A PROPOSAL FROM THE IRISH HAEMOPHILIA SOCIETY

HAEMOPHILIA AND HEPATITIS C INFECTION

INTRODUCTION

Haemophilia is an inherited bleeding disorder where one of the bloods clotting factors is missing or present at a much reduced level. Treatment is administered via injections of the missing clotting factor when bleeding occurs. The treatment used is made from pooled human plasma. This has led to the contamination of the haemophilia population by Hepatitis B, HIV, Hepatitis A and now Hepatitis C. There are approximately 400 people with Haemophilia in Ireland. It has now become evident that a large proportion of people with Haemophilia have been infected with Hepatitis C through the blood products used for treatment. Hepatitis C has much greater long term consequences than Hepatitis B or Hepatitis A infection.

EXTENT OF THE PROBLEM

Based on figures supplied to the Irish Haemophilia Society by the Haemophilia Treatment Centres in Dublin, Cork and Galway and a communication with our members, we estimate that:

- 183 people with Haemophilia have been infected with Hepatitis C.
- 32 have died of HIV
- 3 have died of Hepatitis C
- 148 are alive with Hepatitis C.

Some of these 148 (perhaps 40) are co-infected with HIV.

Those registered with the Centres with Hepatitis C (Alive) are:-

Dublin	123
Cork	23
Galway	2

Of the 155 people with Haemophilia who tested positive for Hepatitis C in the Dublin Centre (123 still alive) the age breakdown was as follows:-

Year of Birth (inclusive)	No. Patients
1920 - 1929	5
1930 - 1939	10
1940 - 1949	14
1950 - 1954	13
1955 - 1959	18
1960 - 1964	22
1965 - 1969	20
1970 - 1974	23
1975 - 1979	15
1980 - 1984	8
1985 - 1989	8
	155

We do not have an age profile for those registered in Cork or Galway. Those infected would include people with Haemophilia A, Haemophilia B, Von Willebrands disease and in some cases female carriers of Haemophilia who would have received clotting factor concentrate because of low factor levels.

MEDICAL CONSEQUENCES OF HEPATITIS C IN HAEMOPHILIA

The medical consequences of Hepatitis C infection for people with haemophilia are more devastating than the consequences for those with Hepatitis C infection who do not have Haemophilia. People with Haemophilia face additional difficulties with regard to diagnosis and treatment and a generally worse prognosis.

DIAGNOSIS

Diagnosis is more difficult. Liver biopsies are not routinely carried out on people with Haemophilia. Earlier studies of liver biopsies in people with Haemophilia showed that the rate of complications (12.5%) was much higher than the rate in other groups being biopsied (0.28%) and the mortality rate (1.3%) was much higher than other groups (0.03%). Techniques have improved considerably. However, it is still not a practical option to biopsy all people with Haemophilia and Hepatitis C solely to diagnose the stage of the disease.

TREATMENT

Results of treatment with Interferon have been very disappointing in people with Haemophilia. In general, when people with Hepatitis C are treated with Interferon, you expect a sustained response in about 25%. In the cohort of people with Haemophilia who have been treated with Interferon in Ireland, a sustained response has been seen in less than 10%. This is similar to results which we have seen in the UK. Long-term responses were seen in

- 6 out of 27 (Sheffield)
- 1 out of 32 (Edinburgh)
- 2 out of 27 (Royal Free, London)

The best response to Interferon therapy is seen in people with Hepatitis C who have a genotype other than type 1, a low viral load, a recent infection, and are relatively young. Most people with Haemophilia would have long standing infection, would have a high viral load and would be genotype 1.

PROGNOSIS

The majority of people with Haemophilia who are infected with Hepatitis C will develop Chronic Persistent or Chronic Active Hepatitis. Between 25% and 50% may develop Cirrhosis or Carcinoma of the liver. The progression rate to serious liver disease in this group is more common for a number of reasons:

1. Multiple exposures. People with Haemophilia received pooled plasma products on frequent occasions and therefore, received multiple exposures to the virus. (This would be in contrast to people who received Anti-D or blood transfusions, where the number of exposures and the number of donors to whom they would have been exposed , would be limited.)

2. Most people with Haemophilia would be expected to have a high quantitative viral load.

3. Most people with Haemophilia in Ireland would have genotype 1 which is less responsive to treatment. Mixed genotypes would also be common.

4. Co-infection with other hepatitis viruses. Many people with Haemophilia would have been infected with Hepatitis B and or Hepatitis A through their blood products. These co-infections may well exacerbate the amount of liver damage.

5. Co-infection with HIV. This is a major problem. 103 people with Haemophilia were infected with HIV through blood products. Approximately 75 of these would also have been infected with Hepatitis C. There is no doubt that co-infection with HIV leads to a more rapid progression of liver disease. One study carried out in London (Dr. P. Dillon, Royal Free Hospital), showed that 10 years after infection, 2.5% of people with Haemophilia would have developed Cirrhosis. 10 years after infection in a group with Haemophilia co-infected with HIV, 15% would have developed Cirrhosis. This is a six times faster progression.

6. Many of the people with Haemophilia would now have been infected with Hepatitis C for a significant number of years and are reaching the point where they can expect to start seeing serious consequences from their Hepatitis C.

The outlook for people with Haemophilia who are infected with Hepatitis C is not good. Of the 183 people who are infected, 35 have died. 3 of these have died directly as a result of Hepatitis C infection. The other 32 were co-infected with HIV and in the majority of these cases, HIV would have been the cause of death. Approximately 12 people with Haemophilia have severe liver disease at this time. In Haemophilia Centres where biopsies have been carried out extensively, the results have shown a much higher rate of liver disease than other groups infected with Hepatitis C. In Sheffield, UK (a leading Centre for studies of Haemophilia and Hepatitis C)., following biopsy,

48% of people with Haemophilia had Chronic Persistent Hepatitis
17% of people with Haemophilia had Chronic Active Hepatitis
28% of people with Haemophilia had Cirrhosis
Of 138 with Hepatitis C, 2 developed Hepatocellular Carcinoma.

SOCIAL AND FINANCIAL IMPLICATIONS OF HEPATITIS C

Hepatitis C infection has social and financial implications for people with Haemophilia which in many ways are similar to the implications suffered in the past by people with Haemophilia who contracted HIV.

- A significant number are, or are going to be, seriously ill, have to give up work and may die.

- There is great fear and uncertainty with regard to prognosis, treatment and transmission.

- There is concern regarding sexual and vertical transmission within families. The risk of sexual transmission is low but is nevertheless real.

* Many people with Haemophilia and Hepatitis C have suffered fatigue and general malaise. This was particularly common in those who received interferon.

* Many have missed significant amounts of time from education or employment as a result of having to attend clinics frequently for ongoing assessment and treatment.

* Individuals are denied life insurance and can only receive it at prohibitive rates or for short terms. This, along with the uncertainty over prognosis, places great stress on the desire of individuals to provide financial security for their families.

* Hepatitis C restricts the ability to enjoy a "normal" lifestyle which might include a social drink.

PROPOSAL

The medical consequences of Hepatitis C for people with Haemophilia have already been devastating. Some of our members have already died from Hepatitis C. Many of our members who were co-infected with HIV and Hepatitis C have died and many members are already suffering from liver disease. For those with Haemophilia, particularly for those co-infected with HIV and Hepatitis C, time is of the essence. In the last 8 months, since we have been discussing this issue with the Dept. of Health, 4 people with Haemophilia and Hepatitis C have died. All were co-infected with HIV. There is no doubt that further deaths will take place in the near future.

People with Haemophilia are a cohesive group who have a strong relationship with the Irish Haemophilia Society. In addition they are treated in a small number of hospitals - St. James's Hospital, Dublin, Regional Hospital, Cork, Regional Hospital, Galway and therefore medical records would need to be obtained only from a small number of centres.

We would ask that the Tribunal urgently consider treating claimants with Haemophilia as a class claim.

We would hope to see a situation where the commonality between these cases would allow for rapid production of medical records from the small number of hospitals. In addition, submissions could be made by a medical expert in Haemophilia and Hepatitis C, who could address common medical issues relevant to all of these cases. We would envisage that the Society would retain one firm of solicitors and counsel, and one medical expert.This team would possibly be used by a large number of people with Haemophilia in making representations before the Tribunal.
We would also envisage that the Irish Haemophilia Society would help their members in processing their applications for the Tribunal, would accompany claimants to the Tribunal and would do everything possible to help the Tribunal to expedite hearing and rapid decision in these cases.

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