

NATIONAL BLOOD TRANSFUSION SERVICE

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HHG/LB

2nd October 1989

Mr. G. Hart,
Department of Health
Richmond House,
Room No. 516,
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Dear Graham,

Mr Dobson

Mr JH James

cc Dr Metcalfe

For advice please.

This could add
substantially to
costs in 1990/91 and
certainly in 91/2.

GAH
4/10

ANTI-HCV TESTING OF BLOOD DONATIONS

As promised I am sending you a letter about this subject.

It has been known for many years that hepatitis can be transmitted by blood transfusion. There are several hepatitis viruses. Hepatitis A virus does not complicate transfusions. Hepatitis B virus was isolated during the late 1960's and tests for its presence in blood donations commenced in 1970 which significantly reduced the incidence of hepatitis B. However, it was found that a small number of transfusion recipients still developed viral hepatitis. These were called, because the agent could not be isolated, non A, non B hepatitis (NANBH).

The viruses causing NANBH have defied isolation until in 1988 the Chiron Corporation (USA) were able to reproduce part of the viral genome by DNA technology. They have called this the hepatitis C virus and have developed a test to detect the antibody to it, called the anti-HCV test.

The Chiron Corporation is a subsidiary of Johnson and Johnson Pharmaceuticals and they have taken careful steps to protect the test with patents and they are marketing it through Ortho Diagnostics another subsidiary of Johnson and Johnson. They have licensed the test to Abbott Ltd, but they cannot produce test kits until July 1990 using Abbott technology which is not used in the RTCs in England and Wales.

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There is no doubt that this test is detecting a virus which causes transfusion transmitted NANBH. With respect to English blood donors we have tested, retrospectively 9000 donor samples from three regions and found on average, a positive rate of 0.77%. Unfortunately, it is not known whether all these positives are truly positive since a confirmatory test is not yet available. This is being worked on at present by Chiron. Currently the test is not licensed by FDA.

I have asked the DH for finance to carry out pilot trials in three further RTCs (Brentwood, Birmingham and Sheffield) to determine how this test fits in with working practices.

The data concerning the test and its introduction will be presented to the DH Advisory Committee on the Virological Safety of Blood which next meets on 6th November 1989. I think that a decision will be made to introduce routine screening during 1990.

The estimated cost of this nationally will be as follows:

	£
Approx. 2.3 million tests at £1.70 + VAT	4,500,000
Staffing costs: £20,000 per RTC	320,000
Counselling and follow-up of donors: 0.5 wte clinical assistant 1 secretary	300,000
Replacement of lost donors, say	500,000
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	5,620,000
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Each RTC has been advised by me to put a bid in their 1990/91 development programme.

With kind regards.

Yours sincerely,

GRO-C

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