Draft Report from the MSBT Subcommittee

Convened at the request of the Chairman, Dr Jeremy Metters, to give further consideration to the recommendation made to the MSBT at it's meeting held on 29/9/94 to adopt an HCV "Look-Back" Policy.

Meeting held at the Royal Free Hospital School of Medicine 3rd November 1994.

In attendance: -

Profcssor A J Zuckerman

Dr E Angela Robinson

Dr D W Gorst

Comments expressed at the MSBT meeting 29th September 1994 re the SACTTI presentation on the merits of introducing an HCV "Look-Back" policy were as follows: -

1. The stated response rate of 60% to treatment with interferon in patients with HCV liver disease is too high. Current evidence suggests a response rate to interferon based on virological criteria in the range of 20 - 40% added to which there is a risk of rebound once interferon therapy is stopped. The long term outcome of this treatment is not yet established.

2. Interferon is not yet licensed as a treatment for hepatitis C liver disease. Response ratcs and occurrence of rebound are difficult to evaluate because of the different dose schedules in use. Interferon has since been licensed for treatment of hepatitis C virus chronic liver damage.

3. In a controlled study (personal communication Professor Zuckerman) the response rate to a combination of interferon and Ribavirim and interferon alone showed no siginificant difference.

4. It is true that transfusion transmitted HCV infections form an insignificant proportion of all cases of HCV hepatitis/cirrhosis

5. As the HCV antibody donor screening programme was introduced in September 1991 if an HCV Look-Back programme is instituted now (1994/95) those recipients who were infected will now have had the infection for at least 5 years. If treatment with interferon is offered at this stage it is difficult to assess what the prospects for success would be. Consideration has to be given to the fact that interferon is an unlicensed expensive drug which can have serious side effects.

Despite these reservations it is recognised that there is a duty of care that needs to be exercised towards these patients and the implicated donors.

Based on previous experience of implementing an HIV Look-Back programme and on the SNBTS pilot study of an HCV Look-Back programme, the best estimate is that up to 3,000 recipients in England and Wales could have been exposed to HCV antibody positive blood and are therefore at risk of contracting transfusion transmitted HCV liver disease. Current evidence suggests that the likelihood of transmission by HCV infected blood is high. It is estimated that at lease 25% of these recipients may still be alive and traceable, although data from a recently reported study from the United States on Long-Term survival after blood transfusion now suggests a post-transfusion survival rate of up to 60% at 5 years (Transfusion June 1994, 3 4 (6): 471 - 7, abstract enclosed).

Long term follow up studies of groups of patients who developed post-tranfusion non-A non-B hepatitis have clearly demonstrated that transfusion transmitted hepatitis can no longer be regarded as a relatively benign disease. 60 - 80% of recipients who develop transfusion transmitted HCV infection will become carriers and it is estimated that 50% go on to develop chronic hepatitis. Under estimates in the past were due to our inability to detect the presence of the HCV virus, whereas now it is recognised that some patients can still be viraemic despite having normal liver enzyme levels.

A recent review by Weiland on the natural history of transfusion transmitted HCV disease suggests that 50 - 80% of infected recipients will develop chronic hepatitis and 20% may develop chronic active hepatitis with cirrhosis within 5 years. (2 slides from this review are

enclosed). An earlier Japanese study demonstrated that chronic hepatitis occurred within a mean time of 20 years and hepatocellular carcinoma within a mean time of 30 years.

Given this time span of events, transfusion transmitted HCV disease has serious implications for the younger transfused population. An HCV Look-Back programme would enable such blood recipients to be identified who could then benefit from appropriate antiviral therapy being administered earlier in the course of their disease.

Issues identified that need further consideration.

1. What are the legal implications of instituting an HCV Look-Back Programme 4 - 5 years after introducing the blood donor HCV antibody screening programme.

2. What are the legal implications of instituting an HCV Look-Back programme limiting follow up to the younger (age-limited) transfused population.

3. What are the ethical implications of instituting an HCV Look-Back Programme i.e. in our efforts to identify infected recipients who may or may not benefit from treatment the mental well being and quality of life of all such recipients infected or uninfected could be seriously compromised. (Similar considerations apply, of course, also to the implicated donors and other groups at "high risk" of infection).

4. Consultation and liaison with hepatologists is essential to ensure that the approach to the assessment of these recipients and donors is carried out in a uniform manner. UK wide guidelines to harmonise the clinical approach to these patients would need to be established together with an estimate of treatment costs. An initiative to start this process has already commenced involving the SNBTS and most of the specialised hepatology services in Scotland and Northern Ireland.

Written comments have been received from various members of the MSBT. The over-riding view appears to be in favour of instituting an HCV Look-Back programme with the proviso

that a uniform UK wide approach is taken and that serious attention is given to the ethical and legal implications of contacting recipients of HCV infected blood.

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Prevelance of antibodies against hepatitis C virus among patients with hepatocellular carcinoma.

Country	Nos	% anti-HCV pos	Reference
Spain	96	75%	Bruix et al
Italy	132	65%	Colombo et al
South Africa	380	29%	Kew et al
Somalia	62	40%	Bile et al
Japan	379	54%	Kiyosawa et al
USA	91	46%	Lang et al

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