NQC/8/5 (E1)

EXTRACT FROM COUNCIL OF EUROPE DOC CDSP(82)22 STRASBOURG 25 JUNE 1982

11. Select Committee of Experts on automation and quality control in blood transfusion services (5th meeting)

/SP-HM (82) 20 and Add./

Professor E FREIESLEBEN (Denmark) presented the report of the Select Committee's 5th meeting. According to its terms of reference, giving high priority to quality control, the Select Committee had concentrated on this subject and discussed 24 reports submitted by its members. Automation and computerisation had to be postponed to the 6th meeting because of lack of time. The committee also discussed the results of exchanges of sera for exercises in red cell antibody detection and identification, in anti-HB_c testing, and in anti-D quantification. The red cell antibody exercise showed an improvement in antibody screening on Groupamatic using the trypsin-polybrene-citrate technique: it also showed the difficulties of the identification of a mixture of antibodies. Anti-HB_c testing showed little variation in results between the laboratories. Automated anti-D quantitation showed a much improved accordance of results in the participating laboratories as compared to the 1980-81 results.

Based upon the reports of the members and the discussions during the present and previous meetings, an editorial committee, consisting of four members (Professor E FREIESLEBEN (Chairman, Denmark), Dr. C HÖGMAN (Sweden), Prof. R BUTLER (Switzerland), Dr. W WAGSTAFF (United Kingdom)), drew up draft quality control guidelines for three chapters (selection of donors and apheresis donors, blood collection procedures, and blood components) out of the planned 10 chapters (see SP-HM (82) 20 addendum). Time did not permit the group to deal with the missing parts, which therefore have been assigned to the four members for home work to be completed autumn 1982 and circulated among members of the Select Committee. The committee will then finalise the guidelines at its next meeting.

The committee asked for approval of its plan of work, of the date and place of the 6th meeting (January 1983, Paris), and of a proposal concerning the appointment of a consultant to assist the Editorial Committee in harmonising and editing the Quality Control Guidelines before approval by the Committee of Experts on Blood Transfusion and Immunohaematology. Members of this latter committee were asked to give their comments on the already prepared draft guidelines, in particular the controversial problems in respect of blood donors with a history of malaria, syphilis or jaundice.

A lengthy discussion took place in which most members took part. A number of proposals for reconsideration or changes of minor details were put forward, and Prof. FREIESLEBEN promised to bring these to the attention of the Select Committee.

More generally, it was proposed that the recommendations should not be too strict and should be considered more as guidelines than as mandatory minimum requirements. Attention should be paid by the Select Committee to work previously done by the Committee of Experts on Blood Transfusion and Immunohaemotology.

The measures for the prevention of transfusion-associated hepatitis were discussed; further to a proposal by Prof. LUNDSGAARD-HANSEN (Switzerland) which was supported by Prof. BINGÖL (Turkey) and Prof. FREIESLEBEN, it was agreed that attention should be paid to geographical differences in the epidemiology of hepatitis, and preventive measures therefore determined on a national basis.

It was agreed that proposals and comments from members of the committee of experts in a written form could be sent to Prof. FREIESLEBEN (with copy to the Secretariat) before the end of June 1982; they would then be brought to the attention of the Editorial Group and the members of the Select Committee. Comments should deal with all items included in doc. SP-HM (82) 20 Addendum.

The committee then approved the report, the plan of work for the 6th meeting of the Select Committee, and also its date and place (Paris, 24-27 (or 28) January 1983). It also requested that a consultant be available to assist in harmonising the final proposed guidelines document.

14. Control of post-transfusion hepatitis

/SP-HM (82) 6/

Dr. H H GUNSON (United Kingdom) presented a report on the control of post-transfusion hepatitis. Routine testing for the presence of HBsAg commenced in the United Kingdom in 1972 initially by immuno-electro-osmosis but was superceded by reverse passive haemagglutination (RPH) in 1975. For several years, however, pools of plasma (approximately 5 litres) submitted for fractionation into coagulation products have been screened by radio-immune assay (RIA). During the past year, all blood donations have been tested by RIA or enzyme-linked assay techniques. Although such testing reduces the chances of post-transfusion hepatitis, particularly following the use of fractionated products prepared from large pools, the incidence is not eliminated and there is evidence to suggest the onset is delayed in patients receiving regular doses of Factor VIII.

With respect to the incidence of non-A, non-B hepatitis in the United Kingdom, there appears to be a low contamination rate in patients receiving cryoprecipitates but a high rate following transfusion of Factor VIII concentrates prepared from large pools. At present there is no move towards the routine testing of donations for increased levels of transaminases and clearly a specific test is urgently required. Avoiding the use of large-pool fractions for the treatment of patients with mild coagulation defects is a practical way of reducing the incidence of post-transfusion non-A, non-B hepatitis.

In the discussion which followed, it was generally agreed that the term transfusion-associated hepatitis, suggested by Dr B P L MOORE (ISBT), was more appropriate to describe this condition which varied in incidence considerably in the member countries.

Committee members reported that it was generally recognised that the frequency of transfusion associated hepatitis was higher when using commercial plasma (which may contain a multiplicity of causative agents.) In order to reduce the risk of such hepatitis, it was again recommended that national blood transfusion services should take steps to ensure that there was an adequate supply of plasma from voluntary, non-remunerated donors in order that national self-sufficiency could be achieved in the production of coagulation factor concentrates (see also Recommendation No. R (80) 5). In the event that importation of products is required, this should preferably be from countries known to have a low incidence of hepatitis. In any case, the committee reiterated the need for implementing Recommendation No. R (80) 14 of the Committee of Ministers with respect to the identification of the source of plasma.