Reference (93)

Minutes of the First Meeting of the Reconvened Transfusion-Associated Hepatitis Working Party

At D.H.S.S., Euston Tower, Room 112 at 2p.m., 24 November 1986

Present: Dr H Gunson (Chairman)
Dr J Barbara (Secretary)
Dr J Craske
Dr B Dow (for Dr R Mitchell)
Dr J Forrester
Dr P Karyannis (for Prof H Thomas)
Dr B McClelland
Mrs J Mortimer
Dr A Smithies
Prof A Zuckerman

Apologies: Dr S Polakoff

1. Introduction

Dr Gunson explained that the working party had been reconvened in order to consider approaches to addressing future requests to initiate routine anti-HBc and ALT donor screening. This stems from USA initiation of such screening although the FDA are delaying decisions until February 1987 (AJZ). Dr Gunson will review recalling the fractionation experts (Dr Lane and Dr Cuthbertson) from the previous TAH working Party. Dr Craske agreed to approach the Haemophilia Centre directors for their views on anti-HBc and ALT donor screening. Also it was suggested that Dr Charles Forbe (Chairman of the haemophilia directors) should be invited to the next working party meeting.

2. Anti-HBc and ALT donor Screening

Anti-HBc and ALT testing have independent predictive values as surrogate markers for NANB hepatitis. Dr Gunson suggested they be considered jointly and identified three main questions:

a. Does USA experience relate to the UK currently?

b. What is the situation with NANB in the UK donor and recipient populations and what hard data is available (including that from haemophiliacs)?

c. Should we propose further studies such as those suggested by the North London and Bristol RTCs?

The working party considered:

a. The USA experience did not relate to the UK. The HBV rates in the USA were higher and any NANB viruses prevalent in one country were not necessarily going to be equally prevalent in the other.

b. That the limited UK data did not of itself warrant introduction of anti-HBc/ALT screening at this time.

3. Discussion on current data available

See: a. Appendix 1 submitted by Dr Gunson, October 1986

b. NANB incidence in UK haemophiliacs; working party report submitted by Dr Craske, 17 November 1986

c. Sporadic NANB hepatitis in the UK. Unpublished report submitted by Dr Vandervelde and Dr Mortimer.

Summaries of available UK data on anti-HBc and elevated ALT prevalences in donors were presented by Dr Gunson, Dr Barbara, Prof Zuckerman and Dr Dow.

Current UK data on PTH NANB was inadequate to base decisions upon, in terms of cost-effectiveness of surrogate screening, even if this had been proved to be of value for reducing PTH in the USA. No USA studies have yet proven this.

Dr Barbara pointed out that many workers in the USA felt that

surrogate screening had been introduced prematurely and the problems there included:

a. High false-positive anti-HBc rates with ELISA tests, compared with competitive RIA. This led to frequent disagreements in results when donors were followed up by their GPs.

b. Uncertainty about, and variation in, the ALT cut-off, often with different action being taken for different ALT levels.

c. Inadequate facilities or instructions for donor management after 'positive' results recorded.

d. Uncertainty about how to take account of the other 'non-specific' factors that may be causing ALT elevations.

e. Reduction in the supply of transfusable blood since anti-HBc and elevated ALT are largely independent factors.

Dr Karyannis said that a monoclonal anti-HBc ELISA was available from the Royal Free Hospital, if required.

4. Discussion on Proposed Studies

a. It was agreed that a full prospective study of a group of recipients of all transfused blood or component units along the lines of the USA TTV study would be too expensive and inappropriate in the UK. However an application for funding of a study to follow up recipients of elevated ALT and anti-HBc positive units, together with controls, had already been submitted by the North London Blood Transfusion Centre. Dr McClella expressed reservations about the value of too small a study

which might not have the power to answer the necessary questions, either in domestic debate or at an international level.

b. As a first step, a meeting was planned at Manchester (10 December 1986) of: Dr Gillon (Edinburgh TC, who would consult with Glasgow TC)

Dr Barbara (NLBTC)

Dr Craske, Dr Fraser (Bristol RTC)

and Dr Gunson

to consider a protocol for screening 3,000 donors at each of 4 Centres for anti-HBc and ALT. Centres from around the UK would have to be included to cover the known geographical differences in the prevalence of the surrogate markers.

This study would:

a. Gather current information on the prevalence of surrogate markers in different areas in the UK and

b. Follow up 'positive' donors prospectively.

Permission would need to be sought from donors enrolled in the study. An Edinburgh protocol would serve as a basis for discussion.

In the absence of more data, meaningful comparisons of money spent on surrogate testing of donors vs costs of treating acute and chronic PTH NANB could not be made.

5. Date of Next Meeting

1987: Jan 22nd ; see Agenda.

Dr John Barbara

Secretary