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NOT FOR PUBLICATION

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EXPERT ADVISORY GROUP ON AIDS

SCREENING TEST SUB-GROUP

NOTE OF MEETING OF 10 JUNE

PRESENT: Dr A Smithies (Chair)
Dr H Gunson
Dr P Mortimer
Dr R Tedder
Dr A Pinching

SECRETARIAT: Mr A J Williams
Mr M E Arthur

OBSERVER: Mr P Lister

APOLOGIES FOR ABSENCE

1. Apologies were received from Dr McClelland. Dr Rodin had retired on health grounds and Dr Bell had retired from SHHD before the meeting.

MINUTES OF THE LAST MEETING

2. The minutes of the last meeting were agreed subject to an amendment to para 5 last sentence, 'communicate a putative AIDS risk' to 'transmit HTLVIII'.

MATTERS ARISING

3. There were no matters arising other than those listed as agenda items.

PROGRESS ON EVALUATION OF DIAGNOSTIC KITS FOR HTLV III ANTIBODY

4. It was reported that 'Production Pasteur' were marketing a kit; Dr Pinching would advise the name of the Cambridge manufacturer who would be handling the product in this country. A kit using genetically engineered antigen is expected to be available from Ortho in the autumn.

5. It was noted that while ENI and Organon were separate companies they used the same antigen.

6. Members examined the evaluation flowchart produced by Dr Mortimer. Dr Gunson welcomed the provision for "training days". He thought there could be pressure to shorten the August to October timescale for the field trials.

7. PHLS proposed 7 confirmatory laboratories to provide facilities for the NBTS and NHS generally. Sera for quality control, particularly those whose positive reaction was in the "grey area" were needed by the Virus Reference Laboratory so that they could be circulated between laboratories who were testing.

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8. Dr Pinching expressed concern about the present method of anti HTLV III reporting by laboratories. STD clinics identified samples numerically. He felt there was little control over collection of data in an anonymous system. Cases could be reported twice. It was agreed that this should be put to the CDSC Director. It had already been agreed with Dr Galbraith that the NBTS should not report cases who were found positive but leave this to the Reference Laboratory who confirmed the positive case.

9. Dr Mortimer reported that three manufacturers' kits would be tested by the end of June including the Wellcome kit. The protocol could be amended to allow the field trials to go ahead earlier than presently planned. However Dr Mortimer had reservations about such action before PHLS had evaluated more tests including that of Wellcome but appreciated the NBTS position.

10. It was important that an adequate supply of tests was guaranteed by the manufacturer as part of the qualification for being considered as a recommended test.

11. Concern was expressed at the news that two Regional Transfusion Centres (RTC) were particularly anxious to start routine testing in advance of national NH NBTS commencement date. This was contrary to all previously determined policy.

12. It had been established that Bio-Tech USA could offer Western Blot testing. It was agreed all sera in the PHLS panel should be tested unless the cost was prohibitive. Dr Tedder suggested that Bio-Tech should be asked to test the sera without knowing whether or not the samples were ELISA positive or negative and asked what criteria would be used to determine positives. It was agreed that once the protocol for the Western Blot test had been received from Bio-Tech Dr Tedder and Dr Mortimer would be consulted about the detail. It was advisable that a virologist should deliver the sample sera so that the exact method of testing used in the Western Blot could be observed.

13. Dr Gunson then reported on the protocol for the field trials. This had been discussed with Professor Knox and a draft submitted to the Ad hoc panel. He asked if control sera could be supplied by PHLS and how best to make the introduction of them anonymous. He expected the two testing Centres to process 580 specimens a day on average. Dr Mortimer suggests that Dr Taylor at DMRQC Colindale should be contacted about obtaining specimens for quality control and how they should be delivered. Dr Gunson was meeting Dr Contreras and Dr Barbara on 19 June to discuss the detail document on handling samples by the testing centres; he would forward details to members.

14. Dr Tedder considered the sample size might not produce a single genuine positive; the evaluation was therefore about how to employ in the NBTS rather than a "field trial".

15. Dr Pinching was concerned that the assessment would be flawed if based on serological criteria only, and not back to donors. Dr Gunson advised that donations could be traced via session records if necessary and all donors at the session bled again.

REPORT OF REGIONAL TRANSFUSION DIRECTORS (RTDs) PROPOSALS FOR INFORMING DONORS

16. A small working party of RTDs had advised:

(i) all donors should be informed of testing

(ii) literature providing this information should be issued with call-up cards (or at session otherwise)

(iii) donors should be asked to read and sign to agree that results could be given to their GP

(iv) if they did not agree, they should be asked not to donate blood.

Dr Gunson reported that
17. /on finding a positive the donation would be discarded, the test would be repeated on the pilot tube and on the donor bag; all positively reacting sera would be sent for confirmation to the Reference Laboratory. If the test was confirmed the donor would be called to the RTC for further samples and counselling. If the Reference Laboratory was unable to confirm the positive finding the donor would not be informed but the donor card would be marked and the donor tested again at the next visit.

18. If the next donation shows positive, the donor to be contacted for a further sample and to be told of reason for recall. The name and address of the GP would be sought and results forwarded.

19. Dr Pinching was encouraged to hear that the NBTS proposed to give preliminary explanation and advice to donors recalled to give second samples. Members agreed it was crucial that NBTS staff were suitably trained for this 'counselling' role. He questioned the validity of refusing to accept donations from donors who were not prepared for their GP to be informed. Heterosexuals particularly may not wish their lifestyle to be revealed; some may telephone the NBTS to ask why their GPs name was being requested; blood supply could be affected.

20. It was agreed after discussion that "a medical practitioner" would need to be told: donors who did not agree would be asked not to donate.

21. It would be necessary to consult RTDs again on how to inform those donors the NBTS was unable to counsel; it was agreed however that the term "AIDS" or "HTLV III" could not be introduced via correspondence.

DRAFT PAPER FOR DOCTORS ABOUT THE INTRODUCTION OF SCREENING TESTS

22. Dr Smithies draft paper was discussed and members suggested some textual amendment; the Secretariat would incorporate comments and re-circulate.

FOLLOW UP OF EARLIER POSITIVE DONATIONS

23. Where long-standing donors were found to be antibody positive, it was agreed that only physicians should be informed (via the haematologist). It would be for the physician to decide further action. This line would be presented to the BAGA.

24. Reporting of Glandular Fever type illnesses in transfused patients was taken to be an important area for research; Dr Tedder was invited to the next RTDs meeting to discuss such clinical measures of acute infection which could be used in parallel with testing.

ANY OTHER BUSINESS

25. The Australian AIDS Task Force Bulletin 1/85 was circulated; it was considered that the BAGA should advise on employment consequences.

DATE OF NEXT MEETING

26. It was considered that the Sub-group did not need to meet again before the next BAGA meeting.