

NATIONAL BLOOD TRANSFUSION SERVICE

National Director:

H.H. GUNSON, DSc MD FRCP FRCP(Ed) FRC Path.

Deputy Director (Administration):

R.J. MOORE, PhD CEng MIM FIQA



THE NATIONAL DIRECTORATE
GATEWAY HOUSE

PICCADILLY SOUTH

MANCHESTER M60 7LP.

Tel: 081-236 9456

Fax: 081-236 0519

HHG/LB

9th May 1991

BY FAX

SAME LETTER TO: All Regional Transfusion Directors
- England and Wales

Dear Colleague,

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 2nd generation kit. This will still be regarded as a study 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,

GRO-C

H.H. GUNSON,
National Director

Enc.

c.c. Professor J.D. Cash

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