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EXTENDED TRIAL OF ANTI-HCV TESTS ON BLOOD DONATIONS

1. BACKGROUND

The multi-centre trial using 1st generation Abbott and Ortho anti-HCV tests was completed some weeks ago. It was agreed at the last meeting of the ACVSB that the 2nd generation tests from Abbott and Ortho should be tested using the frozen samples from the multi-centre trial, together with tests from other manufacturers which may be available.

This series of tests is now in progress and a preliminary report will be available for the meeting.

Northern RTC commenced routine anti-HCV tests on blood donations, unilaterally, in the last week of April 1991 using 2nd generation Abbott test kits.

2. PROPOSAL

2.1 I suggested to Dr. H. Pickles that the premature introduction of the test in the Northern Region could be used to extend the scope of the 2nd generation tests by including tests from other manufacturers. With Dr. Pickles' agreement I contacted Yorkshire and Mersey RTCs and they agreed to commence an evaluation using the Ortho test kit and Professor Cash has agreed that Glasgow and West of Scotland RTC would enter the extended trial using Abbott test kits. Northern RTC have agreed that they will enter their results into the extended trial.

Subsequently, I held a meeting with Mr. Eric Evans and Mr. Mark Fuller at the Procurement Directorate and they have been holding discussions with a third Company supplying anti-HCV tests (UBI) and I was asked if I could arrange for test kits from UBI to be included in the extended trial. To this end I have contacted Trent and S. Western RTCs and they have agreed to do this work.

2.2 The donations used for the trial will be those that are collected currently. The protocol calls for donations to be tested at the RTCs according to the flow chart attached to my paper ACVSB 10/2 (without ALT tests being performed). Repeatably positive samples will be referred to PHLS, Manchester for RIBA tests and to PHLS Colindale for PCR tests.

2.3 A major objective of this extended trial is to evaluate PCR tests as part of confirmatory studies. The number of RIBA positive results which could be subjected to PCR tests from the first multi-centre trial (para. above) was only six. This is an insufficient number on which to conclude whether PCR should be included routinely as a confirmatory test.

It is estimated that in the extended trial there will be 30-40 RIBA positives and the data obtained from these tests will be invaluable in assessing the status of PCR testing.

If PCR need not be used routinely, then the savings to the NHS in the first year of anti-HCV testing will be in the order of £180,000 for testing alone to which has to be added the not insignificant costs of storage and transport of samples as described in the paper ACVSB 10/1.

2.4 **Financial Consequences**

The contribution of the RTCs to the extended trial will be the purchase of ELISA screening test kits and the performance of the screening tests. However, since routine testing was not due to commence until 1st September and financial assistance is requested for the confirmatory testing for the Yorkshire, Mersey, S. Western and Trent RTCs. Northern RTC have agreed to pay for confirmatory testing on their samples and SNBTS will finance the testing at the Glasgow RTC.

In Appendix I an estimate of the cost of the confirmatory testing is given. This is set-out in two parts. The costs of my original proposal for the extended trial using Ortho test kits at Yorkshire and Mersey RTCs and the estimated costs of confirmatory testing if Trent and S. Western RTCs carry out an extended evaluation on UBI tests.

H.H. GUNSON

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