

ANTI HBc TESTING OF BLOOD DONORS WITH A HISTORY OF JAUNDICEIntroduction

Anti-HBc testing of donated blood has been used in the US and in France as a surrogate marker for non-A non-B hepatitis. Following the development of hepatitis C antibody testing the place of anti-HBc testing has been questioned. Although it is not this use of the test that is being considered on this occasion by the Committee, it is trials concerned with surrogate testing that have yielded much of the information which is summarised below. The question being considered is whether all healthy blood donors with a history of jaundice more than 12 months prior to the proposed donation should be tested for anti-HBc in addition to HBsAg, and if positive should be deferred from donation. This matter was considered by the Department of Health's Advisory Group on Hepatitis in 1989 which felt that no specific answer could be given and that more investigation was required. Is information available today which would change that advice?

Multi-Centre UK NANB surrogate marker study

A DH funded study report was presented by Dr Gunson in April 1990. 9711 blood samples from healthy blood donors from North London, Bristol and Manchester were studied. Repeat reactive rates of initial screening using Wellcome EIA were 0.9%, 0.7% and 0.94% respectively. Confirmatory testing by RIA and haemagglutination gave rates of 0.73%, 0.53% and 0.65%, with an overall rate of 0.63%. 48 of the 62 anti-HBc positive donors had risk factors for hepatitis and details are given in the appendix. It can be seen that 6 had a history of jaundice. 13% of the anti-HBc positives were anti-HBs negative and of the confirmed anti-HBc positives there were no other hepatitis B markers in 17.7% in samples. None of the confirmed anti-HBc positive samples had detectable levels of hepatitis B virus DNA (>0.5pg HBV DNA per ml serum).

Other Studies

Many of the previous studies are from the period prior to self-exclusion for HIV infection. In Bristol in the mid 1970's the incidence of anti-HBc positivity in a limited study was 0.5%. 2 studies from North London gave figures of 1.4% and 0.82% in British born new donors who had not lived or worked in countries where hepatitis B is common, and who were HBsAg negative. Three-quarters were positive both for anti-HBs and anti-HBc. West of Scotland had a positive rate of 1%, while in Manchester in 1985 a much larger study of 6163 random donors gave a rate of 0.6%. This latter study differed from others in that only 7 of the 34 positives were positive for both anti-HBc and anti-HBs.

A study in the US (Koziol et al, 1986) showed an incidence of 4% over the period 1973-1980. There was an increased incidence of NANB hepatitis following transfusion of anti-HBc positive blood (11.9%) compared with transfusion of anti-HBc negative blood (4.2%). However there was no statistically significant difference in the incidence of hepatitis B or serological markers for hepatitis B (3.6% vs 1.7%). A recent review of 6 other prospective studies showed an overall incidence of 0.7%.

Information Required

1. How many donors with a history of jaundice more than 12 months ago and who are HBsAg negative present to the UKBTS?
2. How many cases of hepatitis B occur in the UK each year following transfusion with HBsAg negative blood, and what proportion of the implicated donors are anti-HBc positive and what proportion are anti-HBs positive also?
3. Would anti-HBc screen positives need confirmation by Reference Centres and what would be the implications for these Centres?
4. Is the approximate 10% of indeterminate results obtained during confirmatory testing acceptable?
5. Would anti-HBc positive donors need to be counselled and should they be referred for further investigation?

Provisional Information from Dr Gunson

With respect to question 1, the only means of obtaining an estimate was to contact Sheffield. I have done this and between 29 January 1989 and 21 December 1990 they tested 1694 donors with a history of jaundice and found 21 anti-HBc positive and 15 anti-HBc + anti-HBs positive. During this period they collected 336,640 donations. If Sheffield are typical this total of donors with a history of jaundice is approximately 1 in 200 donations collected. For 2.2 million donations collected in England and Wales annually this would amount to 11,000 donations requiring tests for anti-HBc.

Sheffield also report that approximately 1 in 200 of donors with a history of jaundice are HBsAg positive. If anti-HBc tests were confined to HBsAg negative donors this would reduce the number of tests in England and Wales by about 0.5%.

RECOMMENDATIONS SOUGHT

1. Should all donors with a history of jaundice more than 12 months prior to donation be tested for anti-HBc and anti-HBs?
2. Should all such donors positive for anti-HBc be deferred, or only if they are also anti-HBs negative?
3. Should this recommendation apply to plasma as well as whole blood?
4. Is there a case for screening all donations for anti-HBc to avoid transmission of hepatitis B rather than as a surrogate test for NANB hepatitis?

TABLE V. HEPATITIS RISK FACTORS IN 48 donors
(repeat FIA reactive + RIA or CORECELL positive)

Ethnic origin	
Southern European	2
Indian Asian	1
Occupational hazard	7
Surgery	31
History of Jaundice	6
Hepatitis contact	10
Transfusion history	6
Scarification	
Ear piercing	16
Tattooing	3
Electrolysis	2
Acupuncture	5
Travel to high risk areas	18