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# PILOT STUDY TO ASSESS THE INTRODUCTION OF ROUTINE ANTI-HCV TESTS IN RTCs

## DRAFT PROTOCOL

1. **PARTICIPATING RTCs** - West Midlands
   North-East Thames
   Trent

2. **AIMS OF THE STUDY**

   2.1 To carry out anti-HCV tests on approximately 5000 donations during a two week period commencing early December 1989. The testing should be incorporated in the daily work of the RTC.

   2.2 To assess the performance of the test in the following respects:

   (i) The ease of the performance

   (ii) The diagnosis of negative and positive results

   (iii) An assessment of its introduction into routine working practices

   2.3 To assess the costs of carrying out anti-HCV screening other than the costs of the test kits and related equipment, i.e.:

   (i) Staff costs for: performing the test
   documentation
   recall of donors
   counselling

   (ii) Replacement of donors who will have to be withdrawn

   (iii) Collection and other costs of donations which have to be withdrawn (for this purpose NHS handling charges can be used)

3. **PROTOCOL**

   3.1 The test kits and related equipment will be supplied by Ortho Diagnostics Ltd. The staffing costs will be borne by RTCs.

   3.2 The manufacturer will be responsible for instructing the staff on the performance of the test prior to commencement of the study.

   3.3 Samples of serum for testing will be prepared in the normal manner at the RTC from the donations which are undergoing other routine tests on that day. Donations will be identified.

3.4 The manufacturer's instructions for the performance of the tests, including the use of controls as indicated, shall be followed at all times.

3.5 The initial reactives (IR), as defined in the manufacturer's protocol, will be identified and their donation numbers recorded.

3.6 Each IR will be subjected to two further tests as follows:

3.6.1 (i) A repeat test from the original sample used

(ii) A sample of plasma taken from the "bleed" line of the particular donation

3.6.2 If one or both of these tests are positive the test will be regarded as repeatably positive (RR).

3.6.3 If both tests are negative on repeat the test will be regarded as negative.

3.7 Any donation which is repeatably reactive will be regarded as anti-HCV positive and the donation, together with any products prepared from it, will be withdrawn and not issued for use.

3.8 The donor records will be flagged to indicate that a positive anti-HCV result was obtained, but the donor will not be recalled at this stage.

3.9 A report will be prepared detailing the serological results, stating the OD values of controls and anti-HCV positives. (Computer print-outs should be attached to the report).

3.10 From the experience of performing the tests an assessment of performance (para. 2.2) should be made. From the number of RR results obtained an estimate should be made of the costs referred to in section 2.3. These should be included in the report.

3.11 The reports should be sent to the National Director for collation and preparation of the final report for the Department of Health.

H.H. GUNSON
National Director
8.11.89.

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