1st February 1996

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Dear Jeremy

Study on Anti-HBc - Update

First, my apologies for not responding sooner to your helpful comments re this NBA study. Things have progressed since I last wrote to you, as follows: -

1. Since the protocol was produced both Richard Tedder and John Barbara have joined the study group. John will be responsible for patient testing, so that this is done in a centre not involved in donor testing. Richard will undertake detection of HBV DNA by PCR. Both made constructive comments which resulted in some methodological modifications but the essence of the protocol remains unchanged.

2. The phase of the study involving patient identification and tracing is just now beginning in those hospitals that have completed tracing of patients in the HCV Lookback. This study will not generate any extra work for the hospitals, as each of the 2 participating centres have appointed a research nurse to undertake the work. The East Anglian Haematology Advisory Committee and the South Thames Haematology Advisory Committee are both fully supportive of this proposal. Dr Pat Hewitt is overseeing donor health at Tooting and she will supervise the Tooting nurse. Dr Chris Moore at Colindale will provide counselling training for them.

3. There are 3 patient groups who have received blood from donors with the following markers: -
   a) anti-HBc only
   b) anti-HBc and anti HBs < 0.1 iu/ml
   c) anti-HBc and anti HBs > 0.1 iu/ml (control)
   These donors have been identified from the ongoing study of donors in Cambridge and Tooting.

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All patients identified will be tested for HBsAg and anti-HBc plus anti-HBs if indicated. Those in the study group with negative markers (but not the control group) will also be tested for HBV DNA.

In Cambridge, all 9 Ethics Committees have approved. Addenbrookes Ethical Committee (the first submission made) approved the protocol with only minor modifications to the enrolment forms and contact letters. They did not raise any specific concerns about the testing of low risk recipients.

External funding has been obtained from Abbott Diagnostics to cover the cost of test kits and nurse salaries. As you suggested, Lorna Williamson and John Barbara have been in contact with Arie Zuckerman re this study and I am enclosing with this letter the update on where this study has reached. This study is already beginning to provide us with the data on what the actual incidence of anti-HBc is in our donor population is and should be able to answer the unresolved question as to whether or not anti-HBc positive donors, with or without low levels of anti-HBs can cause transfusion transmitted HBV disease.

The proposed plan of action within the UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) with regard to anti-HBc is as follows: -

SACTTI will reassess the available evidence in Autumn 1996, with a view to a follow up submission to MSBT if this is felt to be appropriate. This review will include the following: -

1. National post transfusion hepatitis B collation
2. Outcome of Cambridge anti-HBc study
3. Results of enhanced security PCR on 'anti-HBc only' donors
4. Outcome of Professor Tedder's combined anti-HBc/anti HBs assay evaluations
5. Information arising out of HCV Lookback programme (anti-HBc only donors)

I think you will now find that under the new chairmanship of Dr Peter Flanagan, and with your helpful clarification of the remit of SACTTI and the MSBT, a more productive relationship will develop between the two. From my point of view I will certainly now have recourse to an expert professional advisory group within the UK Transfusion Service which will enable me to function more effectively within the MSBT.

Best wishes.

Yours sincerely

GRO-C

Dr E Angela E Robinson
Medical Director