RM/MM

NOTE OF THE MINUTES OF THE UK WORKING PARTY ON TRANSFUSION ASSOCIATED HEPATITIS HELD AT EDGWARE ON TUESDAY 27 SEPTEMBER 1983

Dr Harold Gunson was not able to be present and Dr John Barbara took the chair.

The following items were discussed:

1 **AIDS**

All of the members of the panel were acutely aware of the numerous publications which had appeared in medical journals. Some more important review articles and larger articles have been circulated by Dr Cash from time to time. There was discussion on the DHSS leaflet, which I indicated had been discussed at the English RTD Meeting. The group are disappointed to note the responses in the various regions and the manner of distribution. It was felt that the RTDs should have freedom to decide in their regions how best to publicise the leaflet. Some regions were making a letter drop to all donors, some are making the pamphlet freely available at sessions and others were making it available on demand. I explained that the English RTDs had decided to run the various schemes for 2 or 3 months to see what was the general effectiveness.

The question of reprints was discussed and the question of notification to the Council of Europe Experts on Blood

Transfusion Committee concerning the national and local arrangements for publicising AIDS among blood donors. Since the pamphlet had been discussed at the RTD Meeting, where some suggested changes had been made for any subsequent reprint, it was decided to await the outcome of the regional evaluations.

It was reported that a haemophiliac patient with AIDS had died in Bristol. This was also reported at the English RTD Meeting. The full post-mortem results were not yet to hand but Dr Craske confirmed that pneumocystis pneumonia had been confirmed as well as the T4,T8 ratio studies. The patient had had a lot of cryoprecipitate and some commercial Factor VIII. Dr Fraser was being contacted, with a view to following up the donors but Dr Craske realised the delicate nature of this and would be guided by Dr Fraser's views.

The question of surrogate marker tests for AIDS was discussed. Reference was made to the English RTD Meeting at which the question of syphilis testing, CMV testing and anti-core testing had been mentioned. Dr Thomas reported that there seemed to be some high association between some HLA class 1, A-substance proteins. This work was not yet complete.

2 **INTRAVENOUS IMMUNOGLOBULIN AND NORTHWICH PARK PATIENTS**

Dr Lane and Dr Craske were anxious to discuss the recent incidents of apparent non-A non-B hepatitis-like illnesses in patients receiving high dose intravenous human normal immune globulin when compared with the regular intramuscular preparation. It would seem that a 20,000 donor pool of source material was used to provide intramuscular immune globulin and intravenous immune globulin which was used in a 12 patient crossover study. Of

the 12 patients who had received the intramuscular preparation, there was nothing to report. Of the 12 patients who received the intravenous preparation, early transaminitis had occurred. The Medicines Inspectorate had been informed and Dr Lane said that the use of the intravenous preparation had been suspended. He was anxious to have a meeting with other fractionators. It was hoped that the meeting would be convened as a matter of some urgency.

There was a review of his method of production using gel column chromatography as a downstream from the Cohn II fractionation system.

Dr McClelland was anxious to discuss the anti-CMV study since it was also an intravenous preparation. He reported briefly on the ALT studies on the recipients of human normal immune globulin prepared by the Swiss protocol at the Scottish Fractionation Centre. Dr Lane was unwilling to concede that the different methods of manufacture might explain the problem at Northwich Park. He would be writing to the Lancet to draw the matter to the attention of other fractionators. It was almost impossible to trace all of the donors who had entered into the original pool. Dr McClelland reported that ALT studies in the recipients of the Scottish material had not shown, so far, any cause for concern.

3 **AIDS TRANSMISSION IN IMMUNOGLOBULINS**

There was discussion on the best methods of identifying possible AIDS carriers who might be inadvertently entered into a pool of immunoglobulin for production. It was known that high titre antibodies of hepatitis, CMV were commoner in homosexuals. I indicated some of the work previously reported by Dr Crawford showing that homosexuals are about

half as likely to be CMV positive than random donors and 14 times as likely as random donors to have anti-HBs. I also indicated a survey of the anti-CMV panel at this Centre showing that women were more likely to have anti-CMV than men. It may therefore be that the anti-CMV should only be collected from women. Some of Dr Crawford's work has already been reported to Directors by cover of a note from Dr. Cash, reference Microbiology Investigation X8/83 of 14:9:83. Dr Crawford has agreed to update this paper and to send a copy to each Director.

4 USE OF HEPATITIS B IMMUNOGLOBULIN

Dr. McClelland referred to the difference between the Edinburgh protocol and the protocols used elsewhere. The question of risk benefit versus safety and the overall efficacy of the product was discussed. Dr Crawford and I are preparing a paper for publication on the follow-up of recipients of gamma globulin. Dr Polakoff felt that the original MRC protocol was still adequate and production should be aimed at about 50 doses/million of the population per year.

5 VERTICAL TRANSMISSION

Reference was made to Dr Bharucha's paper in the British Medical Journal of 5 February 1983. It was agreed that the number of Caucasian women carriers was much less than the number of non-Caucasian women and that the use of mass screening of Caucasian women might not be cost effective. Dr. Polakoff felt that it was better to test a group of patients known to be at risk but that if Caucasian screening was being used then there was nothing to prevent this still continuing, to identify the small number of Caucasian babies that might be at risk. Dr. McClelland (I think), stated that his Centre was testing all of the antenatal samples from

all women referred from Edinburgh. This is similar to the same arrangement in the Glasgow & West of Scotland Centre. Where cases of need were established, then the vertical transmission protocol was instituted.

6 **TRANSFUSION ASSOCIATED HEPATITIS**

The retrospective study of samples from the Newcastle area from the patients of Dr Oliver James was briefly discussed. Dr. McClelland has obtained samples and these will be distributed to the testing laboratories for non-A non-B marker studies.

7 Dr Craske mentioned that recommendations had been published on 1 April from the American Bureau of Biologics concerning the types of donation which could be entered into immunoglobulin pools. He agreed to provide copies of this to the members. Dr McClelland would respond after studying the document.

8 Dr Howard Thomas mentioned some studies being done on the possible use of monoclonal anti-HBs. Although of murine origin (with problems of oncogenes) the problem of possible AIDS transmission may be averted by this form of therapy.

R. Mitchell **3 October 1983**

GRO-C