MINUTES OF THE 12TH MEETING OF THE U.K. HAEMOPHILIA CENTRE DIRECTORS' HEPATITIS WORKING PARTY HELD AT THE OXFORD HAEMOPHILIA CENTRE ON SEPTEMBER 14TH 1983

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PRESENT:
Dr. J. Craske (Chairman)
Dr. C.R. Rizza
Dr. R. Lane
Dr. E. Preston
Mrs. M. Fletcher
Miss R.J.D. Spooner
Dr. P. Kernoff
Dr. C. Ludlam
Dr. J. Trowell

Apologies for absence were recieved from Dr. Howard Thomas.

1) The Minutes of the previous meeting held on January 19th 1983 were approved.

2) Matters arising from the Minutes

A) Prospective studies of factor VIII and IX associated hepatitis. Recent information.

Dr. Craske said that after discussions at the Haemophilia Reference Centre Directors meeting in January, he had drawn up a protocol for use in trials of hepatitis reduced factor VIII concentrates as a model for any studies which might be undertaken by Haemophilia Centre Directors. This had been circulated to each Haemophilia Centre Director in March 1983 with a covering note from Dr. Craske, Dr. Rizza and Professor Bloom.

Products of commercial factor VIII were at present being considered for trials. These were the dry heat treated Travenol Laboratories product and the Armour product. The Travenol product had been granted an exemption from a clinical trial certificate, and Armour Laboratories had applied for exemption for their product.

In discussion, it became apparent that there was still considerable concern about the possible transmission of an infection related to the acquired immune deficiency syndrome (AIDS). It was not known whether the inactivation procedures used in various products inactivated the putative AIDS related virus. Any Director considering using the commercial products in such a clinical trial would, therefore, have to take this into account when considering the best product to use. It was proposed to discuss this problem at the annual meeting of the Haemophilia Centre Directors.

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With regard to NHS factor VIII, the paper describing the prospective study of NHS and commercial factor VIII would shortly be submitted for publication, and this showed that there was a hundred per cent chance of contracting non-A, non-B hepatitis whether the product was made from NHS factor VIII or commercial sources. There was little information available on the risk of hepatitis in relation to the number of plasma donations in a pool. The use of accredited donor panels of regularly monitored repeat blood donors from whom plasma was obtained by plasmapharesis was under consideration by the Blood Products Laboratory. It was hoped to study special batches of known pool size in order to obtain more information to see if reducing the size of the plasma pool effected the incidence of hepatitis. Dr. Lane said that a heat treated NHS factor VIII might be available within a few months from Elstree, and Edinburgh were also manufacturing their own product.

The present position in relation to the occurrence of cases of AIDS in haemophilia A patients treated with commercial factor VIII was reviewed. There had been two cases of the syndrome as defined by the Centers for Disease Control, Atlanta, in the U.K. One of these had contracted Pneymocystis carinii pneumonia and had died in the second week of August 1983. The precise cause of the syndrome was as yet unknown, but it seemed most likely that an infective agent might be involved, transmitted by factor VIII. Dr. Craske said that the protocol for a study of the follow up of the products received by the two AIDS cases would be discussed at the annual meeting of the Haemophilia Centre Directors. The implications for hepatitis B vaccine were as yet uncertain, but the epidemiological information available from the U.S.A. from the follow up of homosexuals who had undergone the original trials of hepatitis B vaccine showed that there was no evidence of an increased incidence of AIDS in vaccinees compared with those who had not received vaccine. It seemed likely that hepatitis B vaccine was probably safe, but further studies were needed.

B) Factor VIII and IX associated hepatitis B

The results of the current reports of hepatitis in U.K. haemophiliacs were reviewed. It seemed evident that hepatitis B still occurred with an annual incidence of between 0.2 and 0.5 per cent in patients and there was no difference between different products with regard to the associations with factor VIII treatment. Dr. Craske said that he was proposing to review the incidence of hepatitis B carriage in the haemophilia population since the first introduction of commercial concentrate in 1973/4. This was to determine the actual incidence of hepatitis B carriage and the factors which effected any variations found.

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3) Hepatitis B Vaccine

Strategy of hepatitis B immunisation in relation to the current information about its efficacy in haemophiliacs was discussed. The results of the Oxford study showed that there was no impairment of the immune response by using subcutaneous inoculation. Dr. Craske agreed to produce a paper for the annual meeting of the Haemophilia Centre Directors about the recommendations for the use of hepatitis B vaccine in Haemophilia Centres.

4) Any other business

There was none.

5) Date of next meeting

To be arranged.

J. Craske
29.8.84