

Minutes of a meeting held at the Oxford Haemophilia Centre on 22nd May, 1975 to discuss the study of the incidence of hepatitis in haemophilic (factor VIII deficient) patients

1) Those present were: -

Dr. R. Biggs
Dr. C.R. Rizza
Dr. E. Bidwell
Dr. J. Craske
Dr. Y. Cossart
Dr. Polakoff
Dr. D. Magrath
Dr. S.G. Rainsford
Dr. P. Kirk
Dr. J. Trowell
Miss R.J.D. Spooner

2) Dr Biggs welcomed the visitors to Oxford. She thanked Dr. Craske for drawing up the Agenda and providing documents for discussion. She asked Dr. Craske to speak about item 1 on the agenda which concerned a retrospective study of patients who had received certain specific batches of Hyland factor VIII (Hemofil).

3) The Retrospective Study Dr Craske said that the purpose of the retrospective study was to obtain the most complete information possible about the incidence of hepatitis in patients who had received certain specific batches of Hemofil. He presented data about the incidence of hepatitis in patients at Newcastle, Bournemouth and Alton. His impression was that hepatitis had occurred most often in patients who had been treated relatively little in the past. There was a wide ranging discussion about the incidence of hepatitis in haemophilic and Christmas disease patients. Dr Magrath pointed out that the batches of commercial factor VIII sent to this country were improving from the point of view of RIA tests for HBsAg and HBsAb. Just over a year ago several batches of Hemofil gave borderline results but that this was not happening now. Dr. Cossart said that blood samples from patients who had been treated with certain designated batches of Hemofil might still be stored in various laboratories and might be available on request for further and more delicate virus tests. Dr Biggs said that she had devised a draft form for completion for the retrospective study.

She said that a space for giving the address of the local virus laboratory should be added to the form so that Dr Cossart could contact the laboratory to obtain specimens.

It was agreed that a letter should be sent to Haemophilia Centre Directors who had made returns for 1974 and who had used Hemofil. The letter would seek co-operation for the retrospective study using a form of which Dr Biggs had presented a draft to the meeting. The letter should also request permission to send to Dr Craske certain information that had already been sent to Oxford. Dr Biggs agreed to make a draft of the letter and send it to Dr. Craske for approval.

4) Prospective Study In general discussion there seemed to be some rather major difficulties in planning a formal controlled trial of various therapeutic materials. For example in Oxford material made from large pools was not given to patients who had received relatively little previous treatment or to small children (Dr Biggs and Dr Rizza). Thus patients could not be allocated to treatment in a random manner and patients thought to be most likely to develop hepatitis would not receive the commercial factor VIII. Different batches of Hemofil could not be selected as a result of pre-issue testing since all batches submitted were now equally satisfactory from the testing point of view (Dr Magrath). The present system of using first one type of preparation and then another in the same patient could make it virtually impossible to attribute infectivity to any particular material.

An attempt was made to devise an agreed protocol for some form of trial based on the paper presented by Dr Craske. It was felt that such a trial on a large scale would require to be sponsored by the DHSS by the MRC or by the Haemophilia Centre Directors and that the present adhoc meeting could not do this. It was felt that perhaps the best thing that could be done at present would be to arrange a pilot study at Oxford and at the Treloar College.

The proposed pilot study was discussed and it was decided that in the first instance twenty patients at Alton and twenty from Oxford should be studied. At Alton ten patients would receive cryoprecipitate only and ten Immuno concentrate only. At Oxford ten would receive Dr Bidwell's factor VIII concentrate only and ten would receive Hemofil only. It was felt that restriction of materials to particular patients would greatly improve the definition of the cause of Hepatitis.

Dr Cossart already receives specimens from the Treloar Centre and it was agreed that Dr Cossart and Dr Rizza should discuss the transmission of Oxford specimens.

It was agreed that the study should start in the middle of September 1975 and continue for eighteen months. Dr Rainsford for Treloar and Dr Rizza for Oxford would devise more detailed plans and Dr Craske would consider what type of records he required for these forty patients.