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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. An additional sample of 10 ml clotted blood will be collected from each donor admitted to the study.

3. The screening 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.

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

5. Initial positive results by either 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.

6. A repeatably positive donation is defined as one which is positive in one or more of the repeat tests. If the plasma sample from the donation is the only one which fails to give a positive reaction then steps must be taken to verify that the correct donation has been identified.

7. The plasma will be separated from the repeatably positive donations and three aliquots, each of 2 ml will be separated and these, together with the remainder of the plasma will be frozen at -30°C under suitable quarantine arrangements and reserved for future use.

8. The serum remaining from the donor samples of repeatably positive donations will be separated and stored frozen at -30°C in 0.5 ml aliquots.

9. There must be no heat inactivation of either serum or plasma samples.

10. The RTC will flag the donor records of repeatable anti-HCV positives, but will not contact the donors at this stage.

11. From each repeatable positive donation one aliquot of 0.5 ml of serum and one 2 ml sample of plasma each labelled with the donation number should be sent at the end of the RTC phase of the study to **each** specialist laboratory. The samples need not be transported in the frozen state.

12. The specialist laboratories are:

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

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

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

The three specialist laboratories will define a unified protocol for testing the referred samples. Basically, however, the repeatably positive samples will be tested by the Ortho RIBA and the Abbott neutralisation test and by immunoassays based on other HCV proteins (if available). Those donations that are reactive in these assays will be tested by PCR.

13. 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.

14. 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. The 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.

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.

H.H. GUNSON
27.6.90.

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