NATIONAL DIRECTORATE OF THE NBTS

U.K. ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED DISEASES

Minutes of the seventh meeting of the above Committee held at the North Western Regional Health Authority on Monday 25th March 1991.

PRESENT: Dr. H.H. Gunson (In the Chair)

Professor J.D. Cash Dr. Marcela Contreras

Dr. J. Craske Dr. E.A. Follett Dr. R. Mitchell

Professor R.S. Tedder

Dr. W. Wagstaff

The Chairman welcomed Dr. Craske to the meeting

- 1. Apologies for absence Dr. P.P. Mortimer
- 2. The minutes of the sixth meeting held on Tuesday 8th January 1991 were approved.
- 3. Matters arising
 - Or. Contreras reported that at North London RTC there were approximately 300 donors per month returning from malarious areas. Approximately 20 were ELISA screen positive with 6 confirmed antibody positive. The comparable data for South London RTC were 150 donors per month, with 20-25 screen positive by immunofluorescence (the number of confirmed antibody positives was not known).
 - Dr. Contreras tabled a letter from Dr. Saad Abdālla to Dr. Mary Brennan at North London RTC in which he gave reasons for not including the taking of malaria prophylaxis in determining the policy for handling donations from persons returning from malarious areas (Appendix 1 to minutes). He also stated that he considered six months to be too short for such donors to resume normal donations.

After a detailed discussion it was decided that the flow chart produced at the last meeting did meet the requirements and it should stand. To implement this policy it was important that an "approved" malarial antibody test should be made available as soon as possible.

The Chairman reported that a suggestion had been made that the present Committee and the UK BTS/NIBSC Working Group on Microbiology were carrying out work which had a considerable degree of overlap. An approach had been made to Dr. Wagstaff, Chairman of the UK BTS/NIBSC Liaison Group to suggest that the UK Advisory Committee on Transfusion Transmitted Diseases should be expanded

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and take over from the Working Group. Dr. Napier had agreed to this suggestion. Dr. P. Minor and Dr. J. Barbara have been put forward to join the present Committee.

The constitution of the Committees and Working Groups would be discussed at an ad hoc meeting between the UK BTS and NIBSC representatives on 19th April 1991.

It was agreed that the UK Advisory Committee should have a Working Group to consider the practical aspects of microbiological testing at RTCs and the relevant confirmatory tests. Dr. Barbara should be invited to Chair this Group which will report to this Committee. The membership of the Group will be agreed when the UK BTS/NIBSC Committee structure is formalised, but Mr. A. Barr was nominated as a member.

4. INTRODUCTION OF ANTI-HCV TESTS INTO NBTS AND SNBTS

4.1 The starting date and its definition

- 4.11 The proposed starting date of 1st July presented difficulties since it was considered essential that the second generation test from both Orth and Abbott should be evaluated prior to the commencement of routine tests. Ortho tests were being evaluated by Dr. Barbara at North London RTC and he had, to-date, only received pre-production batches of the tests. It was known that there was procedural differences between the pre-production and production batches. These test kits should be available within 10 days to 2 weeks. The situation with Abbott was uncertain since they had not yet given an official date for launching their second generation test.
- 4.12 The preliminary results obtained by Dr. Barbara on the test kits from three manufacturers were reviewed and it was agreed that further testing at all three RTCs was essential. It was agreed that Newcastle RTC would provide samples from their donors in the study for Dr. Barbara and Glasgow RTC would do the same once Abbott had provided 2nd generation test kits since this would avoid thawing the samples more than once.
- 4.13 The Chairman was asked to contact Abbott and from the information he received recommend a starting date for the commencement of tests.

ACTION - Dr. Gunson

4.14 It was agreed that testing of blood and plasma donations would commence on a specified date. There would not be retrospective tests carried on donations collected prior to that date.

4.2 Confirmatory Testing

4.21 A letter from Dr. Mortimer was tabled. This was accompanied by a report of a meeting held on 12th February 1991 to consider confirmatory testing for anti-HCV and proposals for a request form to be used for this purpose (Appendix 2 to the minutes).

It was noted that five laboratories were proposed for primary referral for confirmation of serological tests, but during the first year, only University College and Middlesex School of Medicine (UCMSM), the Virus Reference Laboratory (PHLS Colindale) and Edinburgh could provide PCR for HCV RNA.

Since the confirmatory tests will be charged to the RTCs, the Chairman was asked to write to the Directors of the Confirmatory Centres and ask for the charges which will be made for RIBA and PCR as appropriate.

ACTION - Dr. Gunson

- 4.22 The question of RTCs performing RIBA and/or PCR tests was discussed. The view of the Committee was that they should be advised against this. It was considered that the expertise to perform these tests, particularly the PCR, was difficult to obtain.
- 4.23 The five categories for reporting the results of confirmatory tests were approved and conformed to the proposals made at the last meeting.
- 4.24 RTCs would be consulted about the request form as requested by Dr. Mortimer.

4.3 Plasma for Fractionation

- 4.31 Policies adopted in certain European Countries were examined and it was noted that, in general, plasma which had been found HCV seropositive were excluded from pools for fractionation. Some countries excluded all HCV seropositives determined by a repeatable ELISA in the screening tests whilst in other countries the RIBA test was regarded as the definitive test to determine HCV seropositivity.
- 4.32 Professor Cash's proposals were generally agreed for the acceptance and rejection of plasma for inclusion into pools for fractionation. The Chairman was asked to correlate his proposals with those given by Dr. Mortimer for confirmatory serological testing. This is shown in Appendix 3 to these minutes.

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4.4 Information to be given to Blood Donors

It was agreed that this should be given in the form of a leaflet on testing of blood of donors. The SNBTS have prepared a draft for such a leaflet. The contents of this leaflet would be considered at the next meeting of the Committee.

- 4.5 Counselling of Donors

Revised guidelines from Dr. Gillon were considered which had been approved by the Medical and Scientific Committee of SNBTS. Professor Tedder and Dr. Contreras wished to make comments on this document and it was agreed that these should be in writing to the Chairman. These will be considered at the next meeting.

ACTION - Prof. Tedder/Dr: Contreras

4.6 Return of repeatably unconfirmed anti-HCV Donors to active Donor Panels

The continuation of donations for the purpose of collecting plasma was a possibility but it was recognised that this was not a cost-effective use of a blood donation. It was difficult, however, to use cellular products from such donations since confirmatory testing would be required at each donation. Certain donors may be retained on active panels for the purpose of donating plasma for fractionation.

It was agreed that further experience in serological tests was required before a final decision was made on this matter.

4.7 Monitoring anti-HCV test results

The Chairman reported that, with the agreement of Dr. D. Lee, Miss. V.I. Rawlinson would carry out a monthly monitoring system as she had done for anti-HIV testing since 1985. Miss. Rawlinson was designing a report form and was sending this to RTCs for comment within the next two weeks.

5. Any Other Business

Professor Tedder asked that the reinstatement of unconfirmed HIV seropositive donors should be considered at the next meeting. This was agreed.

- 6. Date, time and place of next meeting
 - to be arranged.