Glasgow and West of Scotland
BLOOD TRANSFUSION SERVICE

TELEPHONE NOS. WISHAW 73315/8
TELEX No. 779483

REGIONAL DIRECTOR
JOHN WALLACE B.SC., M.D., F.R.C.P.G., F.R.C.PATH.

AT LAW HOSPITAL,
CARLUKE,
LANARKSHIRE.
ML8 5ES

JW/LC

22nd June, 1976

Dr. A. D. McIntyre,
Scottish Home and Health Department,
St. Andrews House,
EDINBURGH. EH2 3DE

Dear Dr. McIntyre,

Total Screening of Donations for HBsAg

During your recent helpful visit to this centre I discussed with you briefly a problem which I felt would arise in connection with the total screening of donations for the presence of the hepatitis B surface antigen (HBsAg). I now have more information on this vitally important subject and in the unfortunate absence of General Jeffrey I considered that it was advisable to write to you. I am sending a copy of this letter to Miss Corrie for her information and also a copy to Mr. Angus McPhee, Secretary to the CSA which is responsible for managing the SNBTS.

You attended meetings of the Central Advisory Group under the Chairmanship of Dr. Maycock on the testing of donations for HBsAg. The views of the members of the Advisory Group were similar to those reported by the special WHO group on the same subject. It was acknowledged that radioimmunoassay (RIA) was the most sensitive method available for the detection of HBsAg but in practical terms both expert groups recommended that reversed passive haemagglutination (RPHA) should be introduced as the method of total screening because RPHA could be introduced much more rapidly than the more sophisticated RIA technique.

As a member of the Advisory Group I was aware of the views of the members and I decided to continue my original work within the limits of the finance available. I discussed the possibility of a further evaluation of RIA with Abbott Laboratories which is the only firm currently producing reliable reagents for the performance of RIA testing for HBsAg. I had sufficient money available to produce reagents for RPHA testing and Abbott Laboratories agreed to provide me with all the facilities for RIA testing for a period of one year at the same cost as would have been incurred by producing reagents for RPHA.

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This proposal was discussed with General Jeffrey and he agreed that it would be a valuable exercise in respect of (a) the feasibility of total screening by RIA and (b) the comparative sensitivity of RIA and of RPHA. The exercise was started in the middle of August, 1975 and is therefore due to end in the middle of August, 1976. I will present the salient views of the exercise to date.

During the first nine months of the exercise a total of 99 911 donations were tested and 36 examples of confirmed HBsAg positive donors were found. These observations can usefully be broken down as follows -

	New	Previous IEOP Neg	Previous RIA Neg
Donors	23,863	60,600	15,048
HBsAg	22	14	0

During the three years prior to the introduction of total screening by RIA we had undertaken considerable research work in respect of RPHA and RIA as methods of testing donations but for total screening we had relied on the immunoelectrophoretic method IEOP. The lack of sensitivity of the IEOP method is shown in the above figures. Equally important however are the observations which we have made on the detectability of HBsAg in the 36 positive specimens found by RIA.

Of these 36 examples of HBsAg only 13 were detectable by IEOP and only 24 were easily detectable by RPHA. Another 5 specimens gave doubtful positive reactions by RPHA. This means that if we had been relying on RPHA for total screening we would have missed, in a period of 9 months, at least 7 examples of HBsAg positive donations and perhaps as many as 12. Recently we have had an opportunity of evaluating an enzyme immunoassay procedure (EIA) introduced by Organon Laboratories. This method is claimed to be similar in sensitivity to RIA and does not require facilities for Isotope work. It is interesting that all 36 examples of HBsAg detected by RIA were also detected by EIA.

What is not known of course is how many of the donations which give false negative reactions by RPHA would have transmitted viral hepatitis type B. These weak antigens are similar to that found in the donation which may have caused hepatitis in the late [redacted] of [redacted]. You will recall that case because you attended the Fatal Accident Inquiry. Indeed I understand that the [redacted] case is still sub judice. We now have a second case in this region similar to the [redacted] case, but fortunately the patient recovered.

There is, in my opinion, substantial evidence in favour of total screening by RIA rather than by RPHA. I have recently discussed with Abbott Laboratories the situation after the middle of August, 1976. I am informed that Abbott Laboratories are not prepared to continue the existing arrangement and will charge us the full commercial rate if we wish to continue total screening by RIA. The cost/

CONTINUATION

cost of RIA screening at the commercial rate would be £50 000 per annum. The sum allowed for HBsAg testing in the current year is £24 000 which would allow us to undertake total screening by RPHA. Since we are already in danger of overspending under the head of Medical Supplies, there is insufficient money in our present allocation to allow us to undertake total screening by RIA after the middle of August, 1976.

I mentioned above that the new EIA method would seem to have a sensitivity comparable to RIA but the method, at present, produces a high incidence of false positive reactions. If no additional money is available to allow us to continue total screening of donations by RIA I would propose discussing with Organon Laboratories the possibility of the EIA reagents being provided at a nominal charge for the purpose of a continued evaluation of EIA.

As I have indicated above copies of this letter are being sent to Miss Corrie and to Mr. McPhee. I have not, at this stage, informed either the Scottish Legal Office or my own Defence Society of the position because I am hoping that something can still be done to maintain a sensitive method of testing donations. If by the middle of August we are obliged for financial reasons to adopt a less sensitive method of testing then clearly I will have to inform these bodies, particularly as they were involved in the [redacted] case.

Yours sincerely,

John McGlynn

Regional Director.