3686

INTRODUCTION OF TEST TO AIDS RELATED ANTIBODY

You asked for a note of the present situation and arrangements to anticipate the introduction of testing for antibody to the AIDS virus into the NHS.

1. All manufacturers known to be making diagnostic reagents have been informed that DHSS intend to evaluate their kits and to advise the NHS of those that seem sufficiently reliable to be used in laboratories. Responses from five manufacturers have indicated their willingness to co-operate. (It should be noted that the DHSS have no statutory power to prevent the marketing of any diagnosting kits and this is the first time that measures of this kind have been undertaken.

2. The initial evaluation of the kits against three hundred to five hundred sera will be undertaken at the Virus Reference Laboratory PHLS Colindale who have been funded to carry this out. The protocol for this evaluation will be finally agreed by an ad hoc panel of virologists on the 18 March.

3. An Expert Advisory Sub-Group has advised that a field evaluation of the kits is necessary because of the preliminary results of the FDA studies which have been made known to us. A protocol for these field evaluations have been designed and will be considered by the ad hoc panel who will include besides the virologists representatives of the Blood Transfusion Service and a statistician. The field evaluation cannot be started until the kits have gained approval in the initial evaluation. However, arrangements are already being made to collect and store the sera for testing.

4. PHLS have made arrangements for four of their laboratories to collaborate in providing panels of standard sera against which tests can be confirmed. The provision of the PHLS of a reference function has been accepted. Detailed discussion with PHLS of the need to provide facilities for testing sera more generally will be required once the recommendations of the sub group of the Expert Advisory Group is known with regard to counselling/testing etc.

5. Kits which have satisfied the evaluation will be listed by DHSS. PHLS would like the Department (Supply Counsel) to organise bulk buying of kits from commercial sources. If the UK tests can be produced on a large enough scale and proved satisfactory on evaluation it will be the most acceptable one to put in the NBTS. Not only have Regional Transfusion Directors pronounced their resolve to commence testing in each centre at the same time but they have also indicated their wish to use the same test in each centre.

6. It will be recommended by the Screening Sub-Group to the Expert Meeting on the 13 March that diagnostic tests should be available in the NHS before they are introduced to screen all blood donations.

7. [redacted]s are the first US firm to have been given FDA approval for their test. Arrangements are being made for their test to be put to evaluate at PHLS Colindale. There are presently no available kits from [redacted] in this country they are importing a small quantity during this week and [redacted] has agreed with the sales representative to look at the diagnostic kits and the apparatus in a preliminary way.

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[redacted]
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