SEVENTH MEETING OF THE ADVISORY COMMITTEE ON VIROLOGICAL SAFETY OF BLOOD

MONDAY 2 JULY 1990 AT 11.00 AM

IN ROOM 63 HANNIBAL HOUSE, ELEPHANT AND CASTLE, LONDON

AGENDA

1. Chairman's Opening Remarks

2. Apologies for Absence

3. Minutes of the Meeting held on 24 April 1990 (ACVSB 6/6) already circulated

4. Matters arising from the Minutes not covered by the Agenda

5. Hepatitis C Testing

   - UKBTS Action Chart - Anti-HCV Testing (ACVSB 7/1) already circulated

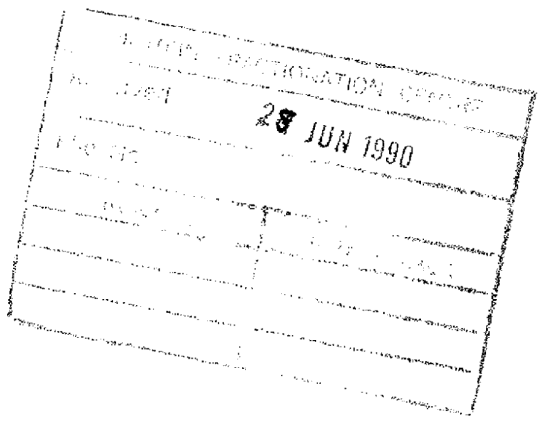
   - Summary of Basis for approval of the HCV ELISA test by FDA (ACVSB 7/2)

   - Draft Protocol comparing the Abbott and Ortho anti-HCV ELISA tests (ACVSB 7/3) to be tabled

   - Chimpanzee study of Anti-HCV tested source plasma (ACVSB 7/4) already circulated

   - Comment on Introduction of Anti-HCV testing. JAMA 4.4.90 (ACVSB 7/5)

6. Date of next meeting



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ACVS7/6

CONFIDENTIAL TO COMMITTEE MEMBERS
NOT FOR PUBLICATION

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD
MINUTES OF THE 7TH MEETING HELD ON 2 JULY 1990

PRESENT:	Dr J Metters (Chairman)	
Members:	Dr R Mitchell	Professor A Zuckerman
	Dr P Mortimer	Dr R Tedder
	Dr R Lane	Dr R Perry
	Dr H Gunson	Dr E Tuddenham
	Dr Garrett (for Dr P Minor)	
Secretariat:	Dr A Rejman	
	Mr J Canavan	
Observers:	Dr F Rotblat	Mr M Fuller
	Dr A George	Mr J Sloggem (for Dr Purves)
	Dr A McIntyre	

APOLOGIES FOR ABSENCE

1. Apologies for absence were received from Dr Summerfield, Dr Flett, Dr Pickles, Dr Minor and Dr Purves.

CONFIDENTIALITY

2. The Chairman reiterated the confidentiality of the Committee's proceedings.

MINUTES OF THE MEETING OF 24 APRIL 1990

3. These had been circulated and were accepted as an accurate record subject to the amendment in Point 7: HIV 1 should read HTLV 1 and Point 23: which should read "1 in 200".

MATTERS ARISING FROM THE MINUTES

4. There were no matters raised.

HEPATITIS C ANTIBODY SCREENING TEST

5. Dr Rejman was asked to summarise the course of events since the last meeting in April, resulting in the necessity of a reconsideration of the Committee's decision. Dr Rejman said that the FDA had decided to approve hepatitis C screening and that America had already introduced screening and other countries were following. More studies had been carried out confirming that hepatitis C testing reduced infection, and RIBA was now available as a supplementary test. It was now felt that a study along the lines of those talked about in April was no longer viable and the meeting had therefore been brought forward so that a decision on the introduction of UK hepatitis C testing could be reached.

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6. The Chairman said that he was aware of the testing carried out in America and other countries. However, the operational matters would need to be carefully considered. The meeting's main purpose was to reconsider the principle of Hepatitis C screening. The secondary purpose was to look at the draft protocol and decide which tests to use.

7. Professor Zuckerman said that he had been concerned that the originating country (America) had not introduced testing, but he now thought that as a screening test for antibodies it was time for the screening to go ahead. However, he expressed concern on the subject of counselling anti-HCV donors because of false positives, and said it would be a very difficult public relations exercise. He also thought that testing would not eliminate NANB viruses, but it would at least reduce the burden. Overall he felt that the screening test should be introduced as a public health measure. Dr Gunson added that there was scanty information but there appeared to be only a 60% overlap of positive results for the two tests.

8. After further discussion the Committee concluded they should recommend to Ministers that hepatitis C testing should be introduced in the UK, but that first a pilot study using the Ortho and Abbott tests was necessary to decide which was the better test for the Regional Transfusion Centres.

9. Dr Gunson mentioned that Wellcome were also developing a test which would be ready in September/October. The Committee decided that the pilot screening should go ahead without delay but that frozen down library samples should be kept so that donations could be retested later against other tests such as the Wellcome one, as these become available.

10. There was general support for the draft protocol comparing the Abbott and Ortho anti-HCV ELISA tests. Dr Gunson briefly summarised the proposals as follows: the blood would be collected at 3 RTC's in North London, Newcastle and Glasgow who would each perform 3500 tests. Any initial positive results would be identified and repeated against both the Ortho and Abbott tests. Repeatedly positive tests would be sent to Drs Mortimer, Tedder and Follett for supplementary testing in their specialist laboratories by the Ortho RIBA and the Abbott confirmatory test procedure, followed by PCR. The specialist laboratories will provide a co-ordinated report.

11. Dr Gunson felt that the relatively low number of predicted screen positives in each centre should mean that the counselling of infected donors in the pilot study was not likely to be an unmanageable problem, though he was aware that donors might need convincing that they did not have HIV.

12. It was agreed that any donations found to be infected with the HCV antibody would not be used, but the donations would be retained for research purposes. Consideration of any look-back procedure was postponed.

13. It was felt that there should be a national consistency on counselling infected donors. The working group agreed to look into this, and to decide whether a seminar for NBTS officials and gastroenterologists to discuss counselling procedures would be beneficial.

14. Professor Zuckerman suggested that a Journal might be approached to see if they would accept a leader setting out the problems of counselling. It was agreed that the working group would consider this option too.

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TESTING OF PLASMA FOR ANTI-HCV ANTIBODIES

15. Dr Lane raised the question of whether the test should be applied to plasma as well as to whole blood.

16. The subject was debated and two main views were put forward:

a. that the fractionation process may be taking care of the virus in plasma, and that there could be a benefit to be had from having antibodies to the virus in the pool. However this had not really been demonstrated.

b. that heat-treating methods, which have a high safety record, would inactivate the virus. However, it was thought unwise to overload the system, and from a good manufacturing viewpoint it was felt that if the virus load in the pool could be lightened then it should be done.

17. In the light of the arguments put forward, the Committee agreed it was necessary to be consistent in the testing of plasma and whole blood and therefore both should be tested for anti-HCV antibodies. This would minimise the virus load in the plasma pool. The Chairman deferred the question of testing plasma for ALT for discussion at a later date.

PILOT SCHEME TO COMPARE THE ABBOTT AND ORTHO TESTS

18. The cost of the pilot scheme was discussed. It was estimated that £150,000 would be needed. Procurement Directorate said that £50,000 was available immediately from their research budget.

19. Dr Gunson reported that Abbott would provide kits at 50% of the normal cost and that Ortho were happy to supply their kits free of charge for the study provided that they could be kept informed of the progress of the study with a view to publication. The Committee felt this was unacceptable and it was decided that Procurement Directorate would pursue the pricing in the normal way.

20. It was estimated that the overall timescale for the study would be approximately four months, after finance had been agreed.

21. A submission outlining the Committee's recommendations would be put to Ministers for their approval.

CHAIRMAN'S SUMMING UP

22. The Chairman summed up the Committee's recommendations:-

- the UK should introduce hepatitis C testing. While this would not abolish NANB hepatitis, it would reduce the number of cases;

- the public relations aspect needed to be handled very carefully;

- blood found to be positive in the pilot study would not be used, with no look back at recipients of previous donations from positive donors;

- the decision as to which hepatitis C test to use will be made after the results of the Ortho and Abbott tests are known;

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- there was general support for the protocol. The working group would continue to co-ordinate the study and decide upon the procedure for counselling hepatitis C positive donors;

- frozen down serum could be used for any other tests coming on to the market;

- the same test should be applied to plasma;

- a submission would be put to Ministers;

- consideration would be given to the funding.

ANY OTHER BUSINESS

23. None.

DATE OF NEXT MEETING

24. The next meeting was set for the end of October.

[This will now be on Wednesday 21 November 1990.]