

INTRODUCTION OF TESTING FOR HTLVIII ANTIBODY - SOME ISSUES FOR CONSIDERATION BY RTD'S.

1. It is essential to have good data on the numbers of true and false positives which will actually be obtained. Therefore introduction of testing must await the results of the UK study since there is some evidence that some tests may give substantially lower false positive rates than others that are currently being marketed.

2. A uniform policy must be adopted about the interpretation of screening test results and the actions taken when they are received. eg. How do we define a positive screening test result?

3. Since donors cannot be told of a non-confirmed result, and since there may be some delay in obtaining full confirmation, each RTC will need to establish a system which makes sure that the next donation given by that donor is not transfused, but at the same time ensures that the donor is not alarmed and that staff problems do not arise.

4. Confirmatory tests must be readily available to each RTC and the turn around time must be fairly short, otherwise incompletely investigated donors will accumulate awaiting a decision and causing serious problems when they reattend.

5. Each Centre will require a system to ensure that a second sample can be obtained from donors who are repeatedly screening test positive and have positive confirmatory tests on the initial sample and pack. In each Region a decision will be needed as to whether the second sample is to be taken by the RTC or will the donor be referred to someone else for the second sample to be taken and initial counselling carried out.

6. Some form of documentation must be available to all donors which informs them that the HTLVIII test will be done and indicates what will be done with the results. The system for distributing this information must take in to account the fact that many donors do not receive call up letters. Donors should be required to sign that they have received this information.

7. A decision must be made about informing the donor's general practitioner about positive test results. If the general practitioner is to be informed, it seems essential that the donor is told in advance that this will be done so that the donor has a chance to withdraw if he/she does not wish the GP to be informed. It is understood that a Department letter will inform all general practitioners before the BTS is required to begin notifying donors of test results.

8. Before Regional Directors make the decision to start telling donors of positive test results, it is essential that each RTD knows who will be responsible for the continuing care of the donor (eg the GP, STD clinic, Infectious Diseases or Medical Consultant, or RTC medical and nursing staff.

Whoever is responsible must be prepared to deal with problems such as the continued clinical and laboratory monitoring of the donor, emotional support, counselling on prognosis, family/sexual counselling, life insurance problems, employment problems etc.

-2-

9. In view of the data recently presented by Seidl and Kuhn (Lancet May 4, 1985 p 1047) very firm decisions will be required about the interpretation of 'grey zone' or 'high positive' test results. Failure to do this could lead to extremely wide differences in false positive rates between Regions.

10. There is an urgent need for a decision, endorsed at a very high level, about the policy governing the tracing of recipients of previous donations from donors found to be positive.

11. RTD's may wish to discuss what laboratory investigations would constitute full confirmatory testing on a donor. Two studies presently on going in the United States involve attempted virus isolation from donors found to be antibody positive. A study of this kind in the UK may be highly desirable as it should provide additional information on which the counselling of antibody positive donors would be based.

12. RTD's may wish to discuss the need to ensure that donor samples currently being collected are retained in such a way that they can be tested for HTLVIII antibody at a later date and recipient follow up carried out to determine the frequency with which transmission occurs.

D.B.L. McClelland
15.5.85.