

Minutes of the Nineteenth Meeting of the Uk Haemophilia Centre Directors'
held in Lecture Theatre 1, The Royal Free Hospital Medical School, London
on Friday, 25th September 1987

Present:

Dr. C.D. Forbes (Resigning Chairman)
 Dr. C.R. Rizza (Chairman)

Dr. M.I. Adelman	Dr. R.S. Mibashan
Dr. A. Aronstam	Dr. E. Miller
Dr. A.J. Black	Mrs R. Miller
Prof. A.L. Bloom	Mr. K. Milne
Dr. P. Bolton-Maggs	Dr. D. Mitchell
Dr. M.A. Boots	Dr. V.E. Mitchell
Dr. M. Chisholm	Dr. M. Morgan
Dr. K.G.A. Clark	Dr. P.J.F. McHugh
Dr. B.T. Colvin	Dr. D.G. Oscier
Dr. J. Craske	Dr. L.A. Parapia
Dr. E.R. Craven	Dr. Pavi
Dr. B. Cuthbertson	Dr. A. Paxton
Dr. H.M. Daly	Prof. F.E. Preston
Dr. I.W. Delamore	Dr. A. Rahemtulla
Dr. S.M. Donohue	Dr. C.D.L. Reid
Dr. J.A. Easton	Dr. J.D.M. Richards
Dr. D.I.K. Evans	Dr. C.L. Rist
Dr. E.A. French	Dr. C.R. Rizza
Prof. C.D. Forbes	Dr. G. Savidge
Dr. S. Ghosh	Dr. G.L. Scott
Dr. B. Gibson	Dr. M. Seaman
Dr. P.J. Green	Prof. N.K. Shinton
Prof. R. Hardisty	Dr. J.A. Shirley
Dr. C.R.M. Hay	Dr. A. Smithies
Dr. J.P.L.A. Hayes	Dr. M.J. Strevens
Dr. J. Kemp	Dr. C.G. Taylor
Dr. P.B.A. Kernoff	Prof. I. Temperley
Dr. P. Jones	Dr. E. Thompson
Dr. C.A. Lee	Sister C. Titley
Dr. R. Lee	Dr. I.D. Walker
Dr. G.D.O. Lowe	Mr D.G. Watters
Dr. C.A. Ludlam	Dr. D.N. Whitmore
Dr. S.J. Machin	Dr. M. Winter
Dr. E.E. Mayne	

Afternoon Session

Mrs M. Fletcher
 Dr. R.A. Hutton

Dr. I. Peake
 Dr. D. Thomas

1. Apologies

Dr. W.S.A. Allan
 Dr. S. Al-Ismael
 Dr. S. Ardeman
 Dr. B. Attock
 Dr. C.J.T. Bateman

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Dr. T.E. Blecher(Rep. Dr. E.A.French)
Dr. R.P. Britt
Dr. D. Burman
Dr. J. Cash(rep. Dr. S. Ghosh)
Sister M. Fearn(Rep. Sister C. Titley)
Dr. I.M. Franklin(Rep Dr. S.M. Donohue)
Dr. Greaves
Dr. H. Gunson
Dr. P. Hamilton
Dr. I.M. Hann(Rep. Prof. Hardisty)
Dr. A. Heppleston
Dr. D.T. Howes
Dr. J.M. Hows(Rep. Dr A. Rahemtulla)
Dr. R.M. Ibbotson
Prof. G.C. Jenkins(Rep Dr. B.T. Colvin)
Dr. M.W. Kenny
Dr. R.S. Lane
Dr. J. Leslie(Rep. Dr. A.J. Black)
Dr. J.S. Lilleyman
Mrs J. Lovie(Rep. Mrs R. Miller)
Dr. S. Mayne (Rep. Dr. D.C. Mitchell)
Dr. M. Mills
Dr. D.A.. Montgomery
Dr. B. Murphy
Dr. G.A. McDonald (Rep. Dr. I.D. Walker)
Dr. M.W. McEvoy
Dr. B.A. McVerry
Dr. H.F. Parry
Dr. R.W. Payne
Dr. R. Perry (Rep. Dr. B. Cuthbertson)
Dr. M.J. Philips(Rep. Dr. E. Thompson)
Dr. E.G. Rees
Dr. J.R.Y. Ross
Dr. A.H. Sawers
Dr. M.J. Semple
Dr. J.K. Smith (was representing Dr. Lane)
Miss R.J.D. Spooner
Dr. L.M. Swinburne
Dr. T.G. Taylor
Dr. D.S. Thompson
Dr. J.M. Trowell
Dr. R. Vaughan Jones
Dr. H.J.H. Williams
Dr. J.R.B. Williams
Dr. J.K. Wood

2. Minutes of the last Meeting

The minutes of the last meeting were approved and signed. There were no amendments.

3. Matters arising from the Minutes

No matters were raised additional to those covered by the Agenda.

4. Report on meetings of Haemophilia Reference Centre Directors

Prof. Forbes reported on some of the main issues which had been dealt with at meetings of the Reference Centre Directors (RCDs) over the previous year.

a) Reorganisation: Although a 'Regional' organization of haemophilia care had been agreed by Haemophilia Centre Directors (HCDs), there were several aspects of such a system which had still to be clarified before it could be implemented. These included whether 'Regional' Centres should be designated, and if so, by what mechanism; whether the Reference Centre Directors group should become a 'Regional' Centre Directors group, and how the members and officers of such a steering group should be nominated and elected. The Chairman stressed the importance of a strong and cohesive organization if it was to have any credibility as a policy-making and negotiating body. It had been felt that a fundamental weakness was the lack of a constitution, which spelt out the purposes, modes of operation and administrative structure of the organization. The Reorganization Working Party had therefore been asked to extend its activities to the development of such a constitution, which would need to be agreed before meaningful advances in reorganization could take place. The Chairman asked for input from all HCDs to be sent to Dr. G. Savidge, who would be Chairman of the Constitutional Working Party.

b) AIDS Research: The HCD organization, and in particular its Oxford Secretariat was uniquely well placed to contribute to research into AIDS. It was felt, however, that more could be accomplished at a National level by enlisting the help of expert epidemiological and statistical advice, which the Secretariat was already looking into.

c) Special Medical Card: A new 'Green Card' had been produced and sent by the DHSS to Reference Centres for distribution to Centres in their Supraregion.

5. Appointment of New Chairman

Dr. C.R. Rizza had been elected as the new Chairman of HCDs, and Professor Forbes congratulated him on behalf of all HCDs.

Prof. Forbes said that because there had been a feeling amongst RCDs that the electoral process should be more democratic, all HCDs had had a vote on this occasion, with votes being weighted according to number of patients treated in 1986 (as recorded in Oxford returns). The system had received the approval of the Electoral Reform Society, and would be applicable on future occasions. The question of the role of the Secretary had been considered by RCDs, without a firm conclusion being reached or an appointment being made. The possibility of appointing a Vice-Chairman who might be Chairman-Elect, had also been discussed. Both these matters had been referred to the Constitutional Working Party.

6. Report on the 1986 Annual Returns from Haemophilia Centres

Dr. Rizza said that he was unable to present a complete report because of delayed returns from several Centres, a computer failure, and Miss Spooner's recent illness. He hoped that all the data would have been received and analysed by the end of the year, and he anticipated that a report would be ready for circulation by early 1988.

He commented that there seemed to be a reduction in deaths due to haemorrhage, but an increase due to AIDS, which was now the leading cause of mortality.

7. Revision of Yellow Booklet listing Haemophilia Centres in the United Kingdom

Dr. Savidge provided hand-out sheets which summarised the activities and recommendations of the Reorganization Working Party. The principle recommendations were that the existing 3-tier system should be replaced by a 2-tier system in which Centres regularly treating 10 or more severely affected haemophiliacs (A and/or B) should be designated 'Haemophilia

Centres', whereas those treating less than 10 should be designated 'Haemophilia Treatment Units' within Haematology Departments. The term 'Reference Centre' would eventually be replaced by the term 'Regional Centre' when appropriate constitutional and administrative problems had been resolved.

Dr. Savidge drew attention to some of the factors, summarised on the hand-out sheets, which had led the working party to reach their conclusions. In particular, it had been noted that current standards of care were patchy, and that the Haemophilia Society was in favour of more centralised treatment; that a sizable proportion of Centres did not participate in NEQAS VIII:c or vWF:Ag exercises; and that any reorganisation should ideally be based on the recommendations of the World Federation of Haemophilia (WFH).

Wide ranging discussion followed. Dr. Machin suggested that 'persistent poor performance' in NEQAS should result in 'de-designation' as a Centre or Treatment Unit. Professor Preston disagreed - participation in NEQAS was voluntary and irrelevant to many aspects of treatment. Professor Shinton asked whether Centres within a Region would meet on a regular basis, and commented that whether there was a 'Reference' or 'Regional' Centre Directors Group, it was essential to have some kind of executive committee. Dr. Savidge agreed with the latter point, and said that intra-Regional organisation, and the designation of Regional Centres, was largely up to each Region. Dr. Colvin felt that the 'Regional' Centre might move from place to place, but this was generally thought to be impracticable. Dr. Kernoff asked why, if WFH recommendations were to be followed, the WFH category of 'Comprehensive Care Centres' (50 or more severely affected patients treated) had not been included, since this reasonably described the ranges of activities of several existing Reference Centres and large Haemophilia Centres. Dr. Savidge replied that the WFH

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structure had been largely designed for the USA, a point with which Dr. Kernoff disagreed. Dr. Savidge emphasised that while the Working Party recognised that several problems in the implementation of their proposals remained to be resolved, members had felt that a key initial step was to issue a new edition of the yellow book. Dr. Mayne agreed that for practical reasons alone, this was an important priority. Although Dr. Smithies felt that it would have been desirable to have prior resolution of reorganisation, including revision of HC(76)4, she agreed to take the proposals of the Working Party to the DHSS, with a view to producing a new edition of the yellow book. This would not indicate 'Reference' or 'Regional' Centres, but would differentiate between 'Centres' and 'Treatment Units'. Mr. Milne said that if there were problems in producing a new edition, the Haemophilia Society would be prepared to take on the task.

The Chairman thanked Dr. Savidge and members of the Working Party for their efforts in this most difficult area.

8. Reports from the AIDS Group

Issues considered by the RCD's AIDS Group over the last year have included product safety, transmission of HIV infection to female sexual partners, and compensation.

Dr. Rizza reported that the third National survey of anti-HIV amongst haemophiliacs was underway, but that only 50% of Centres had reported to date. Only 3 new patients had been reported as being seropositive in 1987, but it was unclear whether these were 'new' seroconversions. So far, the findings strongly supported the safety, as regards risk of HIV transmission, of currently available therapeutic products. Amongst 314 sexual partners of anti-HIV seropositive haemophiliacs who had been treated, 18 (5.7%) had been found to be positive. Dr. Craske commented that this compared with rates of up to 15%

found in the USA, where it had been reported that the risk of transmission was increased when the index patient had clinical disease. Dr. Jones reported 7 successful pregnancies in 6 seronegative wives of seropositive patients. It was noted that there can be transient seropositivity in the infants of seropositive mothers, and that there is a possibility of latent infections in seronegative infants. The situation remains under close review.

Dr. Rizza requested that Directors should submit information on their patients as soon as possible, so that a report could be prepared and distributed. Prof. Forbes said that he had received an offer from CDSC to publish the results of the survey in CDR.

Dr. Craske distributed information sheets on HIV-related disease amongst UK haemophiliacs, representing an update of the continuing survey. He commented that it was certain that there was under-reporting, and urged Directors to contribute this important information. The CDC definition of AIDS had recently been re-defined, and now included encephalopathy and wasting syndrome. He drew attention to the high mortality in patients aged over 40 years.

The Chairman announced that Dr. Delamore had offered to organise a further 1 day meeting on AIDS counselling in haemophilia, which will take place in Manchester on Friday 15th January, 1988.

9. Interim reported on 8Y and 9A

Dr. Smith was unable to be present for this item. However, a summary of the experience to date with these products ('Surveillance for evidence of NANBH transmission by BPL concentrates 8Y and 9A, dry heated 80° 72H') was distributed. The Chairman requested that any questions or comments should be directed to Drs. Smith and Lane.

10. Proposed clinical trial of NHS factor VIII and IX (8Y and 9A)

Dr. Kernoff said that the experience with 8Y and 9A clearly

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indicated that they were more safe than previously available NHS and commercial concentrates as regards HIV and hepatitis transmission. However, it was undeniable that the evidence on safety was somewhat 'soft' in scientific terms. 'Hard' evidence, comparable with that available for certain new commercial products, could only be obtained from a rigorously performed 'virgin patient' study, carried out in accordance with the protocol suggested by the ISTH.

For this reason, a new study was to be mounted of the 8Y product in patients who had never previously been exposed to any blood or blood products. Dr. Kernoff and Dr. Rizza would be the co-ordinators, with data collection at Oxford. A protocol had been agreed and would be distributed. The Treasury had agreed to indemnify participants on the same basis as is normally done by the pharmaceutical industry, and a clinical trial exemption certificate (CTX) had been applied for. Dr. Kernoff said it was important for participants to seek approval for the study from their local ethical committees. BPL had indicated their willingness to fund trial-related experiences.

There was some discussion concerning the difficulty, from an ethical point of view, of including children in this study. This was felt to be a matter for the individual investigator to decide. Prof. Hardisty pointed out that the normal range for transaminase levels is different in children. Thus, paediatric ranges would have to be specified.

The Chairman stressed the importance of this study, and suggested that pending the issue of a CTX, potential investigators might 'clear' the protocol with their local ethical committees. Any questions or comments should be addressed to Drs. Kernoff or Rizza.

11. National External Quality Assurance Scheme for Blood Coagulation

(NEQAS)

Prof. Preston reported on the most recent NEQAS study. Eighty-five

out of 109 Haemophilia Centres had participated in the study. Seventy-five carried out one stage VIII assays and 12 performed two stage assays. Sixty-one Centres took part in the vWFAg assay study. Attention was drawn to the fact that not all Haemophilia Centres had taken part in the study. Concern was expressed about the use of different standards in the NEQAS study and the effect this might have on the results.

12. Provisional date and place for next meeting of all Haemophilia Centre Directors

Dr. Hayne announced that the next meeting was to be held on Thursday and Friday 29th and 30th September, 1988 in Dublin. She and Prof. Temperley were collaborating on the organisation of the meeting and a preliminary programme would soon be sent out. The Business Meeting would be on the Thursday and a Scientific Meeting on the Friday.

13. A.O.B.

Dr. Jones reported that he was trying to organise a suitable Symposium on AIDS as part of the British Paediatric Association meeting in April, 1988.

Dr. Savidge drew attention to the fact that entry to the zidovudine (AZT) trial would close on 31st December, 1987. There were still some places on the trial. Anyone wishing to enter patients should contact him immediately.

Mr. Watters reported on the hardship to Society members caused by HIV infection. The Society is prepared to give financial help where necessary. He reported that the Society was involved in a campaign to obtain recompense for haemophiliacs infected with HIV. The campaign is to be launched on 13th December, 1987. A booklet presenting the case will be sent out by the Society to Haemophilia Centre Directors. This was to be embargoed until 13th October at 11.00 a.m., 26th October at which time the Society is to meet John Moore, Secretary of State for Health. Also, there

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was to be a Parliamentary meeting in the House of Commons on 5th November to discuss the matter. He said there was much lobbying to be done and encouraged Directors to contact their local MP's and Press.

Dr. Rahemtulla asked if there was any chance of funding for Haemophilia Centres which needed money for anti-HIV testing and other work relating to AIDS. During discussion it was made clear that the money given to the Reference Centres in England had been designated specifically for AIDS counselling. Dr. Smithies said she would relay the problem back to the DHSS.

Finally it was reported that Attendance Allowance will be payable to anybody suffering from AIDS.

AFTERNOON SESSION

14. Reports from Working Party Chairmen

a) Hepatitis

Dr. Craske distributed copies of the 'UK Haemophilia Hepatitis Working Party Report for 1986/87' and discussed its findings. He emphasised the importance of Hepatitis B immunisation for young people at risk, particularly now that genetically engineered vaccine was available.

Dr. Craske will be circulating notes on the usage of Hepatitis B vaccine but stresses that these notes represent his views only and DHSS recommendations will follow.

Clinical trials of Interferon in NANB hepatitis are in progress at Sheffield and the Royal Free Hospital.

b) Treatment of patients who have Factor VIII Antibodies

Dr. Kernoff discussed the 'Inhibitor Working Party Report': September 1984 - September 1987 which was distributed. He felt that largely because of AIDS related problems, progress in the inhibitor area has not been as rapid as he had hoped. However, it is important to maintain a National surveillance in order to assess the size of the

inhibitor problem.

Prof. Forbes thanked Dr. Kernoff for his three years work on the Working Party.

c) **von Willebrand's disease**

Dr. Savidge reported that he had not yet received the documentation of the von Willebrand's Disease Working Party from Dr. Tuddenham. He would report when and if this becomes available to him.

d) **Inherited Platelet Disorders**

Prof. Preston thanked all for their forms. In all there were 263 submissions of which eight patients had giant platelet syndrome. Prof. Preston and Dr. S. Machin are organising the writing of a document for the re-standardization of platelet function tests. This will be issued and distributed by the BSH.

e) **Data Collection**

Dr. Rizza reported that certain forms had been streamlined but that several important issues still needed to be addressed.

15. Report on behalf of the Haemophilia Nurses Association

Mrs. Christine Titley, the NHA representative, reported that an HNA Linkline booklet was available for nurses. HCDs should receive copies in the near future. Also, a teaching video entitled 'A little help from my friends' has been produced by the HNA and is available from the Haemophilia Society, price £15.00. This is particularly useful for teaching self-infusion to children.

The blood product reaction survey continues, details being obtainable from the HNA. The survey included DDAVP. So far, most reactions have been minor and associated with home treatment. As regards teaching first aid to deal with reactions, it continues to be important for nurses to discuss treatment methods with patients.

Dr. Jones asked whether nurses were receiving the support they

needed. Mrs. Titley felt a considered response from the HNA would be better than her own views, and said she would take this question to the AGM.

16. Report on behalf of the Haemophilia Society/BASW Special Interest Group

The new Chairman of the BASW SIG is Mrs. Frances Foy and Mrs. Riva Miller spoke on her behalf. She reported that two workshop days had been held: the first in February 1987, was for nurses and social workers and focussed on role conflicts between professional staff; in June 1987 a similar workshop was held for a wider group of staff, and gave particular consideration to sources of HIV-induced stress on staff. Lack of resources was found to be a dominant cause of stress.

Mrs. Miller drew HCDs attention to the major changes in rules for benefits which will take place in April 1988. Mrs. Lovie has made an in-depth assessment of the situation and should be contacted if further information is needed. It should also be noted that many different groups are involved in planning community services for HIV infected patients, and it is important for the interests of haemophiliacs to be represented.

Finally, Mrs. Miller drew attention to the problems in obtaining establishment and funding for social workers in Haemophilia Centres, and the lack of understanding in local authorities of the special problems of haemophiliacs. Dr. Kernoff mentioned that there were acute problems at the Royal Free, where the local authority, responsible for paying social workers (the London Borough of Camden) was, as a matter policy, withdrawing social workers from the hospitals. He warned other HCDs that similar moves would in all likelihood be made in other parts of the country.

17. Further Points

On behalf of all HCDs, Dr. Rizza thanked Prof. Forbes warmly for his two years of skilful Chairmanship and wished him good fortune in the future.

The meeting closed at 4.30 pm