0044

NOT FOR PUBLICATION

ACVSB 2/7

NON-A, NON-B HEPATITIS

Please refer to paper ACVSB 2/6 and annexe to ACVSB 2/5.

1. Surrogate testing - Licensing Authority

The current UK position is that surrogate testing by means of ALT measurement is not a licensing requirement for blood or blood products. However certain companies are now doing this because of such requirements by the Federal German Licensing Authority and the FDA.
The Licensing Authority tends to take the view that each product is assessed separately with regard to its possibilities for transmission of non-A, non-B hepatitis (NANB hepatitis). This is taken as part of the risk to benefit assessment. Since there are currently no specific tests available or validated for the presence of NANB hepatitis, the Licensing Authority has felt that it is not possible to make any definitive demands of companies. Also this clearly means that no company is able to claim that their product is safe in the product literature.
Appended are the results of a questionnaire on NANB hepatitis by the Council of Europe and an extract from the report of the Committee of Experts on Blood Transfusion and Immunohaematology (SP-HM) in 1987.

2. Surrogate testing -UK study

This study (supported by the Health Departments) is being co-ordinated by Dr.Gunson on behalf of the UKBTS. It is too early to report on this yet, but all the samples have now been collected and screened for ALT and anti-HBc. Much of the follow-up has been done, but this is not yet complete. It is hoped that in June a review of the study will take place although conclusions cannot be drawn until the results of the Chiron tests are known. Although there is no UK experience of the Chiron test, arrangements have been made by UKBTS for 10,000 tests, to allow testing of the donors in the NANB study.

3. Cloning of the non-A, non-B hepatitis virus

In May 1988 Chiron Corporation (US) reported cloning of parenteral NANB hepatitis virus. This report has recently been amplified - Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome, Choo Q-L et al, Science, 244, 359-362, 1989. The data suggests that NANB hepatitis agent is similar to the togaviridae or flaviviridae. The authors refer to this virus as hepatitis C virus.

4. Specific assay for non-A, non-B hepatitis - Chiron

In May 1988 Chiron also reported the development of a specific assay for NANB hepatitis. Further details have recently been given - An assay for circulating antibodies to a major etiologic virus of human non-A, non-B hepatitis, Kuo G et al, Science, 244, 362-364, 1989. Although the results of the study indicated a high sensitivity and specificity of the assay for blood-borne NANB hepatitis, acute phase infections were negative for the assay. Positive results were usually not apparent till 3 to 6 months after the transfusion and in one case not for 12 months. All the recipients studied prospectively who developed chronic NANB chronic hepatitis seroconverted, and only in one case was no positive donor identified. Some of the donors had no surrogate markers for NANB hepatitis, neither raised ALT nor HBcAb. Among voluntary blood donors in New York 0.5% were positive for hepatitis C antibody but negative for surrogate markers, while 44% were positive for hepatitis C and both surrogate markers. Retrospective studies of chronic post-transfusion NANB hepatitis in US showed 71% positivity for the assay with comparable figures of 84% for Italy and 78% for Japan. In addition 58% of community-acquired chronic NANB hepatitis were positive for hepatitis C antibody.
Although hepatitis C is a major cause of chronic NANB hepatitis, the assay may not identify other forms of NANB hepatitis transmitted either by blood or other routes.

5. Recommendations to be considered

At present there does not appear to be any urgent need to introduce routine surrogate testing for NANB hepatitis among voluntary blood donors in the UK in respect of public health.
The position should be reconsidered by this Committee when the results of the UKBTS NANB study are available. This should give an indication of the effect of donor testing for surrogate markers of NANB hepatitis on donor panels, the costs involved and an indication of its value in the UK, where NANB hepatitis incidence is lower than in the US. The availabilty of the Chiron test will help with interpretation of the data obtained. The Chiron test may also make surrogate testing obsolete, provided that the UKBTS and other studies confirm the promising results so far reported, and assuming that the cost benefit analysis is satisfactory.