NATIONAL DIRECTORATE OF THE NBTS

UK ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED DISEASES

Minutes of the meeting held on Friday 14th May, 1989

Present: Dr. J. Barbara Professor J.D. Cash Dr. E.A. Follett Dr. R. Mitchell Dr. P.P. Mortimer Dr. W. Wagstaff (In The Chair)

In Attendance: Mr. P.J. Cosgrove

1. Apologies for Absence

ACTION

Apologies for absence were received from Dr. Marcela Contreras and Dr. H.H. Gunson.

2. <u>Minutes Of The Last Meeting</u>

The minutes of the meeting held on 24th February, 1989 were approved.

3. <u>Matters Arising From The Minutes</u>

3.1 <u>HTLV 1:Outline Proposals For The NBTS/</u> <u>SNBTS_Study</u>

> The committee considered the outline proposals for the testing of 100,000 blood donations for Anti-HTLV 1 by the NBTS and the SNBTS using 5000 stored random blood sera collected in Glasgow and the West of Scotland. Preliminary data from this study indicated little correspondence between the Abbott, Du Pont, and Fujireibo test kits. Of the 5000 samples 34 were found to be repeatedly positive, but of these only three were found to be repeatedly positive by the Abbott and Du Pont tests and none were found repeatedly positive by all three tests.

Confirmatory testing is currently being performed on the 34 repeatedly positive samples and until the results of these tests were known no firm conclusions could be drawn. Nevertheless, it was felt that the data did indicate the inability of present technology to provide a reliable system of screening blood donations of HTLV 1.

A second report, a "Comparison of HTLV 1 Assays" was tabled by Dr. Barbara. The report noted that although automated sampling methods were available for the Abbott test, these were bulky and the assay is not compatible with other microplate tests which might lead to some confusion.

Regarding the Du Pont test, it was reported that this takes about three hours and sensitivity appears to be quite good, with a low reactivity rate.

The modified Fujirebio test can produce a result in less than two hours however, specificity is poor, even when using a 1/64 titre as a cut off point 1/200 samples were still repeat reactive. The standard Fujirebio test was not favoured because it was both time consuming and involved a number of filtrations.

The committee was aware that other tests were being developed which should be available in the near future which might be more reliable. These tests would also need to be evaluated when they were available.

With regard to confirmatory testing, it was reported that these tests were also open to question due to the absence of positive control material of human origin.

Dr. Mortimer agreed to set out the present criteria for describing a sample as HTLV 1 positive.

It was also agreed that members of the committee would approach colleagues who had positive control material and this would be passed to Dr. Mortimer for the creation of a panel for use in confirmatory testing. Dr. P.P. Mortimer

Dr. J. Barbara Prof. J.D. Cash Dr. E.A. Follett Dr. W. Wagstaff Dr. P.P. Mortimer

ACTION

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Given the problems identified above the committee requested that the National Director of the Blood Transfusion Service should approach the Minister of Health and advise him of the urgent need to organise the Blood Transfusion Service's response to the problems of evaluating commercial tests; confirmatory tests; quality control support; and research and development.

It was suggested that a group should be set up, to be guided by a steering group of leading European microbiologists who would provide the necessary scientific information and promote international co-operation such as the sharing of scarce materials.

It was also agreed that the examination of existing tests should continue using samples from groups with high risk profiles. It was agreed that the outline proposals for the NBTS/SNBTS study should be amended to include the following paragraph at (6):-

"Preliminary data indicate little correspondence between results obtained with the three test kits, the difficulty being compounded by comparatively poor reliability of confirmatory testing due to unavailability of positive control material of human origin".

It was also agreed that (3) should also be amended to read as follows:-

"The ethnic origin/apparent risk factors of the donors....".

- 3.2 Non-A, Non-B Hepatitis
 - (i) <u>Oral report by Dr. J. Barbara on</u> progress with anti-HCV testing of <u>donors in England and Wales:</u> <u>ALT/anti-HBC_study</u>

Dr. Barbara informed the committee that at present ordinary donor samples from the tri centre trial of ALT Testing were being tested before proceeding with selected groups. ACTION

Dr. H. H. Gunson

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ACTION

An assessment panel had been provided and likely positive figures were available. To date the test is running consistently the manufacturer's with expectations. At present 400 being samples per day were processed and this was а considerable drain on resources.

(ii) Anti-HCV testing of donations from Scotland

Professor Cash reported that the SNBTS would be interested in taking part in evaluative trials of the Ortho Pharmaceutical Company's Chiron test and said he would be grateful if Dr. Gunson would contact him about this matter. In particular the West of Scotland Centre has a bank of frozen donor samples already tested for ALT, from which further samples are available of i.v. IgG known to have produced raised ALT levels in recipients.

4. HBV And Blood Transfusion

Dr. Barbara tabled a preliminary report on donors found positive for HB's Ag in the U.K. in 1987, figures 3, and 4 of which are attached.

Dr. Barbara stressed that the data in the report was incomplete and required checking and further analysis.

With regard to the two regions which had not yet sent in their returns, East Anglia and the East of Scotland, the National Directors Prof. J.D. Cash were requested to urge them to send their Dr. H.H. Gunson returns in as soon as possible.

It was agreed that ideally this project should be funded so that a Scientific Officer could be appointed, for the duration of the project, to be responsible for the analysis of the data which would also be of great interest to other disciplines such as epidemiology.

Dr. H.H. Gunson

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	5.	Anti HBc Testing	ACTION
•		Dr. Follett reported that although he had	
		information regarding Scotland, he was	
		unable to make a report of a lack of	
		information regarding the reset of the U.K.	
		Dr. Follett asked if information could be	
		made available to mint but instant by	Dr. J. Barbara
		to liaise with Dr. Follet on this matter.	Dr. E.A. Follett

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6. <u>Topics For Future Meetings</u>

It was agreed that the committee should discuss the position regarding Malaria in the near future.

7. <u>Date Of Next Meeting</u>

It was agreed that the date of the next the next the date of the date

FIGURE 3.

Figure 3a RATE OF HBsAg PER 100000 DONATIONS (overall figures)

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. Fig 4 RATE OF HBSAg PER 100000 FIRST-TIME DONORS*

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*Assuming that first-time donors are one sixth of total numbers bled