

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

OBJECTIVE:

The desirability and 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 testing was introduced in September 1991, was discussed by an ad hoc assembly of experts on 5th August 1994.

(Drs. F. Ala, J. Barbara, J. Cash, J. Gillon,
P. Hewitt, V. Martlew, D. Mutimer, A. Robinson
L. Williamson, Prof. R. Tedder, with written
contributions from Prof. J. Main,
Dr. J. Garsen and 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, and 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, the prevailing view is 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.

THE POSITION OF THE BLOOD TRANSFUSION SERVICE:

While it is true that transfusion-transmitted Hepatitis C is an insignificant proportion of all cases in the general population, this has little bearing on our duty as providers of blood and blood components.

It must be acknowledged that the National Blood Service bears an ethical responsibility and duty of care towards recipients of potentially infectious blood components such that they deserve to be identified, counselled, tested and offered treatment where that is appropriate. Despite current uncertainties regarding long-term efficacy of treatment, and its impact upon the natural evolution of Hepatitis C, the Service has a moral obligation to inform and advise surviving, potentially infected blood recipients, most particularly patients transfused in the neonatal or paediatric period who are at higher risk for disease.

IMPLEMENTATION OF THE PROGRAMME:

The implementation of a "Look-Back" policy for HCV requires that blood transfusion centres trace implicated recipients through hospitals and General Practitioners; interview and counsel surviving blood recipients; obtain and test a sample of their blood; refer infected patients for specialist counselling, investigation and possible treatment by hepatology centres.

Some thought must be devoted to mechanisms for defraying the additional costs of specialist reference centres.

The very adoption of this policy implies that no arbitrary limit to retrospective analyses will be imposed. In practice, however, there is evidence to suggest that very few, if any, recipients are likely to be traceable and alive more than 5 years after transfusion.

Making a number of assumptions*, it is probable that implementation will involve

an overall case-load of approximately 3,000 for England and Wales alone.

* Assumptions:

- Approximately 1,000 confirmed anti-HCV donors
 have been detected since screening began.
- 50% of blood recipients have died and a further
 17% are untraceable.
- Only 85% of donors after September 1991 were
 established and had donated before.
- Donors give one donation per year
- Each donation is processed into 2
 issuable blood products.
- 80% of components issued are actually
 transfused.

IN SUMMARY:

The SACTTI feels that there is a serious case for considering the implication of a "HCV Look-Back" policy in its operational detail, and recommends to the MSBT that such a policy is adopted as soon as possible.

FAA/MP
12.9.94

FAA/MP

12th September 1994

Dr. A. Robinson,
National Medical Director,
National Blood Authority,
Oak House,
Reeds Crescent,
Watford, Herts WD1 1QH

Dear Angela,

Here is a draft of the very abbreviated "Look-Back" recommendation. Do please attack with red pencil or suggest any changes you wish to make.

With kind regards,

Yours sincerely,

DR. F. A. ALA
Medical & Scientific Director

Encl.