Minutes of the Third Meeting of the UK Regional Haemophilia Centre Directors' Committee held at St. Thomas's Hospital on 3rd September 1990.

Present:
Dr. C.R. Rizza (Chairman)
Dr. A. Aronstam
Prof. A.L. Bloom
Dr. J. Heptonstall (CDSC)
Dr. F.G.H. Hill
Dr. P. Jones
Dr. P.B.A. Kernoff
Dr. R. Lee
Dr. J. Leslie
Dr. G.D.O. Lowe
Dr. C.A. Ludlam
Dr. B.A. McVerry
Dr. E. Mayne
Dr. H. Pickles (DoH)
Prof. F.E. Preston
Dr. A. Rejman (DoH)
Dr. G. Savidge
Prof. I. Temperley
Dr. R.T. Wensley
Miss R.J.D. Spooner

1a) Apologies: Dr. C. Hay, Prof. J. Cash and Dr. H. Gunson

The Chairman welcomed everyone to the meeting, especially Dr. Pickles and Dr. Rejman from the Department of Health, and Julia Heptonstall from the Communicable Disease Surveillance Centre at Colindale who had come to present a report under Item 6(d). The Chairman therefore suggeseted that Item 6 (d) should be taken as the first item on the Agenda.

6d) Adverse Events Working Party

The Chairman invited Dr. Heptonstall to present the Draft Report entitled "Investigation of a Report of Transfusion Associated Hepatitis B For The Haemophilia Centre Directors Adverse Events Working Party" which had been circulated to Committee Members. Some anxiety had been caused earlier in the year after reports that some batches of NHS Factor VIII and Factor IX might have been infected with Hepatitis B. The procedures used to investigate the incident were outlined by Dr. Heptonstall. Questionnaires had been returned by 15/18 Haemophilia Centres. Fifty patients had received the materials and there was no evidence that anyone had been infected by the concentrates. It was thought extremely unlikely that the concentrate would transmit hepatitis B. Dr. Heptonstall commented on the lack of information at some Centres on Hepatitis B immune status of patients. Of the recipients of supplied material 25/50 patients were known to be immune, 2 were not immune and no information was available for 23. It seemed to be very difficult for Centres to

gather together the required information from their records. Dr. Kernoff, Chairman of AEWP, said that he thought that the exercise had been very valuable and the Interim Report had been available fairly soon after the event. He proposed to circulate the Report for discussion at the AGM, but suggested that participating centres should not be identifiable. Dr. Kernoff asked the Committe to let him have comments before the end of the week by FAX if possible (Fax No. GRO-C). Dr. Jones said he would not like the report to become public and Dr. Aronstam suggested that the uncoded version should not be taken away from the meeting. After brief discussion it was agreed that the uncoded version could be taken from the meeting but that a coded version should be distributed for discussion at the AGM.

Dr. Kernoff said he had tried to address the communications problems between BPL and Haemophilia Centres and had arranged for the Secretariat in Oxford to give BPL the addresses etc. of all UK Haemophilia Centres. In the episode under discussion only Centres who had received the suspected batches had been informed by BPL. He had suggested that all Centres should be notified in the future of suspect batches and batch recall, otherwise Directors would be unable to answer questions raised by patients as a consequence of press coverage. Prof. Bloom felt that difficulties of communication might remain where material was being supplied via BTS, which could be issued to non-Centres by BTS. Dr. Pickles said the system had been improved. All events would be notified to Dr. Gunson in future. She asked if a copy of the report had been sent to BPL. Dr. Kernoff said a copy had not yet been sent to BPL and after discussion it was agreed that BPL would be given a copy of the final document after the AGM.

2) Minutes of the last meeting

The Minutes were approved and signed.

3) Matters arising from the Minutes

i) Dr. Rizza reminded the Committee that his term of office as Chairman would end at the AGM and Dr. Elizabeth Mayne would take over in the course of the Annual General Meeting in Sheffield. Dr. Mayne said she was looking forward to the next 3 years with some trepidation. She thanked Dr. Rizza for his work on behalf of the Directors. Dr. Kernoff said he would like to know what his position would be and Dr. Mayne said she hoped he would be willing to continue as Vice-Chairman. This was agreed unanimously.

3ii) Document "Recommendation on choice of therapeutic materials"

Dr. Kernoff said that it had been difficult and time-consuming getting a consensus of views and the result was inevitably a compromise taking account of a wide diversity of views. Some concern regarding the hazards of new technologies etc. had been expressed and Dr. Kernoff would like the Committee's views. Everyone would not agree 100% with the document but he thought it

would be useful nevertheless. Dr. Jones mentioned that there was currently very active marketing of French products and Prof. Preston said that the French manufacturers (Bio Transfusion) would have a stand at the Sheffield meeting.

Dr. Kernoff said that the overwhelming problem for Centres was the cost of the products; the second problem was concern about the new technology. It was pointed out that Directors were budget holders so could not avoid cost problems; many Directors had vast problems with costs. It was suggested that costs should not influence scientific evaluation. There was discussion as to when the next version of the document should be prepared and it was suggested that a mechanism was needed to deal with new products as they appear in relation to the documents. Dr. Mayne suggested that a small Working Party should prepare the document rather than leave it for one person to do all the work and she asked Dr. Kernoff for his views.
Dr. Kernoff said he thought it difficult to see how a Working Party would work; it would just add another layer of time. Dr. Rizza agreed with Dr. Kernoff. After discussion it was agreed that a Working Party should not be set up and that Dr. Kernoff would prepare the next revision of the document. The Regional Centre Directors were asked to let Dr. Kernoff have their views before the next Committee meeting. Dr. Mayne suggested that Dr. Kernoff should have an Administrative Assistant to pursue comments from Directors.
Prof. Bloom expressed concern about the the high incidence of inhibitors in children treated with recombinant materials. He thought Directors should concentrate on material made from British plasma; he felt that overseas products were less safe. Prof. Temperley was concerned about the treatment of von Willebrand's disease, for which separate instructions were required. As products became more refined the treatment of von Willebrand's disease patients needed to be considered. von Willebrand's Factor concentrate was now being advertised. Prof. Temperley had been in touch with BPL about getting 8Y made from Irish Plasma.

Dr. Pickles emphasised that it was illegal for commercial firms to advertise unlicensed products. The Department of Health would like to know if this was happening.

Dr. Rizza referred to the anxieties of the Blood Donors Group regarding charges for plasma and blood products.

Dr. Pickles said that it was expected that BPL would get full licences for their products in the near future.
Dr. Kernoff pointed out that the document stressed that only licensed materials should be used. Dr. Leslie said that Monoclate P was a drug listed in British Pharmacopia and chould be prescribed by anyone and that it was expensive.

Dr. Hill said that the Financial Manager of his BTS tried very strictly to limit the haemophilia budget.

Dr. Pickles said that BPL did not want to have surplus of 8Y.

Discussion followed on the problem of cross-charging. Some Centres had difficulties as they had more patients than expected for their Region.

The Chairman thanked Dr. Kernoff for all his hard work in preparing the current document and reminded Directors that they should let Dr. Kernoff have their comments on the document before the next Committee Meeting.

3iii) System for the Distribution of 8Y and 9A to Haemophilia Centres - Report on meeting with BPL

The Chairman said that an informal meeting had been held at BPL Elstree, with representatives from the Haemophilia Centre Directors, BPL and BTS representatives where the anxieties of the Directors had been expressed about the method of supplying blood products from BPL to the Haemophilia Centres. The Haemophilia Centre Directors has pressed strongly for supplies of Factor VIII to be supplied direct to Haemophilia Centres and not via Blood Transfusion Centres. The Chairman was of the view that probably little would change as a consequence of that meeting. There was concern about the lack of communications between Haemophilia Centres and between Haemophilia Centre Directors and BPL and BTS. BPL were concerned that some Directors were not using 8Y and they now had sales representatives visiting Centres. This should improve communications. Dr. Pickles wondered if the DoH could do anything about the problem and mentioned a Committe liasing between CBLA, BTS, RMOs etc. Dr. Rizza said that some Directors felt that their views were not being considered. Dr. Kernoff thought there was no need for BTS to be an intermediary; there should be direct contact between the Directors and BPL. He had expressed this view to the CBLA. It would seem more logical and sensible to have direct HCDs/BPL contact. Dr. Savidge wondered how BPL could continue to send supplies via BTS if they (BPL) became a commerical company. Prof. Bloom said that the BTS had taken over his Factor VIII budget 2 years ago and this arrangement it worked well. Dr. Jones said he supported Dr. Kernoff's views, that there should be direct links between HCDs and BPL. The Chairman said he would like to know the consensus of opinion regarding BTS involvement in Factor VIII distribution. After discussion it was agreed that the Chairman should write to the DoH and the SHHD stating that the Committee wanted the Factor VIII concentrate to be supplied directly to Centres and not via BTS. A letter was drafted at lunch time by the Chairman and presented to the Committee for approval. After minor amendments the letter was approved.

4) Annual Returns for 1989

The Chairman said that no report had been prepared as several Centres, including some Regional Centres, had not yet sent in their returns. He hoped the missing returns would soon be received in Oxford so that a report could be written before the end of the year.

Dr. Wensley said he had a good new computerised system for use when

preparing his Annual Returns and offered to provide information about it if anyone was interested. Dr. Hill also offered information about the system he used.

5) 8Y Study Progress Report

The Chairman presented the written report (Appendix A) which had been circulated with the Agenda. Entry to the Study was now closed. To date there had been no proven case of viral transmission.

Dr. Kernoff suggested that Factor VIII inhibitors be looked for at entry and exit from the Study. This was agreed.

6) Reports from Working Party Chairmen

a) von Willebrand's Disease

Dr. Savidge said there had been no formal meetings of the Working Party but he hoped to have one later this year.

b) Inherited Platelet Disorders

Prof. Preston reported that he had sent a questionnaire to all Regional Haemophilia Centres and had received 12 replies. Analysis of the replies showed that only 6 of the 12 Centres could assess platelet secretion and he had come to the conclusion that only 50% of Regional Haemophilia Centres can diagnosis the commonest platelet disorders.

c) Reorganisation of Haemophilia Care - Draft Constitution for the Haemophilia Centre Directors' Organisation

Dr. Savidge said that there had been 1 meeting of the Working Party earlier in this year. Dr. Rizza had produced a copy of a draft Constitution which had been drawn up by Prof. Ingram in 1977. With regard to the document on reorganisation of Haemophilia Centres this had been sent to the Department of Health but there had been no response by the Department.

Dr. Pickles said that it would at present be very difficult to proceed with the recommendations in the document. The new Health Act was attracting most of the DoH's attention she could not see the Directors' document being given any priority. The difficulties which could arise if it was issued now before the Act was working would be counterproductive. She suggested that the re-organisation document could come in on the back of the Supraregional Services Review and that it should wait until the White Paper was operating. Prof. Bloom asked what mechanism the Directors would get to let GP's etc. know where haemophilia expertise was avaiable .

Dr. Rejman said that the Haemophilia Society were worried about the White Paper and the DoH had replied that it foresaw little change in the delivery of service to haemophilia.

d) Adverse Events

A report was tabled by Dr. Kernoff summarising the Adverse Events reported in the period January-July. He said that all the thrombotic events reported were associated with Factor IX therapy. He felt the card system was gathering information which had previously not been reported to the Haemophilia Centre Directors. This was encouraging.

Dr. Savidge said he was concerned about the thrombotic events and asked if the manufacturers would be asked to look into the matter.

Dr. Wensley said that he was dealing with all reports of thrombotic events and gave brief details of the incidents.

Dr. Lowe advised giving prophylaxis with heparin to patients undergoing surgery and suggested that AEWP ask for historic information on thrombotic episodes when the next Quarterly Report Card was sent out.

Dr. Kernoff did not think a retrospective survey would be effective.

The question of pure factor IX and its availability now and in the near future was discussed. Dr. Kernoff said that recent recommendations from BSH suggested use of Factor IX concentrates for anticoagulant reversal and every hospital would need to keep a stock. This might place a strain on supplies.

Dr. Rizza said that Dr. Richard Lane would be at the AGM and there would opportunity for the Haemophilia Centre Directors' views concerning production of high purity NHS factor IX to be made known to him.

e) Chronic Hepatitis

A written report was tabled by Prof. Preston and discussed. The Working Party recommended that all patients should be checked for evidence of previous exposure to HCV. In reply to a question regarding the role of Interferon, Prof. Preston said that it seemed to be useful in only about 40% who showed improvement in liver histology and liver enzymes. It was suggested that there should be a trial of the use of interferon. It was agreed that Prof. Preston would prepare an amended version of the report for the AGM.

7) NEQAS Report

Dr. Kernoff had nothing to report and suggested that as a routine the item be removed from all future Agenda. This was agreed.

8) Haemophilia Chartered Physiotherapists Association

The Chairman said that the Chair of the Association had written to inform the Directors of the Association's existence and asked if she

as Chair could attend the AGM. It was agreed that the Chair of the HCPA could attend the AGM and should be asked to give a brief report on the Association's activities.

9) Arrangements for the 1990 A.G.M.

Prof. Preston reported that the arrangments were going well.

10) Arrangements for the 1991 and 1992 AGMs

Dr. Savidge was making arrangements for the 1991 (1 day) meeting to be held at St. Thomas's and would let the Secretariat know the date as soon as possible.

Dr. Leslie said that arrangements were progressing well for the 1992 (2 day) meeting to be held in Norwich.

11) Any Other Business

i) The Chairman informed the Committee that a letter had been received from David Watters of the Haemophilia Society saying that the Haemophilia Society wished to raise at the AGM their concern about the widely varying levels of care available in Haemophilia Centres to those patients who have both haemophilia and HIV infection. This was noted.

ii) Dr. Mayne said that she was planning to suggest at the AGM that the Directors should establish a system for Medical Audit. A System for Medical Audit was already operating in Scotland and Northern Ireland and worked well.

iii) A Meeting which was to be held in Amsterdam in November was mentioned.

12) Date and Place of next meeting

It was agreed that the next meeting would be held on Monday 4th February 1991 at the Royal Free Hospital.

The meeting closed at 1.00 pm.