

IN CONFIDENCE

MSBT 3/4

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF BLOOD AND
TISSUES FOR TRANSPLANTATION

Meeting - 29 September 1994

AGENDA ITEM 6:

Members are invited to consider and comment on the attached
paper:-

"Recommendations of the Standing Advisory Committee on
Transfusion-Transmitted Infection to the MSBT, Concerning the
Merits of Adopting an HCV "Look-Back" Policy."

**RECOMMENDATIONS OF THE STANDING ADVISORY
COMMITTEE ON TRANSFUSION-TRANSMITTED INFECTION TO
THE MSBT CONCERNING THE MERITS OF ADOPTING AN HCV
"LOOK-BACK" POLICY**

Objective:

An ad hoc assembly of experts met on 5th August 1994 to discuss the feasibility of initiating a "look-back" policy to identify, test, counsel and, if necessary, refer surviving past recipients of blood components from donors later found to be anti-HCV seropositive after tested was introduced in September 1991.

Dr F Ala	Dr J Barbara	Dr J Cash	Dr J Gillon	Dr P Hewitt
Dr V Martlew	Dr D Mortimer	Dr A Robinson	Dr L Williamson	Prof R Tedder
With written contributions from :		Prof J Main	Dr J Garsen	Dr G Alexander

Current Knowledge:

Although clinically inapparent in most cases, HCV infection is not trivial, and may cause serious, progressive liver damage leading to cirrhosis and hepato-cellular carcinoma in the long-term.

Current evidence suggests that the likelihood of transmission by HCV-infected blood is high. Epidemiological information gathered during interviews with HCV positive blood donors indicates that the majority have been infected for many years, particularly through intravenous drug use in the late 1970s/early 1980s. Although most blood recipients are middle-aged or old, a significant number are children or young adults. Patients infected early in life will suffer morbidity after 30 to 40 years, whereas the life-expectancy and quality of life of patients over 50 are unlikely to be affected.

Specialist opinion regarding the efficacy of treatment with Interferon alpha given either alone or in combination with nucleoside analogues is heterogeneous.

In general, however, there is a view that:

- Treatment offered early after diagnosis is most likely to be effective in arresting liver damage, while patients with established fibrosis and portal hypertension will not benefit.
- The severity of disease must be assessed, and where there is evidence of progression, a trial of therapy to determine responsiveness is worthwhile.
- Early evidence from pilot studies shows that combination therapy with Interferon and Ribavirin may achieve virus clearance in up to 60% of patients.

- It is still not known whether therapy will affect the long-term natural history of the disease and prevent relapse after therapy is discontinued.
- Furthermore, Interferon alpha is not yet licensed for use in HCV infection.

The Position of the National Blood Service

When anti-HCV screening of blood donations was introduced in October 1985, the NBS undertook to perform look-back on recipients of previous donations from donors newly identified as HIV positive. This look-back programme has identified small numbers of blood recipients, transfused before 1985, who have been infected with HIV. In some cases, the recipient was already known to be HIV positive (although not reported to NBS as potentially infected through transfusion). In these cases, anti-HIV testing was carried out because of clinical suspicions, and/or routine surveillance in patients who have been multi-transfused during the treatment of haematological malignancies or coagulation disorders.

When anti-HCV screening of blood donations was introduced in September 1991, a look-back programme was not recommended. Doubts about the long term effects of hepatitis C infection, coupled with the lack of an effective therapy for individuals so infected, appear to be the main reasons behind this recommendation. Furthermore, secondary transmission of HCV to sexual partners and offspring appears to occur rarely. This is in contrast with HIV, where secondary transmission is more likely and effective counselling can reduce the likelihood of such transmission.

Transfusion-transmitted hepatitis C is likely to form an insignificant proportion of all cases of HCV infection in the general population. This is also true for HIV infection. Nevertheless, the National Blood Service bears a duty of care towards both donors and recipients. Donors who are identified as being infected with hepatitis C are offered counselling and appropriate referral to a specialist unit. The NBS has the facilities to trace previous donations from individuals newly found to be HCV infected when screening was introduced. A look-back programme for hepatitis C could be instituted, to identify those recipients who are most likely to suffer long term consequences of HCV infection. Look-back could therefore be targeted, which would reduce the resources required. Despite current uncertainties regarding long term efficacy of treatment and its impact upon the natural evolution of hepatitis C, the Service has the ability to identify blood recipients who may benefit from appropriate therapy in the future, most particularly patients transfused in the neonatal or paediatric period.

Implementation of the Programme

A look-back programme for HCV would be based on the current procedures for HIV. Blood Transfusion Centres trace potentially infected recipients through hospitals and general practitioners. The recipients would be offered interview and counselling, during which a blood sample could be obtained for testing. Recipients confirmed to be infected could be referred for specialist advice through their general practitioners. If the decision is made to follow only recipients in the young age group, the workload would be appreciably reduced.

Implementation of a look-back programme for HCV will produce an additional workload for the clerical/secretarial and counselling services in the NBS. Those centres which do not currently counsel donors for HCV infection would need to agree appropriate arrangements for the counselling and testing of potentially infected recipients.

The majority of donors identified as infected with HCV are likely to have acquired their infection many years ago. This implies that no arbitrary time limit should be set on the look-back for infected recipients. Evidence from pilot studies in Edinburgh suggest that very few, if any, recipients are likely to be traceable and alive more than five years after transfusion. Similar experience with HIV look-back, however, indicates that some recipients are alive and traceable up to ten years after transfusion and these are likely to be recipients transfused in the neonatal and paediatric period.

Making a number of assumptions, it is probable that implementation of a look-back programme for HCV will involve an overall caseload of approximately 3,000 for England and Wales. The impact on the specialist units will need further consideration.

Summary

The SACTTI feels that there is a serious case for considering a look-back policy for HCV. To do otherwise, when a look-back programme for HIV already exists, suggests double standards. The wider implications of such a policy will need further consideration and the SACTTI recommends that the Hepatitis Advisory Group and the MSBT consider the matter further as soon as possible.