

LW (from J-PA)

ANTI HBc PROJECT

Minutes of the coordination meeting 28th June 1995

Attendance: JP Allain, B Cant, R Challis, S Knowles, C Parkhouse, A Perigo, I Reeves, D Wenham, L Williamson.

Apologies: J Barbara

1 Minutes of last meeting approved.

2 Study update.

Cambridge tested 9894 donations, 96 initial reactives, 44 confirmed. 40 contain anti-HBs (6 below 0.1 IU/mL). 4 isolated anti-HBc. These results are almost exactly those found three years ago and suggest that predictions of numbers for DNA and lookback are accurate.

SLBTS tested 3665 donations; 51 reactive and 20 confirmed. 19 are anti-HBs positive (4 below 0.1 IU/mL) and 1 isolated anti-HBc. Prevalences are similar to Cambridge.

3 Testing

Technical issues at SLBTS are nearly solved and full morning testing (700/d) will be running next week.

HBV DNA: no formal agreement or quotation have been received yet from Prof Tedder.

Storage of samples for additional testing at SLBTS has been resolved. A large aliquot from the unit will be saved and stored until needed.

4 Lookback protocol

- Various bodies such as NBA and BBTS infectious disease committee are kept informed of the study but no approval will be sought.

- Definition of control group. The appropriate number of controls among the antiHBs over 0.1 IU/mL will be determined by the EABTS consultant statistician (LW). *CP/LW*
This group will be matched for age and sex among the whole group irrespective of anti-HBs titre.

- The five year limit to lookback appears suitable.

- As in other trials, the lack of regional ethics committee leaves to each participating hospital ethics committee to approve or reject the project.

Action: LW will develop a standard format; individual hospital's forms will be collected, filled and submitted.

- As in the HCV lookback, it appears desirable to commission an independent lab to perform the recipient testing. For economical reasons, the NLBTS microbiology lab is proposed.

Action: JPA will write to J Barbara to ask.

*LW
protocol
for AR*

Continued ...

- Funding. It is recognised that identifying 720 recipients and tracing a third of them will be a major task requiring dedicated staff for approximately six months. It will be two half-time nurses, one attached to each participating centre. Approximately £12,000 is needed.

Action: LW and BC will provide JPA with a budget before July 6.

: JPA will discuss the issue on July 7th with C Wistar and CP.

: LW and BC will advertise as soon as funding is obtained.

- Patient counselling: numbers are expected to be small. Existing forms and procedures for HBV infected donors will be used.

- Referral to hepatologist will be minimal as no more than 2 chronic hep B are anticipated.

- Archived donor samples. Both EABTS and SLBTS have 3 year archives available.

Next: meeting 16th August, 1995

LW
Job
deimphon

JPA. 29.6.95.