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SECOND REPORT OF THE ADVISORY GROUP ON TESTING FOR THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN

Final Draft Reply to R.C.P. from D.H.S.S.

1. The recommendation in the Advisory Group's Second Report para 18 that "the practice of excluding from the panel donors with a history of jaundice should be discontinued provided that HB_sAg is not detected by reversed passive haemagglutination or a test of at least equal sensitivity described in chapter 3 and that the donor has not suffered from hepatitis or jaundice during the previous 12 months" agrees with recommendation 6 in WHO Technical Report Series No. 570, VIRAL HEPATITIS, page 49. On page 11 of this report it is also stated that "Although antigen-carrier status has not been clearly associated with a recognized previous episode of hepatitis, a history of such an episode has been considered for many years to be a sufficient reason for rejecting donors. However, the presence of specific antibodies indicating previous infection with hepatitis B virus has not been made a basis for exclusion and, in general, blood donated in such circumstances is still readily and regularly transfused. During recent years a number of studies, mostly retrospective, have failed to show any significant increase in the risk of hepatitis among recipients of antibody-positive, as compared with antibody-negative, blood transfusions. On the basis of the results obtained more recently still in a fairly large prospective study, it is again concluded that blood containing anti-HB_s carries no increased risk of transmitting hepatitis B infection."

2. U.K. is one of the few, if not the only, countries where presence of anti-HB_s was made an indication (First Report of the Advisory Group 1972) for rejecting individuals as donors on the ground that, because a history of hepatitis had been widely regarded as a ground for rejection

since the publication of WHO Test Report No. 62, 1953, the presence of anti-HB_s, which indicates a previous infection with HB_sAg, should therefore be regarded in the same way. However, as stated in WHO Report No. 570, (see above) it has not been shown that anti-HB_s positive blood carries a greater risk of transmitting hepatitis B.

3. It is worth looking in greater detail at the terms in which the WHO Expert Committee in 1953 based its recommendations regarding the exclusion of volunteers with a history of hepatitis (jaundice). "In the light of present knowledge, the committee is unable to fix the period following an attack of hepatitis after which it could safely be assumed that the virus is no longer present. In one case the carrier state is known to have persisted for five years, the maximum duration of observation, and it is possible that it may persist much longer. Therefore, the committee advises that, when circumstances permit, no person should be accepted as a blood donor if there is a history of hepatitis (jaundice) at any time.

However, circumstances will arise in which it may be necessary to accept as a blood donor a person with a history of hepatitis (jaundice). Under these circumstances, the committee recommends that

(1) no donor should be accepted, except in case of life-saving emergency for a single transfusion, if he has a history of hepatitis (jaundice) within one year;

(2) if the donor has a history of hepatitis (jaundice) more than one year before, liver function tests should be performed;

(3) the blood from a donor with a history of hepatitis (jaundice) should not be used in the preparation of large pool plasma until methods of sterilization are available".

Thus this recommendation which was based upon observations in one case of hepatic cirrhosis, whose blood had been shown to be infective, was not an absolute one. In a footnote, the Expert Committee referred

to the fact that few lay people will understand what is meant by hepatitis, so that their recommendation would have to be based upon a history of jaundice, although hepatitis without jaundice often occurs.

4. It is now known that few patients who recover from hepatitis B become carriers of HB_sAg (Dane, personal communication) and it is probable that many more individuals suffer from subclinical, and therefore unrecognized, hepatitis than suffer from overt illness with jaundice or are aware that they are ill at all.

In a paper in the press, Barbara, Howell, Cleghorn, Cameron, Briggs and Dane report that no HB_sAg positive individuals were found among 371 volunteers who gave a history of hepatitis (jaundice) and who were tested by RIA. On the other hand B. Bevan, Cardiff, reports (personal communication) that among 300 donors who gave a history of jaundice, 5 were positive by RIA.

5. When the recommendation of WHO Committee on Hepatitis 1953 was adopted by NBTS up to 10 per cent of donors were "lost" in some regions but it is not unreasonable to assume that donor panels would not be increased by this number now, if this bar is dropped.

6. At intervals since 1953, when the recommendations of the WHO Expert Committee were accepted by NBTS, Regional Transfusion Directors have discussed the difficulties of applying the criterion that donors with a history of jaundice should be excluded. Donors in this category may say, for example, "I remember being told as a child" or that they think they had jaundice at birth, or as a small child; in others it seems probable that the jaundice was due to, for example, mechanical obstruction. In practice individuals giving histories of this kind have usually been accepted as donors. Reliance upon history in this way seems far less satisfactory than performance of a test, which, though it will not detect

all specimens containing HB_sAg, will detect all but a very few.

7. No evidence has been collected yet in U.K. to substantiate the presence of a hepatitis C.

8. In view of the above facts, it is proposed to retain the recommendation in paragraph 18 of the Second Report of the Advisory Group:-

"We therefore recommend that the practice of permanently excluding from the panel donors with a history of jaundice may be discontinued provided that HB_sAg is not detected by reversed passive haemagglutination or a test of at least equal sensitivity described in Chapter 3 and that the donor has not suffered from hepatitis or jaundice during the previous 12 months".

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COMMENT BY :
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COMMENTS ON TESTING FOR HEPATITIS B SURFACE ANTIGEN AND ITS ANTIBODY.

There is little doubt that reversed passive haemagglutination (RPH) is now the method of choice for testing for HB_sAg and should be adopted by all Regional Transfusion centres and indeed all hospital laboratories who undertake this test. One also would not quarrel with the recommendation that the detection of anti-HB_s should no longer be a criterion for excluding donors from the panel although it might be better to restrict the use of this blood for the preparation of anti HB_s immunoglobulin. I do however have some misgivings about discontinuing the current practice of permanently excluding from the panel, donors with a past history of jaundice or hepatitis. Even with the most sensitive techniques false negatives may occur, and furthermore transfusion hepatitis may be caused by viruses other than Hepatitis B for which at present no tests are available (the existence of Hepatitis C was postulated recently). Although the chance that such individuals might transmit hepatitis is admittedly remote, the risk is there and not worth taking unless it can be shown that many donors are being lost to the panel in this way - what are the figures for such rejections at present.

If the practice referred to above is retained, then the recommendation of permanently excluding any donor who is once positive for HB_sAg from the panel becomes consistent. Otherwise it could be argued that persons positive for HB_sAg should be reinstated on the panel once they had become HB_sAg negative again. Personally, however, I would agree with the recommendation that once a person has been found to be positive he should be permanently excluded from the panel.