CONFIDENTIAL

NATIONAL DIRECTORATE OF THE NBTS

U.K. ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED DISEASES

Minutes of the first meeting held on Friday, 24th February 1989 at the National Directorate, Manchester.

PRESENT: Professor J.D. Cash
Dr. Marcela Contreras
Dr. E.A. Follett
Dr. H.H. Gunson
Dr. R. Mitchell
Dr. P.P. Mortimer

IN ATTENDANCE: Mr. P.J. Cosgrove

ACTION

1. Apologies for absence - Dr. W. Wagstaff.

2. Dr. Gunson introduced the meeting by saying that he had, about a year ago, discussed the forming of a U.K. Group to determine policy with respect to transfusion transmitted diseases with Drs. McClelland and Pickles. The Department of Health were in the process of forming such a group but its brief would be wider than blood transfusion medicine, embracing transplantation and other aspects of disease transmission.

   This present Committee had been formed to discuss transfusion transmitted diseases and to provide advice to the Departments of Health.

3. Dr. H.H. Gunson was elected Chairman of the Committee and Dr. W. Wagstaff was elected in his absence as Deputy Chairman. Dr. Gunson would ask Dr. Wagstaff if he was agreeable to taking on this task. — Dr. Gunson

4. TERMS OF REFERENCE

   The draft terms of reference were agreed.

   It was also agreed that whilst decisions of the Committee would be subject to consultation with RTD's any dissent would require good reasons.

5. HTLV I

   5.1 The decision to commence routine HTLV I screening in the USA was discussed in detail. It was considered that the USA's decision, taken on the tests of 40,000 blood donations with an incidence of 0.025% positives, was premature and many more tests should have been done.

   A recent conversation between Dr. Gary Tegtmeier of Kansas City and Dr. Contreras had revealed that 0.1% of all tests on donors, performed by the ELISA technique were repeatably positive. They had, to date, found 16 positives and of the 8 which had been sent for confirmation 1 was positive, 1 was negative and 6 were indeterminate. Confirmatory tests were RIPA and Western Blot.

ACTION

5.2 The virologists on the Committee commented that HTLV I testing was not yet satisfactory in that it may be difficult to pick up all persons infected with HTLV I (and also HTLV II) since whilst the tests detected antibodies to core proteins they may not detect the envelope glycoproteins.

This may change over the next year or two but the technology was not fully developed as yet.

Whilst this scientific data was appreciated it would not be a satisfactory reason for not testing blood donations if otherwise good reasons for testing were put forward.

5.3 STUDIES ON HTLV I

5.3.1. U.S.A. Study: It was noted that in the paper by Larson and Taswell it did not state the name of the ELISA Test used. Dr. Contreras undertook to speak to Dr. Roger Dodd and find this out. — Dr. Contreras

5.3.2 BIRMINGHAM study: It was noted that 1 in 308 Afro-Carribean donors had proved to be positive.

5.3.3 EDGWARE study: Of 4134 routine blood donors none was found positive, although initially 26 were inconclusive. Further studies at the PHLS had shown that these were negative. There was, however, a possibility that 1 or possibly 2 donors selected out of a high risk group of 2376 donors might be positive.

The initial screening tests for this study was the Fujirebio particle agglutination which had a high percentage of initial reactives and 0.85% repeatable reactives in the routine donors and 2.19% in the high risk group. It was considered that the number of reactive samples may have been reduced by using an ELISA screening test.

5.3.4 EDINBURGH study: Dr. Mitchell reported that in the 5000 new blood donors there were 4 initial reactive positives and 1 repeatably reactive sample. This seemed to confirm the opinion concerning the use of ELISA for screening.

5.4 Whilst it appeared that the incidence of HTLV I was probably extremely low in the overall donor population in the U.K., there was no doubt that 3 positive samples had been detected in the limited studies performed to-date. These could have resulted in the transmission of this infective agent to 9 patients.

5.5 RECOMMENDATIONS

5.5.1 It was agreed that it was not appropriate at the present time to recommend routine screening of all blood donations for anti-HTLV I. — WTD/ 1325

ACTION

5.5.2 It was agreed that three lines of action should be undertaken.

(i) To repeat the U.S.A. Study in the U.K., but with increased numbers. A study should be mounted to test 100,000 random donors throughout the U.K. of which approximately 90,000 would be in England and 10,000 in Scotland. The format of the study should await the results of (ii) below in order that the most appropriate test for initial screening could be determined.

It was estimated that it would cost approximately £1.00 per test. Dr. Gunson would enquire into the possibilities for funding the exercise. Drs. Mortimer and Follett would advise on the costs for confirmatory testing. — Dr. Gunson; Dr. Mortimer; Dr. Follett

(ii) That Dr. Contreras who had obtained finance should test 5000 donations with the anti-HTLV I tests from Fujirebio, Du pont and Abbott.

This was considered to be an essential investigation and there was a possibility that a similar study could be carried out in Glasgow. Prof. Cash agreed to consider the financing of this study. — Prof. Cash

(iii) That a study proposed by Mrs. Janet Mortimer who had obtained the co-operation of the organiser of a leukaemia therapeutic trial, for the identification of patients should be supported (Appendix I). Application should be made to the MRC for the funding of this project.

6. ANTI-HIV 1 and ANTI-HIV 2

6.1 The general situation with respect to HIV 2 disease in the U.K. was given by Dr. Mortimer. No more than 3 or 4 cases had been found. With regard to the test kits available, Dr. Mortimer said that the Pasteur had a poor reputation and the Abbott combined kit was sensitive for anti-HIV1 and detected anti-HIV 2. The Biochrom and Mercia tests which relied upon synthetic peptides have missed anti-HIV 2 with variable sensitivity against anti-HIV1. Wellcome were planning to introduce a combined sandwich test in the summer of 1989.

6.2 The general policy of anti-HIV 2 testing throughout Europe was discussed and it was thought that selective screening was still being carried out in most countries. France had had access to an anti-HIV 2 screening test for some time but had not yet introduced routine screening. Dr. Gunson had recently sent a questionnaire to all Council of Europe member countries and would report the results as soon as possible. As far as he was aware only Portugal were carrying out significant testing. — Dr. Gunson

6.3 Dr. Mortimer circulated a paper on the results of the tests for anti-HIV 2 in the U.K. to-date. (Appendix II). — WTD/ 1326

ACTION

It was pointed out that there were a number of inconsistencies in the referral of samples. The comforting fact was that there had not been any anti-HIV 2 positive results. It was agreed that this should be circulated to RTD's and repeat tests should be discouraged. — Dr. Gunson

6.4 It was agreed that pressures to use a combined test for anti-HIV 1/2 may occur during the year and this may be at an additional cost. Any such test should be evaluated at PHLS prior to introduction. Dr. Mortimer commented that the financing for the evaluation of test kits for anti-HIV had been withdrawn by the Supply Division of DOH. Dr. Gunson agreed to enquire into this. — Dr. Gunson

7. NON A, NON B HEPATITIS

7.1 Dr. Contreras outlined the results of the study in England and Wales (Appendix III).

7.2 Dr. Mitchell reported that in a Glasgow study of 5000 donations the ALT exceeded 50 i.u. in 2.8%. With respect to anti-HBc tests in a separate study, 17 out of 2000 donations were found positive, of which 15 were reproducible.

7.3 Prof. Cash reported that in Scotland the methodology for ALT testing had been examined and a standardised method had been agreed upon. This was available in the RTC's if ALT testing was agreed.

7.4 It was agreed that there should be no recommendation to institute ALT testing until the current study was completed in England. However, there was a degree of inevitability about the introduction of the test which was required by regulatory authorities in other countries to determine the acceptability of fractionated plasma products. This would be discussed with BPL in the near future.

7.5 Dr. Gunson reported that Ortho Pharmaceutical Company had approached him with respect to trials with the Chiron Test in the U.K. He would report on this later when further details were available. — Dr. Gunson

8. TOPICS FOR FUTURE MEETINGS

8.1 HBV. Dr. Contreras would ask Dr. Barbara to report on the national testing of donors. HBV 2 should also be discussed. — Dr. Contreras

8.2 ANTI-HBc. Dr. Follett would prepare a paper. — Dr. Follett

8.3 MALARIA

ACTION

9. DATE OF NEXT MEETING

Friday, 19th May, 1989, the National Directorate, Manchester at 11.00 a.m.

(Dr. Contreras cannot attend on this day and it was agreed that Dr. Barbara should attend in her place).

WTD/ 1328