Minutes of the Eighteenth Meeting of the UK Regional Haemophilia Centre Directors' Committee held at the Lansdowne Club, London on Monday 30th January, 1995.

PRESENT: **Chairman: Dr. B.T. Colvin**

Dr. A. Aronstam
Dr. P. Bolton-Maggs
Dr. P.L.F. Giangrande
Dr. K.K. Hampton
Dr. C.R.M. Hay
Dr. F.G.H. Hill
Dr. P.M. Jones
Dr. J. Leslie
Prof. G.D.O. Lowe
Dr. C.A. Ludlam
Dr. B.A. McVerry
Prof. F.E. Preston
Dr. A. Rejman
Dr. G. Savidge
Miss R.J.D. Spooner
Dr. R.F. Stevens
Prof. I. Temperley
Dr. Waller } MCA (for
Dr. Price } Item 11a)

1. **Apologies for Absence**

Dr. H. Dasani
Dr. I.M. Hann
Dr. C.A. Lee (represented by Dr. J. Pasi)
Dr. E.E. Mayne
Prof. I. Peake
Dr. S.M. Wood - for Item 11a (represented by Dr. Waller and Dr. Price)

The Chairman welcomed those present to the meeting, especially Dr. Hampton, who was attending the meeting for the first time as the representative from Cardiff.

2. **Minutes of the Meeting of 15th September 1994**

The Minutes were approved.

3. **Minutes of the AGM on 30th September 1994**

The Minutes were noted.

4. **Matters arising from the Minutes**

Professor Preston requested further discussion on the issue of authorship in studies organised by manufacturers. **It was agreed** that this subject should be discussed at the next RCD meeting as a separate Agenda item. No other matters were raised.

5. Chairman's Business

a) Hepatitis C Litigation

Dr. Colvin said that a small amount of litigation was pending and he had sent out a memorandum about co-ordinating actions on behalf of the defendants. It had been suggested by Dr. Peter Jones that Wilkinson Maughan should co-ordinate the defence and Dr. Savidge asked who would pay for this work, UKHCDO or the Health Trusts. Dr. Colvin replied that Directors must go through their Trust solicitors and that UKHCDO would not be instructing solicitors directly. Dr. Colvin also said that Deas Mallen Souter were co-ordinating the preparation of some of the plaintiffs' cases and that Keith Park might also be encouraging some HIV+patients to sue, despite the terms of the ex gratia payments already made. What Dr. Jones had already done had been very helpful and Dr. Colvin said that he would be willing to meet solicitors to discuss the subject, if requested to do so.

b) Change of Constitution

The Chairman said that he had written to the Charity Commissioners and only an acknowledgement dated 11th October had been received. Dr. Savidge was concerned about the way in which the Constitution document had been drawn up. After discussion **it was agreed** that Dr. Hay would check the papers regarding the formulation of the Constitution.

c) Proposal to set up a "user group" to advise the National Blood Authority

The Chairman said that he had attended a meeting at the Royal College of Pathologists on the recent proposals of the NBA to rationalise the Blood Transfusion Service. The outcome was that a "user group" for the NBA had been proposed and Dr. Colvin had requested that UKHCDO should be represented. Professor Temperley who was involved with the Irish Blood Transfusion Service thought that this might create a difficult position for the Directors as representatives would have to abide by the decisions of the NBA. Dr. Colvin said that he thought that the proposed "user group" was different to the Irish Group and would act as a regulatory body. Dr. Rejman said that no one apart from Dr. Colvin had written to the NBA since the meeting at the Royal College of Pathologists. Professor Preston suggested that UKHCDO should write to the National Blood Authority nominating a member for the "user group". Dr. Savidge suggested that Dr. Colvin should find out the Terms of Reference for the NBA "user group". What would happen if, for example, a commercial company wanted a "user group" for their products? Dr. Rejman confirmed that the NBA was part of the NHS and said that it was proposed that any views received would be looked at by three or four "Wise Men" who would consider what action should be taken by the NBA.

d) Haemophilia Symposium at the BSH meeting in April 1995

The Chairman said that he had been invited by BSH to put forward plans for their meeting in April 1995. He had suggested that three papers should be

given on the subjects of Prophylaxis for Children, Inhibitors and Immune Tolerance and von Willebrand's disease.

e) **HIV/AIDS Funding**

The Chairman said that Professor Preston had reported that one purchaser might doubt the value of high purity material for the treatment of HIV+patients. He had replied saying that there was no change in UKHCDO policy regarding the use of high purity material.

f) **Meeting with Dr. Rejman and colleagues from the Department of Health (DOH)**

The Chairman tabled a written report on this meeting, which was discussed briefly. Dr. Savidge queried who would be expected to pay for interferon. Regarding Factor VIII/IX concentrates Dr. Colvin had given an approximate cost of prophylactic treatment for all patients less than ten years of age based on the 1993 statistics from Oxford. At the conclusion of the discussion Dr. Colvin said that he felt that the meeting had not achieved any commitment by DOH to the funding of haemophilia care but had proved a platform for a useful exchange of views. He had suggested that further meetings should take place, perhaps on an annual basis. Dr. Rejman said that DOH representatives thought that the meeting had been useful. The Department wanted patients to be treated properly but not at great expense when effective but less expensive treatment could be provided. With reference to hepatitis, Dr. Rejman said that DOH thought that UKHCDO guidelines from the Hepatitis Working Party would be helpful. Professor Preston tabled the final draft document on the hepatitis guidelines and Dr. Rejman asked if he could have a copy to pass to DOH. **This was agreed.** Dr. Hill asked Dr. Rejman if Directors should aim at State of the Art treatment for their patients or less than that. Dr. Rejman said that if Directors wished to change from standard treatments they needed to justify this with their purchasers. Professor Lowe said that presumably DOH accepted the UKHCDO guidelines on the treatment of patients. Dr. Rejman said that the last guidelines document had not been shown to DOH before it was issued. Therefore the Department had not approved the guidelines and they were not approved of by many purchasers. There were criticisms from the Department on the technical legal aspects of the document, not on clinical grounds. Professor Preston asked if DOH would wish to see and comment on all future guidelines before they were issued and if so would there be a quick turn round of the documents? Dr. Rejman said that the Department would like to see drafts of guidelines which would then be reviewed by a Haemophilia Centre Director not on the Regional Centre Directors' Committee and by others. A scientific opinion would be sought and it was likely that it would take three months or so to give an opinion. Dr. Colvin suggested that this matter should be discussed further under **Item 7** on the Agenda. Dr. Jones thought that Dr. Rejman's comments were very useful. Dr. Rejman said that publication would not be prevented by sending the draft to DOH.

g) **Other Matters**

i) The Chairman said that Professor Roger Hardisty had written to him to ask if he could have copies of all the minutes of UKHCDO meetings, including minutes of the meetings on the subject of AIDS to pass on to solicitors he was advising on HIV litigation in the Irish Republic. The Chairman asked if the committee would agree to the documents being released to the solicitors for this purpose. Dr. Rejman said that Eire was a foreign country and he therefore wondered whether UKHCDO was obliged legally or morally to provide this information. Dr. Colvin wondered whether UKHCDO was prepared to pay for legal advice about this. Dr. Rejman thought that with the HIV litigation UKHCDO minutes were kept confidential by the lawyers and were not released in court. Dr. Hill asked what the status of the Eire centres was. Professor Temperley said that he attended meetings as the Eire DOH representative, not as a member of UKHCDO. Dr. Colvin suggested that he should write to Mr. Bradbeer of Wilkinson Maughan for legal advice. **This was agreed.**

ii) Dr. Colvin said that Dr. Jones had reported that the NHS Executive was offering money for central audit funding. After discussion **it was agreed** that Dr. Jones should fill in the application form before the deadline in three weeks time.

6. Haemophilia Centre Designation

a) **Audit Reports, Designation of Comprehensive Care Centres (CCCs) and the List of Haemophilia Centres**

The Chairman said that he had appointed Auditors for three Centres Cambridge (Dr. Ludlam and Dr. Hill), Leicester (Dr. Lee and Dr. Hay), Nottingham (Dr. Colvin and Dr. Giangrande). **It was agreed** that Cambridge and Nottingham should be recommended for CCC status and it was noted that the appointment of a Haemophilia Nurse Specialist had been approved at Cambridge, partly as a result of the Audit. The Leicester audit would be performed in the near future and the report was awaited. Dr. Colvin had drawn up the list of Haemophilia Centres which would be made available to The Haemophilia Society. Dr. Colvin asked for agreement of the Committee for action to be taken by himself and the other UKHCDO Officers when the Leicester report arrived. Dr. Savidge asked whether the "Three Wise Men" would be involved in approving the designation of new CCCs. Dr. Colvin said that if a Centre was rejected as a CCC then it would be sensible to offer the possibility of an appeal to the "Three Wise Men". Dr. Rejman asked if the Haemophilia Society had been asked for their opinion and the Chairman said they had not been involved in decision making.

b) **Audit and Accreditation**

The Chairman said that it might be possible to audit centres not recommended as CCCs. A number of Centres were mentioned but he particularly suggested

that St. George's and Southampton should be audited during the next year to help them with their work. Dr. Ludlam suggested that an audit should be offered to St. George's only as they had about thirty severely affected patients. After further discussion **it was agreed** that only St. George's Hospital would be audited in the near future but without any commitment to an offer of CCC status. Dr. Hay reminded the Committee that CCC status would be reviewed in any event in three years time.

c) **Declaration of Interests**

Dr. Colvin said that he had received a letter from Dr. Mayne regarding a previous meeting with solicitors about the wording of the Constitution. The declaration of interests was a requirement of the Charity Commissioners so that the Chairman of UKHCDO would know at meetings if there was any conflict of interests if and when votes were taken. Dr. Colvin had received replies from about 75% of the Directors. One Director had asked for further information about the purpose of the declaration. Dr. Jones thought a reason for the declaration of interests was also to clarify the situation when guidelines of UKHCDO were published.

7. Use of Recombinant Factor VIII

Dr. Colvin quoted letters from Dr. Mayne regarding a meeting of the Scottish / Northern Ireland Directors. He suggested that Dr. Mayne, Dr. Lee and either Dr. Ludlam or Professor Lowe should prepare a paper for the next meeting of the Regional Committee on this matter. Dr. Savidge suggested a questionnaire to Regional Centre Directors asking them for information and Dr. Hill suggested that Dr. Paula Bolton-Maggs should be on the Committee. After discussion **it was agreed** that Dr. Lee, Dr. Mayne and Dr. Bolton-Maggs should design a questionnaire for circulation to Committee members. Dr. Bolton-Maggs should be the convenor.

8. Consent for Treatment

Dr. Colvin asked whether UKHCDO should recommend that written consent be obtained when a first dose of treatment was given to a patient or when there was a change in the type of treatment given. Dr. Pasi said that the Royal Free required consent before the first treatment with concentrates. Dr. Rejman said that BCSH had considered the question of consent to Blood Transfusion, but that no agreement had been reached although DOH was in favour of consent being obtained. Dr. Colvin asked if the Regional Centre Directors agreed to require written consent for first treatment and invited Dr. Pasi to adapt the Royal Free's consent document for UKHCDO use. After a brief discussion Dr. Colvin also asked Dr. Pasi to put together a patient information sheet to go with the consent form. Dr. Ludlam suggested that there should be a guidelines sheet for the doctor who was planning to treat the patient and Dr. Giangrande asked if the NHS Trusts should be involved in the drawing up of these documents. Dr. Colvin said that the Trusts should be involved when the document was ready for distribution to each of the Centres.

9. Treasurer's Report

a) Dr. Hay tabled details of the accounts which were approved. The AGM in Oxford had made £9,387.14p profit for UKHCDO. Dr. Colvin thanked Dr. Giangrande for making the arrangements for the AGM which had been a great success thanks to his efforts.

b) **Liability for Taxation**

Dr. Hay said that Professor Machin had raised the question of whether commercial firms putting up stands at AGM's were asked to pay fees. He had consulted his accountants about this matter and read out their reply regarding income tax and VAT. It appeared that there were no implications for UKHCDO at present. Dr. Colvin asked whether the setting up of stands should be free but that voluntary donations should be requested by UKHCDO.

10. Annual Returns

A document prepared by Dr. Giangrande and Miss Spooner was tabled and presented. Discussion was invited after which the Chairman asked that Regional Centre Directors should send any suggestions regarding the future of the data collection to Dr. Giangrande for consideration. Dr. Jones asked if the new system was acceptable within the restrictions set by the Data Protection Act and Dr. Giangrande said that it was.

11. Working Party Reports

a) **Acute Adverse Events**

The Chairman welcomed the MCA representatives to the meeting. He said that he had attended a meeting last year with Dr. Wood at the MCA about adverse events in haemophilia treatment and that Dr. Wood had asked if she or one of her staff could come to the next Regional Directors Meeting. Dr. Giangrande tabled and presented a report on the Adverse Events which had occurred between July and September 1994. Professor Preston said that he was very worried about Factor XI concentrate therapy and he referred to a meeting which had been held with BPL regarding the concentrate. Reports had been received of problems with other brands of Factor XI concentrate and he thought that further work on this subject was required. He asked if UKHCDO could draw up new guidelines regarding the use of Factor XI concentrate. Dr. Hay said that he had had a problem recently which had not yet been reported to Dr. Giangrande. Dr. Pasi said that there was another case at the Royal Free of an adverse event to Factor XI and suggested that there should be an urgent discussion with BPL. A study had been planned by BPL involving Manchester and the Royal Free of which Dr. Hay gave details. Dr. Colvin asked if the UKHCDO guidelines on the use of Factor XI should be changed in the light of the new reports. Dr. Hay suggested that the concentrate should only be used for patients with very low factor XI levels (who were likely to be homozygotes or double heterozygotes). Dr. Jones suggested that a cautionary note be sent to all Haemophilia Centre Directors to say that fresh frozen plasma should be used

for patients wherever possible. The Chairman summed up the discussion by saying:-

i) All additional reports of Adverse Events with Factor XI concentrate should be sent to Dr. Giangrande as soon as possible.

ii) BPL should be kept informed.

iii) The Haemophilia Centre Directors should be told about the problem and be referred to the guidelines.

Dr. Waller was invited to comment on behalf of the MCA and he outlined the remit of the MCA and the type of information collected from doctors and pharmaceutical companies. There had been a decline in the number of yellow cards received. The MCA thought that it would be very valuable to make a close link with UKHCDO and Dr. Colvin asked how UKHCDO might help. Dr. Waller suggested that perhaps UKHCDO should treat the orange Adverse Events report cards like yellow cards but pointed out that the MCA was only interested in serious reactions. Dr. Giangrande said that he would be happy to give the MCA a copy of reports of serious adverse events after investigation. Dr. Giangrande said that he was concerned about passing on named patient data to the MCA and Dr. Hill suggested that the Directors would need to be told that serious adverse events would be reported to the MCA. Dr. Giangrande said that he was worried that if the informal reporting in confidence to him was changed then the reports might not come in at all. Dr. Colvin suggested that the orange cards should be amended and that the MCA should liaise with Dr. Giangrande about the events in which they were interested. **This was agreed.**

b) **Chronic Liver Disease**

Professor Preston tabled a report on the hepatitis questionnaire and a copy of draft guidelines which were almost in their final form. Professor Preston stressed the great importance of collaboration with hepatologists. Dr. Hill asked for clarification regarding the age at which interferon could be used and Dr. Jones asked about the issue of liver biopsy. Professor Preston said that he would be nervous about everybody doing liver biopsies on their patients. Dr. Jones said that his Centre was doing them routinely and that they had had significant side effects in some patients treated with interferon. Dr. Giangrande said that he was unhappy about ultrasound being performed at four-monthly intervals and wondered if this was really necessary. Dr. Hay asked about the value of genotyping and who would pay for it to be done. Dr. Hill said that the Paediatric Working Party needed a copy of the guidelines from the Chronic Liver Disease Working Party. Dr. Ludlam suggested collecting data on the treatment of hepatitis patients and Professor Preston said that he planned to discuss this with Dr. Giangrande and Miss Spooner.

c) **Genetics**

A letter from Professor Peake to Dr. Colvin regarding the setting up of a National Database was tabled.

d) **Paediatrics**

Dr. Hill said that a meeting of the Working Party would be held soon.

e) **von Willebrand's Disease**

Dr. Colvin said that a meeting of the Working Party had been held the previous day and he outlined the content of a note he had received from Dr. Mayne. In particular it was noted that a guidelines document was in the final stages of preparation.

f) **HIV**

In Dr. Lee's absence minutes of the last meeting of the Working Party were tabled along with a copy of the guidelines for the treating of HIV infection which had already been circulated to all Haemophilia Centre Directors.

g) **Inhibitors**

Dr. Colvin said that a paper on the Incidence of Inhibitors in the UK 1990-93 had been accepted for publication by the British Journal of Haematology. The Working Party was due to meet again in the near future.

12. **1995 AGM**

Dr. Giangrande suggested that the date of the meeting be changed as it clashed with a meeting to be held in the Channel Islands. Dr. Hay said he would investigate the possibility of changing the date.

13. **1996 AGM**

It was agreed that the 1996 AGM would be held in London at the Royal Free Hospital and that the Scientific Meeting would be incorporated into the BSH meeting in Birmingham when Professor Preston would be President. **It was agreed** that a Scientific Meeting would also be held in 1997 at the same time as the AGM and that this meeting would take place in Cardiff. Dr. Hampton kindly agreed to organise the 1997 meeting.

14. **Date of Next Meeting of Regional Directors' Committee**

Monday 5th June, 1995 at the Lansdowne Club.

15. **Any Other Business**

None.

The meeting closed at 4.00 p.m

23.03.95