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S 5–02

HEPATITIS - A TRANSFUSIONISTS VIEW

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In a non remunerated donor system which employs third-generation hepatitis B tests, hepatitis B following transfusion of fresh single donor blood and blood components is extremely rare. Clinically apparent Non A Non B post transfusion hepatitis is also a small problem. Although a few transfused patients develop asymptomatic elevations of liver enzymes, the importance of this remains undefined. Thus for the recipient of blood or single-donor components the benefits of improved donor testing are not quantifiable.

The transfusion centre which supplies plasma for fractionation, and the clinician using large pool plasma fractions, face quite different problems, since present-day coagulation factor concentrates have a very high risk of transmitting NANB hepatitis.

This may be improved by a combination of approaches including: use of small pool alternative products for suitable patients, reduction of number of donors contributing to fractionation pools "dedication" of batches for designated patients, improved fractionation technology, chemical or physical sterilisation or immunological intervention. The potential value and limitation of these approaches will be reviewed.

S 5–03

VIRAL HEPATITIS: IMMUNE PROPHYLAXIS

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Immune prophylaxis of viral hepatitis is possible for Hepatitis A and Hepatitis B but not for Hepatitis non-A, non-B.
Normal Serum Immunoglobulin has been used in the prevention or attenuation of Hepatitis A in the deleloped countries.
For the post-exposure prophylaxis a single intramuscular injection of at least 0.02 ml 16% immunoglobulin per kg bodyweight is recommended. For the pre-exposure prophylaxis -travellers to endemic areas- different amounts and different schedules are recommended with a minimum of 0.02 ml per kg bodyweight. For replacement of the pre-exposure passive immunization in developed countries and for the immunization of the population in endemic areas where sanitation and living conditions are rapidly improving, active immunization with a Hepatitis A vaccine will be preferred in the near future. How far passive-active immunization will be needed in unknown, but can be expected.
For more than 10 years passive immunization with Hepatitis B immunoglobulin (HBIg) has been started. Although the HBIg (>100 IU/ml) has been standardized almost from the beginning, different schedules and different amounts have been recommended for the pre- and post-exposure prophylaxis dependent on the way of contamination and dependent on the country. These recommendations have to be or have been rewritten after the introduction of the Hepatitis B vaccines especially the pre-exposure prophylaxis. Pre-exposure prophylaxis with HBIg can be replaced by active immunization with vaccines; in case of vaccination failure, e.g. in hemodialysis patients, still the HBIg has to be recommended. In the post-exposure prophylaxis the HBIg is still recommended in combination with active immunization especially in new borns as recently has been shown. Addition of HBIg to pool plasma derivatives, which are potentially infectious is still preferred.

S 5–04

PASTEURISATION OF FACTOR VIII AND FACTOR IX CONCENTRATES

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There is now considerable interest in different heat treatment methods for the inactivation of viral contaminants in coagulation factor concentrates (1,2). Nevertheless, to be suitable, a method should result in both an adequate viral kill and a good product yield so that self-sufficiency can be maintained.

We have used sorbitol and glycine as stabilisers and have found good recoveries of both FVIII and FIX activity after heating in solution at 60°C for 10 hours (3).

In a subsequent study of viral inactivation using a range of model viruses we found that sugar stabilisation reduced the degree of viral heat inactivation compared to a standard albumin solution stabilised with caprylate. For example, heating at 60°C inactivated a challenge of 8.5 logs of vaccinia/ml in 30 minutes using caprylate stabilised albumin, but only 4 logs after 10 hours using sorbitol (or sucrose) stabilisation.

More severe heating conditions have therefore been developed to increase the degree of viral inactivation without major loss of coagulation factor activity. In the presence of 65% sorbitol and 1.7% glycine a FVIII solution, prepared by zinc fractionation (4), was heated at 60°C for 9.5 hours followed by 0.5 hours at 70°C giving a 77% recovery of clotting activity over the heating step with inactivation of at least 7 logs of vaccinia virus/ml. In this process, careful control of pH, ionised calcium concentration and temperature are all important to avoid major loss of FVIII activity. Further viral inactivation may be achieved by adding ethanol to the stabilised FVIII solution.

A FIX concentrate has been pasteurised in a similar manner giving about 60% recovery of clotting activity over the heating step with no increase in thrombogenicity as measured by standard in vitro tests (NAPTT, TgtSO).

1. N. Heimburger et al. Haemostasis 10 (Suppl 1):204 (1981)
2. G. Dolana et al. Clinical Research 30:A722 (1982)
3. A.J. MacLeod et al. Thromb. Haemostasis 50:432 (1983)
4. P.R. Foster et al. Thromb. Haemostasis 50:117 (1983)

AIDS

Action Taken in S.E.B.T.S. To Endeavour to Make Blood Transfusion Safe

APPENDIX

May 1983 - First draft "Background to Recent Publicity" leaflet.

June 1983 - Discussions with Scottish Homosexual Rights Group and issue of first leaflet. S.H.R.G. gave publicity to the effect that high risk homosexual donors should not give blood, in Gay Newspapers.

Leaflets available at all sessions, sent to Honorary Organisers and some Press interest noted. 1

Dr. Smith (Donor Consultant) issues Guidelines to Donor Staff. 2

Scottish AIDS Monitor Group established.

. 1983 - Availability of AIDS leaflet from B.T.S. reported in Communicable Disease Newsletter which is sent out regularly to all G.P.'s in Lothians [Editor: Dr. Condie, Bonnyrigg Health Centre.].

November 1983 - Donor call-up letter, handbills, volunteer lists, etc., over-printed with message regarding AIDS. This advises donors to ask for leaflet or to speak to doctor at session if they are at all concerned they may be in Risk Group. Donor Office staff instructed to make sure leaflets are clearly visible within reception/interview area at all sessions.

?December 1983 - D.H.S.S. leaflet "AIDS and How It Concerns Blood Donors" published. 3

S.E.B.T.S. leaflet withdrawn and new leaflet available at all sessions.

May 1984 - Donor letters reprinted and AIDS message becomes permanent feature. 4

August 1984 - S.N.B.T.S. leaflet "Important Message to Blood Donors" published. Received 16.8.84. 5

- :h September, 1984 - All call-up letters enclose new S.N.B.T.S. leaflet and copies on display at Hb/reception at all sessions.

19th November, 1984 (Week Beginning)

1. Donor questionnaires redesigned to include declaration that donor has read and excluded him/herself from AIDS risk group (effective from 26.11.84). 6
2. Leaflets put on more positive display and attention seeking notices prepared.
3. All industrial organisers asked to distribute leaflet where possible to donors making appointments.
4. Honorary Organisers asked to help at sessions by checking that donors have read leaflet before they reach interview desk.
5. B.T.S. staff briefed by Director and advised how to respond to donor questions.
6. Mrs. MacDonald, S.N.O., issues new staff guidelines. 7
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APPENDIX

7. Acknowledged that a very few donors are unable to read or may be blind so staff must satisfy themselves that these people understand declaration and definition of risk groups. This is established practice anyway for medical questionnaire.

8. Plasmapheresis donors health questionnaires reprinted to include declaration on AIDS and staff instructions for checking and recording issued by Sister Wye. 8

26th November, 1984 - Established practice that all signatures on donor questionnaires/declarations are to be witnessed by Donor Attendant then double checked by Clerical Officer who will tick nameslip for "laboratory sheet". If staff at Issue notice this verification missing, they will ask Team Leader to refer back to Office. At this time, forms need not be retained. 9

- Cost and labour analysis of retaining completed questionnaires, pack numbered to be undertaken and submitted to Dr. McClelland.

30th November, 1984 - New Guidelines to Donor Staff issued by Mrs. MacDonald. Procedures for ?Infective? donations clearly laid down. 10

M. Thornton 30th November, 1984.