Minutes of the Tenth Meeting of the UK Haemophilia Centre Directors' Organisation Executive Committee held at the Lansdowne Club, London on Friday 20th March 1998.

PRESENT: **Chairman: Dr. Christopher A. Ludlam**

Dr. M. Chisholm
Dr. P. Collins
Dr. B.T. Colvin
Miss C. Corrigan (rep. Dr. M. McGovern)
Dr. K. Forman (rep. Dr. G. Dolan)
Dr. E. Gascoigne (BPL)
Dr. P.L.F. Giangrande
Dr. F.G.H. Hill
Dr. P.M. Jones
Prof. C.A. Lee
Dr. V. Martlew (rep. Dr. C.H. Toh)
Dr. E.E. Mayne
Dr. B. Perry (SNBTS)
Dr. M. Smith (rep. Prof. G.F. Savidge)
Miss R.J.D. Spooner
Dr. R.F. Stevens
Dr. M. Winter

1. **Apologies for Absence**

Dr. T. Baglin
Dr. S.V. Davies
Dr. G. Dolan
Dr. I.M. Hann
Dr. V.E. Mitchell
Dr. M. McGovern
Dr. B.A. McVerry
Dr. J. Pasi
Prof. G.F. Savidge
Dr. O. Smith
Dr. C.H. Toh
Dr. J.T. Wilde

Dr. Ludlam welcomed Dr Perry, Dr Gascoigne and Miss Corrigan to the meeting. They had been invited particularly to take part in the discussion on nvCJD and recombinant factor VIII..

2. **Minutes of the meeting held on 6th February 1998**

Dr. Colvin's name was added to the list of those present. The Minutes were then approved.

3. Matters arising from the Minutes

a) Factor XI Guidelines

The Guidelines had been revised by Professor Lee and Dr. Bolton-Maggs. Dr. Ludlam asked that the Executive Committee members should let Professor Lee know, within two weeks, if they had any comments on the revised Guidelines otherwise they would be circulated to all Haemophilia Centres.

b) Recombinant Factor VIII

The views of the Directors of Public Health for Scotland and Wales on rVIII had been circulated to Committee Members.

c) Letter for publication in the Lancet in reply to the letter from Tony Baxter and Colleagues

Professor Lee said that she did not think that the reply to Baxter et al's letter should come from the three Officers of UKHCDO, but would prefer that the letter came from the Chairman only on behalf of UKHCDO. Dr. Colvin asked if there was a policy where the Chairman had taken Chairman's action. He thought that perhaps there should be three signatures in some circumstances particularly when there was not time to consult the Executive Committe. As the draft reply letter had been circulated previously to the Executive Committee for comments and these had been included it was appropriate for the Chairman to sign on behalf of the organisation. After further discussion **it was agreed** that the letter should be submitted for publication with a single author, the Chairman.

d) The reply from BASW in relation to social work support had been circulated to the Committee. **It was agreed** that this should be discussed at the next Executive Committee Meeting. Dr. Jones said that social workers were essential to Haemophilia Centres and suggested a survey about social work at Centres should be conducted. Dr. Ludlam asked Miss Corrigan to note the Executive Committee's concerns about the withdrawal of Social Workers from Haemophilia Centres. Dr. Jones said that it was mainly the local authorities who were withdrawing the funding. The special HIV-related money was becoming less available. After further discussion **it was agreed** that Dr Jones would conduct a small survey of social work support at Centres and a paper be put together for discussion at the next meeting.

4. Meeting at the Department of Health on 27th February 1998

Dr. Ludlam said that the Officers of UKHCDO had had a constructive meeting with Dr. McGovern, Miss Corrigan, Dr. Hewlitt and Dr. Winyard. Minutes of the meeting had been drafted and were currently with Dr. McGovern; they would be circulated when available. The discussion was summarised by Dr. Ludlam. The topics discussed included:

i) *nvCJD risk assessment and leukodepletion issue*. The main report for the DOH risk assessment of leukodepletion to SEAC was expected in May.

ii) *Recombinant Factors VIII and IX*. Dr. Ludlam welcomed the press statement of the previous day indicating that rVIII would be available to new patients and children under 16 years attending Haemophilia Centres. They had discussed the inclusion also of HCV negative patients but no commitment was made by the DOH. The Department had indicated that central funding would be available for patients not previously in receipt of rVIII.

iii) *The White Paper and its impact on Haemophilia Services*. This was still under discussion at the Department of Health.

iv) *UKHCDO Guidelines.* The Department of Health indicated that it would not be approving guidelines but that they should be produced in keeping with the guidance offered by the NHS Executive Clinical Guidelines publication.

v) *Review of UKHCDO activities and in particular data collection.* This project was reviewed positively by the Department and would be taken forward by the IT Working Party in conjunction with Dr McGovern.

5. Treatment of Patients with Recombinant Factor VIII

The Department of Health circular HSC1998/033 describing the new arrangements for rVIII had been issued in the week prior to the Executive Committee. Dr. Ludlam said that it would have been useful for all Haemophilia Centre Directors to have been sent a copy as soon as the circular was issued. Miss Corrigan said that this had not been done because the Department of Health did not have a list of Haemophilia Centres. Dr. Jones said that patients were getting information before Directors. Miss Corrigan said that the Haemophilia Society had not been sent a copy of the circular by the Department of Health. Miss Corrigan tabled copies of the circular for the Committee. It was noted that additional funding for rVIII was for one year only. Professor Lee asked about situations where central funding was not given and NHS Trusts were paying for patients to be treated. Miss Corrigan said that this was the first time that she knew about this. She assumed that if Trusts were already paying for rVIII they had budgeted for this. Dr. Colvin said that Professor Doyal had suggested that eighteen not sixteen was the right ethical age for the cut-off. Miss Corrigan said that it would be very helpful for the Department of Health to have examples of the problems envisaged or encountered by Directors. Dr. Hill said that the ethics of providing services seemed to be a priority for purchasers. Dr. Ludlam suggested that Directors should write to Miss Corrigan pointing out their difficulties. He offered to circulate a memo to all Haemophilia Centre Directors asking them to write to Christine Corrigan. **This was agreed**.

Dr. Ludlam asked whether similar arrangements would be made for recombinant Factor IX. Miss Corrigan said this would be considered when rIX was available. Dr. Ludlam said that there was an apparent lack of medium term planning and this would create difficulties when rIX became available. Miss Corrigan said that she would convey this view to the Department.

As the Department had not given prior notice of the new arrangements for rVIII the manufacturers would not be able to supply all under 16 year olds immediately; it would probably take about six months. After discussion it was agreed to recommend the following order of priorities for implementation:

1. Maintenance of existing patients on rVIII.
2. PUPS
3. Children under 16 years should have a phased introduction starting with those under 5 years in April and May, under 10 in June and July and the remainder by the end of September. Children within one family should if possible receive it simultaneously.

It was agreed that Dr Ludlam would let the Haemophilia Society know of the above proposal and seek their support. A letter giving guidance to Haemophilia Directors would be drafted and distributed.

6. Availability of plasma derived factor VIII

Dr. Ludlam indicated that there was a review underway by the CSM of source for plasma for manufacture of various concentrates and other plasma products. Dr Gascoigne thought that the CSM would recommend a move to non-UK plasma, probably within the next financial year. If this happened BPL would need to be cleaned and then they would start using US plasma late in the summer. They were currently stock piling factor VIII to cover the demand while the plant was closed. Dr Perry indicated that SNBTS were committed to maintaining continuity of supplies of plasma derived products. They were co-operating with the CSM and a meeting was to be held on the 1st April. Dr. Mayne asked if new product licences would be needed if there was a change in the source of plasma, Dr Perry indicated that a licence variation only would be necessary. Professor Lee said that the patients would find the use of US plasma disturbing and would need a lot of reassurance about this. Dr. Gascoigne said that PFC and BPL were taking slightly different views. BPL would need to be convinced of the quality of screening not whether the donors were paid or not paid. Dr. Ludlam enquired whether Directors and patients views on source plasma would be taken into account. Professor Lee was concerned about the risk to patients of switching product and emphasised the possibility of inhibitors and that Directors needed more information from BPL. Dr. Gascoigne said that BPL would like Directors to give an estimate of their requirements. Dr. Ludlam emphasised that there was a need for medium and long-term planning but this was difficult because of the opacity of the Departments view on further funding for rVIII and rIX. Dr. Jones said that the World Federation of Haemophilia would like all plasma products kept not destroyed until a decision had been taken over risk.

Virally Inactivated Plasma

Dr. Ludlam reported that methylene blue plasma production in England and Wales would now not start in the near future but it would be available in Scotland in May. The MB FFP for Scotland would be available for England and Wales at cost and subject to availability.

A preference had been expressed for using virally inactivated fresh frozen plasma for the treatment of Factor V and Factor XI patients. Dr. Perry said that figures regarding the estimated usage of plasma for Factors V and XI deficiency would be helpful. Miss Spooner offered to obtain the information.

8. Risk Assessment for Leukodepletion

Miss Corrigan told the meeting that the report by the DOH risk assessment on leukodepletion would not be available until May.

9. nvCJD Surveillance

Dr. Ludlam tabled a brief summary, prepared by Dr Will of the CJD Surveillance Unit, on the clinical features of nvCJD. Any Director suspecting a case of nvCJD should contact Dr Will directly and liaise over further assessment of the patient. Dr Ludlam would hope that Directors with possible cases would also let him know. Dr Ludlam was awaiting a response from Dr Ironside, Neurohistopathologist, about some of the practical and ethical issues in relation to assessment of biopsy tissue from patients or at autopsy. No nvCJD cases were known in patients with Haemophilia.

10. Review of UKHCDO activities

Dr. Colvin as Chairman of the IT Working Party tabled a paper entitled "UKHCDO, Structure Function and Future". Anyone with further comments on the document was invited to contct Dr Colvin as soon as possible after the meeting. After discussion it was agreed that the paper had the support of the Executive Committee and that the questions posed were appropriate. It was also agreed that the paper might need to be modified in the light of further discussions particularly when the details of the review process were being considered. It was also agreed to accept Professor Doyal's offer to review the legal and ethical standing of the UKHCDO patient database. The fee of £2,000 for two days' work was considered reasonable and should be set against the £30,000 offered by the DOH for the review (subject to DOH approval).

11. Appointment of a Solicitor

At the previous meeting it had been proposed by Dr Mayne that UKHCDO should appoint a solicitor. Dr. Jones had written to Dr Ludlam suggesting Mr Ronald Bradbeer and no other suggestions had been received. Dr. Ludlam had informally asked Mr. Bradbeer if he would be able to help and he was enthusiastic to do so. His firm, Eversheds, now had a large health department and the expertise to enable them to advice UKHCDO. Dr. Mayne said that it was important that the differences in the laws in Northern Ireland and Scotland to be taken into account. After further discussion **it was agreed** that Dr. Ludlam should contact Mr. Bradbeer again to take forward the proposal.

12. Any Other Business

i) Dr. Ludlam said he had received an EU discussion document from Dr. McGovern regarding blood donor screening. He had responded making some minor suggestions. Any Director wishing a copy should contact Dr Ludlam.

ii) The World Federation of Haemophilia had published a paper on CJD and Dr. Ludlam drew the Committee's attention to it.

13. Date of Next Meeting

The meeting would take place at the Lansdowne Club on Friday 29th May as previously agreed.

The meeting closed at 1.45 p.m

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