

NATIONAL BLOOD TRANSFUSION SERVICE

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HHG/LB

9th May, 1991

SAME LETTER TO: All RTDs - England and Wales

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Dear

ANTI-HCV TESTING OF BLOOD DONATIONS

As you may know Dr. Lloyd decided to implement routine anti-HCV testing approximately two weeks ago in order that all products issued from the Northern RTC by 1st July 1991 will have been tested. He is using 2nd generation Abbott ELISA.

This is in conflict with the Department of Health's (DH) agreed starting date for anti-HCV testing of about 1st September. DH have reviewed their policy in the light of Dr. Lloyd's action and have concluded that this date should remain.

The 2nd generation tests do not have FDA licences and until they have been validated we have only the manufacturer's opinion of their efficacy. It is clearly important that the evaluation is completed before nationwide testing commences. The library samples from the study of the 1st generation tests are being tested with 2nd generation kits as part of this evaluation. This work was scheduled to be completed during June so that, after analysis of the data, RTCs would have the information available for the September start date.

Dr. Lloyd's premature introduction of the test, however, can be used to extend the scope of the evaluation if it is developed as part of a national policy. To this end DH have agreed that two other RTCs in England, namely Leeds and Liverpool, will take part in an extended trial using the Ortho 2nd generation kit. This will still be regarded as a trial and not the commencement of routine testing. This extension of the original study will give us additional information on confirmatory testing, i.e. RIBA and PCR. It is not anticipated that donors from the study will be counselled at this time.

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It may well be that the activities in the Northern Region will attract press interest in HCV testing. I enclose with this letter a briefing note which suggests the line which you may wish to take if questioned by the media. It does not attempt to explain the reasons for Dr. Lloyd's actions and I suggest that questions on this topic are referred to him.

I should like to thank those of you who have expressed your solid support in what has been a difficult period.

With kind regards.

Yours sincerely,

H.H. GUNSON,
National Director

Enc.

c.c. Prof. J.D. Cash

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N.B. This is not intended to be issued to the press but can be used as a brief to answer press queries.

INTRODUCTION OF HCV TESTING

LINE TO TAKE

1. Policy

A DH committee of experts has advised that screening for Hepatitis C antibody should start routinely throughout the U.K. as soon as the evaluation of suitable tests has been completed. It is expected that this will be around 1st September 1991.

2. Funding

Regions in England and Wales are expected to meet the increased blood handling charges from their general allocation. Similar considerations apply in Scotland.

3. Evaluation Programme

A large scale study has already been completed on the first generation of tests and a significant rate of false positivity has been recorded. Second generation tests, which the manufacturers claim will be more effective, have recently been made available and are currently being evaluated. These studies have underlined the importance of doing supplementary tests to distinguish positive donors from those found falsely to be positive. The names of the manufacturers involved are commercial-in-confidence.

4. Current Situation

All NHS Regions in the UK are following the DH policy except Northern Region where the RTC has recently started routine testing. The National Directorate of the NBTS and the National Medical and Scientific Director of the SNBTS regard this decision as premature but hope to be able to put the action to good advantage by extending testing on a trial basis to other selected RTCs.

It is important that the HCV tests which are chosen for general use are of proven reliability. This is essential to avoid incorrect results which would cause considerable unnecessary anxiety to donors.

Importance Of Testing

The new test will improve the safety of the blood supply but it should be noted that Hepatitis C is normally only a mild infection (not like AIDS),

6. Legal Liability

The BTS will continue to make every effort to maintain the high quality of the blood supply. Medical opinion is that only properly evaluated tests should be used so that the donor and the patient can be protected from false results. This procedure is likely to reduce the possibility of legal claims.

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