MINUTES of the TWELFTH MEETING of U.K. HAEMOPHILIA CENTRE DIRECTORS held at the ROYAL FREE HOSPITAL on FRIDAY 9th OCTOBER 1981

Present:

Professor A. Bloom (Chairman)
University Hospital of Wales, Cardiff.

Dr. S. Ardeman,
Edgware General Hospital.

Dr. A. Aronstam,
Lord Mayor Treloar Hospital,

Dr. M. Azawi,
Lister Hospital, Stevenage.

Dr. P. Barkhan,
Guy's Hospital, London.

Dr. D.L. Barnard,
Leeds.

Dr. C.J.T. Bateman,
St. Richard's Hospital, Chichester.

Dr. O.H.A. Baugh,
Chelmsford and Essex Hospital.

Dr. F.E. Boulton,
Scottish NBTS, Edinburgh.

Dr. M.A. Boots,
Essex County Hospital.

Dr. D.G. Chalmer,
Addenbrooke's Hospital, Cambridge.

Dr. P. Chipping,
Hammersmith Hospital, London.

Dr. M. Chisholm,
Southampton.

Dr. B.T. Colvin,
The London Hospital.

Dr. J. Craske,
Manchester.

Dr. E.R. Craven,
Kettering General Hospital.

Dr. I.W. Delamore,
The Royal Infirmary, Manchester.

Dr. Helen Dodsworth,
St. Mary's Hospital, London.

Dr. J.A. Easton,
Slough.

Dr. J.O.P. Edgcumbe,
Royal Devon and Exeter Hospital.

Dr. B.S. Ely,
DHSS, London.

1394

46/400

Dr. D.I.K. Evans,
Manchester Children's Hospital.

Sister M. Fearns,
Royal Victoria Infirmary, Newcastle-upon-Tyne.

Dr. E.A. French,
University Hospital, Nottingham.

Dr. A.H. Goldstone,
University College Hospital, London.

Dr. N.E.M. Harker,
Middlesbrough General Hospital.

Dr. J.P.L.A. Hayes,
All Saints Hospital, Chatham.

Dr. P.R. Hill,
St. George's Hospital, London.

Dr. R.L. Holman,
Bath Royal United Hospital.

Dr. R.M. Ibbotson,
Central Pathology Laboratory, Stoke-on-Trent.

Dr. M. Inwood,
Canada.

Dr. S.A. Johnson,
Musgrove Park Hospital, Somerset.

Dr. P. Jones,
Royal Victoria Infirmary, Newcastle-upon-Tyne.

Dr. P.B.A. Kernoff,
Royal Free Hospital, London.

Dr. R.S. Lane,
B.P.L., Elstree.

Dr. D. Lee,
Blood Transfusion Centre, Lancaster.

Dr. J. Leslie,
Norfolk and Norwich Hospital.

Dr. C. Ludlam,
The Royal Infirmary, Edinburgh.

Dr. S.J. Machin,
The Middlesex Hospital, London.

Dr. J.M. Matthews,
Oxford Haemophilia Centre.

Dr. S. Mayne,
Derbyshire Royal Infirmary.

Dr. R.S. Mibashan,
King's College Hospital, London.

Dr. Liz Miller,
Hillingdon Hospital, London.

Dr. V.E. Mitchell,
Leicester Royal Infirmary.

4-6/401

Dr. M.W. McEvoy,
Harrogate General Hospital.

Dr. P.J.F. McHugh,
Kingston Hospital, Surrey.

Dr. B.A. McVerry,
Royal Liverpool Hospital.

Dr. Una O'Callaghan,
Great Ormond Street, London.

Dr. V.E. Oxley,
Princess Alexandra Hospital, Harlow.

Dr. L. Parapia,
Bradford Royal Infirmary.

Dr. R.J. Perry,
Protein Fractionation Centre, Edinburgh.

Dr. J.R.H. Pinkerton,
Salisbury General Infirmary.

Mr. K.R. Polton,
The Haemophilia Society.

Dr. C.R.M. Prentice,
Glasgow Royal Infirmary.

Dr. F.E. Preston,
Royal Hallamshire Hospital, Sheffield.

Mr. J. Prothero,
The Haemophilia Society.

Dr. E. Rarasinghe,
Charing Cross Hospital, London.

Dr. J.D.M. Richards,
University College Hospital, London.

Dr. C.R. Rizza,
Oxford Haemophilia Centre.

Dr. Diana M. Samson,
Northwick Park Hospital, Harrow.

Dr. G. Savidge,
St. Thomas' Hospital, London.

Dr. J. Seghatchian,
Edgware B.T.C.

Dr. N.K. Shinton,
Coventry and Warwickshire Hospital.

Dr. Janet A. Shirley,
Frimley Park Hospital, Surrey.

Dr. J.K. Smith,
P.F.L., Oxford.

Mr. T. Snape,
P.F.L., Oxford.

Miss R.J.D. Spooner,
Oxford Haemophilia Centre.

46/402

Dr. H. Sterndale,
Isle of Thanet District Hospital.

Dr. L.M. Swinburne,
St. James' University Hospital, Leeds.

Dr. D.S. Thompson,
Luton and Dunstable Hospital.

Dr. N.E. Traub,
Southend Hospital, Westcliffe-on-Sea.

Dr. E.G.D. Tuddenham,
Royal Free Hospital, London.

Dr. G.R. Tudhope,
Ninewells Hospital, Dundee.

Dr. Diana Walford,
DHSS, London.

Mr. D.G. Watters,
The Haemophilia Society.

Dr. J.M. Webster,
Ashford Hospital.

Dr. R.T. Wensley,
Manchester Royal Infirmary.

Dr. D.N. Whitmore,
Lewisham Hospital.

Dr. D.A. Winfield,
Derbyshire Royal Infirmary.

Dr. P.J. Wyld,
Sheffield Children's Hospital.

Afternoon Session

Dr. T. Barrowcliffe,
N.I.B.S.C., London.

Dr. I. Peake,
University Hospital of Wales.

Dr. Joan Trowell,
John Radcliffe Hospital, Oxford.

Apologies for Absence were received from:

Dr. W.S.A. Allan,
The Royal Hospital, Wolverhampton.

Dr. B. Attock,
North Devon District Hospital.

Dr. A.M. Barlow,
Huddersfield Royal Infirmary.

Dr. A.J. Barrett,
Westminster Hospital, London.

Dr. B. Bennett,
Aberdeen Royal Infirmary.

Dr. A.J. Black,
Norfolk and Norwich Hospital.

46/403

Dr. T.E. Blecher (Represented by Dr. E.A. Black)
Queen's Medical Centre, Nottingham.

Dr. J. Bridges,
Royal Victoria Hospital, Belfast.

Dr. R.P. Britt (Represented by Dr. Liz Miller)
Hillingdom Hospital, London.

Dr. D. Burman,
Bristol Children's Hospital.

Dr. J.D. Cash (Represented by Dr. F.E. Boulton)
Scottish National B.T.S., Edinburgh.

Dr. I. Chanarin (Represented by Dr. Diana Samson)
Northwick Park Hospital, Harrow.

Dr. I.A. Cook,
Raigmore Hospital, Inverness.

Dr. P.E. Crome,
Queen Mary's Hospital, London.

Dr. A.A. Dawson,
Aberdeen Royal Infirmary.

Dr. T.J. Deeble,
Cumberland Infirmary, Carlisle.

Dr. C.D. Forbes (Represented by Dr. C.R.M. Prentice)
Glasgow Royal Infirmary.

Dr. C. Giles (Represented by Dr. R.M. Ibbotson)
Central Pathology Laboratory, Stoke-on-Trent.

Professor P.T. Flute (Represented by Dr. P. Hill)
St. George's Hospital, London.

Dr. R.C. Hallam,
Bedford General Hospital.

Dr. T.J. Hamblin,
Royal Victoria Hospital, Bournemouth.

Prof. R.M. Hardisty (Represented by Dr. Una O'Callaghan)
Hospital for Sick Children, London.

Dr. F.G. Hill,
Queen Elizabeth Hospital, Birmingham.

Dr. J.F. Horley,
Royal Sussex County Hospital, Brighton.

Dr. A.M. Hurdle,
Epsom District Hospital.

Dr. R.M. Hutchinson (Represented by Dr. V.E. Mitchell)
Leicester Royal Infirmary.

Prof. G.C. Jenkins (Represented by Dr. B. Colvin)
The London Hospital,

Dr. Judith Kemp,
Lewisham Hospital.

Dr. J.S. Lilleyman (Represented by Dr. P.J. Wyld)
Sheffield Children's Hospital.

46/404

Dr. J. Martin,
Alder Hey Children's Hospital, Liverpool.

Dr. Elizabeth Mayne,
Royal Victoria Hospital, Belfast.

Dr. G. McDonald,
Glasgow Royal Infirmary.

Dr. M. Mills (Represented by Dr. N.E. Traub)
Southend Hospital, Westcliffe-on-Sea.

Dr. T.R. Mitchell (Represented by Dr. E. Rarasingh·)
Charing Cross Hospital, London.

Dr. R.A.M. Oliver,
Mayday Hospital, Surrey.

Dr. A. Paxton,
Redhill General Hospital, Surrey.

Dr. E.G. Rees,
Shrewsbury Hospital.

Mr. I. Rhymes,
Oxford Haemophilia Centre.

Dr. G.L. Scott,
Bristol Royal Infirmary.

Dr. J.L. Stafford,
Freedom Fields Hospital, Plymouth.

Dr. P.A. Stevenson,
Walton Hospital, Liverpool.

Prof. J. Stewart (Represented by Dr. S.J. Machin)
Middlesex Hospital, London.

Prof. J. Stuart,
Queen Elizabeth Hospital, Birmingham.

Dr. Elizabeth Thompson (Represented by Dr. S.A. Johnson)
Musgrove Park Hospital, Taunton.

Prof. R.L. Turner (Represented by Dr. L. Parapia)
The Royal Infirmary, Bradford.

Mr. J. Watt (Represented by Dr. R.J. Perry)
PFC, Edinburgh.

Dr. H.J.H. Williams,
West Kent General Hospital.

Dr. J.R.B. Williams (Represented by Dr. M. Azawi)
Lister Hospital, Stevenage.

Professor Bloom opened the meeting and extended a special welcome to: Dr. Martin Inwood from Canada, the three representatives of the Haemophilia Society (Mr. Prothero, Mr. Polton and Mr. Watters) and the two representatives of the Department of Health (Dr. Diana Walford and Dr. B. Ely).

46/405

Professor Bloom also welcomed Dr. M.A. Boots who had succeeded Dr. Nicholas as Director of the Colchester Haemophilia Centre. Three other new Directors had been appointed in recent months but were unable to attend the Meeting. These were Dr. P.A. Stevenson of the Walton Hospital, Liverpool who had succeeded Dr. Robb as Director of the Centre on Dr. Robb's retirement; Dr. T.J. Hamblin of the Royal Victoria Hospital, Bournemouth who had become Director of the Bournemouth Haemophilia Centre when Dr. Green moved to Portsmouth and Dr. M. Mills who was Director of the new Associate Centre at the Southend Hospital, Westcliffe-on-Sea, Essex. There had been several retirement of Directors during the year, Professor E.K. Blackburn of the Royal Hallamshire Hospital, Sheffield; Dr. J. O'Brien of Portsmouth; Dr. H. Greenburgh of Plymouth; Dr. J.W. Nicholas of Colchester and Dr. P.M. Robb of the Walton Hospital, Liverpool.

2. Minutes of the last meeting

The Minutes of the meeting which was held in Glasgow on 30th September 1980 were approved and signed.

3. Matters arising from the Minutes

Professor Bloom said that several items arising from the Minutes would be dealt with under the main items of the Agenda for the day.

(a) Dr. Poller's Quality Control Study

The decision had been taken at the Glasgow meeting and at subsequent Reference Centre Directors meetings, that Dr. Poller should be invited to report on his Quality Control Study to the Haemophilia Centre Directors at their Annual Meeting. Professor Bloom had written to Dr. Poller for information about the scheme and Dr. Poller had suggested that

46/406

a representative of the Haemophilia Centre Directors should join the Committee dealing with the Quality Control Study. Dr. Geoffrey Savidge had agreed to be the Haemophilia Centre Directors' representative on the Committee. It was agreed that since the Directors now had a representative on Dr. Poller's Committee it was now not appropriate to invite Dr. Poller to the Directors meeting to report on his studies.

4. Reports on meetings of Haemophilia Reference Centre Directors

Professor Bloom said that two meetings of the Haemophilia Reference Centre Directors had been held since the Glasgow meeting of all Haemophilia Centre Directors. The first meeting of the year was held on the 23rd January when several matters of major importance to the Haemophilia Centre Directors had been discussed. The role of the Haemophilia Centres in Belfast and in Edinburgh had been discussed and the question of the designation of these Centres as Reference Centres had been raised. The Centre in Belfast had now been officially recognised by the Northern Ireland Office as a Reference Centre. The situation in Glasgow and Edinburgh had not changed, although the question of official designation of the Glasgow and Edinburgh Centres as Reference Centres was under discussion at the Scottish Home and Health Department. Mr. Rosenblatt of the Haemophilia Society had sent a report on Life Insurance to the Haemophilia Reference Centre Directors. The Directors had noted Mr. Rosenblatt's report and were awaiting further news on this matter.

Reports on the Annual Returns from Haemophilia Centres for 1979 and 1980 were discussed and approved and would be presented later in the meeting.

46/407

The question of purchasing, holding and distribution by Blood Transfusion Centres of blood product stocks of all types including Factor VIII and Factor IX concentrate (Commercial as well as NHS) had been raised by the Department of Health. The Haemophilia Reference Centre Directors were very disturbed at this suggestion. An ad hoc committee had been set up by the Department of Health on which the Elstree Blood Products Laboratory, Haemophilia Centre Directors and Blood Transfusion Service were represented and two meetings had been held. The matter had been exhaustively discussed and at the last meeting it was agreed that responsibility for the control of stocks of coagulation factor concentrates should not be moved from the Haemophilia Centre Directors to the Blood Transfusion Service. In accepting this decision the Department of Health had expressed a wish that accurate records concerning purchase and use of commercial factor VIII concentrates should be kept by Haemophilia Centre Directors and the Directors should take note of this request. The Department of Health had said that although they appreciated the detailed information provided by Haemophilia Centre Directors through their Annual Returns they did not feel that these gave sufficiently rapid and complete data on the use of commercial factor VIII concentrates throughout the U.K. The Department of Health would like to have data available earlier in the year than was at present available via the Haemophilia Centres annual returns, and asked if the Directors would undertake to keep records in such a manner as would enable them to provide data on the commercial factor VIII concentrates used in their area (including materials used at hospitals not designated as Haemophilia Centres) to the

46/408

Department of Health at short notice should the Department require this. The majority of the Haemophilia Reference Centre Directors thought that it would not be difficult for the Haemophilia Centre Directors to make this undertaking to the Department of Health. The Department need the information to assist with their long term planning for the Blood Products Laboratory at Elstree. It was suggested that the Department of Health might be able to get the information they required from the Pharmacy Departments of all hospitals. It was also suggested that to get a favourable price the Haemophilia Reference Centre Directors should arrange for supplies to be purchased on a contract basis for the whole of their Region and should distribute the material to the Haemophilia Centres. The payments would be made in the usual way by the hospitals which had purchased the material although they would have the advantage of the contract price. Professor Bloom said that he thought that an undertaking was now required from the Haemophilia Centre Directors that they would provide the Department of Health with the data which they required and that organised Regional services purchasing of factor VIII might help with this. It was agreed that the local arrangements for purchase of factor VIII were for discussion within the Regions and that there were advantages in contracts with the commercial firms for the bulk purchase of the concentrates at favourable prices. Professor Bloom emphasised that the Haemophilia Centre Directors must ensure in the future that data was available at the Centres for transmission to the Department of Health whenever the Department wished, for example, at a months' notice. Various alternative methods for the Department obtaining the data were discussed including

46/409

an arrangement whereby the commercial firms would send data directly to the Department of Health but it was not thought that any of the alternative suggestions was practicable.

Professor Bloom said that he had received an additional item for the Agenda from Dr. Chanarin. Dr. Chanarin who was unable to attend the meeting wished to put a motion to the meeting that "this meeting advise the DHSS that the manufacture of factor VIII concentrate be handed over in toto to the Pharmaceutical Industry and that the DHSS withdraw from this activity". Professor Bloom said that a similar suggestion had been discussed at previous meetings of the Haemophilia Centre Directors and it had been the clear view of the majority that the Directors would prefer to see the DHSS providing increased funding for the expansion of the NHS Fractionation Plants rather than transfer the manufacture of the concentrates to industry. Some discussion followed and again there was no enthusiasm for the suggestion that the DHSS should withdraw from manufacturing factor VIII concentrates.

The Chairman briefly outlined the proceedings of the second meeting of the Haemophilia Reference Centre Directors. This was held on the 14th September and most of the items discussed at that meeting were covered by the Agenda for the 12th Meeting of the U.K. Haemophilia Centre Directors. The question of publication of the Haemophilia Centre Directors data had been discussed and it had been agreed that there would be no objection to individual Directors presenting at meetings, the data given in the annual reports, provided that the Chairman's permission was given beforehand and so long as presentation of the data did not prejudice the copyright for the Haemophilia Centre Directors when they came to publish the data in full.

46/411

5. Report on the 1980 Annual Returns from Haemophilia Centre Directors

Dr. Rizza thanked the Haemophilia Centre Directors and their staff for the hard work they had put into sending in the data to Oxford for analysis. Dr. Rizza briefly discussed the data which had been precirculated drawing attention to points of interest. The most significant feature was an increased use of factor VIII for Haemophilia A patients and an increased number of patients treated by Haemophilia Centres. There had been a further increase in the amount of commercial factor VIII concentrates used but very little change in the amount of National Health Service factor VIII. There had also been a slight increase in the amount of factor IX used and in the number of Christmas disease patients treated. With regard to factor VIII antibodies, there had been no increase in the incidence of antibodies since the Haemophilia Centre Directors had started to collect data in 1969. Approximately half of the total materials used to treat haemophilia and Christmas disease had been used in home therapy. Dr. Rizza asked the Directors if they would like Oxford to continue to analyse data on home therapy on their behalf and present the data as set out in Tables 6-8. This was agreed. The analysis of the cause of deaths as reported by Haemophilia Centre Directors in 16 Haemophilia A and 7 Haemophilia B patients during 1980 was discussed. The increased number of patients reported as having died in 1980 compared with 1979 was thought to be due to better reporting from Centres rather than to a real increase in the number of deaths. There was still a large number of patients for whom the severity of the coagulation defect and/or date of birth was not known. Directors were

46/412

urged to try to obtain this important information. Dr. Rizza said that he and Miss Spooner were in the process of writing up the report for publication in the medical press after it had been approved by all the Reference Centre Directors. A copy of the final report would be sent to all Haemophilia Centre Directors. Professor Bloom thanked the Oxford Haemophilia Centre for preparing the report on the data and the Directors for sending in the data for analysis.

Following the 1979 meeting of all Haemophilia Centre Directors, the Reference Centre Directors had discussed the estimated annual requirements of factor VIII and had agreed a revised estimate of 100 million units per annum. Professor Bloom asked Dr. Lane if he could let the Directors know what the availability of NHS factor VIII was at present and the long term estimates and what collaboration he would like from the Haemophilia Centre Directors. Dr. Lane said that 20% of the total donations collected by the Blood Transfusion Service were at present separated as fresh frozen plasma for fractionation: it was hoped that this percentage would shortly increase to above 40%. The interim increased fractionation capacity scheduled to come on-stream at Elstree during 1982 should enable factor VIII production to increase to at least 30 M international units per annum, and in spite of difficulties, approximately 20 M units of factor VIII had been supplied to the NHS during 1981. Contrary to certain opinion, the limitation on factor VIII preparation lay with the supply of fresh frozen plasma for fractionation. The long-term redevelopment of the Blood Products Laboratory was aimed at producing 100 M international units of factor VIII intermediate concentrate with a small percentage of material

46/413

as freeze dried cryoprecipitate and high purity concentrate. Methods for improving yields of factor VIII were being investigated but did not include recourse to the technology involving genetic manipulation. The laboratory also had an active programme concerned with the reduction of hepatitis transmission by protein fractions which were unsuited to inactivation of virus by heat: donor selection was also under consideration as a means of gaining accreditation through repeated plasmapheresis.

6. Provisional data and place for next meeting of all Haemophilia Centre Directors

The Chairman said that Dr. Delamore and Dr. Wensley had invited the Haemophilia Centre Directors to hold their next annual meeting in Manchester. To secure a suitable hall for the meeting and residential accommodation in one of the colleges, it would be necessary for the meeting to be held in mid-September and it was suggested that it should be a two-day meeting. The provisional dates were 13th and 14th September 1982.

7. Any Other Business

a) Letter from Dr. Shinton

Professor Bloom said that he had received a letter from Dr. Shinton raising several matters and invited Dr. Shinton to speak to the item. Dr. Shinton said that there were at present a number of changes taking place in the organisation of the treatment of haemophiliacs which he felt warranted consideration. 1. The appointment of Consultant Haematologists to District Hospitals who had received training in the treatment of haemophilia as Senior Registrars. 2. The availability of factor VIII concentrate commercially.

46/414

3. Re-organisation of NHS based on Districts with appropriate funding at the expense of Regional Services. 4. The desire of the haemophiliacs to be treated locally. Dr. Shinton felt that while all the above factors had their own merit or advantage, the sum total could lead to a drastic change in the treatment of haemophiliacs based on Haemophilia Centres. He was very concerned how the re-organisation of the NHS and the allocation of funds to Districts would affect the Haemophilia Centres. It was pointed out that Dr. Shinton's letter raised again the question of the designation of Haemophilia Centres and Associate Centres. The document issued in 1976 by the DHSS (Reference: HC(76)4) was the last one officially setting out the Department's policy. The number of Haemophilia Centres/Associate Centres in the U.K. had increased since 1976 and difficulties arose with the designation of some Centres/Associate Centres where only two or three patients were treated per year. The Haemophilia Reference Centre Directors had discussed this matter and Dr. Peter Jones and Dr. Peter Kernoff were looking into ways in which the DHSS document on the functions of Centres might be revised. This would be discussed by the Reference Centre Directors at their next meeting. It was hoped that some recommendations would be made to the Department of Health regarding the revision of the document. Dr. Preston asked whether junior doctors working at Haemophilia Centres were able to gain much experience in the day-to-day treatment of haemophilic patients. With the increase of home therapy and many of the treatments at Haemophilia Centres being given by nursing staff, the junior medical staff at Haemophilia Centres

were getting very little experience of the routine treatment of haemophilic patients. Mr. Prothero of the Haemophilia Society said that the Society were getting reports from its members that out-of-hours treatment at some Haemophilia Centres was not as good now as it had been previously because the staff on call at Haemophilia Centres did not have the experience to know how to cope with straight forward bleeds. The Society felt that with the wider spread of the patients throughout hospitals in the U.K., the experience of the staff at the hospitals would lessen and the quality of the treatment received by the patients would diminish. The Society was very concerned at this apparent backward step in the treatment of patients at hospitals. There was some discussion about the question of the facilities and services available at Associate Centres/Haemophilia Centres and the number of patients attending the Centres which was necessary for a Centre to be able to provide a full service for haemophiliacs. It was generally agreed that the Directors would not like to see an increase of small Associate Centres with few patients. It was thought very important that a fully functional Haemophilia Centre should have the involvement of other professional staff in the care of the patients, including nursing staff, physiotherapists, social workers and other medical and paramedical staff. Professor Bloom invited the Directors to write to Dr. Jones if they had any additional comments or suggestions to make regarding the designation of Haemophilia Centres/Associate Centres.

b) <u>The Haemophilia Nurses Association</u>

Sister Maureen Fearns from Newcastle was invited to

46/416

speak to the Directors about the foundation of the Haemophilia Nurses Association. The Association had been established early in 1981 although since 1975, drug companies had financed annual meetings for nurses involved in haemophilia work. Nurses felt that they would like a formal Association to be formed and asked the Haemophilia Reference Centre Directors if they approved of this. The Reference Centre Directors had given their approval to the formation of the Haemophilia Nurses Association and nurses throughout the U.K. who were involved in work with haemophiliacs had been contacted. Sister Fearns discussed plans for the future which included meetings, newsletters and training programmes. The nurses hoped that they would be permitted to send a representative to the annual meeting of Haemophilia Centre Directors to report on the activities during the previous year. Professor Bloom said that the formation of the Haemophilia Nurses Association was an important development and it was agreed that a representative from the Association should come to the annual meetings of Haemophilia Centre Directors to give a report.

c) The Special Interest Group of Social Workers

Mrs. Riva Miller from the Royal Free Hospital said that the British Association of Social Workers and the Haemophilia Society were setting up a Special Interest Group in Haemophilia and Related Disorders. The first meeting of the Special Interest Group was held in Birmingham in 1979 and several more symposia were planned. The Special Interest Group would work on multi-disciplinary involvement at their meetings and membership of the Group would not be restricted to qualified social workers. The Group was planning to publish regular

46/417

newsletters, to hold a symposium once or twice a year and to give support to new appointees to the staff of Haemophilia Centres. The Group hoped that it might be possible for them to send a representative to future meetings of the Haemophilia Centre Directors. It was agreed that a representative of the Special Interest Group should come to future meetings of the Directors.

d) Pre-natal Diagnosis of Haemophilia

Dr. Mibashan raised the question of pre-natal diagnosis of haemophilia and the administrative costs and funding. He had had referrals of 180 patients to his Centre over the last two-and-a-half years, there were no funds available to cover the cost of running this service apart from grants from King's College Research Trust and the Haemophilia Society. These grants were coming to an end and the King's College Research Trust would not be able to continue their support as they now regarded the work as routine. The DHSS had been asked for funds to cover the cost of a clerical assistant and an MLSO. It was agreed that Professor Bloom would write to the DHSS supporting Dr. Mibashan's application for funding.

e) Haemophilia Society

Mr. Prothero introduced Mr. David Watters, the Haemophilia Society's new Co-ordinator. He hoped that with the appointment of the Co-ordinator the Society would be able to provide a better service to its members. The Society welcomed the setting up of the Haemophilia Nurses Association and the B.A.S.W./Haemophilia Society Special Interest Group in Haemophilia and Related Haemostatic Disorders. The Society were appointing Sister Turk, formerly of the Treloar Haemophilia

46/418

Centre, as their Assistant Co-ordinator (Services). Her appointment would be for two years and would be funded by four pharmaceutical companies. Sister Turk would work very closely with the Society's branches and also hoped to liaise with the Haemophilia Centres.

8. Factor VIII Quality Control Study

Dr. Savidge reported that it had not been possible for him to attend the first meeting of Dr. Poller's group which was held after his appointment as a member of the group. He hoped that it would be possible for him to attend future meetings. It was agreed that Dr. Savidge should continue to represent the Haemophilia Centre Directors on Dr. Poller's group and that Dr. Savidge would report back to the Haemophilia Centre Directors at their next meeting.

9. Reports from Working Party Chairmen

a) Hepatitis

Dr. Craske presented the report which he had pre-circulated to all Haemophilia Centre Directors. The report summarised the findings of the three-year retrospective study which had just been completed. A full written report was in preparation for publication. Following the completion of the study, Dr. Craske had several recommendations to make to the Haemophilia Centre Directors.

i. He recommended that the surveillance should continue as now.

ii. Subclinical hepatitis: A multicentre prospective study of hepatitis in first time treated/seldom treated patients was planned. It was hoped that the study would be supported by a grant from the Medical Research Council. This group of patients seem to be running a higher risk of contracting Non-A/

46/419

Non-B hepatitis whatever type of material was used for their treatment.

iii. Dr. Craske felt that it was important for the Working Party to continue to collect data on the batch numbers of materials received by patients who developed hepatitis. He thought that it might be necessary in the future to again ask for details of all patients who had received treatment with a particular "suspect" batch of concentrate.

iv. Post-Mortem Specimens: Dr. Craske said that he would be most interested to receive samples of liver from patients who came to autopsy, especially where there was evidence of chronic liver disease.

v. Chronic Hepatitis: Dr. Craske hoped the Directors would continue to report cases of chronic hepatitis to the Working Party on the appropriate form.

vi. Merck, Sharpe and Dohme had approached Dr. Craske to ask if the U.K. Haemophilia Centre Directors would be interested in an immunogenicity study of hepatitis B vaccine. He was looking into the possibilities of a trial of the vaccine and would contact the Directors again at a later date.

vii. Hepatitis-Free Factor IX concentrates: There had been claims from commercial firms that a factor IX concentrate was now available which was free of hepatitis. Dr. Craske thought that this may well be true but there were problems in proving the safety of each batch of concentrate made as only a limited number of laboratory animals were available for testing the materials.

Some discussion followed Dr. Craske's report and several questions were raised. Some Directors were unhappy about the

46/420

suggestion that the National Health Service concentrates might have two viruses and the U.S. commercial concentrates only one virus. The grouping of the commercial materials used by Dr. Craske in his analysis was questioned and it suggested that information regarding the fractionation methods used by the commercial firms was available. The method for fractionating Hemofil was quite different from that used by the other commercial firms. It was suggested that Dr. Craske might get the information regarding the fractionation methods from the Department of Health as all the firms had to provide information on their fractionation methods when applying for licensing of their products for use in the U.K. Dr. Walford of the DHSS said that the information on the fractionation methods held by the licensing department was strictly confidential and could not be revealed.

b) Home Treatment

Dr. Jones said that the membership of the Home Treatment Working Party was the same as in previous years. The Working Party had undertaken a study of prophylaxis in collaboration with the Treloar Haemophilia Centre at Alton. In addition a collaborative study at Alton and Newcastle was carried out to investigate the claim of Armour Pharmaceutical that their high purity factor VIII had a prolonged in vivo ½-life. 12 patients, 5 at Newcastle and 7 at Alton were studied. The high purity factor VIII had been compared with Hemofil and the claim of the Armour Pharmaceutical Company had not been substantiated. A report on this study was currently being prepared for publication in the medical press. Regarding the Survey of prophylaxis at U.K. Haemophilia Centres, only three Centres

46/421

had more than 10 patients on prophylaxis during 1980. Dr. Jones did not think that it was necessary for him to continue to ask for data on prophylaxis from all Haemophilia Centres in the U.K. He felt that sufficient data would be available from the Centres which had patients on prophylaxis. It was agreed that the Home Therapy Working Party would no longer request information from all Haemophilia Centres regarding prophylaxis.

Regarding home therapy Dr. Jones said that there were a few questions arising from the report on the 1980 annual returns presented by Dr. Rizza and Miss Spooner:-

i. Why some mildly affected haemophiliacs were receiving home therapy?

ii. Whether all patients who should be on home therapy were now receiving home therapy?

Dr. Jones was considering the best method for obtaining the answer to these questions. The usage of factor VIII in Newcastle had dropped in 1980 compared with 1979. Dr. Jones thought that this was because all patients who should be on home therapy from Newcastle were now receiving home therapy and all patients who should be receiving regular prophylaxis were now receiving prophylaxis.

c) Treatment of patients who have Factor VIII Antibodies

Dr. Prentice presented a document outlining the Working Party's plans for a trial of materials used to treat patients with factor VIII antibodies, and also a graph summarising the data from the 1977-1980 Annual Returns which showed an increase in the amount of factor VIII concentrates used to treat patients with factor VIII antibodies and a

46/422

decrease in the usage of FEIBA and other similar products. Dr. Prentice sought the Director's comments on the proposed trial, which he hoped would start early in 1982. There was some discussion as to whether the Porcine factor VIII concentrate should be included in the trial. Dr. Prentice said that this had been considered but it would be too difficult to include three types of materials in the initial study. The Working Party felt that it was probably necessary to take the trial in several stages comparing different materials in different stages. The inclusion of Autoplex as the material to be studied in the trial was also questioned as this was a very expensive material. Dr. Prentice said that several papers had already been published regarding the use of FEIBA and it was felt that little would be gained by using FEIBA in the U.K. study. Moreover, Travenol would be providing Autoplex free for the patients in the study. The use of a placebo rather than factor VIII concentrate as the alternative treatment to Autoplex had been considered but it was thought that insufficient patients would be included in the study if a placebo was used. Dr. Prentice said that the patients included in the trial would be those who had five units of antibody or more at the start of the study. After further discussion it was agreed that the Working Party should go ahead with the study as soon as possible.

d) Factor VIII Assay

Dr. Rizza said that the aims of the Working Party were to try to improve factor VIII assays and to standardise methods. A short report had been published in Clinical and Laboratory Haematology (Ref: Clin. Lab. Haematol. 3,186-189 (1981))

46/42

giving the findings of the Working Parties survey of factor VIII assay methods in the U.K. The Working Party was also involved in the calibration of the International Reference Plasma for Factor $VIII_c$, Factor $VIII_{Cag}$ and the Ristocetin Co-factor. There was some concern about the discrepancy between the labelled content of certain batches of factor VIII and batches found by users assay. The Working Party were planning to make a study of the problem. Dr. Barrowcliffe then gave a report on the International reference plasma which had just been calibrated.

e) Von Willebrand's Disease

Dr. Tuddenham presented the Directors with a written report from the Working Party including recommendations for the setting up of a Central Register of von Willebrand's disease patients. It was suggested that the Register should be held in Oxford and Miss Spooner was looking into the practicalities of this. There was some discussion regarding the report and it was agreed that the Directors would send in data so that a register of von Willebrand's disease patients could be set up. Forms would be sent to all Directors at the same time as the request for the 1981 Annual Returns data.

10. Pre-natal diagnosis

Dr. Mibashan presented data on the women referred to King's College Hospital for pre-natal diagnosis since 1979. In 1979 40 patients had been referred, in 1980 70 patients and Jan-Aug. 1981 66, making a total of 176 referrals over the two-and-a-half year period. 44% of the referrals were from overseas. 31 pregnancies had been terminated, 29 for foetuses with coagulation defects and 2 for foetuses with other defects.

46/424

49 patients had decided to continue their pregnancies. Dr. Mibashan outlined the requirements for the referral of patients for pre-natal diagnosis.

There followed some discussion regarding the work on pre-natal diagnosis at King's College Hospital and it was agreed that this work was of the utmost importance and that all Haemophilia Centre Directors should support it.

Professor Bloom thanked Dr. Tuddenham for organising the meeting, which finished at 5.00 p.m.

46/425