COMPARATIVE STUDY OF ANTI-HCV TESTING USING ORTHO AND ABBOTT TEST SYSTEMS

Previous studies using the Ortho ELISA test have revealed an incidence of HCV seropositivity of 0.2-1.0% in the U.K. It is not known if the Abbott test, available from 1st July 1990, will detect the same or different donors in a given population. In order to test this, it is proposed to examine the same 10,000 random blood donations by both tests. Also, repeatably reactive samples by either or both tests (estimated to be between 50 and 100) will be sent for supplementary testing at three specialist laboratories. Based on evidence obtained from screening blood donations in Finland, the supplementary tests should eliminate approximately two-thirds of the reactive samples leaving one third where there is a higher probability of HCV infectivity. This, if correct, will substantially reduce the need for donor counselling.

PROPOSAL FOR STUDY

1. Three RTCs, North London, Newcastle and Glasgow will each perform 3,500 tests on donations which can be identified.

2. The initial tests will be performed on serum according to the manufacturer's instructions and the definition of a positive reaction will be by the cut-off determined by the manufacturer.

3. The O.D. results for the entire series of tests will be recorded.

4. Initial positive results by any of the screening tests will be identified and repeated by both Ortho and Abbott tests in duplicate on the serum samples and a sample of plasma from the donation.

5. Those donations which are repeatably positive, i.e. give a positive result in at least one of the repeat tests, using either test system will be withdrawn from use, the plasma separated and, using suitable quarantine arrangements, stored frozen and reserved for possible future use.

6. Before freezing a minimum quantity of two mls of plasma which must not be heat inactivated from repeatable positives should be sent to each of the following:

Dr. P.P. Mortimer - PHLS, Virus Reference Laboratory, Colindale

Dr. R.S. Tedder - UCMSM Hospital, London

Dr. E.A. Follett - Ruchill Hospital, Glasgow

The repeatably reactive samples will be tested by the Ortho RIBA and the Abbott confirmatory test procedure and by immunoassay based on other HCV proteins (if available). Those donations that are reactive in these assays will be tested by PCR.

7. The above specialist laboratories will provide a co-ordinated report following the supplementary tests indicating which donations should be considered free of HCV

markers which contain antibodies to HCV proteins and which contain HCV RNA.

8. After discussion with the specialist laboratories any frozen library samples from previous donations of the positive donors may be subjected to tests with the two test systems.

9. The RTC will flag the donor records of initial reactives found subsequently to be either HCV negative or equivocal, but will not contact the donors who will be allowed to donate on a future occasion.

10. Those donors who are regarded by the specialist laboratories as anti-HCV positive will be recalled by the RTC and interviewed by a member of the medical staff. A careful medical history will be taken and arrangements will be made for tests of liver function. It will be appropriate if this aspect of the study is conducted in conjunction with a specialist in liver diseases.

REPORTING ARRANGEMENTS

Dr. H.H. Gunson will act as co-ordinator of the study and the following reports should be sent to him at the National Directorate, Manchester.

1. After the 3500 tests at each RTC, the raw data from the tests including O.D. values and any analyses of the data. These results should include the total number of tests

performed, the number of initial positives and the number of repeatable positives. With respect to repeatable positives the O.D. value of each test should be quoted.

2. A copy of the report from the specialist laboratories following the supplementary tests on the repeatable positives.

3. A report on the clinical evaluation of the donors whose sera contain anti-HCV.

These three reports will be provided by Dr. H.H. Gunson for participants in the study and other interested parties on the phases of the study outlined above, within a short time of the data being made available.

ESTIMATED COSTS

The best estimate that can be given at the present time for the entire study would be in the order of £150,000. Of this approximately £100,000 will be required at the specialist laboratories and up to £50,000 at the RTCs depending upon the initial cost of the test kits.

R. MITCHELL
H.H. GUNSON
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