Dear

I am writing to tell you about the new anti-HCV test.

Many haemophiliacs who have been treated in the past with unheated clotting factor concentrates or other blood products have been exposed to the non-A non-B hepatitis (NANBH) virus, so called because it is unrelated to hepatitis A and unrelated to hepatitis B.  One agent responsible for NANBH has now been identified by recombinant gene technology as the hepatitis C virus (HCV).  We have a new test available which measures antibody to HCV (anti-HCV) and shows past infection.

Your anti-HCV was positive on

Some people who have been exposed to NANBH (HCV) in the past may after many years go on to develop chronic hepatitis, but we cannot determine who will progress in this way.  Although there are some trials of treatment for such liver disease, no-one is using treatment on a regular basis in haemophiliacs at the present time.  Although it is possible that NANBH (HCV) can be spread sexually, information in this area is at present very limited.

We should be very pleased to further discuss with you any of these issues either at your next review or sooner if you would like to make an appointment.

Yours sincerely,

GRO-C .

Dr Christine A Lee
Consultant Haematologist

CL/HCV                                                    LRB/4.6.90

3

# HCV - POLICY DOCUMENT FOR THE HAEMOPHILIA CENTRE
(For circulation to STAFF ONLY)

## Introduction

The agent responsible for at least the main type of transfusion transmitted non-A non-B hepatitis (NANBH) has now been identified by recombinant gene technology as the hepatitis C virus (HCV). A number of seroprevalence studies of anti-HCV in multitransfused haemophilic patients worldwide have been performed. The seroprevalence ranges from 53% to 89%.

We know that the past incidence of NANBH following treatment with unheated clotting factor concentrate was 100%. Prospective studies post blood transfusion have shown that half of such infections lead to chronic infection and of these 20% lead to cirrhosis of the liver.

## Studies at the Royal Free Haemophilia Centre.

We have been able to study the longitudinal behaviour of antibody to HCV using the Ortho HCV antibody assay and testing stored sera from patients who developed NANBH following exposure to unheated pooled factor concentrates. All such patients have been found to be seropositive for anti-HCV. We have thus demonstrated reliability of the Ortho anti-HCV assay. In our haemophilic population HCV accounts for the NANBH seen and in the majority of patients the antibody is long lasting and may reflect virus replication. In some patients, however, the antibody disappears after initial seroconversion. The significance of this is unclear.

We have also demonstrated a 7% seropositivity rate in 30 female sexual partners of 30 anti-HIV and anti-HCV positive haemophiliacs. In other studies the seropositivity rate amongst sexual partners has been higher. It seems likely, therefore, that sexual transmission of HCV may occur.

## Criticisms and problems about the Ortho assay

There have been various criticisms which are summarised below:

1. There may be more than one NANBH agent, therefore this test might not account for all NANBH

2. There has been a suggestion that stored frozen sera may give false positive results.

3. In patients with liver disease the test may give false positives in the presence of increased gammaglobulins.

As yet, there is no test available for antigen and there is no confirmatory test.

1

## Policy for anti-HCV testing, result provision and counselling in the haemophilia centre.

1. All patients should be tested at review appointment.

2. Patients should be counselled at the review as to:

   (i)     the nature of the test

   (ii)    its deficiencies

   (iii)   its meaning (eg the possibility of chronic liver disease)

   (iv)    the possibility of sexual transmission and how this might be prevented (in the same way as HIV).

   (v)     the offer of anti-HCV testing for a sexual partner.

3. A letter should be sent to a seropositive patient only to give him/her the result when this is available.


Christine A Lee

4th May 1990