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NOT FOR PUBLICATION

EXPERT ADVISORY GROUP ON AIDS

SCREENING TEST SUB-GROUP

NOTE OF MEETING OF 1 MARCH 1985

PRESENT: [redacted]

SECRETARIAT: [redacted]

APOLOGIES FOR ABSENCE

1. Apologies were received from [redacted]. Members noted with regret that [redacted] had been taken ill since the last meeting and wished him a speedy recovery.

MINUTES OF THE LAST MEETING (Item 1)

2. The minutes were agreed but in regard to paragraph 4 [redacted] wished to stress that his sera panel required further preparation before it could be used for an evaluation.

MATTERS ARISING (Item 2)

3. [redacted] and [redacted] tabled a paper which outlined a proposal for the evaluation of test kits in a field trial using ten thousand specimens collected routinely from blood donors. It was proposed that ten Regional Transfusion Centres (RTCs) would each collect a thousand specimens and would be responsible for dividing each into ten aliquots. They would then send these to the

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co-ordinating centre. After discussion it was agreed that as many as ten thousand would be required as it was possible that less than one in a thousand of the specimens would be truely positive. The number of aliquots into which each specimen was divided would it was hoped provide sufficient to test all those kits which were found to be reliable in the evaluation undertaken at the PHLS. There would also be sufficient for evaluating tests developed in the 'second generation'. It was thought if possible that Regional Transfusion Directors (RTDs) who agreed to take part in collecting the specimens should be encouraged to select donor sessions where they knew that the frequency of hepatitis B positive donations was high. It was accepted that as there was need for some speed in collecting the specimens it might not be possible for all centres to comply with this request.

4. It was believed that there would be a distinct advantage for the evaluation of all the diagnostic kits to be undertaken at one centre if this could be arranged.

[redacted] and [redacted] would amend their paper taking account of further comments so that it could be included with the paper of recommendations which would go to the Expert Advisory Group. The paper should also go to the ad hoc panel which was being set up to supervise the evaluation of the diagnostic kits.

6. [redacted] confirmed that he would be able to collect specimens of sufficient volume from about a hundred and twenty individuals attending clinics and believed to be at high risk and this could be achieved without difficulty. These would provide materials for evaluation of test kits in a population where the number of positives would be expected to be high. The sera could

also be used to provide a panel of serum against which tests could be evaluated and were of importance. The ad hoc panel supervising the evaluation could be told that the sera could be available and arrangements could be made for their collection.

AVAILABILITY OF TESTS (Item 3)

7. It had been agreed at the previous meeting that tests should be available at Regional Transfusion Centres and at STD clinics. [redacted] reported that the sub-group on counselling had recommended that a consultant should be designated in each district to provide counselling facilities. It was agreed that this consultant should also have access to tests as should in certain circumstances some gps. On the whole it was considered that most general practitioners would prefer to refer their patients to the district designated physician. Members were concerned that an introduction of open access clinics as is the case in Denmark would result in a large number of people attending who did not need tests and for whom there would be inadequate time to provide counselling.

8. It was agreed that counselling should be available to those requesting tests in order that they should appreciate the limited information that a test result would give. [redacted] pointed out that the advice given on how to conduct their lives to members of high risk groups would not differ whether or not their tests were positive. It was already evident that in the United States at least there was a move by homosexual groups to recommend that their members should not subject themselves to tests.

9. A letter to the Lancet signed by a majority of RTDs in England Wales and Scotland was tabled. It was agreed that the letter whilst in danger of being misinterpreted in that it might be regarded as recommending open access screening did point to the concern felt about the early reports of the

unreliability of commercial tests produced in the USA and the need for their full evaluation before they were introduced into Regional Transfusion Centres.

INFORMED CONSENT (Item 4)

10. The field evaluation proposed by [redacted] and [redacted] would not require consent of the participants because the sera would not be able to be identified with the donors.

11. [redacted] and [redacted] recommended that when tests for blood donations were introduced blood donors should be informed that their blood would be tested for AIDS. This could be by informing them through leaflets sent with their call up cards or providing leaflets at the donor session. They thought that a lot of donors would not be prepared to give blood if they knew it was going to be tested for AIDS. Efforts would have to be made to recruit more donors. It was agreed that Departmental legal opinion should be sought on the need to inform or for informed consent of blood donors.

12. [redacted] expressed his ~~dis-ease~~ unease. at 'freezer' studies being carried out on samples collected from individuals attending STD clinics who would not necessarily have given consent for such investigations to be carried out. It was pointed out that such studies provided invaluable information about the spread of the disease for which there was no other way of finding out. It was agreed that the manner in which these studies should be conducted should be given further consideration.

RETESTING (Item 5)

13. At least two tests on the original sample should be carried out if the first test proved positive. [redacted] advocated that the original sample should be referred to the Reference Centre for confirmation before a donor was recalled and referred to the designated physician in his district. [redacted] thought that the donor should be recalled if two tests on the first sample were positive and the second sample taken for confirmation. It was agreed that practise at different RTCs would depend on local decision but all were unanimous that a positive test on two samples one of which would have been confirmed by the reference centre was required before an individual was regarded as being truely sero positive.

POSITIVE TESTS (Item 6)

14. It was agreed that all sera found to be positive should be regarded as potentially infectious and treated as would specimens found to be Hepatitis B positive.

15. [redacted] thought that all donations found positive even if not confirmed should be regarded as inappropriate to use for transfusion and the donor should be taken off the panel. In view of the current lack of knowledge about the exact significance of the test it was considered that such a donor might be deferred. Dealing with these donations would depend on the circumstances and would be a matter for local judgement.

CONFIDENTIALITY (Item 7)

16. It was agreed that the group should recommend the need for strict regard of confidential measures over results in view of the effect that a positive

result could have for a person's future employment. Concern was expressed about possible requests which might arise for test results to be made available although it was agreed that previous experience had been that it would only be for persons believed to be involved in very serious crime.

ANY OTHER BUSINESS

17. There were no other matters raised.

18. Members agreed that they would comment on a paper which would be drafted by the Chairman and Secretariat providing a report of the sub-groups recommendations and to the next meeting of the Expert Advisory Group on 13 March.