Minutes of the Twenty-Second Meeting of UK Haemophilia Centre Directors, held in Sheffield on Friday 21st September, 1990.

Present

Dr. C.R. Rizza (Retiring Chairman)

Dr. Elizabeth E. Mayne (Chairman)

Dr. M.I. Adelman
Dr. S. Al-Ismail
Dr. A. Aronstam
Dr. B. Attock
Mr. G. Barker
Dr. O.H.A. Baugh
Dr. D. Bevan
Dr. A.J. Black
Dr. T.E. Blecher
Prof. A.L. Bloom
Dr. L.R. Bond
Mrs. B. Buzzard
Dr. C. Carter
Dr. M. Chisholm
Dr. K.G.A. Clark
Dr. B.T. Colvin
Dr. A. Copplestone
Dr. J. Craske
Dr. R.G. Dalton
Dr. H.M. Daly
Dr. A.A. Dawson
Dr. S.I. Dempsey
Dr. H. Dodsworth
Dr. G. Dolan
Mr. M. Doyle
Mrs. M. Elliott
Dr. D.I.K. Evans
Dr. S.A Fairham
Mrs. M. Fearns
Dr. E.A. French
Dr. B.E. Gilliver
Dr. D.I. Goff
Ms. D. Hallatt
Dr. I.M. Hann
Dr. J. Harrison
Dr. C.R.M. Hay
Dr. J.P.L.A. Hayes
Dr. J. Heptonstall
Dr. F.G.H. Hill
Dr. R.M. Ibbotson
Dr. P. Jones
Dr. M.W. Kenny
Dr. P.B.A. Kernoff
Dr. H. Kershaw
Dr. H.E.T. Korn
Dr. Anne Kyle
Dr. R.S. Lane
Mrs. P. Latimer
Dr. C. Lee
Dr. R. Lee
Dr. J.S. Lilleyman
Dr. C.A. Ludlam
Dr. M. Makris
Prof. P.N. Mannucci
Dr. S. Mayne
Dr. P.J.F. McHugh
Dr. B.A McVerry
Mr. K. Milne
Dr. D.A Mitchell
Dr. V.E. Mitchell
Dr. D.A. Montgomery
Dr. M. Morgan
Dr. D.G. Oscier
Dr. L.A. Parapia
Dr. A.M. Patel
Dr. I. Peake
Prof. F.E. Preston
Dr. C.D.L. Reid
Dr. A. Reyman
Dr. H.R. Roberts
Dr. G.F. Savidge
Dr. G.L. Scott
Dr. M.J. Semple
Dr. J.A. Shirley
Miss R.J.D. Spooner
Dr. R. Stewart
Dr. M.J. Strevens
Dr. D.M. Swirskey
Rev. A.J. Tanner
Dr. C.G. Taylor
Dr. R.S. Tedder
Prof. I. Temperley
Dr. D. Thomas
Dr. J. Thomas
Dr. E. Thompson
Prof. A.R. Thomson
Dr. D.R. Triger
Dr. R.T. Wensley
Dr. D.N. Whitmore
Dr. J.B.M. Winter

1. Apologies

Dr. T. Baglin, Cambridge
Dr. L. Ball, Liverpool
Dr. A.S.J. Baughan, Ashford
Dr. J. Berhens, Carshalton
Dr. R.P. Britt, Hillingdon
Prof. J. Cash, SNBTS
Dr. J.E. Chandler, Middlesbrough
Dr. P.M. Chipping, Stoke-on-Trent
Dr. E.R. Craven, Kettering
Dr. B.E. Gibson, Glasgow
Dr. P.A. Gover, Eastbourne
Dr. H.H. Gunson, B.T.S. Manchester
Dr. J. Leslie, Norwich
Dr. G.D.O. Lowe, Glasgow R.I.
Dr. R.F. MacDonald, SHSCLO
Dr. A.L.C. Miller, Chertsey
Dr. D. Moir, Milton Keynes
Dr. P. Mortimer, CPHL
Dr. B. Murphy, Torquay
Dr. H.F. Parry, Salisbury
Dr. J.R.Y. Ross, Northampton
Dr. C.N. Simpson, Ipswich
Dr. I.G. Simpson, MDDUS
Dr. T.G. Taylor, Inverness
Dr. C.J. Tew, Stevenage
Dr. E. Watts, Grays
Dr. H.J. Williams, Maidstone

The Chairman welcomed everyone to the meeting, especially Mr. K. Milne and Mr. G. Barker representing the Haemophilia Society, Dr. A. Rejman from the Department of Health, Dr. R.S. Lane and Dr. D.P. Thomas from Bio Products Laboartory (BPL), Miss Diane Hallett and Mr. Mike Doyle of Oxley and Coward (Solicitors), Mrs Maureen Fearns representing the Haemophilia Nurses Association, Mrs. B. Buzzard representing the Haemophilia Chartered Physiotherapists Association and Mrs. P.A. Latimer representing the British Association of Social Workers/Haemophilia Society Special Interest Group.

2. Minutes of the last meeting

The Minutes were approved and signed.

3. Matters Arising from the Minutes

a) Election of new Chairman

Dr. Rizza welcomed Dr. Elizabeth Mayne who had been elected to succeed him as the new Chairman. Dr. Rizza said he had enjoyed his 3 years as Chairman and thanked the Directors for their help.

Dr. Mayne thanked the Directors for the honour of her election and Dr. Peter Jones for his kindness and support since her election. She also thanked Dr. Rizza for his expert guidance, not only for the last 3 years but for his work since 1968. Dr. Mayne would send by post to Directors details of her telephone number, Fax numbers etc. With regard to formal mode of address she would like to be addressed as either "Chairman" or as "Madam Chairman".

b) "Recommendations on Choice of Therapeutic Products for treatment of non-inhibitor patients with Haemophilia A, Haemophilia B, or von Willebrand's disease."

Dr. Kernoff said that the 3rd Edition of the document had been distributed about 1 month ago. Because of the rapid changes in the field it now seemed necessary to revise the document annually. Dr.

Kernoff commented on the difficulties encountered in trying to write such a document given the widely held views, equally with regard to the place of high purity concentrates in treatment. Internationally no agreement had been reached but pressure was growing to use high purity concentrate and Dr. Kernoff referred to the paper presented by Prof. Mannucci at the Scientific Meeting held the previous day. No recommendations were available yet regarding HP Factor IX but this situation might change over the next year. The method for licensing of products had been discussed and was not thought to be very satisfactory.Dr. Mayne thanked Dr. Kernoff for his hard work in preparing the document.

Prof. Bloom pointed out that in 1979-85, when he was Chairman, all the Haemophilia Centre Directors and the Haemophilia Society were pushing the Department of Health to purchase imported products; everyone knew the result of that.

The UK was now self-sufficient but Directors were under some pressure to use products like Monoclate, Hemofil M etc. He also alluded to Prof. Mannucci's talk at the Scientific Meeting and pointed out that Italy did not have the UK's BTS and BPL System for manufacturing concentrates and as a consequence the options in Italy were different. He felt that it was up to BPL to produce new high technology products. He was concerned that there would be a repeat of the past situation, with pressure to use American concentrates and possible litigation implications again. He was not convinced that there were good reasons to use imported concentrates rather than British products.

Dr. Savidge said he supported the policy of using High Purity products. British products were obviously very safe and very good. The question was whether enough plasma would be available in the future to meet needs. EEC recommended the use of volunteer donors.

Dr. Jones raised the problem over tenders to produce Factor VIII concentrate. The Northern Region was opting for commercial concentrates due to their lower price and they were fully licensed; he thought this was something BPL needed to consider. Dr. Jones was concerned about the development of inhibitors in children, PUPs etc receiving high purity concentrates and suggested that more information was needed.

Dr. Hill suggested that there was a need for collaborative studies to be set up to get information to guide standards of care in the long term; no-one wanted to re-live the last few years.

Prof. Bloom said it was important to consider treatment of HIV+ patients; time was limited for them. He was concerned about hidden dangers with the American concentrates. One needed to consider the risks of paid volunteer donors.

8. Haemophilia Medical Audit

Dr. Mayne circulated a document which had been prepared by Dr. Gordon

Lowe outlining a system for Clinical Audit which was proposed for Centres in Northern Ireland and Scotland. The annual audit would involve 3 days work. There would be random selection of 5 patients and the Director would be sent a questionnaire. Two Directors would get together to discuss results and review the situation. It was thought that the system would work in Northern Ireland and Scotland. Dr. Mayne suggested that a similar scheme be set up for England and Wales. Dr. Mayne also suggested that an extra meeting be held of the Regional Haemophilia Centre Directors Committee and that all Haemophilia Centre Directors should let Dr. Mayne or their Regional Haemophilia Centre Director have their comments within the next six weeks.

ACTION: ALL

Discussion followed.

Laboratory control was discussed briefly.

The question of comparison of costs between Centres was raised. The costs at some Centres were high and they provided good service. Other Centres had low costs and gave poor service. It was feared that Administration would like to keep the costs low.

Dr. Shirley asked how small Treatment Units would be audited; they could not provide the same facilities as larger Centres.

Prof. Preston asked if platelet and thrombotic disorders would be included. Dr. Mayne replied that the audit would concentrate on haemophilia.

Dr. Jones said that his Lawyer had said he should not participate in an Audit until the HIV Litigation was settled.Dr. Savidge pointed out that the Department of Health was sitting on the re-organisation document regarding haemophilia and other coagulation disorders.

Dr. Bevan suggested that the proposal was for an unwieldly audit which would be complex and involve a vast amount of work.
Dr. Duncan Thomas (BPL) said he thought it would be much better for the Haemophilia Centre Directors to do an Audit themselves than for someone else to insist it was done. It was inevitable that it would need to be done.

4. Report on Meetings of Regional Haemophilia Centre Directors' Committee

Dr. Rizza said that there had been two meetings of the Committee. The items discussed were the same as those involved in the Agenda for the AGM.

5. Report on 1989 Annual Returns

Dr. Rizza said that there was no written report available at present as several Centres, including some Regional Centres, had not yet sent in their returns. He urged Directors to send in the late returns as soon as possible so that a report could be prepared and circulated before the end of the year.

6. Progress report on 8Y/9A Study

Dr. Rizza presented a written report (Appendix A). Five more patients had been included in the Study. More than 20 patients fitting the protocol criteria had been entered. There had been no adverse events reported. Dr. Rizza thanked the Directors for all their hard work, especially those who had entered children into the Study.

Dr. Kernoff said that the protocol had not required testing for factor VIII antibodies but in view of the interest in incidence of factor VIII antibodies with other products he felt it was important to find out if 8Y was associated with a high incidence of antibodies in first time recipients. He asked partcipants to try to get entry and exit inhibitor checks for all patients in the Study. Dr. Kernoff suggested all the tests should be done at a Central Laboratory.

7. Report on Bio Products Laboratory Plans

Dr. Lane thanked the Directors for inviting him to their AGM and said he hoped the privilege would not disappear with the disappearance of Crown Indemnity. Licence applications had been submitted for 8Y over a year ago. In 1992 all licences would be under review in Brussels. 8Y would probably be licensed by the end of the fiscal year. 100M Units of Factor VIII would be produced by the end of the year. Dr. Lane showed tables giving figures for production and issue throughout 1990. Critical steps were the introduction of the new 8Y presentation in 500u as well as 250u vials and the new packaging. Dr. Lane also gave details of the new Factor IX product in 10m vials. He would like Directors to evaluate the products. For some time BPL had been considering revising their production method for 8Y. They would be making monoclonal Factor VIII next year using Baxter Laboratories technology. An extended Study of the new products would be necessary and Directors would be asked to collaborate with the study and evaluate the product over a 1-2 year period. Dr. Lane thought sufficient plasma would be available to make both high purity and intermidiate purity (8Y) products. The yield of HP was likely to improve. Discussion followed. Dr. Colvin queried the advisability of BPL making 2 products, perhaps differently priced. He suggested it would be better to have 1 good product. Dr. Lane replied that BPL could switch to high purity material but this would depend on the Directors experience in using the product.

Dr. Savidge said he thought Directors were happy with 8Y and queried whether they wanted a new product.

Dr. Lane replied that BPL was driven by market forces and needed to stand up to competition. Dr. Lane then gave technical details of the production methods. Prof. Bloom said he was very happy to hear what Dr. Lane had said.

Dr. Lane said that bureauocratical procedure in Newcastle had resulted in BPL losing the contract to supply products. BPL had an agreement with the Blood Transfusion Service to purchase plasma at a set price. A price list for products was published by BPL and

Regional contracts negotiated. As a consequence BPL could not be flexible with regard to price and adjust to customers' requirements when tied to BTS charges. BPL would from now on deal directly with Haemophilia Centre Directors, not via BTS, and would negotiate prices with Haemophilia Centre Directors. Dr. Mayne said this was welcomed news from Dr. Lane and thanked him for his report.

9. Report from AIDS Group

Dr. Mayne said that in future the Group would incorporate Hepatitis.

a) Update of Seroprevalence Study

Dr. Rizza said that the Group planned to send Directors soon a printout showing the HIV status of their patients (without names) as reported to Oxford along with (under separate cover) a list of patients names to enable Directors to identify the patients and check that the HIV status records were correct and up-to-date. Updated information regarding the sexual partners' HIV status would be also be requested.

b) Progression of AIDS/ARC in UK Haemophiliacs

Dr. Rizza presented 2 tables (Appendix E). Prof. Bloom asked if information was available regarding patients on AZT. Dr. Rizza said some information was available but was probably incomplete.

c) Surveillence of Paediatric HIV infection.

Dr. Rizza thanked Directors for their help with the Study. Several forms had already been returned to Oxford. A report would be given at the 1991 AGM. Dr. Hill said he was concerned that there might be duplication of paediatric data as the information was being requested from 3 sources.

d) Lymphoma

Dr. Ludlam referred to his letter dated 6th September and attached form (Appendix B). He said that he had had 5 patients with lymphoma, 2 of them HIV-. He had circulated forms 2 years' ago to HCDs asking for information and so far had received information about 21 patients, 4 HIV- and 17 HIV+. It would be useful to have information when patients were being considered for treatment. Any cases which had occurred over the last 10 years or more would be helpful. Dr. Ludlam asked if he could have access to the information Directors send to Oxford regarding patients who develop lymphoma. This was agreed.

e) Litigation

It was requested and agreed that this item should not be minuted.

10. Date and Place of 1991 and 1992 Meetings

The 1991 AGM would be held in OXFORD on Monday 7th October.

The 1992 AGM would be a 2-day meeting and would be held in NORWICH in September (18th & 19th)

11. Any other business

No items were raised.

12. Reports from Working Party Chairmen

a) von Willebrand's Disease

Dr. Savidge said there had been no meetings of the Working Party and he had nothing to report.

b) Inherited Platelet Disorders

Prof. Preston said that he had sent a questionnaire to 16 major Centres enquiring about methods used to diagnose platelet disorders. 12 of the Centres had replied. The main conclusion was that all 12 Centres looked at platelet aggregation and bleeding time. Only 6/12 assessed platelet secretion, therefore only 50% of the Centres could accurately diagnose important platelet disorders. Prof. Preston queried whether Haemophilia Centres should deal with only haemophilia or also with other coagulation defects, including platelet disorders. During the discussion which followed it was queried whether there was the need for platelet diagnosis to be done everywhere or just at a few specialist hospitals. It was pointed out that many Centres had staffing problems.

c) Chronic Liver Disease

Prof. Preston presented a report (Appendix C) from the Working Pary. Results of the questionnaire sent to all UK Haemophilia Centres were given in the report. Replies had been received from 74 Centres. The Working Party recommended surveillance and screening of patients for HCV and felt it important for all Haemophilia Centre Directors to establish a professional relationship with a specialist in liver disease.

A short time of discussion followed Prof. Preston's report. In reply to a question, Prof. Preston said the Working Party had not yet decided if information regarding Hepatitis C should be included in the Directors Annual Returns to Oxford. A prospective non-biopsy study of Interferon was proposed. The protocol for the Study was available from Prof. Preston. Both HIV+ and HIV- patients would be included.

d) Reorganisation of Haemophilia Care

Dr. Savidge reminded Directors that the up-dated document on reorganisation had been ratified at the 1989 AGM and sent to the Department of Health. Regarding England and Wales the DOH now take the view that things have moved on so rapidly with the new Health Bill that it was not now desirable to issue the new document on reorganisation. The White Paper and other considerations needed to be

taken into account. More data was needed from Centres and the document would need to be re-written. Dr. Rejman referred to Dr. Pickle's statement at the last meeting of the Regional Haemophilia Centre Directors Committee that it was not an appropriate time to issue the document. Litigation was one of the reasons for holding back at the moment. The Department will not issue the present document.

Dr. Savidge said the Working Party on Reorganisation of Haemophilia Care had now become the Constitution Working Party. There was pressure to product a document "so we know what we are and what we can do in terms of patient care". Dr. Mayne thought it was most important. She suggested that there should be wide ranging discussions, but that the final document shoould be written by only three members.

Prof. Bloom was concerned that the White Paper would decentralise haemophilia care to the cheapest hospitals and this should be resisted.

e) Adverse Events (AEWP)

Dr. Kernoff presented his written report (Appendix D(i)). There had been good response to the orange cards. Details of the events reported were given in the report. There was clearly a thrombotic risk with Factor IX.

In May 1990 BPL had recalled some batches of Factor VIII and Factor IX for possible transmission of Hepatitis B. Dr. Michael Catchpole and Dr. Julia Heptonstall of the PHLS CDSC's Hepatitis Surveillance Section had been asked by AEWP to investigate the problem and a report on their findings had been circulated to Directors (Appendix D (ii)). Dr. Kernoff invited Dr. Julia Heptonstall of CDSC to present the report. Dr. Heptonstall summarised the details given in the report and said that she would recommend that if a similar event occurred again the Chairman of the Haemophilia Centre Directors' Organisation, the Chairman of the AEWP and all Directors should be informed before the press were informed. 15/18 Centres had replied to the AEWP questionnaire. Dr. Heptonstall was surprised at the difficulties some Directors had in answering the questions concerning the Hepatitis B immune status of their patients.

Dr. Mayne thanked Dr. Heptonstall for coming to the meeting and presenting the report.

During a time for discussion more details of the thrombotic episodes were requested and provided by Dr. Wensley. Therapeutic recommendations were also requested but Dr. Kernoff said this was a matter of personal opinion and he did not think AEWP was in a position to make recommendations at present. Treatment regimes were then discussed briefly.

13) Finance

Dr. Mayne said that she felt that all the Haemophilia Centres should

make a contribution towards the costs of their Secretariat in Oxford. Miss Spooner would try to estimate the costs incurred by sending out correspondence, reports, forms etc. to Centres during the previous year. Dr. Mayne suggested that £20 p.a. per Centre would be a reasonable sum to help meet the bills. Dr. Mayne's proposal was discussed. Dr. Evans said he would be happy to pay £20 but would insist that accounts were kept. Dr. Kernoff felt that Directors should pay the subscription from their own funds and not ask their Health Authorities for money as it was best for the Directors to keep their independence. Prof. Bloom agreed with Dr. Kernoff.

14) Haemophilia Society

Mr. Milne said he was grateful for the opportunity to attend the meeting. Rev. Tanner sent his apologies as he was unable to attend; Mr. Barker was attending the meeting in Mr. Tanner's place. There had been expansion in the Society over the last year and Charities Effectiveness Review Trust (C.E.R.T.) had been invited to inspect and advise the Headquarters staff. Mr. Barker had recently been appointed with a remit to look into the effect of changes in the Health Service. The Compensation Campaign was progressing, with the notable success last Autumn of the payment of £20,000 per person. The Society hoped for an out-of-court settlement of claims. A successful weekend had been held for wives and partners of HIV+ haemophiliacs and another weekend would be held in the Spring. A Dr. Barnados social worker was to be attached to the Society soon to work with HIV-affected children in S.E. Thames. The Society had tried along with others to get the U.S. Government to change visa regulations for HIV positive people entering the U.S.A.. The Society's efforts had been only partially successful and as a result no representative of the Society had attended the Washington meeting of WFH. There had been expansion of the range of publications from the Society, notably the "Safer Sex" book. The Society wished to thank Dr. Rizza for his help while Chairman of the Haemophilia Centre Directors' Organisation.

15. Macfarlane Trust Report

Dr. Jones gave a short verbal report on behalf of the Trust. He reminded Directors that it was a Charitable Trust and read out the purposes of the Trust. There were now 1211 HIV+ haemophiliacs and to date the Trust had helped 90% of them. Only 7 claims for £20,000 remained outstanding. Anybody with Factor VIII or IX deficiency, including people with Acquired Haemophilia, who were HIV+ can claim financial help from the Trust.

16. Haemophilia Nurses' Association (HNA)

Sister Maureen Fearns gave a short verbal report on behalf of the HNA. The HNA had 117 nurses registered as members, including nurses working on wards. A new list of members had recently been circulated. The HNA wanted to produce educational tools for the new generation of patients. A video had been produced in association with HSIG, also a booklet which would be available via the Haemophilia Society. The HNA was now working closely with the RCN and attending discussions on important issues.

17. Haemophilia Society/BASW Special Interest Group

Mrs Latimer gave a short verbal report on behalf of HSIG. HSIG had continued to work on Social issues. They were involved in the Haemophilia Society's Women's Weekend and planned further group work. HSIG was working with the HNA regarding child abuse etc. There had been a significant increase in the number of social workers appointed at Centres and Mrs Latimer emphasised the role of social workers in HIV work.

18. Haemophilia Chartered Physiotherapists' Association (HCPA)

Mrs Buzzard thanked the Directors for inviting the HCPA to attend the meeting. The HCPA had been formed in June and were drawing up a constitution. HCPA recommended all Centres to ask for a physiotherapist to work with their patients. The first meeting of HCPA was held in June and 20 people attended. The first project would be to produce two books on exercises for haemophiliacs, in association with the Haemophilia Society. Mrs. Buzzard was thanked by Dr. Mayne for the report and HCPA was wished well.

19. Closure of Meeting

a) Any Other Business

(i) Dr. Cohen asked if the treatment of Thrombophilia could be considered as a sub-section of the HCD's organisation. Prof. Preston suggested that this proposal be discussed in detail at the next meeting and this was agreed.

(ii) Prof. Bloom referred to telephone calls from the press. He thought that Directors should be very careful about commercial sponsorship and subtle advertising to patients which could have undersirable effect.

b) Dr. Mayne thanked Prof. Preston, Dr. Lilleyman and all their staff for organising the meeting.

The meeting closed at 3.30 pm.