Minutes of the Twentieth Meeting of Haemophilia Reference Centre Directors held at the Royal Free Hospital on Monday 18th February, 1985.

Present

Prof. A. Bloom (Chairman)
Dr. J.F. Davidson
Dr. I. Delamore
Dr. C. Forbes
Dr. M. Greaves
Dr. P. Hamilton
Dr. P. Jones
Dr. P. Kernoff
Dr. C. Ludlam
Dr. F.E. Preston
Dr. C.R. Rizza
Dr. G. Savidge
Dr. E. Tuddenham
Dr. A. Aronstam
Dr. J. Craske
Miss R.J.D. Spooner

1. Apologies for Absence were received from:-

Dr. E. Mayne, Dr. J.M. Matthews and Dr. C. McDonald (represented by Dr. J.F. Davidson).

2. Minutes of the Nineteenth Meeting were approved and signed by the Chairman.

3. Matters Arising from the Minutes

3a) Designation of Centres

Dr. Jones referred to the letter dated 11.2.85 which he had sent to Reference Centre Directors raising several points for discussion.

i) Membership of the Proposed Review Body:

One of the Directors nominated at the Cardiff meeting as a member of the Review Body (Dr. S. Ardeman) had withdrawn his name. It was pointed out that 2 of the Centres whose Directors were nominated as members of the Review Body (Leeds and Birmingham) were seeking recognition as Reference Centres, which could unbalance the Review Body. After some discussion about possible membership of the Review Body, it was agreed that nominations for membership of the Review Body should be sought, in writing, from all Directors once the Reference Centre Directors had agreed to its formation.

ii) Reference Centres:

The criteria for the designation of Reference Centres were discussed, especially regarding the question as to whether Reference Centres should be Supraregional or Regional. Dr. Aronstam said that he was the official Wessex Regional Haemophilia Centre. It was agreed that the Reference Centre Directors would let Dr. Jones have their views in writing.

iii) Remit of Haemophilia Centres:

It was suggested that the remit of Centres should be extended to cover all haemostatic and thrombotic problems. Professor Bloom pointed out that the main work of Haemophilia Centres was concerned with haemophilia and related disorders; the remit might be too wide if it were to include thrombosis and its various manifestations. As time was not available at the present meeting for detailed discussion, Dr. Davidson asked for the matter to be included on the Agenda for the next meeting of Reference Centre Directors and this request was seconded by Dr. Preston.

iv) <u>Patient Representative</u>:

Dr. Jones asked if a patients' representative (e.g. Member of Haemophilia Society) should attend the Reference Centre Directors meetings. It was generally agreed that this was not desirable.

v) The problems met by patients attending "small" hospitals and the quality of care at those hospitals was discussed. It was agreed that it was best to deal with any problems at a local level with liaison through the Reference Centre.

vi) <u>Constitution of the Haemophilia Centre Directors Organisation</u>

The question of formalising the constitution of the organisation was discussed and it was generally felt that the present <u>ad hoc</u> arrangements should be continued. The question of re-election of the Secretary would be discussed later on the agenda. With regard to formal links with the DHSS and the Blood Transfusion Service and representation of those two bodies at Reference Centre Directors Meetings, the feeling was that DHSS and BTS representatives should be invited to attend only those meetings where particular items on the agenda required their presence during discussion.

vii) <u>Control of Blood Products</u>

There was some discussion regarding the methods for controlling supplies and issuing of blood products. It was generally agreed that there were no advantages in distributing factor VIII and IX concentrates via the Blood Transfusion Service. As stated at previous meetings distribution direct to

Reference Centres would be preferable. It was thought that the opposition to Reference Centres having responsibility for supplying Centres would now be less in view of the AIDS problem and the increased need for monitoring supplies and usage and for collecting of information about patients.

viii) <u>Questionnaire to identify all hospitals treating haemophiliacs</u>:

After discussion, it was agreed that Dr. Jones should draft a letter for Reference Centre Directors to send to haematologists in their Supraregions in an attempt to identify the hospitals, other than Haemophilia Centres, treating haemophiliacs.

<u>Summary</u>: It was <u>agreed</u> that Dr. Jones would take the following action:-

a) write to <u>All</u> Centres about nominations for the Review Body;

b) work with the Chairman and Dr. Ludlam to finalise a document on Guide Lines for Designation of Haemophilia Centres to go to the DHSS;

c) draft a letter for Reference Centre Directors to send to haematologists requesting information about treatment of haemophiliacs at hospitals which are not Haemophilia Centres.

3b) <u>Supraregional Funding</u>

Professor Bloom presented a document on "Haemophilia Care at Reference Centres: Revenue Requirements" which he had pre-circulated to the Reference Centre Directors. Professor Bloom had used the document as a basis for an application to his Region for increased funds. He had also drafted (with Dr. Jones) a letter to Lord Glenarthur emphasising the financial implication of the AIDS problem. The letter had not been circulated to All Reference Centre Directors. The letter had now gone to Lord Glenarthur but no reply had yet been received. Dr. Forbes suggested that the Haemophilia Society should be informed about the letter to Lord Glenarthur.

The problems of Supraregional funding were discussed and views were sought as to whether there might be a case for the Reference Centre Directors seeking a general Supraregional Funding policy. It was generally agreed that it might be easier for each Reference Centre Directors to seek Regional Funding as indicated by individual needs.

The question of supplies of NHS Factor VIII was raised. The Chairman thought that the new building at BPL, Elstree would be completed on schedule but it was doubtful if the production target for Factor VIII units would be reached soon. The new heat-treated material showed a reduced yield of factor VIII and required increased supplies of plasma which would probably not be available for some time.

4. <u>Report on Special Meeting at BPL</u>

The Chairman summarised the matters raised and discussed at the meeting held on 10th December 1984 regarding the use of heat-treated Factor VIII. The loss of activity on heating would possibly give rise to a shortage of supplies.

The difficulties encountered in getting tests carried out on samples from high risk patients was discussed. Professor Bloom had written to the Medical Defence Society for advice as to his legal position if he could not get tests, important for patient care, carried out. So far he had not received a reply. Financial aid was needed to enable Centres to set up safe containment facilities. The effectiveness and the drawbacks of treating blood samples with β-PL was discussed and Dr. Rizza reported on the experience in Oxford with β-PL.

The question of indemnity and medico-legal cover for doctors using the new BPL heated materials was raised. After discussion Professor Bloom agreed to write to David Smart of the CBLA to ask for an official ruling regarding indemnity for physicians.

5. AIDS

Dr. Craske gave a brief summary of the results of the Surveillance being carried out on haemophiliacs. He strongly suspected under-reporting of AIDS-related complex cases. Three cases of AIDS had occurred in haemophiliacs; 2 of the patients were now dead. Another patient who had died in the North-West last Autumn was retrospectively thought to have had AIDS but the data on this patient were still not available. Thirteen cases of AIDS-related complex had been reported to him in addition to some other patients with thrombocytopenia only. Also, 2 cases of glandular fever-like illness had been reported; it was very important for these latter patients to be identified separately. At present there seemed to be 30-35 haemophiliacs in the UK with AIDS-related complex. The follow-up study of the patients who had received the batch of NHS contaminated Factor VIII was proceeding slowly, partly because 2/3 of the recipients were children. The batch of concentrate which had given rise to the Bristol AIDS case had been identified with certainty; only 2 other patients had received the batch - 1 was HTLV3+ the other was negative. Both patients were alive and well.

Dr. Craske said that the pattern of the disease in haemophiliacs seemed very different from the disease in homosexuals. Some Christmas disease patients were HTLV3+. Dr. Craske wondered if these were true or false positive results and said they would be checked. In reply to a question, Dr. Craske said that he would recommend the Directors to use heat-treated Factor IX now for the treatment of Christmas disease patients. According to reports from Elstree NHS heat-treated Factor IX would possibly be available in July but this was not certain.

The question as to what policy should be adopted if members of the medical staff became HTLV3+ was raised. Discussion was deferred until the AIDS Group meeting on 19th February. The problems over testing staff was also raised and it was suggested that the AIDS Group should give some advice to Directors on this matter. <u>Professor Bloom agreed</u> to raise very strongly with the DHSS the concern at Centres regarding the lack of containment facilities. The AIDS Group were also asked to consider the question of plasma samples from patients potentially positive for HTLV3 being used as laboratory reagents.

6. <u>Annual Returns</u>

Dr. Rizza said that the 1984 returns were coming in steadily. The question had been raised by several people as to whether Directors should report HTLV3+ patients to Oxford for inclusion in the National register. It was agreed that this information should be be collated with the Annual Returns and that the matter should be discussed by the AIDS Group.

7. Election of Chairman of Haemophilia Centre Directors Group

Following a ballot, Dr. Charles Forbes was elected to succeed Professor Bloom as Chairman, subject to ratification by all Directors at the AGM in October.

8. Reports from Working Party Chairmen

8a) Hepatitis: Dr. Craske said that the Working Party had held two meetings since the last meeting of Reference Centre Directors. There were four items he wished to raise:

i) He would like reports on acute episodes of hepatitis to continue to be sent in via Oxford, especially if any patients given heat-treated products developed hepatitis.

ii) HBsAg Carriers: He would like Directors to report known cases and proposed to seek the approval of all Directors to the setting up of a reporting system.

iii) Chronic hepatitis as a clinical problem. Dr. Preston presented interesting data on this subject:

"Thirty liver biopsies have been performed on 34 patients who had elevated transaminase levels for 6 months or more. Twenty-two were found to have chronic persistent hepatitis (CPH), 1 chronic lobular hepatitis (CLH), 7 chronic active hepatitis (CAH) and 3 cirrhosis. Nine patients whose transaminases remained elevated for a minimum of 2 years after the first biopsy were re-biopsied. Of the 6 with CPH at first biopsy 2 remained unchanged, 2 had progressed to CAH and 2 to cirrhosis. Of the 3 with CAH at the first biopsy, 1 had converted to CPH, but 2 had progressed to cirrhosis. Progression of the chronic liver disease has thus occurred in 6 of the 9 re-biopsied patients. In addition, 1 patient with CAH has developed signs of cirrhosis and portal hypertension".

iv) Problems with Hepatitis B Vaccine: The material currently available was immunogenically poor. New products were under trial.

Dr. Kernoff said that heat-treated Profilate (wet) had been used at the Royal Free to treat infrequently transfused patients. After 4-5 months follow-up the results looked encouraging and no patients had developed hepatitis.

8b) Factor VIII Antibodies

Dr. Kernoff presented a written report. He felt that a clinical trial to study the value of factor IX (non-activated) in the management of haemophiliacs with inhibitors would be of value, but did not think this could be done at present in view of the problem of AIDS. He would look at the National Data currently available, in collaboration with Miss Spooner, but did not feel that any useful purpose would be served at the present time by convening formal meetings of a Working Party.

8c) von Willebrand's Disease

Dr. Tuddenham reported that the number of patients in the von Willebrands Working Party Register now exceeded 1,400. The Working Party would be meeting in March to consider a new registration form.

8d) Platelets

Dr. Preston said that the Working Party had now been set up and had held one meeting, as a result of which he had written to all Reference Centre Directors plus a few other Centres that had large numbers of patients asking them to complete and return registration/data forms as soon as possible. A final version of the form would be drawn up in the light of the preliminary findings for distribution to all Directors.

9. National External Quality Assurance Scheme for Blood Coagulation (NEQAS)

Dr. Preston summarised the results given in the report on the latest round of tests organised by Dr. Poller. Dr. Davidson said that the Report had not yet been approved by the National Panel, of which he was a member. After discussion, it was agreed that the Directors should wait until the Report had been approved by the Panel before discussion of the results.

10. 1985 Meeting of All Haemophilia Centre Directors

This would be held on Monday 21st October at the John Radcliffe Hospital in Oxford. Details would be circulated during the summer.

10a) 1986 Meeting of All Haemophilia Centre Directors

Dr. Ludlam was planning a 2-day meeting in Edinburgh, probably to be held in October.

11. Next Meeting of Reference Centre Directors

Monday 7th October at St. Thomas's Hospital, starting at

10.30 a.m.

A.O.B.

1) Dr. Kernoff asked if a formal Working Party on Data Collection could be set up to try to streamline the process. The data would continue to be collated and analysed in Oxford. It was generally agreed that this was an important topic and that it should be discussed in more detail at the next meeting of Reference Centre Directors.

2) Dr. Ludlam put forward a proposal that the position of Secretary to the Directors should be reviewed at some stage; and probably that the post, like the Chairmanship, should be held for a specified period of time.

Professor Bloom thought there was no necessity for the post of Secretary and the work on collection of National data to be tied together. In reply to enquiries Miss Spooner briefly outlined the services provided to the Reference Centre Directors, Working Party Chairmen and all Directors by the Secretariat in Oxford, giving an indication of the departments and staff involved in providing these services and the financial sources. She said she was happy to continue with her work on the National statistics and related matters if the Reference Centre Directors wished her to do so. Dr. Rizza agreed with the views expressed by Professor Bloom and Miss Spooner. He said he was willing to continue as Secretary but welcomed the suggestion of formalising the appointment of Secretary and thought a five-year term of office as Secretary would be reasonable. After brief discussion, it was agreed that the topic be discussed further at the next meeting of Reference Centre Directors.

Professor Bloom thanked Dr. Kernoff and Dr. Tuddenham for their hospitality, and the meeting closed at 4.30 p.m.

GRO-C: Forbes

1/10/85