

EAGA(3)2

NOT FOR PUBLICATION

EXPERT ADVISORY GROUP ON AIDS

SCREENING TESTS SUB GROUP

REPORT ON THE INTRODUCTION OF A TEST FOR ANTIBODY TO THE AIDS RELATED
VIRUS

TERMS OF REFERENCE

1. The sub-group's terms of reference were:

'To advise the Expert Advisory Group on the introduction of a test for antibody to the AIDS related virus'.

BACKGROUND

2. Five manufacturers of diagnostic reagents in the United States have been licensed by the US Government to use the HTLV III virus isolated by Dr Gallo to develop a diagnostic test for the antibody to HTLV III. The Pasteur Institute are also known to be developing an antibody test based on the LAV virus isolated by Dr Montagnier. In the UK, Wellcome Diagnostics are developing a test for antibody to the AIDS related virus based on Professor Weiss's isolate. One European pharmaceutical firm is known to be developing a test and it is to be expected there will be others entering the field. All the tests are believed to be using ELISA techniques.

3. The test developed by the USA companies have been used in trials to provide data to obtain FDA approval. FDA licences have now been granted to Abbott Laboratories and Electronucleonics enabling them to market their test kits in the US and abroad.

4. The Department has informed all companies known to be developing tests and the relevant UK Trade Association that it is intended to mount an evaluation of all those test kits which are to be marketed in the UK. The Department will then give advice to the NHS on which have proved

satisfactory. A group of experts have been invited to form an Advisory Panel and to agree the protocol for the evaluation.

EVALUATION

5. Following discussion with the sub-group, plans for a 2 stage Departmental evaluation of diagnostic kits have been made:-

1st Stage

A preliminary assessment of each diagnostic kit will be made at the evaluating centre (Virus Reference Laboratory Colindale). Results will be scrutinised by the Advisory Panel.

2nd Stage

Test kits found sufficiently sensitive and specific in the 1st stage will be evaluated in a field trial in the Blood Transfusion Service. Results will be scrutinised by the Advisory Panel which for this evaluation will include representatives of the BTS and an epidemiologist.

6. The sub-group have drawn attention to:

a. the importance of using the same panel of sera for testing all the kits. Evaluations required by the FDA were thought to be unsatisfactory because different sera had been used to evaluate each kit.

b. the need to provide sufficient aliquots of the panel of sera to ensure that they were available when 'second generation' kits were developed. (Arrangements are in hand to collect 14 aliquots from 12,000 samples in the Blood Transfusion Service and hold them at one centre).

7. The sub-group agreed that a competitive solid phase immunoassay and an immuno-fluorescence test based on the Gallo isolate would be used to characterise the sera against which the diagnostic kits will be evaluated.

Samples found positive in the field trial will be subject to confirmatory procedures including the Western blot as they become available.

AVAILABILITY OF THE TEST

8. Testing facilities should be available to clinicians involved in caring for patients in the high risk group for AIDS eg genito urinary medicine specialists, Haemophilia Centre Directors, psychiatrists involved in the treatment of drug abuse, infectious disease specialists and other hospital consultants who may be designated by the District to counsel AIDS patients. General practitioners with a special interest in caring for individuals in certain high risk groups should also have access to tests. The availability of tests in the National Health Service should be publicised before or at least simultaneously with the introduction by all Transfusion Centres of the screening of blood donations. The sub-group endorsed the decision taken by Regional Transfusion Directors that the screening of blood donations for antibody to HTLV III should be introduced as far as possible at all Centres at the same time. The sub-group recognised that Transfusion Centres would need a familiarisation period when introducing the test before they started to give the results obtained to donors.

CONSENT TO BE TESTED FOR ANTIBODY TO THE AIDS RELATED VIRUS

9. Tests undertaken as part of the evaluation studies would not require the consent of donors as the sera would be made anonymous.

Tests undertaken on individuals in high risk groups and others considered to be at risk should be with consent after counselling.

Blood donors should be formally notified that all donations will be screened routinely and that the test result will be given to the donors so as to give them an opportunity to withdraw. The sub-group recommends that Regional Transfusion Directors should devise an agreed procedure for all Centres to follow when informing donors.

REFERENCE CENTRES

10. Before routine testing of blood donation is commenced, Reference Centres must be established to which positive sera wherever initially tested can be referred for confirmation. The sub-group identified a need for panels of reference sera to be collected and distributed to laboratories undertaking testing.

SCREENING BLOOD DONATIONS

11. All sera obtained from blood donors and found to have a positive screening test reaction should have the test repeated:

a. if the repeat test is positive a further sample should be obtained from the blood pack and sent to the reference centre. Only if the reference centre confirms the positive result should the donor be recalled, informed and referred for further testing and counselling.

b. if the reference centre does not confirm the screening test result the donation should be discarded. At the next visit the donor will again be screened and steps taken according to the results of that screening test.

c. if the repeat test is negative after a positive initial test a sample should be sent to the reference centre for confirmation. If the confirmatory test is positive then the donor should be recalled as in a. above. If the confirmatory test is negative then that donation should be discarded but the donor should be kept on the panel and tested again at the next visit.

PRECAUTIONS WITH POSITIVE SERA

12. Once a serum specimen has been confirmed to be antibody positive it should be regarded as potentially infectious. Subsequent handling should be with similar precautions as those recommended for hepatitis B positive sera.

CONFIDENTIALITY OF RESULTS

13. The strictest confidentiality of test results should be maintained and the necessary arrangements and facilities provided to preserve such confidentiality.

RESOURCE IMPLICATIONS

14. The sub-group felt that a common feature of all of their recommendations - on freely available diagnostic testing, reference centres, strict confidentiality etc - was that there would be considerable cost consequences that could not be met from within existing resource allocations.