Witness Name: Glenn Wilkinson

Statement No.: WITN2050001

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Dated: 14 August 2020

**INFECTED BLOOD INQUIRY**

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**EXHIBIT WITN2050062**

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ACVSB 10/10

**CONFIDENTIAL TO COMMITTEE MEMBERS**

**NOT FOR PUBLICATION**

# ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD

## MINUTES OF THE 10TH MEETING HELD ON 21 MAY 1991

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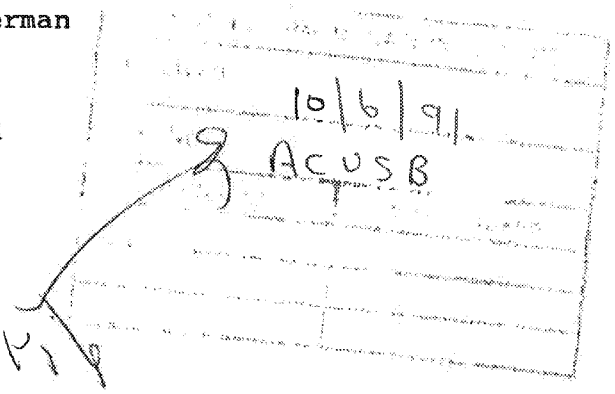
| PRESENT: | Dr J Metters (Chairman) |
| Members: | Dr H H Gunson<br>Dr R S Lane<br>Dr P Minor<br>Dr R Mitchell<br>Dr P Mortimer<br>Dr R J Perry<br>Professor R S Tedder<br>Dr R T Wensley<br>Professor A Zuckerman |
| Secretariat: | Dr A Rejman<br>Mr J Canavan<br>Mr J F Rutherford |
| Observers: | Dr G Mock<br>Dr H Pickles<br>Dr J Purves<br>Dr F Rotblat |




**CHAIRMAN'S OPENING REMARKS**

1. The Chairman welcomed Dr Wensley to the Committee.

**APOLOGIES FOR ABSENCE**

2. Apologies for absence had been received form Dr George, Dr McIntyre and Dr Summerfield.

**MINUTES OF THE MEETING HELD ON 25 FEBRUARY 1991**

3. These minutes had been circulated and were accepted as an accurate record subject to a correction in Minute 23 where "1gm" should read " IgM."

**MATTERS ARISING**

4. Post-transfusion hepatitis cases (minute 3 of ACVSB 9/14)

Professor Zuckerman confirmed the percentage of post-transfusion hepatitis cases identified by HCV screening in combination with surrogate tests in France and Germany as approximately 70%.

5. Single unit transfusions (minute 34 of ACVSB 9/14)

The Chairman reported that since the last meeting:-

- the CMO had asked the Director of Research and Development to consider undertaking a study to establish how widespread the practice of single unit blood transfusion is;
- the Royal College of Physicians is preparing a draft protocol for an audit of blood transfusion practice in District Hospitals with particular reference to medical wards;
- discussions with Departmental officials responsible for medical audit indicate this as a local matter unless Colleges decide to take it up.

6. Professor Zuckerman undertook to write to the Council of the Royal College of Pathologists seeking their involvement in this issue.

**HEPATITIS C : UPDATE ON RESULTS OF 2ND GENERATION TRIALS**

7. Dr Gunson reported on the progress of these trials which involved 2nd generation Ortho and Abbott, and 1st generation UBI and Organon/

UBI and Organon. Organon, which had failed to react to a known positive was to be withdrawn from the trial by its manufacturers due to patent litigation. Ortho 2 had shown a high rate of repeatable reactives (RR) in North London ( 0.84% compared with 0.6% in Newcastle ) which needed further investigation. The initial results from Abbott 2 were encouraging ( 0.39% initial reactive (IR), 0.25 RR ). The cost of the individual UBI kits was attractive but they needed more repeat tests, ( IR 1.85%, RR 1.0% ) than their rivals with the additional cost and work that brought.

8. Dr Mitchell gave the figures from Glasgow using Abbott II - RR for this was 0.42% compared to 0.51% for Abbott I, but some of the RR for Abbott II had not been RR for Abbott I. It appeared that the 2 kits were not measuring the same aspect). Supplementary tests had not yet been done. Prof Tedder said that the sensitivity of the 2nd generation kits were making supplementary testing more difficult as it was possible that some of the RR from the 2nd generation kits were weak true antibody positive and might not be confirmed by RIBA or PCR. Data from Newcastle was not yet available. Trials on the three kits, however, were continuing.

9. The Committee noted that they were not due to meet again before the introduction of routine HCV screening. It was agreed that the results of the trials should be made available to RTCs as soon as they became available. The results would also be copied to Committee members.

10. It was decided that 3 tests could be used for initial screening, Ortho II, Abbott II, or UBI. Individual RTCs would decide which was most appropriate and they would be guided by the results so far obtained as well as those from Newcastle, together with the funding of the supplementary kits. The results would be available by the end of June/early July and would be transmitted by the NBTS Directorate to the RTCs.

**PROTOCOL FOR HEPATITIS C SCREENING AND SUPPLEMENTARY TESTING (ACVSB 10/ and ACVSB 10/9)**

11. As background, Dr Gunson said that Northern RTC had begun routine testing of donated blood for HCV antibody in April. While this unilateral action was regretted, it could be used as an extension of the trial. He presented paper ACVSB 10/9 giving details of a proposed extended trial. Work in Glasgow was under way, Leeds were ready to start and Liverpool and Bristol were to begin trials in June. One of the main aspects was to be an examination of RIBA and PCR supplementary tests on positive donations. Dr Gunson asked for funding of these supplementary tests and not for the initial screening which was funded by Regions.

12. Dr Mortimer introduced paper ACVSB 10/1. He said that there was no firm basis for conclusions on the value of PCR in confirmatory testing. More information was needed on the correlation between RIBA and PCR and further evaluation should ideally extend into the early days of routine screening.

13. After discussion the Committee agreed with the framework for a protocol outlined in ACVSB 10/1 and that Northern RTC were to be included in the main trial. The Committee recommended that all RIBA positives in the extended trial including UBI at Trent and S Western RTCs, and double that number of negatives should be tested with PCR.

14. The Chairman told the Committee that there were restrictions on the Department's Evaluation Budget which would have to be taken into account in considering this recommendation. The Committee noted the position.

**UKBTS ADVISORY COMMITTEE REPORT - (ACVSB 10/2)**

15. Dr Gunson introduced ACVSB 10/2. He said it covered a paper that was to be presented to the UKBTS Advisory Committee and he would welcome ACVSB comments on it first. The testing protocol outlined in this paper was not at variance with that in ACVSB 10/1.

16. Dr Gunson went on to say that it was proposed that no action was to be taken the first time donors and donations were found to be HCV antibody positive. The donations were to be flagged and not used. The donors would be seen if their next donation tested positive. It would be valuable to store the plasma from these donations for the manufacture of control material.

17. The Committee considered ALT testing. It was thought that ALT was used as means of identifying other nonA nonB hepatitis. It was agreed that ALT tests were not specific for HCV and there was poor correlation between HCV antibody and ALT.

18. After discussion it was agreed that ALT was not to be included in the extended trial. Dr Gunson was to supply papers for the next meeting on the UKBTS TTD proposals for counselling following their meeting in June and on proposals for donors who were deferred as well as amendments to paper ACVSB 10/2. Meanwhile nothing would be said to donors who were tested HCV positive at any stage until the ACVSB met again to consider the matter further.

**LOW INCIDENCE OF NON A NON B POST TRANSFUSION HEPATITIS IN LONDON - (ACVSB 10/3)**

19. The Chairman said that this paper was an article published in The Lancet and had been circulated in case members had not seen it. It confirmed the previous understanding of a low incidence of post-transfusion nonA nonB hepatitis in the UK compared to the US. This was taken into account when the Committee advised the introduction of routine screening. The Committee noted the paper.

**ECONOMIC CONSIDERATIONS OF HEPATITIS C SCREENING (ACVSB 10/4)**

20. The Chairman said that this paper, which focused on the costs of HCV screening, was a pre-publication document and therefore confidential. The Committee noted the paper.

**EC DIRECTIVE ON BLOOD PRODUCTS - (ACVSB 10/5)**

21. Dr Purves introduced this paper. He said that following the EC Directive in 1989 which sought to bring blood products under controls similar to those in operation for medicinal products, guidelines were needed to aid the industry in preparing their submissions to the licensing authorities. The draft guidelines were seen as too detailed to serve a useful purpose for industry. A redraft should concentrate on the principles that should apply to the collection of blood and the subsequent manufacture of blood products followed by practical guidance on the screening and testing of donors. There was a need for some comment on the manufacture of blood products but not in the detail that the draft currently proposed. There was much detail on placental derived products, although these only represented a small proportion of total blood products. There was also a need for information on the standards to be met by finished products. Much of the document could be made briefer. It was thought that there was sufficient interest among Member States for a major redraft at this stage.

22. Dr Purves invited written comments from members, particularly from virologists on the essential elements of testing, and fractionators on manufacture, by 3 June.

23. The Chairman thanked Dr Purves and expressed his wish that members would be able to contribute their views.

**ANTI HBc TESTING OF BLOOD DONORS WITH A HISTORY OF JAUNDICE - (ACVSB 10/6)**

24. The Chairman said that following the last meeting, Dr Rejman had collated additional information for the Committee and invited Professor Zuckerman to elaborate on his contribution.

25. Professor Zuckerman said that anti HBc testing by ELISA was not cost-effective because of poor specificity. The quality of anti HBc tests would have to be improved markedly before it would be worthwhile introducing routine screening for any group.

26. Professor Tedder agreed with Professor Zuckerman. He said that donors with a history of jaundice were the wrong group to consider for anti-core screening. It was not a useful test in population with a low prevalence of Hepatitis B. Dr Gunson pointed out that 2 centres, Sheffield and Liverpool were testing donors with a history of jaundice for anti- HBc.

27. The Committee agreed that there was no case for routine anti-HBc testing of blood donors with a history of jaundice. It was further agreed, however, that donations from those where positive anti-HBc was known should be deferred from cellular use. The Committee was to further consider their inclusion in fractionation once a summary of the position in the US was known.

**HEPATITIS BsAg CONFIRMATORY TESTING**

28. Dr Gunson said that his issue was to be discussed by the UK NBTS TTD Committee on 10 June. He undertook to report on the outcome at the next ACVSB meeting.

**READMITTANCE OF DONORS NOT CONFIRMED HIV ANTIBODY POSITIVE**

29. Dr Gunson said that this issue was to be discussed by EAGA on 2 July. He undertook to report on the out come at the next ACVSB meeting.

**PLASMA NOTIFICATIONS - (ACVSB 9/15, 10/7 and 10/8)**

30. Professor Tedder introduced his papers ACVSB 9/15 and 10/8. (paper ACVSB 10/7 covered the Standard Operating Procedures recommendations for plasma failing to meet BPL specifications). He said he was concerned about the guidance under which a RTC would notify the fractionation centre should a donor become implicated in an episode of post-transfusion infection. It was a lengthy and difficult process to identify the donor involved. He wanted the ACVSB to address the question of what would constitute reasonable suspicion of a potentially infective donation in order to trigger investigations at the fractionation centre. Dr Lane said that first knowledge of a positive infection may be in a pool of 13-15,000 donations. At that level of dilution some single infected donations may never be identified. A realistic view had to be taken. He stated that the commercial view was that if a test were performed on the donation at the time of donation and properly validated, then the commercial manufacturer was prepared to abide by it since viral inactivation procedure was good enough.

31. It was agreed that while the ACVSB did not wish to scrutinise the day-to-day operations of the RTCs, they had a legitimate interest in plasma notifications and would welcome an opportunity to comment on the revised SOP.

**ANY OTHER BUSINESS**

32. The Chairman voiced the concern of the Committee that Northern Region had unilaterally begun routine testing for HCV antibody. He said that the policy for a uniform starting date had been endorsed by all UK Health Ministers and despite Northern Region's action this policy remained firm.

33. The Chairman said that The Advisory Group on Hepatitis had asked for sight of ACVSB minutes on Hepatitis C screening. After discussion it was agreed that the Group should be given copies of relevant minutes after they had been agreed.

34. Professor Tedder stated that his proposed study on epidemiology of hepatitis C had not been supported by DH and he was to apply to the Wellcome Trust. He was anxious that the study might not be able to go ahead. He thanked members of the committee for the support in principle of his project. Prof Zuckerman suggested trying for EC funds.

**DATE OF THE NEXT MEETING**

35. It was agreed that the Secretariat were to write to members to establish a date for the next meeting.

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ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD

MINUTE OF THE THIRTEENTH MEETING HELD ON 2 JULY 1992 IN ROOM 311 EILEEN HOUSE, NEWINGTON CAUSEWAY, LONDON SE1

Chairman: Dr J S Metters

Members: Dr H H Gunson
Dr P Minor
Dr Mitchell
Dr P Mortimer
Dr G P Summerfield
Prof R J Tedder
Prof A Zuckerman

Observer: Dr A Keel

Secretariat: Dr A Rejman
Mr J Canavan
Mr J Rutherford

1. Apologies for absence

The Chairman reported that apologises for absence had been received from Dr Lane, Dr Perry, Dr George, Dr Mock and Dr Purves.

2. Introduction

The Chairman thanked Members for coming together at such short notice to discuss HTLV. The subject had been discussed at the last meeting when the Committee asked for further information before agreeing on a recommendation to Ministers. The HTLV sub-group had met again and their report had been circulated to Members as the annex to paper ACVSB 13/2. Members were now asked in the light of all the information available about advice the Committee should offer Ministers on whether screening of donated blood and plasma for the presence of the HTLV antibody should be introduced in the UK.

3. Discussion

3.1 There was general support for the arguments in the sub-group's report and Members found the conclusions acceptable. There were still gaps in knowledge about HTLV. The incidence of transmission by blood transfusion indicated that though very low it could be one of the major routes. Although TSP was emphasised as the main HTLV related disease others may emerge. No cases of transfusion transmitted ATLL had been reported and there was no information available about the incidence of secondary ATLL cases. Against these concerns it was noted that there was no information as to how many HTLV II infected donations had been excluded by anti-HCV testing. HCV positivity appeared to be a surrogate test for i.v. drug abuse in common with HTLV II although there are other causes of positivity.

3.2 There was no case for selective screening for anti - HTLV. Paper ACVSB 12/6 had shown that there would be no benefit in selectively screening donors. Equally there would be no advantage in selectively screening donations before transfusion to certain patients such as neo-nates or women of child bearing age. The potential harm that could be done by HTLV did not equate to that done by CMV to neo-nates or bone marrow transplant recipients.

3.3 Cost was a major factor in considering anti HTLV screening. Members noted the conclusion of the economic appraisal of anti-HTLV testing that it would represent relatively poor value compared with other health service interventions. However, there was concern that the costs of screening options quoted in the report may have been too high as initial screening tests were now more specific and cheaper seriological confirmatory tests had been developed which reduced the need for the more costly PCR tests. However, the initial test would still account for most of the cost as it had to be performed on all donations. There was general agreement that testing could not be undertaken using diluted kits which would lose the protection of product liability.

3.4 Some Members argued that the development of a combination test which included HTLV was relevant to the discussion. Such tests were being developed though none was available for immediate use. Dr Gunson reported that Leeds RTC was negotiating with Bio-kit to run a six month evaluation on their combination HIV I and II/HTLV I AND II Kit. This potential development was welcomed by Members who wished to see the evaluation extended to Glasgow if possible. Each site could continue to use its standard HIV I AND II kit to test the HIV specificity of the new combination kit.

3.5 Members noted the legal advice that a decision to recommend against anti-HTLV testing would not expose the Secretary of State to charges of negligence should a patient transfused with HTLV infected blood come to harm as a result of the infection.

4. Recommendation and further action

4.1 The Committee agreed that their recommendation to Ministers was that at present there was an insufficient case to support the introduction of routine screening of donated blood and plasma for the presence of the HTLV antibody. The Committee intended to keep their recommendation under review in the light of developments in knowledge of HTLV and in particular the outcome of the evaluation of the combination HIV/HTLV kit.

4.2 The Secretariat undertook to:-

i. revise the table of screening options costs in 5.2 of the sub-group's report to reflect the costs of initial screening and the alternatives to PCR/RIPA confirmatory tests;

ii. ask the Department of Health's Medical Services Directorate for funding in respect of the evaluation of the combination HIV/HTLV Kit at Trent and Glasgow.