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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CONFIDENTIAL TO COMMITTEE MEMBERS**NOT FOR PUBLICATION****ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD****MINUTES OF THE 9TH MEETING HELD ON 25 FEBRUARY 1991**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.

MINUTES OF THE MEETING OF 21 NOVEMBER 1990 (ACVSB 8/10)

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/supplementary 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 be circulated 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 number 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 Igm, 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.