12 OCT 1989

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NATIONAL DIRECTORATE OF THE NBTS

UK Advisory Committee on Transfusion Transmitted Diseases

Minutes of the meeting held on Monday 9th October, 1989

Present: Dr. H.H. Gunson (In The Chair)
Professor J.D. Cash
Dr. M. Contreras
Dr. E.A. Follett
Dr. R. Mitchell
Dr. P.P. Mortimer

1. Apologies for absence

Apologies for absence were received from Dr. W. Wagstaff.

2. Minutes

The minutes of the meeting held on 19th May 1989, were approved subject to two minor amendments.

3. Matters arising

3.1 HTLV-1 outline proposals for the NBTS/SNBTS study

Dr. Gunson reported that the outline of the proposed NBTS/SNBTS study concerning the prevalence of HTLV-1 has been considered by the Department of Health's Advisory Committee on the Virological Safety of Blood (ACVSB). The ACVSB wished to gather more information regarding the situation in the USA, where due to the lack of satisfactory confirmatory tests donor management was being adversely affected.

It was initially proposed that a group drawn from the ACVSB should visit the USA on a fact finding mission. However as Dr. Gunson and Dr. Mortimer were already scheduled to visit the USA, it was agreed that they should make enquiries and report back to the ACVSB in November, 1989.

Whilst the Committee agreed that information should be sought from the USA, nevertheless, it was considered essential that the proposed study should go ahead.

Regarding the lack of an available confirmatory test it was suggested that a panel of 100 known positives should be assembled and the tests to be used in this study should be assessed on their ability to positively identify these samples. Dr. Mortimer reported that the panel of HTLV-1 positives at PHLS was now reaching nearly 100.

Of the tests currently available, previous studies by the North West Thames and Glasgow Transfusion Centres indicated that the Abbott and Fujirebio tests were promising and could be used for the proposed study. Both tests were sensitive but may differ in specificty. The fact that different populations were being identified was regarded as a disadvantage of these test systems.

Because of the absence of a suitable confirmatory test it was agreed that repeatedly positive and indeterminant tests should be sent to reference laboratories for testing. Those donations found by these laboratories to be repeatedly positive using several tests should be regarded as truly positive. The difficulty in the management of indeterminant results in the long term was discussed.

It was also agreed that the study should be anonymous, insofar as it would be impossible to trace the donors of any given sample. However, because of the known prevalence of HTLV-1 in certain countries it was agreed that the donor's ethnic origins should, if possible, be recorded.

Concerning the site for the NBTS phase of the study, it was felt that the profile of the catchment population within the North West Thames Region suggested the best possible results could be obtained by conducting the study in this Region.

Dr. Gunson undertook to present to the Department of Health's ACVSB data to support the study with a view to securing funding for the study, an estimated £150,000 for the tests and funding to cover the cost of appointing scientific staff to perform the tests.

With regard to the publication of results of previous trials it was agreed that these should be submitted to the Committee prior to publication.

Action: Dr. Gunson

4. <u>Anti-HCV testing of blood donors</u>

4.1 The Committee were informed that the Department of Health's Advisory Committee on the Virological Safety of Blood had requested a briefing paper on policy regarding Anti-HCV testing of blood donors.

The Committee considered two papers summarising the first international meeting on the Hepatitis C virus prepared by Drs. Gunson and Mitchell, and a paper on the results of an anti-HCV UK study on surrogate markers for NANB post-transfusion hepatitis in blood donors from [redacted] North West Thames RTC.

After a wide ranging and careful consideration of the many problems regarding the test and its introduction for routine screening of blood donations, it was agreed that Dr. Gunson's paper should be used as the basis of the paper to be submitted to the Department's Committee.

It was also agreed that Dr. Gunson's paper should incorporate information from the papers prepared by Drs. Mitchell and [redacted] as well as a number of textual amendments proposed by the Committee.

A copy of Dr. Gunson's amended report is attached at Appendix 1.

4.2 Counselling of blood donors found to be anti-HCV positive

Professor Cash raised the question of counselling services for donors found to be anti-HCV positive and suggested that the Department of Health should be made aware of the possible need for consultation with appropriate consultant physicians since, after initial counselling by RTCs there would be a considerable number of donors requiring referral.

4.3 Flow charts for RTCs

Professor Cash noted the need for flow charts.

The Chairman commented that matters referred to in paragraphs 4.2 and 4.3 would form part of the policy decisions if the DH accepted the recommendations of the Committee.

5. Any other business

5.1 HIV-2

Dr. Gunson appraised the Committee regarding recent developments concerning HIV-2. It was said that a number of companies, including Du Pont and Behring, were now producing combined HIV-1 and 2 tests and that the cost of these tests was comparable with the cost of their present anti-HIV-1 test. The anti-HIV-1 and 2 test being developed by Wellcome was not yet available. It was agreed that Dr. Gunson should inform Wellcome that evaluation of other tests was taking place. Manchester RTC had obtained 5,000 of the Du Pont combined anti-HIV-1 and 2 tests and were proceeding with trials the results of which might be available in November, 1989. Drs. Contreras and Mitchell agreed to contact Behring with a view to securing, free of charge, 5,000 of their kits each for assessment.

It was agreed that reports on the results of these trials should be submitted to the Committee as soon as these were available.

Action: **Dr. Contreras**
Dr. Mitchell

5.2 Malaria anti-body testing

Dr. Mitchell advised the Committee that an increasing number of donors were being deferred because they had visited malarious areas and it was agreed that this matter should be raised at a subsequent meeting of the Committee.

6. Date of next meeting

It was agreed that the next meeting of the Committee should take place at the National Directorate on Wednesday 22nd November, commencing at 11.00 a.m.