

CENTRAL BLOOD LABORATORIES AUTHORITY

CENTRAL COMMITTEE FOR RESEARCH AND DEVELOPMENT IN BLOOD TRANSFUSION

Minutes of the second meeting of the Central Committee for Research and Development in Blood Transfusion held on 7th November, 1983, in the Board Room, The Crest.

PRESENT:- Dr. H.H. Gunson (Chairman)
Professor A.L. Bloom
Dr. I.A. Fraser
Dr. A.M. Holburn
Dr. R.S. Lane
Professor L. Luzzatto
Dr. D.B.L. McClelland
Dr. C. Rizza
Dr. R.S. Tedder
Dr. D.P. Thomas

IN ATTENDANCE:- Dr. A.E. Bell (SHHD)
Dr. P. Clark representing Dr. D. Walford (DHSS)

8/83 Apologies for Absence

Apologies for absence were received from Dr. K.I. Gibson (MRC) and Dr. G.A. Stewart.

9/83 Minutes

The minutes of the meeting held on 21st June 1983 were agreed as a correct record.

10/83 Matters Arising from the Minutes

10.1. U.K. Biotechnology Groups and Committees

A letter from Dr. K. Gibson, MRC (R&D 83/1) giving details including aspects of financial support of the various committees/groups in biotechnology in the U.K. was received and noted. With respect to fund raising, Dr. Lane commented that, although the British Technology Group (BTG) were generally associated, through the NEB and NRDC, with making funds available for biotechnology development in Industry, it may be possible to negotiate with them for funding of public bodies.

The general problem of funds available to the Committee for use in research or development of approved projects, including clinical trials of new products, was discussed at some length. The Chairman confirmed in reply to a question from Dr. Thomas, that the Committee could not be allocated funds by the CBLA and either the Authority would have to apply for funds in competition with other public organisations or individuals would have to submit applications for specific projects to bodies such as the MRC.

It was generally agreed that the situation was unsatisfactory and clarification was required with respect to the policy with regard to the availability of income from the sale of the R.I.A. test for HBsAg and the possible future sale of excess blood products.

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It was agreed that the CBLA should be asked to consider the question of raising funds as an urgent problem. Dr. Bell highlighted the fact that this should be regarded as a U.K. problem, since similar difficulties were encountered in Scotland.

10.2. Response of CBLA to recommendation on developments with respect to genetic engineering

A paper outlining the response of the CBLA to the Committee's recommendations with respect to genetic engineering (R&D 83/2) was received and noted.

With respect to the comment that no expertise was available at Porton Down in the field of Factor VIII and other blood products, Dr. Clarke commented that whilst this was true, the general facilities for fermentation were available and if the CAM-R establishment were to receive the appropriate clones it may be possible to carry out further developmental work.

The Committee appreciated that the detailed questions of methodology would have to be discussed and perhaps a start could be made by:

10.2.1. Discussions with Professor Brownlee of the University of Oxford regarding further developments on the Factor IX preparation he had produced. Dr. Rizza undertook to do this.

10.2.2. In accordance with the previous agreement of the CBLA that the Committee should keep in touch with the P.H.L.S. on this matter, Dr. Lane should enter into discussions with the Director of the CAM-R establishment to determine whether a viable collaborative programme could be effected. If this proved not to be possible other avenues would require exploration.

The committee noted that this country was lagging behind with commercial developments in genetic engineering applied to blood products in the U.S.A. It was also unfortunate that in the latter work, developments with respect to the production of Factor VIII may not be published in the scientific press. It was agreed that active consideration should be given to the furtherance of this line of research and consideration given, after the above consultations had been carried out, to the establishment of a post-doctoral fellowship.

83 Working Group on AIDS in relation to Blood Transfusion

11.1. Membership of the Working Group

A report outlining the membership of the Committee's Working Group on AIDS in relation to Blood Transfusion (R&D 83/3) was received and noted.

11.2. Report on first Meeting of the Working Group on AIDS (Minutes R&D 83/4 attached, Appendix I)

The Chairman confirmed that the MRC had established a Working Party on AIDS and that Professor Bloom had agreed to provide a link between the MRC and the CBLA's Working Group.

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The Chairman outlined the salient points of the minutes of the Working Group and the following points were raised:

- 11.2.1. It was noted that the DHSS had already taken action with respect to involving the Community Health Councils in AIDS and that note was taken of the need to consider modifications to the leaflet at its next printing.
- 11.2.2. The Committee welcomed the action taken with respect to the investigation of the use of surrogate tests and look forward to Dr. McClelland's report.
- 11.2.3. Dr. Thomas asked about the current practice at BPL with regard to the heat treatment of Factor VIII. Dr. Lane reported that a dry heat treated product was available at BPL and that he had approached the Haemophilia Directors on how they wished to proceed with its use. Professor Bloom commented that the product obtained from U.K. plasma was more acceptable for use in a trial than the imported products. The question of embarking upon a trial of the BPL material was discussed and the difficulties with respect to the limitations of available patients was noted. However, the fact that within a relatively short time the commercial companies may introduce such a product which, with its attendant publicity may place the Haemophilia Directors in a dilemma with respect to treatment of their patients, led the Committee to recommend to the CBLA that the BPL heat-treated Factor VIII should be subjected to clinical trials as soon as possible.

11.3. Report of Activities of MRC Working Party on AIDS

Professor Bloom confirmed that the MRC Working Party had held its first meeting on 10th October 1983 and he outlined its terms of reference, which were to review the scientific knowledge and research on AIDS in the U.K. and abroad, review research projects and to advise the MRC accordingly. He briefly commented on the discussions at the first meeting which included a review of the current situation, the opportunities and expertise available in the U.K. and the opportunities for communication, and the setting of standards for safety.

Professor Bloom said that he was the only person connected with blood on the MRC Committee, but it was noted from the CBLA meeting in September, 1983, that Dr. E.L. Harris DCMO, DHSS, had taken up with the MRC the possibility of having a representative from the Blood Transfusion Service on the Committee.

12/83 Trials Involving the use of Anti-CMV Immunoglobulin in Renal Transplantation

Dr. McClelland outlined the background to the trial which was taking place in Sheffield, Manchester, Liverpool and Exeter. In anecdotal cases observed during the past two years the administration of anti-CMV Ig to patients suffering from CMV infections appeared to be very helpful. From these observations the trial of 25 patients over 1½ to 2 years was conceived. All patients entering the trial would be suffering from CMV disease since it was not considered appropriate at present to use the intravenous Ig in a prophylactic manner. The trial will be blind and controls will receive a placebo, which is an albumin preparation but consideration was being given to the alternative use of normal Ig.

In response to a question raised by the Chairman it was noted that no special funding was required for the trial

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Albumin Trials

Dr. McClelland confirmed that albumin trials had been picked up in Scotland after the MRC Committee had ceased to operate in this respect. He referred to two current trials using Plasma and PPF with 50 patients in each group and said that results would be in evidence in approximately two years' time.

Dr. Lane commented that the question of support fluids for the treatment of patients with burns were also being discussed with the Burns Unit at Billericay and various albumin and balanced crystalloid solutions were being evaluated.

14/83 Update on the Transmission of Non-A, Non-B Hepatitis by Intravenous Immunoglobulin

Dr. Lane outlined the reasons behind his letter to the Lancet about the intravenous immunoglobulin clinical trial which had revealed the short incubation period for hepatitis A and B virus. He felt that all preparations of immunoglobulin which had not been previously validated should be tested for their viral safety and, similarly, modifications in the manufacture of intramuscular or intravenous immunoglobulin should be introduced only after appropriate testing.

It was noted that none of the results of the clinical trial had cast any doubt on the standard intramuscular preparations which had been prepared by the established cold ethanol methods for many years.

15/83 Any Other Business

Following a question raised by Dr. Thomas, the status and function of the Committee were discussed. It was noted that the Committee had wide terms of reference and it was hoped that it would be possible for it to make a significant contribution to research and development in this field.

16/83 Date and Time of Next Meeting

The next meeting would be held at Eistree on Tuesday, 28th February, 1984 at 11.30 a.m.

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