

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: 061-236 2263

Fax: 061-236 0519

Our Ref: HHG/DCW

29th April, 1991

Dr. H.L. Lloyd,
Director/General Manager,
The Transfusion Centre,
Holland Drive,
Barrack Road,
NEWCASTLE UPON TYNE, NE2 4NQ.

Dear Sir,

ROUTINE ANTI-HCV TESTING ON BLOOD DONATIONS

Further to our telephone conversation today, I understand that you commenced routine screening of blood donations for anti-HCV at the Newcastle RTC during last week, using the second generation anti-HCV tests manufactured by Abbott.

I was sorry to learn that you had taken this unilateral decision to proceed with testing without first discussing the issue, not only with me, but with your colleagues in other RTCs given you must have been aware of the implications for them of your decision.

At a meeting of the Advisory Committee for the Virological Safety of Blood on 21st January 1991, it was agreed that the UK should introduce testing for anti-HCV as soon as practical and the importance of a common starting date for introduction throughout the UK was stressed.

I wrote to RTDs on 22nd January 1991, stating that I had been asked to try and ensure that testing started simultaneously in the RTCs in England and Wales and was co-ordinated with the commencement of testing in Scotland. Following this memorandum I received proposed dates for the commencement of tests spread over the period April to October 1991. After discussions it was generally agreed that the date of 1st July could be applied. I wrote to RTDs informing them of this date on 15th February 1991.

Even by January and certainly by February it was known that the two major companies in the field were proposing to introduce refined tests for anti-HCV and the Department of Health agreed

HHG 5/9

that there should be a "second-round" evaluation of the revised test kits and Dr. Doughty received a copy of a letter to me from the NHS Procurement Directorate dated 21st March 1991, informing him of this decision.

Unfortunately the timing stated in this letter slipped since production batches of the second generations tests from Ortho were not available until the first week in April and those from Abbott until some time later in the month. This was the reason for my letter to RTDs on 3rd April deferring the date of commencement to be aimed for as 1st September 1991.

In the meantime, the National Procurement Directorate have been negotiating with several companies who are marketing anti-HCV tests in order to conclude the best possible price for the tests on a UK basis. I was asked by them to write to RTCs asking that contracts for the purchase of anti-HCV tests were not concluded until they had had the opportunity to complete their negotiations. This I did on 27th February 1991.

I have written these details in some length to demonstrate that I had kept you fully informed of the national policy with respect to anti-HCV testing. There are still other matters which have not yet been concluded. These principally concern confirmatory tests, the situation with respect to PCR tests, information given to donors prior to testing and the counselling of donors. Later this week, I am sending to all RTDs the minutes of the UK Advisory Committee on Transfusion Transmitted Diseases, in which these matters are discussed, as part of the consultative process.

Since I was unaware that an RTC was preparing to commence screening of donations in advance of other centres, I thought that we had ample time to sort out the implications for donors in the implementation of this test.

You gave me several reasons over the telephone why you did not consider that you could follow national policy in this matter, and I will be grateful if you could put these in writing to me.

Also, I asked you last week if you would test the 3,500 test samples from the multi-centre trial with the Abbott second generation tests, I will be grateful if you could advise me when the results of these tests will be available.

Yours sincerely,

GRO-C

H.H. GUNSON
National Director

C.C. Mr. J. Canavan - Department of Health

HHG 5/10