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NOT FOR PUBLICATION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 bid for Departmental funds for it for the 1993/94 year.

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 provideed 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 view and 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. It was not wholly scientific but gave 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 were not 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. 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 unacceptably 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 small and the 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 AIDS

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.

ACVSB - OUTSTANDING BUSINESS

Funding HCV screening in NW Thames (item 4.1 - Secretariat are chasing this).

Funding for Professor Tedder's study of epidemiology of HCV (item 4.2 - Secretariat:a bid has been made).

Professor Tedder's proposal on the re-admittance of donors not confirmed antibody positive (item 4.3 - Professor Tedder - now received).

Draft protocol for evaluation of HCV kits (item 4.4 - to be considered by NBTS first).

East Anglian RTC's changes to its HCV testing protocol (item 4.4 - to be considered by UK BTS TTD first).

Dr Mitchell's draft article on the incidence of Yersinia in blood donors (item 5.2 - Dr Mitchell).

HCV antibody screen positive RIBA negative plasma - outcome of submissions (item 6.7 Secretariat are progressing this).

Plasma and blood products not tested for anti-HCV - report on developments (item 7 - Dr Purves).

Virally inactive FFP - report on the results of the trial so far (item 8.3 - Dr Lane).

Professor Tedder to circulate information on association between HTLVII and TSP (item 9.3 - Professor Tedder).

Paper on parvovirus B19 contamination (item 10.3 Secretariat and Professor Tedder).

Human pituitary derived gonadotrophins and the safety of the blood supply (item 11.1 - Secretariat to keep under review).

Information on HIV seronegative AIDS (item 11.2 Dr Mortimer and Professor Tedder).

HbcAb testing - report back (item 11.4 - Dr Gunson).

<u>New Topic</u>

Paper on Hepatitis E (item 11.3 - Secretariat suggest this is deferred to the new Committee).