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Department of Health

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TO: All Members and Observers of the Advisory Committee on the Virological Safety of Blood

Your reference

Our reference GEB 1/8

Date 12 September 1990

Dear Member

I am writing to confirm that the next meeting of the Advisory Committee on the Virological Safety of Blood will be held

on: Wednesday 21 November 1990

in: Room 67 Hannibal House
Elephant and Castle
London SE1

at: 11.00 am

Minutes of the 7th Meeting held on Monday 2 July will be distributed as quickly as possible and an agenda for the November meeting will follow nearer the time.

Yours sincerely

GRO-C

for J CANAVAN
For the Secretariat

14 SEP 1990

ACVSB 8/10

CONFIDENTIAL TO COMMITTEE MEMBERS
NOT FOR PUBLICATION

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD
MINUTES OF THE 8TH MEETING HELD ON 21 NOVEMBER 1990

PRESENT: Dr J Metters (Chairman)

Members:

Dr H Gunson	Dr R Perry
Dr R Lane	Dr G P Summerfield
Dr P Minor	Dr R Tedder
Dr R Mitchell	Dr E Tuddenham
Dr P Mortimer	Professor A Zuckerman

Secretariat:

Dr A Rejman
Mr J Canavan

Observers:

Dr G Mock	
Dr A George	Dr H Pickles
Dr A McIntyre	Dr J Purves

APOLOGISE FOR ABSENCE

1. Apologise were received from Dr Rotblat, Dr Glenda Mock, from the Department of Health, Northern Ireland, was welcomed on to the Committee in place of Dr Flett.

MINUTES OF THE MEETING OF 2 JULY 1990 (ACVSB 7/6)

2. These had been circulated and were accepted as an accurate record, subject to the words "public measure" in paragraph 7 being amended to read "public health measure".

MATTERS ARISING FROM THE MINUTES

EC Directive in Blood Products

3. Dr Purves reported that a drafting group representing France, Germany and the UK had met in Brussels in August to review progress on the guidelines for the EC Directive on Blood Products. An updated version would be available shortly and this would be discussed with Dr Gunson and those others who were advising the MCA on this matter.

HCV Testing Abroad

4. Dr Minor said that there would be a meeting organised by the NIBSC in December to discuss other countries' approach to HCV testing of plasma.

HEPATITIS C TESTING (ACVSB 8/1 & 8/7)

5. The Chairman recalled the summing up of the last meeting and said that a note had gone to Ministers telling them that the ACVSB was in favour of introducing routine HCV testing in the UK. A further submission was awaiting the decision of this meeting as to which test would be the most suitable. The Chairman reiterated the recommendation that all plasma should be tested for HCV. He also emphasised that the reference to a "no look back" procedure in the previous minutes referred only to work done on the pilot study. A decision on this aspect of routine screening of donors was deferred to a subsequent meeting of the ACVSB.

6. Dr Gunson introduced his paper (ACVSB 8/1) on the results of the pilot study, saying that the results of the supplementary testing would be the decisive factor when considering whether one screening test was better than the other; both screening tests could be deemed to be satisfactory for routine use within RTCs from an operational viewpoint and the choice would be influenced by the equipment available in the RTC.

7. Dr Tedder then spoke to his paper (ACVSB 8/7) and Dr Mortimer tabled a paper (ACVSB 8/9) on the respective findings. Although broadly there was agreement, there were some discordance close to the cut-off point. Overall there seemed little to choose between the two screening kits. Of the 68 screen positive samples 6 were shown to be positive using PCR. The RIBA test was shown to be preferable to the neutralisation test as a supplementary test. It was suggested that a combination of RIBA followed by PCR would provide a useful confirmatory service.

8. The results from Glasgow were not yet available.

9. Professor Zuckerman pointed out that while the study was very worthwhile and encouraging, he felt that it was impossible to choose between the two screening tests because of the discordant results. He agreed that there were difficulties with the neutralisation test. Experience elsewhere suggested that in cases of strong positives in high risk groups the screening tests followed by RIBA produced an accurate indication of infectivity. However, the problem lay with low risk groups such as donors where the screening test proved not so reliable. Professor Zuckerman went on to say that studies in France and Germany, where the HCV screening tests had been used

extensively in combination with surrogate tests, only identified 30% of post-transfusion hepatitis.

10. The Committee agreed that it was important to start screening as soon as practicable as a measure which would further enhance the safety of the blood supply.

11. Dr Gunson said that it was necessary to identify which of the screen positive donors should be counselled, although all screen positive blood would not be used. Both Dr Gunson and Dr Mitchell felt that if the results of the pilot study giving 6 true positives out of 10,000 donors were borne out in practice then counselling would be manageable. Dr Mitchell indicated that one test only should be performed by each RTC.

12. Professor Zuckerman pointed out that the two screening tests did not identify the same donors as being positive. This was confirmed by Dr Tedder who stated that the 6 PCR positive donors were among the 22 concordant screen positive tests.

13. Several members of the Committee were able to confirm that better tests were about to be issued. Dr Gunson said that Ortho had brought out a 2nd generation test and had offered 2500 free test kits for use on frozen down samples used in this study at the North London Transfusion Centre. Dr Mitchell reported that Abbott had brought out a third generation test and it was decided that he would ask for 1000 tests to be supplied to be used in the same way.

14. The Chairman put forward a proposal that on the introduction of screening any donation yielding a repeatedly positive test result from either the Abbott or Ortho tests would be set aside and a sample sent to the reference laboratory for repeat screening of testing and supplementary testing. The donor would not be notified unless the results were confirmed positive by the reference centre. The Committee agreed with this proposal.

15. Dr Mortimer suggested the data from the 3 reference laboratories involved in the pilot study should be aggregated. However he was concerned about the significance of the screen positive PCR negative result. The Chairman suggested the use of a central database containing results from this study and any additional studies in view of the emergence of new tests.

16. It was decided that Drs Tedder and Mortimer would agree on the protocol to be followed at reference centres and that they would circulate a brief note on this to other Committee members. They would also consider and advise on which centres should undertake the work.

17. Dr Gunson reported that a PScO based at the Manchester Transfusion Centre had offered to keep a detailed database of HCV positive test results, along the same lines as that kept for results identified as HIV positive. The Chairman and Committee welcomed this suggestion.

18. The Chairman summed up the discussion by saying that there was agreement that the UK should introduce hepatitis C testing as soon as practicable. RTC's would decide individually whether to use Ortho or Abbott test. The blood from any repeat positives would be set aside. Test samples would then be sent to the reference centre where both the Abbott and Ortho tests, followed by the RIBA test would be performed. At this stage some cases would no longer need to be deferred and the reference centre should inform the RTC of these cases. The repeat positives would then be subjected to PCR. The RTC would be informed which samples were confirmed positive and which were negative. The reference centres would determine a common protocol for supplementary costing and would revise this in the light of developments in the testing field. A submission would go to Ministers regarding this significant policy decision and the Management Executive would consider the funding aspect.

19. It was suggested that the results of the pilot study should be published in a scientific journal when all the results had been collated. Dr Gunson agreed to take this forward.

COUNSELLING OF HCV POSITIVE DONORS (ACVSB 8/6)

20. Dr Gunson introduced his paper and said that the UKBTS Advisory Committee on Transfusion Transmitted Diseases would be meeting to discuss the problems of counselling positive donors.

21. In addition two further aspects would be considered:

a. the question of look-back in relation to routine screening;

b. the date of introduction.

He reported that some centres had asked for a 6 month period in which to set up testing. Dr Gunson himself thought this to be excessive, but he said he would need to consult with other Directors first. It was agreed that he would hold off consultation until the submission had been put to Ministers. The Chairman stressed the importance of a common date of introduction throughout the UK.

22. Dr Mitchell report that Scotland had already discussed the problem of counselling and that they had produced a draft document which could form the basis of the discussion at the UKBTS meeting.

23. Professor Zuckerman said that any donors identified as true positives should be referred to a physician for counselling. In the case of a screen positive not confirmed by supplementary tests the donations should be stopped but there was no need for referral.

24. It was agreed that Dr Gunson would convene a meeting of the UKBTSAC TTD to devise a strategy to be followed. Guidelines could be drawn up for physicians to use in cases were there is no local gastroenterologist.

ANTI-HBc TESTING (ACVSB 8/2)

25. Dr Gunson presented the paper. There was general support for uniformly introducing throughout the Blood Transfusion Service a test for hepatitis B core antibody for those donors with a history of jaundice more than 12 months prior to donating. However, the Committee thought that they should not rush into this decision without considering the consequences. It was agreed that a paper setting out the details would be prepared in time for the next meeting.

26. Dr Summerfield asked whether results were available for anti-HBc tests or ALT levels for the 68 screen positive donors in the pilot study. Dr Tedder said that plasma was still available but this had not been part of the study protocol.

27. The following papers had been circulated for information - no points were raised at the meeting:

Sexual Transmission of hepatitis C virus (ACVSB 8/3)

Alanine aminotransferase screening and hepatitis C virus antibody)

Hepatitis C virus in symptomless donors) (ACVSB 8/4)

HCV testing in low-risk population (ACVSB 8/5)

ANY OTHER BUSINESS

REINSTATEMENT OF DONORS FOUND TO BE REACTIVE IN PREVIOUSLY-USED HIV SCREENING TESTS (ACVSB 8/8)

28. Dr Tedder presented the paper and said that he thought patients should be readmitted to the donor panel provided there was a 6 month follow up test and that they proved to be repeat negative on later assay tests. The Committee agreed. Dr Gunson pointed out that the BTS had issued guidance on dealing with this situation. He said he would reissue the guidance making it clear that the re-issue was for the avoidance of doubt.

HCV in the Community

29. Dr Tedder said that there were some very important questions to be answered about the incidence of HCV in the community that could be addressed by the BTS the PHLS and other interested parties. Dr Tedder agreed to produce a paper for the next meeting.

DATE OF NEXT MEETING

30. The next meeting was set for late January 1991.