disease. They were advised that in due course they would be referred to a liver clinic for monitoring of hepatitis C and discussion of possible future treatments.

Patients (and/or parents of children) were given current educational information leaflets published by the UK Haemophilia Society and/or the British Liver Trust, which reinforced the above advice, and included current estimates of the risk of complications. An example from 1993 is included in Annex 3.

The UKHCDO's first guideline on hepatitis C was published in 1995 (Annex 14). By that time it is our recollection that its recommendations had generally been followed

across Scotland, including referral to liver clinics for management by consultant hepatologists.

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Annexes

1. Jones P, 1981 chapter.
2. Haemophilia Society, 1986 Treatment Survey
3. Haemophilia Society, information on hepatitis in educational/information leaflets.
4. Information leaflets (already provided to the Inquiry by the SNBTS)
5. Hep B and Hep A vaccination information
6. Information for PUP study.
7. Bennett et al 1993 PUP study.
8. Scottish HCD's priority list for recombinant products.
9. Rizza CR, 1981 chapter.
10. Jones P, extracts from Haemophilia Home Therapy, 1980.
11. Jones P, extracts from Living with Haemophilia (1974, 1984, 1990, 1995). (editions 1-4)
12. Edinburgh Royal Infirmary home treatment consent form.
13. Edinburgh NANB test study letter.
14. UKHCDO guideline on hepatitis C, 1995.
15. The Haemophilia Society - Scottish Group - Minutes of meeting of 29 March 1980 at GRI
16. Minutes of Haemophilia Directors Meeting, 26 February 1990
17. Minutes of Haemophilia Directors Meeting, 4 September 1992
18. Local Patient Information Sheet on Hep C and Investigation Checklist