Annex 17

Minutes of the Ninth Meeting of the UK Regional Haemophilia Centre Directors Committee held at the Lansdowne Club, London, on Friday 4 September 1992

Chairman: Dr E E Mayne

Present:	Dr A Aronstam
	Dr H Daly
	Dr H Dasani
	Dr I Hann
	Dr P Jones
	Dr C Lee
	Dr J Leslie
	Dr G Lowe
	Dr C A Ludlam
	Dr B A McVerry
	Prof F E Preston
	Dr A Rejman
	Dr G Savidge
	Dr R F Stevens
	Miss R J D Spooner

1. Apologies

Apologies were received from Professor Bloom (represented by Dr H Dasani), Dr F Hill, Dr G Lowe, Dr C R Rizza and Professor I Temperley.

The Chairman welcomed Dr Stevens who was attending the Committee meeting for the first time as the new Regional Representative for the North-West. She also welcomed Dr Dasani who was representing Professor Bloom.

2. Minutes of the previous meeting

A. Constitution

The application for charitable status had been with the Commissioner since early July and the Chairman had asked for a decision to be taken before the AGM was held in Norwich.

B. The Chairman stated that she had written to all Haemophilia Centre Directors informing them that there would be a fee of £20 per person for membership of the Haemophilia Centre Directors' Organisation. At present funds were healthy with over £7,000 on deposit. The Chairman suggested that the Organisation should make a donation annually to the Oxford Haemophilia Centre to offset the expenses of the Secretariat. She suggested that the annual income from the membership fee would make an appropriate sum. Dr Jones said he thought this was an excellent idea; it was agreed unanimously.

C. It was suggested and agreed that the Constitution should be printed and circulated to all Haemophilia Centres. Attention was drawn to the situation regarding the Chairman and Vice-Chairman. In the Constitution there is an allowance for a second person from the Centres of the Chairman and Vice-Chairman to attend the Directors' Committee meetings should either officebearer wish them to do so. At the next meeting of the Regional Committee, the appointment of a new Chairman should be considered for election in March by ballot of all Haemophilia Centre Directors. The Chairman asked members of the Committee to consider nominations for her successor.

D. The list of Regional Representatives appended to the draft Constitution document was queried by Dr Lee. It was agreed that this was to be checked and amended if necessary.

E. Dr Savidge indicated that the International Society of Haematology meeting at the Royal Festival Hall had been a financial success. He suggested that the Haemophilia Centre Directors' Organisation should apply for a proportion of the profits made by that meeting. He suggested that the Treasurer of the Organisation, Professor Shinton, should be approached. Discussion followed and it was agreed that Dr Hay, as Treasurer of this Organisation, should be asked to write to Professor Shinton.

F. Guidelines on Haemophilia Treatment

The Chairman said that Dr McVerry had agreed to draft a document in the autumn and it was hoped that it would be available before Christmas.

The Minutes of the Eighth Meeting were approved.

4. Chairman's Business

A. HC76(4)

The Chairman thanked colleagues for their letters regarding the proposed revised document. She indicated that several meetings had been held and a further revised draft had been prepared by the Department of Health. There had been difficulties in the designation of Comprehensive Care Centres and Centres; this had been resolved. On page 4, referring to the section on Medical Audit, this had been queried and amended to exclude Centre Directors making any comment regarding cost-effective treatment. The Haemophilia Society had been invited to provide models of contracts to the Department of Health for inclusion. Dr Rejman indicated that these documents were awaited from the Haemophilia Society. Afterwards they would be sent to the Management Executive for approval. As the Haemophilia Society had collected examples of contracts, the Department of Health thought that they were the best source to supply the information. However, the Haemophilia Society indicated that their surveys had encountered difficulties. The Chairman said that she had reservations about the Haemophilia Society's input to the document and she felt that Centre Directors would need to view the material provided by the Society. Thereafter Dr Rejman was asked if the document was for distribution only in England or was it also to include Wales, Scotland and Northern Ireland. He replied that it was only intended to issue it in England but as was customary, Wales, Scotland and Northern Ireland would issue a similar document at a later stage. Dr Savidge said that he would like someone who was actually involved in haemophilia care and in the drawing up of contracts to be involved in the drafting of the document. There then followed a wideranging discussion regarding the whole contractual process and its relationship to Haemophilia Centres and Comprehensive Care Centres. Finally it was agreed that a special meeting of the Centre Directors in England should be held as soon as possible to discuss contracting. Dr Lee suggested that financial advisers should also be invited to attend. Dr Rejman said that it would be necessary to check with the Department if the draft document could be made available to the financial advisers. He would let the Chairman know as soon as possible. It was agreed that the present draft document should be presented at Norwich and Dr Rejman agreed to present it to the meeting.

B. Recommendations on choice of therapeutic materials

The Chairman reported that the publication of the above document had provoked substantial comment and criticism. Some of the critics implied that the Regional Centre Directors had over-reacted to the HIV problem by recommending high purity material for these patients. As an example of the criticisms received, copies of a letter from Dr Christopher Prowse, SNBTS, had been circulated to members with his permission. It was clear that the Recommendations document would require future update. The Chairman indicated that this was an important activity of the Committee and that it should not be left to the responsibility of one person to prepare the final paper for publication. Arising from the Recommendations, Dr Lee showed Committee members a letter she had received from the Department of Health dated 19th August 1992. It was circulated to Regional Haemophilia Centre Directors, Public Health Laboratory Directors, AIDS advisers, etc. It contained advice regarding the use of AIDS money for the purchase of high purity Factor VIII. It indicated that this was not an acceptable practice. Dr Lee was very concerned about this letter. During discussion, it transpired that not all Centre Directors present had received a copy of the letter but those who had received it were much dismayed by its content. Dr Rejman confirmed that the rules would not allow AIDS money to be used for the purchase of materials for the treatment of haemophilia patients. The Chairman asked that all Centre Directors who had received the letter would let her have comments about it as soon as possible. This was agreed.

C. Haemophilia Medical Audit

The Chairman said that all the Regional Centre Directors had by now received the information regarding the forthcoming cross-regional audit in England and Wales. She asked them to let her know if they wished to alter any of the arrangements. She requested that the audit be completed, if possible, before the end of the current year.

D. Miscellaneous

1. Genetics

The Chairman reminded members that Professor Bloom had introduced this subject some two years ago. The Department of Health, in conjunction with the Royal College of Physicians, is carrying out a national confidential inquiry into counselling for genetic disorders. Dr Mark Layton from King's College Hospital is providing the input regarding haemophilia for this survey. A draft questionnaire has now been compiled and copies are to be sent to all Regional Centre Directors. The Chairman has agreed to meet with Dr Layton and discuss any funding to be provided for this project. Secondly, Dr Rejman indicated that there was a forthcoming letter from the Chief Medical Officer giving guidance regarding genetic counselling which also included haemophilia patients. The CMO's letter suggested that genetics was a specialty and that patients should be referred to regional genetic units, haemophilia being included in this category. The CMO's letter would be sent to every registered NHS doctor and might contravene views of the Regional Centre Directors. It was agreed that Dr Rejman would let the Chairman unofficially see the draft letter and she would advise him as to steps that should be taken. There was considerable concern expressed by members that it would not be appropriate for haemophilia families to be referred to regional genetic units, rather than Haemophilia Centres. It would contravene the instructions listed in the new HC76(4) document.

2. The Haemophilia Society

The Chairman reported that the National Haemophilia Society had requested they be invited to today's meeting and that the afternoon should be devoted to discussing the Society's strategic plans. This suggestion had been declined by the Chairman. Members at the meeting agreed with this decision.

7. **Update on HIV Litigation**

Dr Rejman said that 37 cases had been settled since he last reported to the Regional Directors. The settlements had ranged from nil to £13,000. Most of the settlements were for £10,000, £15,000 or £20,000. Several cases had been withdrawn and there were four cases with offers outstanding. Five cases were listed for trial in October but it was thought that one or more of these cases may settle at the door of the Court.

8. **1992 Annual General Meeting**

Dr John Leslie said that the arrangements for the Norwich meeting were well in hand. He reported that 15 firms were putting on a trade exhibition in a room adjoining to the main meeting. £23,000 had already been received to fund the meeting. This included the registration fees. One hundred people booked to attend the scientific meeting, whereas only fifty had accepted to come to the annual business meeting.

6. **HIV Statistics**

Miss Spooner presented two tables showing the current situation. The first showed the number of cases of AIDS reported to Oxford, the number still alive and the number who had died. The second gave the up-to-date figures for the numbers who had been HIV tested and been found to be HIV positive. The Chairman asked the Directors if they felt that a further survey was necessart. After discussion it was agreed that no further surveys of HIV in haemophilic patients was required at present. It was also felt unlikely that any valuable information could be obtained regarding the transmission of HIV to the sexual partners of haemophilics. Dr Lee asked if there was any information available about vertical transmission of HIV. She suggested that a very simple survey should be undertaken to provide this information. After discussion it was agreed that Dr Lee would draft a document for the collation of information regarding the number of children born to HIV positive haemophilics and their wives/partners in order to ascertain the incidence of vertical transmission of the HIV virus. The draft would be sent to the Chairman and to Miss Spooner for further discussion.

5. Annual Returns

The report on the 1991 Annual Returns was tabled. Miss Spooner said that two additional pieces of information was provided this year; namely a list of the dates on which the completed Annual Returns were received (Appendix A); secondly, a graph (Figure 1) to show the number of severely affected patients treated by Centres during 1991. The latter would provide the information required for the definition of Comprehensive Care Centres. The figures showed a larger than usual increase in the usage of factor VIII. Dr Jones suggested that all Directors check the accuracy of their statistics. Dr Hann thought that the column headings should be altered as the concept of NHS Factor VIII no longer existed. Dr Rejman disagreed; he said that the present format fulfilled the Department's requirements: BPL was part of the NHS, not a commercial company. After discussion it was agreed that the report should not be changed at present. Concern was expressed that plasma was still being used to treat haemophilic patients. The Chairman asked to be provided with relevant details of plasma usage. Miss Spooner agreed to provide the information. Professor Preston asked about the number of patients treated with DDAVP alone; Dr Savidge asked if Fibrin Glue should be included among the treatment materials recorded in the Annual Returns. Professor Preston requested more detail about cancer deaths and Dr Lee asked for details to be provided of the postmortem reports. Miss Spooner indicated that very few postmortem reports were received but she would provide any further available information for the next meeting of Regional Directors.

Rare Defects

Miss Spooner said that she had received registration forms for patients with Protein S deficiency. There was a brief discussion about such cases of thrombophilia and the Chairman suggested that registration should be considered as an agenda item for the next Regional Centre Directors' meeting. **This was agreed.**

Haemophilia Society

The Chairman said that the Haemophilia Society had requested a Regional Report. She reminded the Directors that they had received reports in previous years of Regional Statistics. She asked if the Directors would like an update to include Factor VIII and IX in this respect and if so, should the Haemophilia Society receive a copy as requested. Following discussion it was agreed that a regional report should be prepared but that the circulation should be confined to the Regional Centre Directors. The Haemophilia Society and the Department of Health should only receive the present format of Annual

Returns. The Chairman indicated that she would inform the Haemophilia Society.

9. Working Party Reports and Related Topics

A. Liver Disease

Professor Preston said that a meeting was to be held in 4-6 weeks' time. He had received 65 replies to his questionnaire. 23% of the Centres did not do HCV testing, only 46% of the Centres discussed the results with the patients. He had reports of 341 deaths but autopsy evidence only in 80 patients. The Working Party was particularly interested in the incidence in hepatocellular carcinoma. Professor Mannucci had published information about ten patients in 12,000 who had hepatocellular carcinoma. Professor Preston indicated that there were higher figures in the UK, namely nine cases.

Hepatitis A

Dr Savidge raised the problem of the reported four cases. Additionally it was known that cases had occurred in both Ireland and Italy. These countries both use product manufactured by Octapharma technology. The Chairman said she would seek information from Professor Temperley regarding the Irish cases. Dr Ludlam asked Professor Preston about the relevance of hepatitis A vaccine and whether the Working Party intended to make recommendations for using the vaccine in HAV negative patients. Professor Preston replied that the topic was on the agenda for the next meeting. Dr Ludlam thought it was important to discuss it as it was likely to be raised at the AGM by members.

Hepatitis C

Dr Lowe asked about the Working Party's recommendations regarding the use of alpha interferon in this condition. Professor Preston replied that he had written to all those who had expressed an interest in participating in an alpha interferon trial for these patients. Dr Jones said that following a meeting in Newcastle, he did not think the Directors should be recommending safer sex for prevention of HCV. He requested a consensus view of members. Dr Lee disagreed; she felt that patients should protect themselves and quoted various references, some of which related to practices of homosexual individuals. No policy was adopted by the Committee. Dr Lowe asked if there were any uniform recommendations of giving advice to blood donors who were found to be HCV positive. Dr Rejman replied that the Department desired agreement between the Haemophilia Centre Directors and virologists before a policy could be adopted. Dr Savidge asked if there was agreement from the Department regarding the use of alpha interferon in these patients. Dr Rejman replied that it was not licensed for the treatment of HCV.

B. Adverse Events Working Party

Dr Savidge felt that as the Adverse Events orange card scheme had now been running for two years, it would be useful to publish the results in the journal Thrombosis and Fibrinolysis. **This was agreed.**

Thrombotic Complcations

Professor Preston said that he had received the data from Miss Spooner regarding the thrombotic events previously reported to the Adverse Events Working Party and he gave a summary of the findings. There had been nine thrombotic events in eight patients and all but one had been related to surgery. It was agreed that Dr Hay, Professor Preston and Dr Savidge would present the Adverse Events Working Party data at the AGM.

C. Von Willebrand Working Party

Dr Savidge presented the data which he received on disc from Oxford and which he had analysed. The results indicated the apparent failure in making a basic and accurate diagnosis for the condition in many instances. The Chairman requested Dr Savidge to make helpful recommendations in this respect to members at the annual general meeting. Dr Savidge indicated that he had felt that some 30-40% of the data was of poor quality and he requested an updated tape of the data held in Oxford. He said that the data would give information about approximately 4,000 patients. Miss Spooner agreed to let Dr Savidge have an updated tape.

D. Paediatric Working Party

In the absence of Dr Hill, Dr Hann said that a meeting had been held at the Royal Free Hospital and the problem of prophylaxis had been fully discussed. Unfortunately Dr Hill possessed the only copy of the protocol so he was unable to give members precise details. The Working Party hoped to have further meetings in the near future and have the protocol ready by the end of September. Dr Hill intended to present the information to the AGM. Dr Lee reported that at the meeting in the Royal Free, members had expressed their unanimous view that central vein access lines should not be used for product infusion during the prophylaxis programme.

10. Any Other Business

Miss Spooner said that Dr Clare Davison had sent a copy of a booklet entitled "Guidelines for Management of Children with HIV Infection" which she felt would be of interest to the Haemophilia Centre Directors. Miss Spooner suggested that details of this publication should be circulated to all Haemophilia Centre Directors. **This was agreed.**

11. Date of next meeting of Regional Directors

It was agreed that the next meeting would be held on 8th February 1993 at the Lansdowne Club.

12. Date and place of 1993 and 1994 Annual General Meetings

The 1993 Annual General Meeting would be held on 1st October at the Royal London Hospital and the 1994 Meeting would be held in Birmingham.

The meeting closed at 4.15 p.m.