Penrose Inquiry – Topic C5 – Dr Brenda Gibson

I have read, contributed to, and endorsed the collective response of past and present Haemophilia Centre Directors in Scotland on topic C5, previously submitted to the Inquiry.

(5a) ***THE INFORMATION GIVEN TO PATIENTS (OR THEIR PARENTS) ABOUT THE RISK OF NON A AND NON B HEPATITIS BEFORE THEIR TREATMENT WITH BLOOD OR BLOOD PRODUCTS***

I was appointed to my post of Paediatric Haematologist at RHSC, Glasgow in 1984, but did not assume responsibility for haemophilia care until 1988, when I become the Haemophilia Director.

My recollection is that once referred to the Haemophilia Centre at RHSC, Glasgow the parents (patients) of boys with haemophilia received information on the best treatment for their son, including all treatment options if more than one existed. As part of that discussion the benefits and risks of treatment were discussed and parents (patients) routinely informed of the risk of hepatitis (B, and non A non B). Patients were managed by a multidisciplinary team with a haemophilia nurse specialist playing a pivotal role in counselling and education. The risk of hepatitis was explained by medical staff and regularly reinforced by the haemophilia nurse specialist. Information was given and reinforced at every opportunity.

(a) The haemophilia nurse specialist trained the mothers in venepuncture so that they could administer the clotting factor concentrate at home. They were educated to take precautions to avoid transmission of infection whilst preparing and administering the factor concentrates. This included the use of disposable gloves, safe disposal of needles, syringes and concentrate. Bins for disposing needles, syringes etc were issued with factor concentrate to mothers of boys on home treatment in line with good clinical practice. The families were well cautioned and educated on the risk of hepatitis from needle stick injuries and blood spills. They were also trained on how to deal with both scenarios.

(b) Patients and mothers who were administering clotting factor concentrate at home were vaccinated against hepatitis B (1985) and later hepatitis A (1992). They would have understood that each vaccine gave specific immunity and not protection against all causes of hepatitis.

(c) The families were introduced to the Haemophilia Social Worker who encouraged them to join the Haemophilia Society, which was a useful source of written information on haemophilia, its treatment and complications of treatment including hepatitis. The Social Worker held parent support group meetings where treatment and complications were discussed. The Haemophilia Society held and attended meetings and, as I remember, at least one was focused on hepatitis. They produced written literature and made available a book called "Living with Haemophilia" written by Peter Jones. Most families had a copy and latterly it provided information on hepatitis.

(d) Many of the mothers had male relatives with haemophilia and were aware of the risks of hepatitis from them. The haemophilia nurse specialist spent a great deal of time with the mothers who often told her about health problems affecting other members of their family with haemophilia. Many of the families forged deep friendships and information readily cascaded through the haemophilia community.

(e) The boys 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 treatment would bring these bloods to a clinic visit to prevent an unnecessary venepuncture and would have understood why these bloods were being checked.

(f) 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. Parents were aware of these school visits.

(g) Parents of patients on home treatment, whether this be with NHS or commercial clotting factor concentres, would read the information leaflets provided in the

box with these concentrates, which included the possibility of transmitting hepatitis.

(h) 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. Accordingly, UKHCDO, and others, recommended that boys who had never received clotting factor concentrate, or who had had limited previous exposure, should receive cryoprecipitate in preference to clotting factor concentrates. This recommendation was to reduce the risk of non A, non B hepatitis associated with the use of pooled concentrate, and the reason for using or reverting to cryoprecipitate would have been explained to the parents/patients. Cryoprecipitate was much more cumbersome to administer and the families had to understand the rationale for its use if they were to accept this change in practice.

(i) Children were generally the first beneficiaries of high purity or virally treated concentrate and the advantages, primarily the reduction in risk of viral transmission, would have been explained to parents. From 1988 patients not previously exposed to clotting factor concentrates were invited to participate in a clinical trial of virally inactivated SNBTS clotting factor concentrates aimed at showing that virally inactivated concentrates could reduce the risk of non A, non B hepatitis or hepatitis C. An information sheet stating the aims and risks of the concentrate was provided for this clinical trial and consent required. Children were also the first to receive recombinant clotting factor concentrates when this became available and again this was part of a clinical trial with information on the rationale for using recombinant products.

INFORMATION GIVEN TO PATIENTS (OR THEIR PARENTS) ON THE SEVERITY OF NON A, NON B HEPATITIS BEFORE THEIR TREATMENT WITH BLOOD OR BLOOD PRODUCTS AT RHSC, GLASGOW.

Most of the information on the severity of non A, non B hepatitis/hepatitis C came from adult experience. Initially (at least prior to 1985) non A, non B hepatitis was generally thought not to be a serious illness. This is the information which would

have been given to patients/parents, when discussing the risk of hepatitis. Later, it became apparent that the natural history of non A, non B hepatitis was less clear but that it could progress to cirrhosis and liver cancer. However, the significance of non A, non B hepatitis was even less clear in children than adults because children had none of the co-morbidities common in adults; for example alcohol consumption, other drugs, co-infection, which were thought to contribute to liver dysfunction in adults. From 1985 onwards parents/patients 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.

INFORMATION GIVEN TO PATIENTS (OR THEIR PARENTS) ON ALTERNATIVE TREATMENTS TO BLOOD OR BLOOD PRODUCTS AT RHSC, GLASGOW.

Patients/parents were informed that the only alternative treatment to factor concentrates for raising low levels of factor VIII was Desmopressin. They would also have been told that Desmopressin was only appropriate for mild/moderate factor VIII deficiency and patients with von Willebrand's disease. There was no alternative treatment for boys with factor IX deficiency. However, Desmopressin has several limitations:

- Response unpredictable and had to be demonstrated before use
- Response moderate
- Repeat injections 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
- Not recommended in small children because of the recognised risk of water intoxication which can predispose to seizure activity
- Desmopressin was ineffective in most patients with haemophilia A (severe or moderately severe patients) and in all patients with haemophilia B

Whilst clotting factor concentrates were avoided in mild haemophiliacs, and wherever possible in moderately affected haemophiliacs, Desmopressin was not suitable for most patients because it could not achieve a factor VIII level which could prevent haemorrhage.

(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 RHSC, Glasgow, prior to hepatitis C testing from 1991 onwards.

Boys were routinely and regularly monitored for complications of haemophilia and its treatment. This included anaemia, inhibitor formation, abnormalities of renal and liver function, immunity post vaccination and viral transmission. No specific consent was required for blood tests, which were either taken at clinic or at venepuncture for treatment at hospital or at home. In the latter circumstances the blood samples would have been brought to clinic by the boy's mother. Testing included:

- Full blood count to measure haemoglobin and ensure that the patient was not anaemic due to occult blood loss
- Liver function tests to detect any liver disturbance which would most likely have been caused by hepatitis
- Renal function tests: Urea and electrolytes to assess kidney impairment which can occur in haemophilia.
- Assessment of clotting factor deficiency, e.g. factor VIII/IX level and for presence of an anti-factor VIII/IX inhibitor
- Sample for virology for hepatitis B antibody and antigen

Abnormalities of liver function tests varied within any one patient over time, in the absence of any obvious reason, and lacked specificity. They could be affected by a number of factors including other medication. This made it very difficult to predict their significance. Any patient with a significant abnormality would have been

referred to a Paediatric Gastroenterologist, as would have been the practice for any patient with worryingly abnormal liver function tests.

Patients/parents who were non immune to hepatitis B received vaccination, and 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. When did they start testing their patients for HCV?

The testing of children who might have been exposed to the HCV through treatment followed the same time frame as in adult practice. This is turn followed recommendations from the UKHCDO. Hepatitis C antibody testing became part of routine hepatitis screening in 1991. Hepatitis C antibody positivity indicated previous exposure to hepatitis C virus. The initial tests for hepatitis C antibody were unreliable and were replaced by the improved RIBA-2 test in 1992. Antigen tests became available in 1994. Antigen testing identified patients who were carriers for HCV and all patients were tested.

3. In what circumstances were blood tests carried out during the periods 1990-1995 and from 1995 onwards? Were patients tested individually or as a group? Were fresh blood samples taken for the purpose of testing or were stored samples used? Who carried out the HCV tests?

During these time periods blood samples were taken from all patients who had previously received blood or blood products. This was done either when they attended the Haemophilia Clinic, or were brought by their mother who had taken the blood when administering factor concentrate at home. Blood samples were sent to the Regional Virus Laboratory, Ruchill Hospital for testing.

4. Did they tell their patients that HCV tests were being carried out? What did they tell their patients about HCV testing? Did they obtain consent from their patients before carrying out HCV tests?

Parents/patients were routinely informed that HCV testing was being carried out. They would have been told a virus had been identified which was thought to be the cause of non-A, non-B hepatitis and that it was called hepatitis C. The parents of boys who were hepatitis C antibody positive were told that their son had been previously exposed to Hepatitis C and that this was the likeliest cause of any abnormal liver function tests. They would also have been told that most patients who received treatment before the introduction of viral inactivation would be hepatitis C antibody positive. Hepatitis/liver monitoring was considered a routine test and as such consent was verbal. Medical Defence Unions advised that hepatitis C testing could be treated like any other monitoring test.

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

1. **What was their practice in relation to telling their patients of an anti-HCV positive test? Did they inform their patients immediately upon receiving their results? If not, why not? What arrangements were made for patients to be told of positive test results?**

Parents/patients were given the result of hepatitis C testing at their next clinic visit or next visit to the department after the result was available. This practice was irrespective of whether the result was positive or negative. It was not appropriate to inform parents/patients immediately by telephone, particularly for positive patients, because parents/patients had to be given the opportunity to discuss the significance if the result was positive and ask any questions they wished answered. There was no immediate treatment to be given and therefore no immediate urgency to inform them, or to do so in a less than optimal setting.

2. **What did they tell their patients about the implications of HCV?**

Parents of boys/patients who were hepatitis C antibody positive were informed that their son had probably been previously exposed to the hepatitis C virus through treatment with clotting factor concentrate or cryoprecipitate, and that this was likely to have happened with their earliest treatments. They would have been informed that

antibody positivity did not necessarily mean that they were a chronic carrier of hepatitis C or that they would develop chronic liver disease. They were also told that their child's liver function tests would be carefully monitored. The older boys were told to avoid alcohol.

Parents of boys/patients who were hepatitis C antibody positive were informed that their son was probably a chronic carrier of the hepatitis C virus, and had a risk of developing chronic liver disease. They were also told that their child's liver function tests would be carefully monitored and that he would be referred to a liver specialist and offered any possible treatments available. The older boys were told to avoid alcohol.

Parents/patients were given information leaflets published by the UK Haemophilia Society and/or the British Liver Trust, which discussed the complications of hepatitis C and provided advice. The recommendations of the UKHCDOs first guideline on hepatitis C were well in place at RHSC, Glasgow before these guidelines were published in 1995.

3. **Were there any written guidelines or policies on communicating positive results to patients produced by their unit at this time?**

I do not recall any local written guidelines or policies on communicating positive results to parents/patients. However, these boys were cared for in a haematology unit, which also cared for children with leukaemia and cancer and staff were skilled at communicating with families and at breaking bad news.

4. **Were there any written guidelines or policies on HCV tests produced by their unit at this time?**

I do not recall any written guidelines or policies. However, the UKHCDO guideline was used.

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November 2011