Anti-HBc Screening Project Study Group meeting

East Anglian Blood Centre Wednesday, 22nd May 1996

Present: Professor Jean-Pierre Allain Dr Lorna Williamson Chris Parkhouse Andrew Perigo Dr Pat Hewitt Una Whicheloe Barbara Cant Joanna Griffiths Ian Reeves David Wenham Division of Transfusion Medicine Division of Transfusion Medicine Abbott Diagnostics Abbott Diagnostics South Thames Blood Transfusion Centre South Thames Blood Transfusion Centre East Anglian Blood Centre East Anglian Blood Centre East Anglian Blood Centre

Apologies received from:

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Professor Richard Tedder	University College London Medical School
Dr John Barbara	North London Blood Transfusion Centre

ACTION

1. Minutes of Last Meeting, 29th March 1996

Accepted as correct, with the following amendments:

Page 3, paragraph 5.2. The second sentence should read `Patient samples to be tested for HBs by Murex with overnight incubation, anti-HBc, and anti-HBs if previously immunised for hepatitis B.`

In the third last sentence in the final paragraph, the mysterious word `braced` should be omitted.

2. Supplemental Testing

As listed in the minutes of last time, there was a considerable difference in the sample to cut-off ratio in IMX between samples which were Ortho positive and Ortho negative (13.5 versus 3.4). The data had not been plotted to show IMX positivity/negativity in relation to Ortho sample to cut-off ratio and it was agreed that this would be interesting to examine. Up to 50-60% of results may still be false positive.

JPA

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3. DNA Testing

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Professor Allain reported from Professor Tedder that of the 3 South Thames samples which had tested positive for HBV genome, only two had been positive on repeat testing. Moreover, sequencing of one of these samples had revealed a different sequence in the initial and repeat samples. However, samples 2 and 3 had different sequences from each other. The possibility of primary contamination at the time of processing could therefore not be excluded. Two samples showing high HBsAg had been entered into the study initially by error, and it was agreed that it would be important to find out whether those samples, or any other HBsAg positive samples, had been processed around the same time as the 2 which were consistently HBV DNA positive.

If any such samples were identified, sequencing of those would be of importance.

4. Donor Testing

As positive donors were now re-attending, the policy was re-emphasised. A fresh sample from each donor would be required before undertaking any counselling. For EABC this would be tested locally. For South Thames a reference sample would go to Richard Tedder, as is their usual protocol, with an aliquot to EABC for study purposes.

Repeat testing at EABC would consist of Corzyme, IMX and Ortho anti-HBc. Decisions on counselling would then be taken on a case-by-case basis. It was agreed that any results available would be brought to the next meeting.

5. Look-back EABC

Joanna Griffiths gave an update of the status of patient follow up (summary to follow). Both the percentage of patients still alive, and the percentage for whom the GP has given permission to contact the patient are both higher than originally anticipated. Depending on patient agreement, it would seem that up to 40% of initially identified patients may be eventually available for testing. In most cases GPs seemed willing to take blood samples.

South Thames

Virtually all hospitals had now given ethical approval. There had been considerable difficulty in obtaining archive records to identify where components had been issued to from South Thames. With the help of computer staff at South Thames, this was now complete. It was recognised that for South Thames considerable extra resources will be needed to complete the study within a reasonable time frame. Professor Allain had requested from Abbott an extra \$17,000 (\$2,000 for Professor Tedder and \$15,000 for the look-back). This would be equivalent to a 7-month full time equivalent member of staff. Calculations revealed that even then it would be difficult to have all the data available for the proposed SACTTI meeting in October to consider anti-HBc testing. The view point of the NBA should be sought, as it was just possible that additional funding might be made available. The considerable help of Charlotte Llewelyn in setting up the database was acknowledged.

JPA to write to Dr A Robinson

DW/IR/ BC

BC

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6. Matching with NLBTC TTI Study

Pat Hewitt outlined the design of the study. It was emphasised that donors were neither identified in relation to specific donations, nor were they systematically tested for anti-HBc. As yet, no hepatitis B tranmissions had been specifically identified relating to donors, making the value of a comparative study rather dubious. The few donors who had been tested for anti-HBc were in association with possible transmissions and therefore were a highly biased sample unsuitable for matching. No resources were available at NLBTC to input the donor information. It was agreed that no immediate action was possible, and that further consideration of this issue could take place as results from this study became available.

7. Any Other Business

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7.1 John Barbara had sent a letter suggesting that the 3 apparently HBV DNA positive samples be tested on PRISM for HBsAg. This had been done once (all 3 negative) but would be repeated.

John Barbara had also suggested that all anti-HBc negative samples be tested on PRISM for HBsAg. This would be done on a fresh sample.

Ideally patient testing should also be done on PRISM as an additional sensitive test for HBsAg. Lorna Williamson pointed out that this would have to be done concurrently with other testing, so that a final result could be given to the patient. It was agreed that this should not present any difficulties if PRISM has been approved for NBS use by the time patient samples become available.

7.2 The protocol for patient testing in the TTI study included ALT testing. It was agreed that this would also be useful for this study.

8 Date of next meeting

Thursday, 11th July 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, University College London Medical School Dr Patricia Hewitt, North London Blood Transfusion Centre Professor J-P Allain, Dr Loma Williamson, Cambridge University Division of Transfusion Medicine Mr David Wenham, Mr Ian Reeves, Joanna Griffiths, East Anglian Blood Centre Una Whicheloe, Research Nurse, South Thames Blood Transfusion Centre David Howell, North London Blood Transfusion Centre

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IR

BC/IR

DW

PH to

discuss with

JB and DH