DR R J PERRY

ACVSB 4/5

0069

FILE NOTE DATE OF NEXT MEETING IN DIARY

NOT FOR PUBLICATION

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD
MINUTES OF THE 4TH MEETING HELD ON 6 NOVEMBER 1989

PRESENT

Dr J Metters (Chairman)

Members:	Dr H H Gunson
	Dr R Lane
	Dr P Minor
	Dr P Mitchell
	Dr P Mortimer
	Dr R Tedder
Secretariat:	Dr A Rejman
	Mr J Canavan
	Miss P Reenay
Observers:	Dr H Flett
	Dr Jacobs
	Dr A McIntyre
	Dr H Pickles
	Dr J Purves
	Dr F Rotblat

Chairman's Opening Remarks

1. Dr Metters welcomed Dr Jacobs, who was substituting for Dr Penhyrn-Jones, who has succeeded Dr George as observer for Welsh Office.

2. It was decided that due to difficulties that some members had in travelling to London, future meetings would begin at 1100hrs.

Apologies for Absence

3. These were received from Drs Perry, Summerfield and Tuddenham, and Prof Zuckerman.

Minutes of the Last Meeting

4. With the exception of the erroneous inclusion of Dr Pickles in the list of observers in attendance, the minutes were agreed as a true and accurate report.

Matters Arising from the Minutes

5. Further to paras 14-15 of the last minutes, Dr Lane had produced a copy of CBLA's Standard Operating Procedure for selection and rejection of plasma on the basis of viral marker tests. This was tabled as paper ACVSB 4/5. As the intention was to compare this with the Scottish equivalent procedure, it was decided to defer discussion to the next meeting.

Human Growth Hormone Recipients

6. Dr Rejman was called upon to give an update. He explained that as of 13 November recipients of hGH will be deferred from donating blood.

7. In view of the medical interest at the time, it was thought that a press release should be produced to advise of the need for recipients of hGH to be excluded as donors of blood in addition to tissue or organs. After extensive consultation it was felt that as the media interest had abated it would be better to hold back the press release, prepare a defensive statement if needed, and send a letter to the appropriate Colleges for them to inform their members as they see fit.

8. Dr Rejman also gave details of the research project to be undertaken by Prof Preece. A new database had now been established, and approaches to FPCs and GPs should begin during November. A pilot study, approaching 10% of recipients identified will then begin early in 1990.

9. The Chairman expressed his personal view that media interest may well be revived with the changes taking place on 13 November.

10. Dr Gunson advised the Committee that it is intended to incorporate the receipt of hGH as a reason for exclusion on the form which donors sign at the reception desk at donor sessions. These forms are being updated at the present, however, and the amendment will be incorporated in the new form available in the New Year. In the meantime a note will be placed on all reception desks noting the change.

11. Dr Mitchell stated that Scotland was adopting the same procedure. He also raised the question of what was to happen about individuals who were deferred for this reason. It was agreed that the most appropriate action would be for the transfusion director to interview the person, as the director has clinical responsibility in the first instance, and then to make them known to Prof Preece.

12. A note will be appearing in MAIL about exclusion of hGH recipients from donors of blood for manufacture of blood products. Dr Lane brought up the question of the possible need to change the wording of data sheets on blood products. It was agreed that he and Dr Rotblat would agree a statement to be included.

EC Directive on Blood Products

13. Paper ACVSB 4/1 was tabled, and spoken to by Dr Purves. He gave details of the background which led to the present directives, and explained that discussions on the modifications to the technical directive 75/318/EEC (which would have force of law) and on the guidelines (advisory only) for blood products

would be discussed at the Biotechnology Working Party meeting on 5/6 February. A UK view would be needed at that time, and NIBSC and MCA would be looking to the BTS and the Department for advice.

14. Dr Lane spoke to paper ACVSB 4/2. He emphasized the point that there is a drive in Europe for use of voluntary unpaid donors, with a subsequent dependence on recovered plasma, as opposed to commercial plasmapheresis. He welcomed the concept of regulation of collection agencies.

15. Dr Gunson advised the Committee that the UKBTS and NIBSC had been preparing guidelines over the last two and a half years, which are at the printers and will be available in early 1990. He thought that these would be an excellent basis for the guidelines and that the specifications would be of value towards the technical directive. In addition Dr Gunson informed the members that the EC Commission also has asked the Committee of Experts on Blood Transfusion to form a Working Party to discuss this matter. The first meeting will be in January, and Dr Gunson will be in attendance.

16. It was decided that MCA, HS, BTS, and NIBSC would agree a paper giving the UK views, which would need to be ready by early January. This paper would then be circulated to all members.

[ACTION: HS1]

17. A paper on virological aspects of biological products is being prepared, with guidelines expected in autumn 1990. It was felt to be important that the Committee be aware of the direction that this paper was taking, and Dr Minor agreed to bring the latest version to the next Committee meeting.

[ACTION: DR MINOR]

HTLV1

18. Dr Gunson spoke to the paper he tabled "Status of Anti-HTLVI/II Testing of Blood Donations in the USA" (ACVSB 4/7). The recommendations given at the end of the paper had since been amended, so that he now felt that the study to be carried out on 100,000 donations in NW Thames should not be anonymous, but should be followed-up. It was expected that it would take approx 9 months to complete.

19. Although he had not visited the US, Dr Mortimer had spoken to a member of the FDA who has responsibility for regulatory aspects, and from that discussion felt that the reasons for going ahead with the study are now even stronger. Confirmatory tests were still unsatisfactory, and IV drug abuse, which contributed to HIV I and II positivity, was less in the UK, and appeared to be better excluded at screening.

20. Dr Tedder also had been unable to travel to the US, but had been in touch with the Retrovirus Labs, who were using Elisa in conjunction with Western Blot and RIPA. He felt that there was

still a need to differentiate between the HIV I and II, and that the US approach was not the best. To progress, he felt that it was essential to identify donors, so that lymphocytes could be obtained to allow differentiation.

21. There was some discussion about the absence of confirmatory tests, the question of couselling and the amount of work that would be caused to the transfusion director.

22. It was agreed that the need for general screening had not been shown, and that the study was needed - on identified patients, with necessary follow-up. Dr Gunson, with Drs Tedder, Mortimer and Contreras would prepare a protocol. Funding would be looked at once the protocol was available. Until the study results were known, a watching brief would be maintained here and on the US.

[ACTION: DR GUNSON]

Non-A Non-B Hepatitis

23. Dr Gunson spoke to paper ACVSB 4/3, and summarised the meeting in Rome to discuss Chiron testing. The conclusions of the BTS committee were that the test will detect a viral marker to NANB, a positive test may mean blood is infected (but not always), and that routine testing for anti-HCV will reduce NANB, but estimates of the extent of the reduction range from 20%-60%. The problems that were identified were the lack of a confirmatory test, and a question mark hanging over the status of the ALT and anti-HBc testing. The recommendations were that routine screening should be introduced only after a confirmatory test becomes available, after the FDA have approved the test and urgent pilot studies have been carried out in this country.

24. During the discussion that followed, members voiced their concerns that the test did not appear to be suitable for testing UK pooled plasma (which tested negative compared with US positive, that test results varied from kit to kit and that diluting a positive sample (by 1:10, in Scotland's experience) resulted in a negative result.

25. Dr Tedder gave the Committee a summary of the history of the Chiron test, and explained that its development used only small proteins (middle section of the RNA), whereas there were better tests on the way which tested for structural proteins.

26. Dr Metters explained that although the Department must bear in mind the possible litigation that could arise from a prolonged delay in the introduction of general screening, the NHS Management Executive would want to know more facts and figures before backing such a move.

27. Dr Gunson said that based on the North London Transfusion Centre's experience, 1:200 patients could be going on to develop chronic hepatitis. Other members felt that the figure (taking account of asymptomatic seroconversion) could be higher. A full

discussion followed.

28. The feeling of the Committee, as summed up by the Chairman, was that the test represented a major step forward, but that the Committee need to know a great deal more about it, and acknowledged the need for a confirmatory test. It was agreed that while the UK would not want to go on in advance of an FDA decision, it could prove difficult if the FDA do not decide in favour of the test. Nevertheless, it was felt that if the UK do put the test into general use RTCs will need to have had experience with it, and therefore pilot studies should go on in Birmingham, Sheffield and Brentwood, to show the feasibility of adding this test to routine practice.

29. The Committee's feeling was that there was no case for using surrogate tests for NANB. ACVSB would support the general introduction of the Chiron test if the FDA approves it, and the pilot shows it to be feasible and non-problematic. For these reasons it was felt that the Committee should be developing an economic case (ie % of NANB that would be prevented and any other data to support) for the Department to fund the routine use of the test (some £5-6mill pa). Prof Zuckerman was seen as one person who would be able to help with such data collection, and Dr Gunson was to be given names of other microbiological experts.
[ACTION: DR GUNSON]

30. The Chairman advised the Committee that the Procurement Department has now made available the £25,000 needed for the pilot study. He also acknowledged Dr Lane's concern over the possible effect that deferral of such donors might have on the plasma pool.

Any Other Business

31. A paper on ALT and Anti-HBc Screening of Blood Donations was tabled by Dr Gunson (ACVSB 4/6). He drew members' attention to table 2, which showed the non-specificity with ALT testing.

32. Dr Gunson also informed members that the first positive HIV2 donor has been found at Lewisham. This was a Mozambique national who should not, strictly, have been bled, and was detected when the test for HIV1 gave an unusual result.

33.There are now 3 centres looking at combined HIV1 and 2 tests. There are 5 companies in competition, and at least two (DuPont and Behring) are offering the combined test at the same price as the HIV1 test. Scotland are testing the Welcome and Abbott tests. All results should be known in time for the matter to be discussed at the next Committee meeting.
[ACTION: DRS GUNSON AND MITCHELL]

Date of Next Meeting

34. This was agreed to be held on Wednesday 17 January 1990, commencing at 1100hrs.

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