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DRAFT NOTES ON PROCEDURES FOR THE INTRODUCTION OF ANTI HCV SCREENING

IN THE UK TRANSFUSION SERVICE

INTRODUCTION

In a pilot study in Autumn 1990 three regional transfusion centres (Glasgow, Newcastle, North London) each tested approximately 3500 by the current Ortho and Abbott screening EIA for anti HCV. Of a total of 10633 donations tested, 69 reactive ones were referred as plasma and serum to three confirmatory centres, two in London (the UCH/Middlesex Department of Virology and the PHLS Virus Reference Laboratory) and one in Glasgow. Approximately 6 of the referred specimens were confirmed by Ribatest and PCR as anti HCV positive. Therefore, the initially routine rate in these UK blood donors was 0.7% and the confirmed positive rate 0.06%. If this rate were repeated c15000 donations would be initially positive and 1200 confirmed positive per year, ie as many HCV positives per week as there are HIVs in a lean year.

This pilot study has raised several issues which must be resolved before or soon after universal screening of UK donors for anti HCV starts (if that is to be the Health Departments' decision). They are:

(i) A central database is needed, first to collate findings of the pilot study and then to collect data (as is currently done for anti HIV screening) on the operation of anti HCV screening.

(ii) An agreed algorithm is needed for confirmatory testing in three or more UK virology laboratories. Referral arrangements will also have to be decided.

(iii) Epidemiological study of the characteristics of confirmed HCV positive donors is called for, probably in the form of a 'case control' investigation.

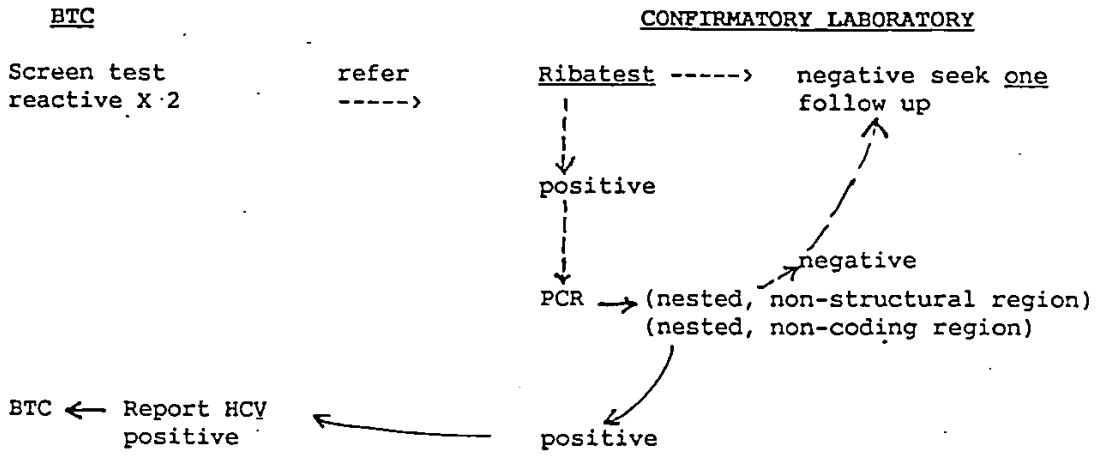
(iv) The clinical state, the management and the prognosis for anti HCV donors ought to be the subject of a long term gastroenterological investigation. Arrangements for the individual care and the collective study of implicated donors have urgently to be considered.

FURTHER NOTES ON THESE ISSUES

(i) A central database. It has been suggested that Miss Violet Rawlinson (Manchester BTC) might extend her work on HIV transmission data to setting up an anti HCV database. Consideration must be given to what minimum data she must collect from regional transfusion centres and confirmatory laboratories. She will probably need support for this.

The DofH has asked for a report and the possible publication of a summary of the findings of the pilot study just completed. Referral of data to Miss Rawlinson from the three Transfusion Centres and the three virology laboratories must be arranged as well as staff time to load the information onto a database and analyse it with regard to reproducibility and strength of OD reactions.

(ii) A confirmatory algorithm. The pilot study suggests that only specimens positive by both Ribatest and PCR should be reported as anti HCV positive. Thus:



Further discussion is needed to define the precise operation of this algorithm.

It would also be desirable to design a referral form for requesting and reporting results of confirmatory tests for HCV infection in donors.

(iii) Epidemiological study. The screening of blood donors is an opportunity to study the pattern of HCV infection in the healthy community in UK. It is suggested that a detailed questionnaire should be agreed and administered to HCV positive donors and, for each one of them, to several age/sex matched controls. Ideally this questionnaire should be administered by a single trained individual and it is tentatively suggested that one or more research nurses should be appointed to do this in the Thames Regions.

(iv) Clinical referral, management & prognosis of HCV positive donors. The HCV screening programme will be unusual in that it will identify donors who are infected with an agent that has a very ill understood clinical evolution and end stage. It is therefore important that as well as a mainly retrospective epidemiological inquiry there is a collaboration with gastroenterologists. This should take the form of a long-term study. There will be difficulties in maintaining continuity and preventing donor default, but it will be important to do this study, nevertheless.

FUNDING

It would be an error to think that the cost of this proposed new screening test will simply be the cost of providing the test in every BTC, expensive though that will be.

Proposals (i to iv) above have significant cost consequences though more clearly defined proposals are needed before good estimates of them can be made. The starting point must be the expected numbers of screen reactive donors and confirmed HCV positive donors. These will lead to the estimates of the resources needed.

At present it seems that 0.5% of UK donors will be repeatedly anti HCV positive = 12,500 donors approximately per year

$\therefore$ 12,500 X $^{6}/_{69}$ = 1,000 per year HCV positive

This means about 25,000 Ribatests per year (allowing for follow ups) and 2500 PCR.

This implies that funding will be needed for a 'case control' study on about 500 individuals (minimum) and a prospective follow-up study on 1000 confirmed HCV positive donors.

COMMENT

There is a danger of seriously underestimating the full costs and burden on existing services of dealing properly with this new screening programme. The Departments of Health should carefully consider the costs, including the add-on costs of screening. ACVSB should look urgently at the implications for procedure and costs of HCV screening and make recommendations to the Departments. In addition, colleagues in the Communicable Disease Surveillance Centre and specialist gastroenterologists (? including their national association) should be included in discussions of arrangements preliminary to the introduction of HCV screening of blood donors.

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AC/STD/HCV-PPM