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ACVSB 12/10 0001

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NOT FOR PUBLICATION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.

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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.