Minutes of

Anti-HBc Screening Project Study Group meeting

East Anglian Blood Centre

Friday, 29th March 1996

Present:	Professor Jean-Pierre Allain	Division of Transfusion Medicine
	Dr Pat Hewitt	South Thames Blood Transfusion Centre
	Una Whicheloe	South Thames Blood Transfusion Centre
	Barbara Cant	South Thames Blood Transfusion Centre
	David Howell	North London Blood Transfusion Centre
	Professor Richard Tedder	University College London Medical School
	Dr S Ijaz	University College London Medical School
	Joanna Griffiths	East Anglian Blood Centre
	Ian Reeves	East Anglian Blood Centre
	David Wenham	East Anglian Blood Centre
	Dr Lorna Williamson	Division of Transfusion Medicine

Apologies received from:

Chris Parkhouse	Abbott Laboratories
Dr John Barbara	North London Blood Transfusion Centre

ACTION

1. Minutes of Last Meeting

The minutes of the meeting held on 28th February 1996:

6.1 Dr Hewitt wished the minutes to be clarified to specifically state that the ruling not to test children if the information could be obtained from adult testing was a Department of Health ruling. The previously agreed plan of testing all the adult recipients first would be followed.

2. Supplemental Testing (see attached)

69 Category 5 samples have been tested with Ortho anti-HBc; 39 (57%) were positive and 30 negative. The split between positives and negatives was the same between EABC and South Thames. These results were rather surprising in view of the previous study, where there was a better correlation between IMX and Ortho. All the Ortho negative samples were also negative for IgM anti-core and anti-HBe. The OD to cut-off ratios show a significant difference in 1:S/CO (- 13.5 for IMX positive, Ortho positive; 3.4 for IMX positive and Ortho negative). Although there is a considerable overlap close to the cut-off (see graph). It was agreed that the Ortho negative donors still needed to be included in the look-back.

3. **DNA Testing**

Dr Ijaz presented UCMS's results. Despite some initial difficulties with contamination, there appeared to be 3 repeatably positive samples out of 173 tested (1.7%). All 3 are from South Thames, 2 are from anti-HBc only donors (1 negative by Ortho). The third has low level anti-HBs at 0.0067 iu/ml. Fresh aliquots on these three will be sent from South Thames to RST for repeat testing and sequencing. **BC**

BC also to investigate whether the donors have re-attended and therefore whether later archive samples are also available. It was agreed that the donors would not be contacted for counselling until the results had been repeated on a new sample. **BC**

Discussion followed on possible referral of these donors to a hepatologist. Dr Hewitt reported that the protocol for counselling and referral of HBsAg positive donors was in any case being reviewed throughout the Zone, and to this end she had written to seek the view of five or six hepatologists throughout the Zone. It was agreed that these three donors required liver function tests, but that they should probably not be regarded as either sexually or socially infectious.

4. **Look-back EABC** (Update attached)

No children had yet been identified as recipients. The three babies of women who had received blood close to delivery would not be tested until results on the mothers were available, and then only if the mothers proved HBV positive.

South Thames

Sixty percent of ethics committees have now approved the study, including most of the major hospitals. An additional number had given conditional approval, pending some changes to the donor letter, but one committee had specifically given high praise to the content of the patient letter. LW and PH had previously agreed that at the end of the study they would write a short letter to flag up inconsistencies in ethics committees approval. The database difficulties at South Thames were being resolved.

RST mentioned that additional recipients of anti-HBc only donations may arise from the National HCV Look-back, depending on whether such donors had had anti-HBc performed at the time of counselling, and on the availability of recipient archive samples.

Relationship with NLBTC TTI Study

To overcome the possible confounding protective effect of high level anti-HBs in Category 3 recipients, it had been considered whether a matched group of donors could be identified from the NLBTC TTI study so that their recipients could be statistically compared with recipients in the other three categories. Unfortunately the database for the study is not set up to provide donor data, and it was not clear whether a simple SQL could be used to block-link the donation numbers back to donor characteristics. This would be investigated. **DH**

However, although 6,000 donations had so far been tested for anti-HBc, no hepatitis B transmissions had been definitely identified. In view of this the usefulness of a potentially time-consuming matching exercise was queried. It was agreed that the views of a statistician would be useful. Dr C Palmer, statistician in the Department of Community Medicine, University of Cambridge, considers having 70 matched donors selected from the ITT study a preferable option. It will be a group with biases that can be calculated. In general having homogeneous and equilibrated groups is preferable. **JPA**

TTT

5. Any Other Business

5.1 Contracts for JG and UW

PH estimated that at least an extra six months work at Tooting would be required to complete the study, with an extra two to three months at East Anglia. JPA thought that Abbott US would probably be agreeable to additional funding but required a budget estimation of costs. **PH to send to JPA**

5.2 DH raised some logistical questions regarding patient testing. It was confirmed that there would be approximately 100 patient samples to be tested for anti-HBsAg anti-HBc with overnight incubation, and anti-HBs. Samples would not be available until at least the beginning of May. For East Anglia samples would come to EABC, where they would be aliquotted into NLBTC standard tubes and a standard request form completed. This would allow the use of bracket positive ID. Results should be relayed back to JG with a turnaround time of ideally less than one week. NLBTC would require an IMX kit. **JPA to arrange**

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5.3 RST asked whether he could be reimbursed for the costs of sequencing the 3 HBV positive donors and would send a budget figure to JPA. **RST**

6. Date of next meeting

Wednesday, 22nd May 1996, 09.30 EABC (large committee room).

Copy to: Dr John Barbara, North Thames Blood Transfusion Centre
Barbara Cant, South Thames Blood Transfusion Centre
Dr Sue Knowles, North London Blood Transfusion Centre
Mr Chris Parkhouse (+3), Abbott Laboratories Limited
Prof R S Tedder, Dr S Ijaz, University College London Medical School
Dr Patricia Hewitt, North London Blood Transfusion Centre
Professor J-P Allain, Dr Lorna Williamson, Cambridge University Division of Transfusion Medicine
Mr David Wenham, Mr Ian Reeves, Joanna Griffiths, East Anglian Blood Centre
Una Whichelow, Research Nurse, South Thames Blood Transfusion Centre
David Howell, North London Blood Transfusion Centre

LW/cmh
1st April 1996