MEMORANDUM

TO : Dr.R.S.Lane

cc : Dr.J.K.Smith

FROM : T.J.Snape

DATE : 7th February, 1985

Haemophilia Director's Hepatitis Working Party, 6.2.85

As requested, I attended this meeting on your behalf. Jim Smith was also present for most of the meeting.

Jim and I were invited to comment on BPL's proposals for supply of heat-treated factor VIII concentrates; we summarized the situation as last agreed at BPL :

i. immediate issue of HL(H) and 8CRV(H) to all haemophilia centres via RTCs but to designated clinicians for named patients, with such control as to allow safety and efficacy to be monitored (though probably not enforceable);

ii. clinical trial of small amount (~200 vials) of 8Y for study of safety and efficacy only (probably only 3 or 4 centres);

iii. clinical trial of larger quantity (<1,000 vials) of 8Y using complete protocol for viral follow-up;

iv 8Y to replace HL(H) and 8CRV(H) by May or June - subject to success of clinical trials.

Peter Kernoff argues that Profilate (wet-heat treated) would, at the moment, be the material of choice in virgin patients, given indications of freedom from transmission of NANB - accepted as an accurate assessment.

Eric Preston was advised that information on severe clinical hepatitis after treatment of two patients with heated Armour Factorate should be reported since the product was still available in the UK.

Chris Ludlum described experience with one batch of Scottish factor VIII used to treat 32 patients. 15 patients seroconverted in 3 to 4 months; 1 patient seroconverted after 9 months; 16 have remained negative for HTLV-III AB.

The safety of HBsIg preparations, for treatment of episodes threatening Hepatitis B infection, was questioned - safety vis-a-vis HTLV-III transmission. I volunteered the information that recent batches of BPL HBsIg were negative for HTLV-III Ab. (We need to secure a report of these tests from Richard Tedder; it would also seem sensible to arrange for inclusion of HTLV-III Ab in the specification for HBsIg.)

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John Craske is accumulating information on HTLV-III Ab status of Christmas disease patients. The following statistics are available to date :

Centre	Patients tested	Seroconverted
Sheffield	5	3
Royal Free	30	0
Oxford	12	0
Cardiff	?	2
St.Thomas's	?	3
Edinburgh	8*	0

(* All 8 received factor IX from the same donor pool(s) as were implicated in the factor VIII batches used to treat haemophiliacs who seroconverted.)

The data is strongly suggestive of infection by one or two batches - batch relation data not yet available however. In any case, a significant number of HTLV-III Christmas disease patients, treated only with NHS IX and with no other risk factors, argues strongly for haste with manufacture of heated factor IX. (To date two centres have indicated their unwillingness to continue with unheated factor IX.)

Eric Preston presented further strong evidence, based on paired liver biopsy results with a time interval of 5 years between biopsies, of progression of haemophiliacs to increasingly severe forms of liver disease, arguable attributable to repeated exposure to NANB hepatitis virus. The data will be presented at the Annual meeting of HCDs.

Next meeting of the hepatitis working party set for 2nd October, 1985.

GRO-C: Snape

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