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NOT FOR PUBLICATION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.