

0049

ADVISORY COMMITTEE ON VIROLOGICAL SAFETY OF BLOOD

3RD MEETING

ROOM 67 HANNIBAL HOUSE

10.30 AM

MONDAY 3 JULY 1989

3/7/89
Hjghnd

AGENDA

1. Chairman's opening remarks
2. Apologies for absence
3. Minutes of meeting on 22 May 1989 (ACVSB 2/10)
4. Matters arising from minutes not covered later in the Agenda
5. EC Directive on Blood Products - update (ACVSB 3/1) to be tabled
6. Human growth hormone recipients - current position

Comments from:

Dr Rejman re: Professor Preece's Study

Mr Canavan re: UK Health Departments' action

Dr Gunson re: NBTS

7. HTLVI - Proposed NBTS Project (ACVSB 3/2)
8. Non A Non B Hepatitis (NANB)
 - Update from Dr Gunson on Council of Europe questionnaire on surrogate testing for NANB
 - Preliminary report from Dr Gunson on UKBTS Survey of surrogate testing and Chiron Screening
 - Need for prospective study of post transfusion NANB (in blood recipients or stored sera from haemophiliacs)
9. Action in response to reports of blood or blood product infectivity (ACVSB 3/3)
10. Any other Business
11. Date of next meeting

ACVSB 3/7/89

- 1. - EEC modification rejected
- Appendix 2 of Directive now being developed
- Pass on contract Medicines Control Agency
- important for PDC - 5 Sch. 1 & 2

2. W.G.H.
Prevalence Study

Study found point prevalence study of full
of samples - established under a not full
broad based or has been done - no look
back action.

expansion - does not seem to put H/A as
caught by change of prevalence treatment
of low by previous treatment

DOH does not seem happy about this
US specifically mentions H/A recipients.

Need specific data to show point & period
license.

DOH very worried indeed!!!

DOH to issue press release later in the summer

3. HIV 1

Tests confirm (Comp. Conf. Antib. tests) all
detected positive but also high level of false
positives.

US proposing that PCR is also confirmatory test!!!

NIBSS have looked at plasma pools from UK
US - no positive pools but suggest might
become serological test in UK trial & look donors

NBS Study (IAS)

1. Definit to select ethnic groups

R. Tildan - Fiji & Aborigines best OK - what HIV test
As part - no good

Support for serological study - good
- blood test preferred

Study still posed now - not doing
despite non-specificity.

Sarkis - seems to have had results to indicate
ambiguity.

Now worried about availability of serological testing
at various centres

DSH - seem to want to help - why do project - request
this project be worked up in more detail by
sub committee

NANB

P. Morrongiolo has been but is seeing
something for

Page to be revised for committee for discussion
next time

Data on Haemophilus data to A. Rayman

NB, PFC SOP needs to be reviewed

NOT FOR PUBLICATION

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD

MINUTES OF THE 3RD MEETING OF 3 JULY 1989

PRESENT

Dr E L Harris (Chairman)

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|----------|---------------|-----------------------|
| Members: | Dr R Mitchell | Professor A Zuckerman |
| | Dr P Mortimer | Dr R Tedder |
| | Dr H H Gunson | Dr R Perry |
| | Dr R Lane | Dr E Tuddenham |
| | Dr P Minor | |

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|--------------|---------------|
| Secretariat: | Dr A Rejman |
| | Mr J Canavan |
| | Mr M H Arthur |

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|------------|-----------------|---------------|
| Observers; | Dr H Pickles | Dr A McIntyre |
| | Mr J S Sloggem | Dr H Flett |
| | (for Dr Purves) | Dr J Metters |

Chairmans Opening Remarks

1. Dr Harris welcomed Dr Jeremy Metters who would succeed him as Deputy Chief Medical Officer, and as Chairman of ACVSB, upon the retirement of Dr Harris on 31 July.

Apologies for Absence

2. Apologies were received from Dr George, Dr Purves and Dr Summerfield.

Minutes of the Meeting of 22 May 1989

3. Subject to a typing error at paragraph 16 which should have read "anti HBc instead of anti HBs", the minutes were agreed as a correct record.

EC Directive on Blood Products (ACVSB 3/1)

4. Mr Sloggem reported that the amendment proposed by the European Parliament to extend the Directive to blood and plasma when used therapeutically had been rejected by the Commission, and that the original Directive therefore remains as it stands. Deadlines for implementation of the framework directive remain as in Appendix 2 of ACVSB 3/1, which includes proposals to take the directive forward. The Chairman noted the position and suggested Dr Lane and Dr Perry pass their comments on Appendix 2 to MCA.

Human Growth Hormone Recipients - Current Position

5. The Chairman thanked members for their past advice which had been forwarded to Health Ministers by the Chief Medical Officers. Professor Preece was to approach GPs through their FPCs about the state of health of hGH recipients. As an extension of this study he would approach patients direct and tell them not to offer themselves as donors; Professor Preece would be seeking a small budget increase to cover some additional computing costs. This action was expected to exclude the great majority of hGH recipients from blood and organ donation.
6. It was agreed that hGH recipients should also be added to the exclusion list shown to blood donors; it was noted that the trend towards licensing of blood products would make explicit exclusion essential to the fractionators if recipients of hGH were unacceptable as blood donors.

HTLV1 - Proposed NBTS Project (ACVSB 3/2)

7. The paper prepared by the secretariat summarised the issues arising from the last meeting. Members considered the NBTS proposals for a 100,000 donor study to determine HTLV1 prevalence (TT 10/89). An indication of repeat reactivity would also be a useful function of any such study.
8. After deliberation of a number of difficulties, including anonymity of sampling and gene detection, it was decided that it would be useful for a small team to visit the USA to draw on their experiences of HTLV1 testing so as to avoid problems encountered in USA. Study proposals would then be worked up further by the secretariat with appropriate experts advising. Members advised that the study should go ahead as soon as possible thereafter. Meanwhile a pilot project, not related to ACVSB, was proceeding at Edgware.
9. Dr Tedder had been awarded a UGC fellowship to develop an effective PCR for the gene of HTLV1; he also hoped to proceed on HTLV2. Members advised that action was required against both viruses, and expressed support for his work. Dr Tedder would give member colleagues full particulars and they would comment to Dr Rejman.

Non A Non B Hepatitis (ACVSB 3/4 and 3/5)

10. A Council of Europe Paper (see ACVSB 3/4) had stated that anti-HCV testing alone was not sufficient to eradicate post-transfusion hepatitis, and members supported this view.
11. The NBTS had undertaken an ALT and anti-core study (ACVSB 3/5) which had shown raised ALTs in 25% of the donors sampled. Members were concerned that this type of study revealed nothing of specificity. They also cautioned against the overtly commercial stance of test manufacturers.
12. The Chiron test had been used in first time recipients of Factor 8Y. Preliminary results had shown no positives, while most recipients of earlier concentrates were Chiron positive. Further study of stored haemophilic sera was advocated.

13. Dr Mortimer had attended a recent conference, and he considered the findings represented a persuasive case that the Chiron test results were reliable. The Chairman therefore considered that a compilation of all the data should be given to the Committee for consideration at the next meeting. Members were asked to forward all contribution on NANB to Dr Rejman.

ACTION IN RESPONSE TO REPORTS OF BLOOD/BLOOD PRODUCT INFECTIVITY (ACVSB 3/3)

14. Members examined the standard operating procedure adopted by the Protein Fractionation Centre (Edinburgh) when notified of plasma contamination. It was considered essential that UK action should be harmonised.
15. The Chairman looked forward to seeing proposals from BPL Elstree, agreed with Edinburgh, to present to the NIBSC/MCA on this important issue.

Any Other Business

16. Effect of Gamma Irradiation on the Human Immunodeficiency Virus and Human Coagulation Proteins (ACVSB 3/6). This Paper was brought to members attention for consideration, and for discussion at a future meeting. It was noted that gamma irradiation could inactivate a whole range of viruses, and that this presented an interesting prospect for the NBTS, BPL and PFC to consider.
17. Dr Gunson asked for clarification of the decision at the last meeting that donors who had had jaundice in the last 12 months should be HBc tested before acceptance; he asked if HBsAb positive donors could be accepted for cell transfusion without the need for HBc Ab testing. The variant form of Hepatitis B présent in Italy was mentioned. It was decided that Dr Rejman should consider further with the Hepatitis sub-group of the JCVI. Meanwhile the NBTS would not change its present procedure regarding people with a history of jaundice.

Date of next meeting

18. The date of the meeting would be Tuesday 17 October 1989.

Apologies for Absence

Apologies were received from Dr ... and Dr ...

Minutes of the Meeting of 22 May 1989

SMD/211

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| PROTEIN FRACTIONATION CENTRE | |
| Received | 18 AUG 1989 |
| File No | |
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