Witness Name: Glenn Wilkinson

Statement No.: WITN2050001

Exhibits: WITN2050002 – WITN2050114

Dated: 14 August 2020

INFECTED BLOOD INQUIRY

EXHIBIT WITN2050061

ACVSB 9/14

CONFIDENTIAL TO COMMITTEE MEMBERS

NOT FOR PUBLICATION

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD

MINUTES OF THE 9TH MEETING HELD ON 25 FEBRUARY 1991

PRESENT:	Dr J Metters (Chairman)
Members:	Dr P Minor Dr R Mitchell Dr P Mortimer Dr R J Perry Professor R Tedder Professor A Zuckerman
Secretariat:	Dr A Rejman Mr J F Rutherford Miss E Webb
Observers:	Mr M Fuller Dr McClements (for Dr Mock) Dr A McIntyre Dr H Pickles Dr J Purves Dr F Rotblat

CHAIRMAN'S OPENING REMARKS

1 The Chairman reported that Dr Tuddenham had resigned from the Committee and that a replacement member was being sought. He welcomed Dr McClements who was attending in place of Dr Mock and Mr Rutherford who had joined the secretariat.

APOLOGIES FOR ABSENCE

2 Apologies had been received from Dr Gunson, Dr Lane, Dr Summerfield and Mr Canavan.

3 These Minutes had been circulated and were accepted as an accurate record, subject to confirmation by Prof Zuckerman of the percentage of post-transfusion hepatitis cases identified by HCV screening in combination with surrogate tests in France and Germany in paragraph 9.

MATTERS ARISING FROM THE MINUTES

Re-instatement of donors found to be reactive in previously used HIV screening tests

4 Prof. Tedder tabled paper 9/14. If archival specimens showed no antibodies and were followed up with a negative assay test then 85-90% of these donors could be re-instated. This suggestion ran counter to the EAGA and UKBTS/NIBSC guidelines. To ensure there were no policy inconsistencies a paper on the use of archival specimens would be referred to EAGA.

HEPATITIS C: UKBTS PILOT STUDY (ACVSB 9/1 & 9/13)

5 Dr Mortimer reported on the results and conclusions of this study. He said he was pleased to note the matching results from the different reference centres in this trial, with the exception of 1 sample found to be PCR positive only at Ruchill. Two candidate screening tests (Wellcome and UBI) had identified the PCR positives from among the samples found to be repeatedly

reactive to Ortho and Abbott tests. It would be important for the evaluation of other candidate HCV tests, to retain the population of 10,000 samples. He thought the Committee may wish to see the results from the second generation Ortho and Abbott tests.

6 Professor Tedder tabled paper 9/13. The Committee discussed the likely availability of the second generation tests and operational factors which might influence the decision by RTCs as to which screening test to choose. Licensing of the tests by FDA had not yet been finalised. Members agreed it was important for proper evaluation of the Ortho and Abbott 1&2 tests to be carried out before RTCs decided which test they would adopt.

7 The Chairman summed up the view of the Committee following discussion:-

the bank of specimens from the original 10,000 should be kept in appropriate form in order to evaluate the 2nd generation tests, as well as any other tests as they became available.

the form of storage should be such that a retest would not risk the integrity of original specimens, with repeated thawing and freezing. MDD would arrange the financial aspects.

any new test should be evaluated against the full 10,000 specimens to ensure it was at least as good as the tests already evaluated.

Ortho and Abbott 1 and 2 should in principle be available among others from 1 July for RTCs to choose;

further tests may identify new markers.

It was also noted that patent rights had not yet been determined but it was thought that the individual companies would look to their own interests.

NIBSC MEETING ON HEPATITIS C: 4 DECEMBER 1990 (ACVSB 9/11)

8 Dr Minor reported on the NIBSC meeting. The main question was whether HCV positive donations should be included or excluded from the plasma pool. A major problem was whether antibody to HCV in the plasma pool was analogous to HBsAb. There was no international consensus.

9 The Committee agreed in principle that positive donations should be screened out. Good manufacturing practice indicated that possibly infected units should not be included in a pool. It was acknowledged that there would be practical problems with licensed American products as the U.S. did not screen out positive donations. The decision as to which product to use in an individual patient was for the consultant in charge of the clinical management of that patient.

10 It was further agreed that more detailed considerations about the use of plasma derived from placentae, the inclusion of screen positive/supplementery test negative donations and the question of recall should a positive donation occur in a pool, were to be made at a later meeting.

PROTOCOL FOR HVC SCREENING AND SUPPLEMENTARY TESTING (ACVSB 9/2)

11 Dr Mortimer reported that Paper ACVSB 9/2 was currently in draft form and had been sent to Dr Gunson. It was agreed to postpone consideration of this item until paper ACVSB 9/2 had been seen by NBTS and their comments were available. The Chairman asked that the document be discussed at the next meeting of ACVSB in May. It was also agreed that the document should be sent to the Department of Health as there were financial implications. The Committee noted that funds for continued testing were to be sought by RTCs through normal channels.

12 The Committee agreed that all 10,000 archived samples be tested by second generation tests, and MDD would seek the necessary funding.

UKBTS ADVISORY COMMITTEE MEETING REPORT (ACVSB 9/3)

13 Dr Mitchell reported on this meeting and referred to the flow chart attached to ACVSB 9/3. He said that two issues had not been resolved at the meeting: the fate of plasma for donations which were anti HCV unconfirmed repeatable reactives; and the return of repeatably reactive unconfirmed HCV seropositive donors to the active panel of donors. Both issues were to be discussed again at the next meeting of the UKACTTD.

14 The Committee discussed the problems of look-back and recommended that it should not be undertaken as a service, leaving the option for those carrying out research. However, all cases of post-transfusion hepatitis should continue to be investigated.

EC DIRECTIVE ON VIRAL SAFETY (ACVSB 9/4)

15 Dr Minor said that this paper which was not addressed solely to blood products was in effect notes for guidance based on existing procedures.

16 The Committee expressed concern about lack of consultation on the document which was close to approval by CPMP.

EC DIRECTIVE ON BLOOD PRODUCTS

17 Dr Purves gave a verbal report. He said that he was co-ordinating the UK response to a draft guideline document which was still in the early stages of consultation. It sought to bring blood products under controls similar to those in operation for medicinal products and to give information as to what was required for licensing purposes. The document has already highlighted approach differences between member states in the preparations of human albumin, since placenta derived product was accepted in some countries eg. France, but not in the UK.

18 The Chairman asked that the draft guidelines becirculated for comment to all interested parties including members of the ACVSB.

19 It was agreed to postpone full consideration of the document and a decision until the next meeting.

HEPATITIS C: COMMUNITY TRANSMISSION (ACVSB 9/6)

20 Prof. Tedder presented this paper which was a proposal for an investigation into HCV infection in blood donors whose serum contained HCV antibodies, in their families and in the recipients of their blood products. An application was being made to DH for funding.

21 The introduction of HCV testing was likely to be a unique opportunity since in later years the mumber of HCV positives was likely to be much less. A similar project for HIV had not been possible because of anxieties over confidentiality and possible misunderstandings. It was agreed that Professor Tedder would keep the Committee informed of any progress.

22 Members agreed that in principle this study should be supported but funding would need to be sought in the usual way. They noted that 'look-back' would probably be involved.

ANTI-HBc TESTING OF BLOOD DONORS (ACVSB 9/7 AND 9/12)

23 Dr Rejman said that doubts had been raised about the value of anti-HBc testing and asked the Committee to consider whether all healthy blood donors with a history of jaundice more than 12 months prior to the proposed donation should be tested for anti-HBc. If positive, should they all be deferred from donation or deferred only if they were anti HBs negative? In addition, the Committee was asked to consider whether this recommendation should apply to plasma as well as whole blood and whether there was a case for screening all donations for anti-HBc to avoid transmission of hepatitis B. Professor Zuckermann stressed the importance of characterizing the type of anti-HBc and advised that if it was 1gm, the donation should not be used.

24 Professor Tedder commented on the results of a trial at the NLBTC. The data collected indicated little evidence for Hepatitis B contributing significantly as a cause of a positive jaundice history.

25 In discussion it was agreed that the Committee needed more information on the issues raised. Dr Rejman was asked to provide a further paper. This was to include information on the position in Europe to be provided by Professor Zuckermann. Further discussion would be held at the next meeting.

HEPATITIS BsAg CONFIRMATORY TESTING (ACVSB 9/8)

26 Professor Tedder reported that since the change to the new HBsAg screening kits there had been a rise in the number of donors whose sera gave false positive reactions.

27 It was agreed after discussion that the UK NBTS TTD Committee should be informed of the difficulties, and the UKBTS/NIBSC guidelines might need amendment. Further information could be presented at the next meeting.

CJD AGENT/PRIONS IN BLOOD DONORS (ACVSB 9/9)

28 Dr Pickles reported that questions had been raised with the Department on a look-back at recipients of blood from donors subsequently confirmed with CJD and the exclusion as donors of those from families with GSS. These issues were related to the ACVSB's advice that recipients of pituitary-derived human growth hormone should not be acceptable as donors of human blood or other tissues. These issues were therefore put forward for the Committee's consideration.

29 Professor Tedder said that there was a dearth of knowledge on this subject to the extent that it was not known how many people may have been adversely affected. It was possible that the numbers involved were so small that raising the issue could cause disproportionate and unnecessary alarm.

30 It was agreed that the Committee was to defer from offering advice until more information was available.

CHRONIC FATIGUE SYNDROME (ME) AND BLOOD TRANSFUSION (ACVSB 9/10)

31 Dr Pickles said that it had been suggested that the Department should introduce routine testing of blood donations for ME to prevent transmission of the infection(s) responsible for this disorder. It was feasible that infection may be transmitted to transfusion recipients, a small proportion of whom might develop chronic symptoms themselves.

32 It was agreed that the evidence available did not support the introduction of a test. The Committee, however, would continue to watch any developments with interest.

ANY OTHER BUSINESS

33 A paper on Plasma Notifications (ACVSB 9/15) was tabled and it was agreed that full consideration would be given to it at a later meeting.

34 The Chairman said that the CMO had expressed concern about unnecessary single unit transfusions. Information on the frequency of this practice was not held centrally. A recent series of articles in the BMJ should have had the effect of discouraging these transfusions but the Committee was invited to consider if further action was required.

35 Members did not favour a survey. The practice of single unit donations was widely condemned and should be routinely addressed through medical audit procedures.

DATE OF NEXT MEETING

36 The date of the next meeting was set for 21 /22* May 1991.

* to be confirmed.

CONFIDENTIAL TO COMMITTEE MEMBERS
NOT FOR PUBLICATION

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD

MINUTES OF THE ELEVENTH MEETING HELD ON 29 OCTOBER 1991

Chairman:	Dr J S Metters
Members:	Dr H H Gunson Dr R L Lane Dr P Minor Dr R Mitchell Prof R S Tedder Dr R T Wensley Prof A Zuckerman
Observers:	Dr A M George Dr J Purves Dr F Rotblat
Secretariat:	Dr A Rejman Mr J Canavan Mr J Rutherford

1. Apologies for absence

1.1 The Chairman reported that apologies for absence had been received from Dr Mock, Dr Mortimer, Dr McIntyre, Dr Perry and Dr Summerfield.

2. Minutes of the meeting held on 21 May 1991

2.1 Dr Lane said that the amendment to minute 30 sidelined in ACVSB 11/1 highlighted his contribution at the meeting. It was agreed to incorporate this amendment in the minutes. Dr Lane said that the question of how the RTCs would inform BPL about infected donations would be addressed in the Plasma Standard Operating Procedures.

2.2 It was agreed that the words "is in the trial" were to be inserted after "The donations" in the second sentence of minute 16.

2.3 It further agreed that the words "during the trials currently being undertaken" were to be inserted at the end of the second sentence in minute 27.

2.4 Subject to these amendments being incorporated the minutes were agreed.

3. Matters arising not dealt with elsewhere

3.1 The Chairman reported that the Plasma Standard Operating Procedures were not ready yet. Discussion on them was to be referred to the next meeting.

3.2 Dr Gunson reported that a working group of the UK BTS TTD was to meet on 31 October to discuss Hepatitis BsAg confirmatory testing. A report was to be available for the next ACVSB meeting.

4. Hepatitis C (ACVSB 11/2 and 11/3)

4.1 The Chairman thanked Dr Gunson for the hard work put into compiling the Compendium of Recommendations made by the UK Advisory Committee on Transfusion Transmitted Diseases which had been circulated as ACVSB 11/2.

4.2 Dr Gunson said that the results of the first HCV test trials were reported fully in the Compendium. Results of the extended trial had been sent to Manchester PHLS where Dr Craske had produced a report which recommended that:-

i. donors whose donations had repeatedly tested positive should be interviewed. Their records had been flagged and their donations held back from use;

ii. Some ELISA negative samples had been checked by RIBA and it had been suggested that some might be infective. Further information was needed;

iii. Funding was needed to continue this work;

Dr Gunson said no decision had been taken as to a look-back study.

4.3 It was agreed that the Secretariat were to circulate Dr Craske's report to Members and invite their views.

4.4 Dr Gunson said that in England counselling had been based on RIBA2 positivity. At 8 RTCs counselling had been undertaken by trained medical staff usually Consultants. 5 RTCs asked the GP to refer the donor for specialist advice.

4.5 Donations which were RIBA 2 indeterminate had been flagged to await developments. Donors who had tested RIBA 2 negative/ELISA positive on 2 or more occasions, were to be interviewed and withdrawn from the donor register.

4.6 Dr Mitchell reported that in Scotland senior medical staff were interviewing donors who had been tested positive and informing their GPs. Scotland were also PCR testing RIBA2 indeterminate donations.

4.7 Although the bulk of indeterminate-tested donors would present themselves for donation again within 2 years, and may then be cleared by negative test, there was concern that indeterminate donations would stock up, especially in the London Regions which were unable to fund PCR confirmatory tests.

4.8 The Chairman acknowledged that ACVSB advice may be called into question if the Regions were unable to fund work arising from the policy established as a result of that advice.

4.9 It was agreed that Dr Gunson was to write to the Chairman giving the Regions' approach to HCV testing. The Secretariat would then bring to the NHS Management Executive's attention the practical effects of the policy.

Press Articles (ACVSB 11/3)

4.10 Dr Minor said that although the high incidence of false positivity in HCV tests had been put forward in press articles as a reason for not introducing routine testing earlier, the equally important rate of false negativity had not been mentioned.

4.11 Dr Gunson reported that the UK BTS TTD were drawing up a paper showing the chronological steps that had been taken from the appearance of the first HCV testing kits in September 1989 to the introduction of routine screening in the UK in September 1991. He undertook to send a copy of the completed paper to the Chairman, who said that the paper should be confidential to the Committee.

5. Hepatitis C: Screening of non UK plasma in blood products (ACVSB 11/4)

5.1 Dr Purves introduced this paper. He said that the Committee on the Safety of Medicines had approved a recommendation that blood products licensed in the UK should be made from HCV screened donations. There is now a proposal for this to be introduced throughout the EC from 1 January 1993 with a 3 year transition period. It seemed probable that the US would follow suit. The proposal was to be put to EC member states for consultation.

5.2 Dr Lane said that the date 1.1.93 was not practical for all the products manufactured by BPL. In suggesting this date he thought that not all member states had consulted their national suppliers. There was also concern expressed that the suggested date would lead to the disposal of valuable collected material, and make self-sufficiency more difficult to achieve.

5.3 Dr Wensley pointed out that manufacture of fractionated products entailed steps which destroyed viral infectivity and there had been no cases of NANB or Hepatitis C since these procedures had been introduced.

5.4 Dr Rotblat suggested having an earlier date for introduction of testing and a later date for excluding previously untested plasma.

5.5 It was agreed that Members and especially the national fractionators would send their comments to Dr Purves who would prepare a note on the UK position for the Committee's next meeting.

6. EC Directive on Blood Products: Update

6.1 Dr Purves reported on the latest position. He said that a problem had arisen in drafting guidelines for preparing submissions to the licensing authorities as to whether placentae should be screened individually for HIV. 3 member states including the UK did not use products sourced from placentae. The UK view was that all raw material should be individually screened. The UK did not propose any change for the EC but recommended a review of the position in 3 years.

6.2 The Committee noted the position.

6.3 The Chairman said that the Committee may wish to consider ALT testing now that a specific test for Non A, Non B Hepatitis was available.

6.4 It was agreed that the Secretariat was to prepare a paper on the EC position and other aspects of ALT for discussion at the next meeting.

7. Use of plasma from anti-HBc positive donors with a history of Jaundice (ACVSB 11/5)

7.1 Dr Rejman introduced this paper. He said that at the last meeting it had been agreed that there was no case for routine anti-HBc testing of blood donors with a history of jaundice. It had further been agreed that donations from donors who had been found to be anti-HBc positive during current trials or incidentally found to be anti-HBc positive should be excluded from cellular use.

7.2 After discussion the Committee agreed with the FDA recommendation that plasma from these donors whether recovered from whole blood or obtained by plasmapheresis could be included in pools of plasma for fractionation into blood products.

7.3 It was agreed that the Secretariat would refer the minute of this item in draft to Prof Tedder and Prof Zuckerman for confirmation that it reflected accurately the Committee's view. Dr Gunson and Dr Mitchell would then disseminate it to RTCs as ACVSB advice.

8. Re-admittance of donors not confirmed HIV antibody positive

8.1 Dr Gunson reported that there were no definite conclusions to be drawn from EAGA's consideration of this topic. Nor was there a common approach in Europe.

8.2 After discussion it was agreed that Professor Tedder was to amend his original suggestion to make a generic suggestion for all viruses. The Secretariat were then to circulate the proposal to Members for comment before drawing it to EAGA's attention in respect of HIV. Subject to EAGA's response the proposal was to be disseminated to RTDs as ACVSB advice.

9. HTLV1 BTS Study: Preliminary Report (ACVSB 11/6)

9.1 The Chairman reminded Members that this study had been undertaken at the request of ACVSB and had been funded by the Department of Health. He asked, in the light of the study did members need more information before discussing this topic.

9.2 After discussion it was agreed that the Secretariat were to arrange for a sub-group consisting of Dr Gunson, Dr Mitchell and Dr Mortimer were to meet to consider the topic and the points raised in the study. Dr Brennan one of the authors of the report and Dr Contreras were to be invited to join the sub-group. The Secretariat were to seek legal and ethical advice on look-back studies and commission a cost/benefit analysis of HTLV1 testing.

9.3 The sub-group were to report back to the main committee with recommendations for advice to Ministers.

10. Evaluation of in vitro diagnostics by the Public Health Laboratory Service (ACVSB 11/7)

10.1 The Chairman said that broad agreement had been reached between the Department of Health and PHLS to replace the present ad hoc arrangements for funding PHLS for the evaluation of IVDs related to screening of blood donations with a 2 year rolling contract. Details of the agreement were still being discussed.

10.2 Dr Gunson, on behalf of the National Blood Transfusion Service, welcomed this news.

11. Any other business

11.1 The Chairman suggested that the Committee may wish to consider Yersinia infection at a future meeting. Although Yersinia was not a virus, ACVSB was a suitable forum for providing advice on this topic to Ministers.

11.2 It was agreed that the Committee would consider Yersinia infection. Dr Mitchell said he was preparing a report on non-viral infections including Yersinia for the UK BTS TTD. He undertook to prepare a paper based on these findings for the next meeting.

12. Date of next meeting

12.1 This was fixed for Friday 21 February 1992.

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ACVSB 12/10 0001

CONFIDENTIAL TO COMMITTEE MEMBERS
NOT FOR PUBLICATION

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD

MINUTES OF THE TWELFTH MEETING HELD ON 21 FEBRUARY 1992

Chairman: Dr J S Metters

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

Observers: Dr J Purves
Dr F Rotblat

Secretariat: Dr A Rejman
Mr J Rutherford

1. Apologies for absence

The Chairman reported that apologies for absence had been received from Dr George, Dr McIntyre, Dr Mitchell, Dr Mock and Mr Canavan.

2. Minutes of the meeting held on 29 October 1991

The minutes of this meeting were agreed subject to Prof Tedder confirming the accuracy of minute 7.

(ACTION: Secretariat, Prof Tedder)

3. Matters arising not dealt with as agenda items

3.1 Funding anti-HCV screening (ACVSB 12/1)

The Chairman thanked Dr Gunson for preparing this paper describing how Regions were funding anti-HCV screening. There were difficulties in North West and North East Thames. The NHS Management Executive had indicated that they were willing to discuss these difficulties with the Regions. The Secretariat undertook to pass details to the Management Executive when they were received from Prof Tedder.

(ACTION: Secretariat)

3.2 Chronology of HCV testing (ACVSB12/2)

The Chairman said that this paper was part of the minutes of an ad hoc meeting of the UK BTS TTD. The paper had been provided for information and was confidential to the Committee.

3.3 Dr Craske's report: Further evaluation of anti-HCV blood donor screening in 5 Transfusion Centres

The Chairman reported that Dr Craske's report had been circulated and no comments had been received. Prof Tedder said that the serology of HCV had proved difficult and there was a need for this work to continue. Dr Gunson said there had been a good correlation between RIBA and PCR tests.

3.4 Preliminary analysis of HCV testing (ACVSB 12/3)

Dr Gunson said that the results of this analysis so far had shown that the need for confirmatory tests could be reduced by undertaking two ELISA tests but the current policy of discarding the donations when the initial screening test proved positive must remain. The Scottish BTS had offered to do 90-100 RIBA tests without charge on donations from England. Prof Tedder said that he would like to test some indeterminate samples, especially anti-P22 for which his laboratory had developed a cheap and accurate test.

3.5 Members expressed concerns about the disparities in the way second and confirmatory testing was being handled. Dr Gunson estimated that to undertake a proper study in England would cost £10-£15,000.

3.6 It was agreed that Dr Gunson, Dr Mortimer and the Secretariat were to draft a letter to the Department of Health's Research and Development Division giving the Committee's views on the importance of funding this work.

(ACTION: Dr Gunson, Dr Mortimer,

Secretariat)

3.7 Prof Tedder mentioned that his request for support on work on the epidemiology of HCV transmission based on screening of blood donors had been turned down by DH and Wellcome. ACVSB had supported the need for this work. The Committee reiterated its support for the project. Members asked the Secretariat to emphasise to RDD the Committee's interest in this proposal and their view that it merited DH funding.

3.8 Re-admittance of donors not confirmed viral antibody positive

Prof Tedder reported that his proposal on the re-admittance of these donors was to be available for the next meeting.

(ACTION: Prof Tedder)

3.9 Evaluation of in-vitro diagnostics by PHLS

Dr Mortimer reported that since the last meeting PHLS had signed a 2 year contract with the Department of Health for a rolling programme of evaluation of diagnostic kits with priority given to transfusion kits. Despite this he anticipated difficulties in having sufficient funding to evaluate the large number of HCV kits that were becoming available.

3.10 In discussion, Members supported the need for PHLS to undertake this work.

3.11 Dr Mortimer undertook to write to the Project Officer about this and copy his letter to the Secretariat who were to take the matter up with the Department of Health on behalf of the Committee.

(ACTION: Dr Mortimer, Secretariat)

4. Non HCV - tested plasma (ACVSB 12/4)

4.1 Dr Purves thanked Dr Lane and Dr Perry for the contributions which helped him to produce a paper on the UK position in respect of non-HCV tested plasma.

4.2 It had been clear that the original consultation in the EC had not included many interested parties particularly the EPFA representing the fractionators of voluntary donated plasma. A more informed paper would now be discussed by the Biotechnology Working Party. It was to concentrate on a Framework of recommendations to give flexibility in interpreting the CPMP recommendations.

4.3 Dr Lane and Dr Perry expressed a special interest in developments particularly with regard to the date on which the recommendations were to become effective.

4.4 The Committee noted the paper.

5. EC Directive on blood products (ACVSB 12/8)

5.1 Dr Purves said that the guidelines for the EC Directive would not now include placentae. The UK had successfully agreed that quality of starting materials and screening were the elements which gave the highest quality standards to finished blood products.

5.2 The Committee thanked Dr Purves and would watch future developments within the Commission.

6. ALT testing of blood and plasma (ACVSB 12/5 and 14/6)

6.1 Dr Rejman said that ALT had first been discussed by the Committee in 1989 when there was no commercially available anti-HCV test. Since the introduction of anti-HCV screening there had been a marked decrease in the transmission of NANB hepatitis by blood transfusion. [The ALT test therefore had largely lost its main use as a marker for HCV. The case for introducing ALT testing was that it may identify donors in the early stages of HCV infection. Although the cost of routine screening would be small, the loss of between 1.1 and 3.2% of donors would be considerable to the NBTS in terms of finding replacements and undertaking further investigations on those identified by the test as having raised ALT.] There was no European requirement for ALT testing.

6.2 The Committee recommended that an amendment be made to the paper, the addition of words "reporting of" before "transmission of NANB hepatitis" in the summary. This was to reflect the incompleteness of reporting of NANB hepatitis.

6.3 After discussion members agreed that taking into account the potential loss of healthy donors, there was insufficient reason to justify a recommendations to Ministers that ALT screening of donated blood should be introduced in this country.

7. HTLV1 testing of blood donations (ACVSB 12/6)

7.1 Dr Rejman reported that a sub-group had met to consider HTLV1 testing and a record of their meeting was included as the annex to paper ACVSB 12/6. The sub-group's view was that there was no case to support the introduction of anti-HTLV testing of blood donors in the UK. It was inappropriate and impractical to attempt to screen for anti-HTLV by geographical area within the UK or by limiting screening to donors from races or nationalities where HTLV was endemic or widespread. The cost of introducing routine anti-HTLV screening would include the loss of between 0.1 and 0.4% of donations, the permanent loss of donors and the difficulty of counselling them, the unnecessary worry caused to donors and the financial cost together with staff and premises implications for the NBTS.

7.2 In discussion concern was expressed that a decision not to test for anti-HTLV would be difficult to defend on purely medical and scientific grounds as an acceptable test was available. It was agreed that in arriving at a recommendation the Committee must take into account all factors some of which would not have a medical or scientific bearing. Some Members were uneasy that a recipient of HTLV infected blood who went on to develop a related illness, would be able to sue for compensation in the courts as a test was available. However, the introduction of a new routine test was not a simple matter for the NBTS. A minor amendment was suggested to 7.4 to exclude the word "greatly" and replace "any" with "the".

7.3 Members wished to see the evidence re-assembled with the emphasis put on costs and psychological harm done to donors.

7.4 Members agreed they could not at this stage decide on their recommendation to Ministers on whether anti-HTLV should be introduced. It was agreed that the HTLV sub-group was to be reconvened to consider the evidence again in the light of discussions at this meeting.

(ACTION: Secretariat)

7.5 The Chairman reminded the Committee that its role in advising Ministers needed to be considered. The Committee could not just consider the accuracy and availability of a test in isolation of other relevant factors.

8. Non-viral infections of Blood Transfusion including YERSINIA (ACVSB 12/7)

8.1 Dr Gunson said that one in 1 million donations caused death by bacterial infection. The FDA were taking an educational approach to this and there was a rapid test for bacterial entotoxin under development.

8.2 The information gathered by the UK BTS TTD had given rise to concern about the variability of the action taken when a bacterially infected donation was identified. The TTD Committee were producing guidance for hospitals which was to underline the need for post-transfusion incidents to be reported.

8.3 The Committee agreed with the educational approach adopted by the FDA. Dr Gunson undertook to let the Committee see the NBTS guidance when it was ready.

(ACTION: Dr Gunson)

9. Any other business

9.1 Hepatitis A (ACVSB 12/9)

The Chairman said that this paper gave a summary of a hepatitis A outbreak among Italian haemophiliacs It was a local incident and served as a cautionary tale. The Committees noted the paper.

9.2 Virally inactivated fresh frozen plasma

Dr Perry said that virally inactivated fresh frozen plasma was being produced in Europe and should be considered for use in this country.

9.3 Dr Gunson said that the matter had been discussed by the UK BTS TTD. The NBTS were to get some domestically-sourced plasma treated by this process for tests. He undertook to inform the Committee when clinical data on efficacy and safety were available.

(ACTION: Dr Gunson)

10. Date of the next meeting

This was fixed for Wednesday 17 June.

CONFIDENTIAL TO COMMITTEE MEMBERS

NOT FOR PUBLICATION

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD

MINUTES OF THE FOURTEENTH MEETING HELD ON 29 SEPTEMBER 1992 IN ROOM 63 HANNIBAL HOUSE, ELEPHANT AND CASTLE LONDON SE1

Chairman: Dr J S Metters

Members: Dr J Garrett
Dr H H Gunson
Dr R L Lane
Dr R Mitchell
Dr P Mortimer
Dr R J Perry
Prof R J Tedder

Observers: Dr A Keel
Dr J Ludlow
Dr F Rotblat

Secretariat: Dr A Rejman
Mr J Canavan
Mr J Rutherford

1. Chairman's Introduction

The Chairman opened the meeting by reporting the resignation from the Committee of Dr Wensley.

2. Apologies for absence and welcome

The Chairman reported that apologies for absence had been received from Dr Minor, Dr Mock, Prof Zuckerman and Dr Purves. He welcomed to the Committee Dr Garrett who was attending in place of Dr Minor and Dr Ludlow as observer from the Welsh Office.

3. Minutes of the meetings of 21 February 1992 and 2 July 1992

The minutes of these meetings were agreed.

4. Matters arising not dealt with as agenda items

4.1 Funding anti-HCV screening.

Mr Canavan reported that the Secretariat had raised the issue through Departmental channels but would now go directly to North West Thames Region for information and report the finding at the next meeting.

4.2 Study of epidemiology.

Dr Rejman report that the Department's view was that funding for this study was more appropriate to MRC than to the Department. Prof Tedder undertook to approach MRC for funds to start the study. The Chairman said that the Secretariat would enter a bid for Departmental funds for it for the 1993/94 year, but funding could not be certain as the bid would be considered in competition for limited resources.

4.3 Re-admittance of donors not confirmed antibody positive.

Prof Tedder reported that various difficulties had delayed the preparation of this proposal but it should be ready in the next few weeks. Dr Gunson confirmed the need for such a proposal in the NBTS.

4.4 Evaluation of in-vitro diagnostics.

Dr Mortimer reported that following correspondence with the Departments MDD a draft protocol for evaluation of HCV kits was being proposed. It was agreed that this would be considered by NBTS before it was put to the Committee.

Dr Gunson reported that a case was being brought against North West RHA by a patient who had aquired HCV before the test was introduced. He further reported that East Anglian RTC had proposed a change to its HCV testing protocol. There was some concern in the NBTS about this. It was being considered by the UK BTS TTD Committee. It was agreed that although the outcome may be a matter for the ACVSB it was proper for the TTD Committee to consider it at this early stage.

5. Non-viral infections of blood (ACVSB 14/1)

5.1 The Chairman said that paper ACVSB 14/1 consisted of two recent articles from the medical press on Yersinia.

5.2 Dr Mitchell said that he had provided some of the information for the author of the BMJ article. He was now writing up the UK survey on the incidence of Yersinia in blood donors with a view to publication. The paper was to be available for the next meeting.

6. HCV antibody screen positive, RIBA negative plasma (ACVSB 14/2 and 14/3)

6.1 The Chairman said that papers ACVSB 14/2 and 14/3 gave the different views of the English and Scottish fractionators on whether plasma which is HCV screen positive but RIBA negative is acceptable for fractionation. A co-ordinated UK approach and he was looking to the Committee for advice on what this should be.

6.2 The fractionators and Blood Transfusion Service representatives from both England and Scotland put their views. Dr Perry put the view that as the scientific evidence showed that ELISA reactive, RIBA2 negative donations did not pose a signficant risk of HCV infection there was therefore no virological reason why such plasma should not be used for fractionation.

6.3 Dr Lane said that the HCV testing criteria for releasing cellular components for tranfusion should apply to plasma for fractionation. He accepted that this was not a wholly scientific argument and it would mean turning down plasma with a high probability of being safe. Viral inactivation procedures did not change this view.

6.4 Dr Gunson and Dr Mitchell took the view that there was no safety reason for discarding the plasma. Also, they had concerns about the difficulties of counselling donors who were deferred because of HCV screen positivity. It was estimated that 2,000 to 2,500 donations of plasma a year would be lost if Dr Lane's approach were adopted.

6.5 Dr Lane's view was supported by the virologists on the Committee. While the argument was not strictly scientific it provided a consistent line for the treatment of blood and plasma arising from the same donation. Instances had occurred of some ELISA positive and RIBA negative donations being shown to be positive on subsequent testing. Virologists pointed out that PCR testing in plasma pools of 500 units would not be reliable.

6.6 In wide-ranging discussion the two positions could not be reconciled. The Chairman said that he was satified that there was no real safety issue involved. The argument was one of scientific evidence indicating that this plasma posed no significant risk of transmitting HCV infection being set against the problems of public perception that would arise from treating differently the cellular components and plasma coming from the same donation. Despite the scientific data it would be difficult for Ministers to convince the public that one type of component was safe for use but not the other.

6.7 It was agreed that a summary of the discussion was to be forwarded to Members for comment. Their views would then be put to the 4 Health Ministers to decide on UK policy.

7. EC Directive on blood products

Dr Rotblat reported that there had been no major developments on the Directive. Dr Perry expressed concern about plasma and blood products which had not been tested for anti HCV. Dr Rotblat was to ask Dr Purves to let the Committee know about any developments on this matter.

8. Virally inactivated fresh frozen plasma

8.1 Dr Lane reported that an evaluation of virally inactivated plasma would be undertaken once the CTX had been approved and the manufacturing unit had been inspected. A trial would also be undertaken on a French product. Although the French firm had imposed conditions on the plasma specification there would be value in running both trials.

8.2 In discussion concern was expressed that once virally inactivated plasma was available there would be an immediate demand for it and a move away from fresh frozen plasma. The virologists view was that virally inactivated pooled plasma would not necessarily be safer than fresh frozen plasma drawn from UK donors.

8.3 Dr Lane undertook to report the results of the trial when they became available.

9. HTLV1 testing of blood donations

9.1 The Chairman reported that following the last meeting a submission had been put to Ministers giving the Committee's advice on HTLV testing.

9.2 Dr Gunson reported that the preliminary trial at Leeds RTC of the Biokit HIV/HTLV combination test kit had been abandoned after the kit was found to give an unacceptabily high rate of false positives for anti HIV.

9.3 Prof Tedder reported that he knew of information which indicated an association between HTLVII and TSP. He undertook to enquire whether the information had been published and if so to furnish a copy for circulation to Members.

10. Parvovirus B19 contamination (ACVSB 14/4)

10.1 The Chairman said that this paper had been prepared in order to seek a view on whether the Committee should consider the matter more fully at a later meeting. The EC and the Council of Europe were not active in this field which may limit any UK action in view of harmonised licensing arrangements.

10.2 In discussion there was no agreement as to the degree of risk B19 posed in fractionated products. It could be eliminated but effective testing could only be done on single donations and not on pools. Viral inactivation might be an alternative to testing.

10.3 The Secretariat undertook to investigate screening possibilities in consultation with Prof Tedder and prepare a paper for the next meeting.

11. Any other business

11.1 Recipients of human pituitary derived gonadotrophins (ACVSB14/5) The Chairman said that the Committee may wish to consider whether gonadotrophin recipients should be excluded from donating blood. These patients were much less well documented than recipients of human growth hormone. In discussion it was agreed that the risk to the safety of the blood supply was very small indeed and there would be particular difficult in ensuring self exclusion by these donors. The Committee agreed to keep the subject under review in the light of further information that may emerge.

11.2 HIV seronegative AID.

Dr Gunson wanted the Committee to take note of developments of this disease. Dr Mortimer and Prof Tedder were aware of information that was available from the Communicable Disease Surveillance Centre and undertook to provide this for the next meeting.

11.3 Hepatitis E.

Dr Gunson reported that Abbott had offered anti Hepatitis E kits to some RTCs for evaluation. The Secretariat undertook to prepare a paper on Hepatitis E for the next meeting.

11.4 HbcAb testing.

Dr Gunson reported for information that HbcAb core testing was about to begin in 4 RTCs.

12. Date of next meeting

This was fixed for 9 February 1993 at 11.00am.