ACVSB 1/9

NOT FOR PUBLICATION

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD

MINUTES OF THE FIRST MEETING ON 4 APRIL 1989 AT THE DEPARTMENT OF HEALTH, HANNIBAL HOUSE, ELEPHANT AND CASTLE

PRESENT	Dr E L Harris - Chairman		
Members	Dr R S Lane	-	Blood Products Laboratory
	Dr P Mortimer	-	Public Health Laboratory Service
	Dr R J Perry	-	Protein Fractionation Centre, Edinburgh
	Dr G P Summerfield	-	Consultant Haematologist Middlesbrough General Hospital
	Professor A Zuckerman	-	London School of Hygiene and Tropical Medicine
	Dr Garrett (attending for Dr Minor)	-	National Institute of Biological Standards and Control
Secretariat	Dr A Rejman MED SEB/B)		Department of Health
	Mr J Canavan HS1A)		
Observers	Dr H Pickles)		
	Dr F Rotblat)		Department of Health
	Mr J S Sloggem)		
	Dr S Lader (for item on Human Growth Hormone)		
	Dr H Flett	-	DHSS (Northern Ireland)
	Dr A M George	-	Welsh Office
	Dr A McIntyre	-	SHHD

Introduction

1. The Chairman welcomed members to the new Committee and conveyed apologies from the CMO who wished to be present at the first meeting of the Committee.

2. He reminded members that their advice on the subjects under discussion could be publicly sensitive and should not be discussed outside the Committee, unless specifically indicated.

Terms of Reference (Paper ACVSB 1/1)

3. The Chairman spoke to this paper. He explained that the Committee had been set up to give advice to the UK Health Ministers. A number of different interests were represented and it was hoped to avoid conflicting views to Government from other committees. ACVSB's views would initially be referred to the CMOs. The Committee would be concerned with the major policy issues and the implementation of the policy would be for others. While the Committee would be specifically concerned with blood donation their advice would be made available to those responsible for tissue and organ donation where this was appropriate.

Overview of Problems and Workplan (Paper ACVSB 1/2)

4. The Chairman drew attention to the proposed work plan set out in the paper. The issues which required early attention were Creutzfeldt-Jakob Disease (CJD), the EC Directive on blood products and HTLV1 and were the main item of business for this meeting. He said that CMO had particularly asked that CJD should receive early consideration, as Ministers had been promised definitive advice by the end of April.

5. The intention was that the next meeting should concentrate on viral hepatitis. The Chairman asked for suggestions for other items for future meetings, Professor Zuckerman mentioned CMV testing and Dr Lane mentioned Parvovirus.

Human Growth Hormone Recipients (Papers ACVSB 1/5 and 1/7 (tabled))

6. The Chairman explained the background to this issue. The human growth hormone (hGH), derived from post mortem pituitaries, had been withdrawn from use in May 1985 because of concern over the transmission of Creutzfeldt-Jakob Disease (CJD). At that time, a Government committee chaired by Professor Donald Acheson advised that hGH recipients should not donate blood or organs. This committee decided that there was no need to create anxiety among hGH recipients by telling them not to donate blood or carry donor cards and further action was considered unjustified as the risk of infection was so small and the risk of transmission through transfusion so uncertain. The use of hGH was stopped and it was fortunate that a recombinant form of GH became widely available a year later. In 1986 Professor Preece (Institute of Child Health, London) had put forward proposals for following up recipients of hGH. However concern had been expressed at the ethics of informing young people that they might have a lethal infection which could not be identified and for which there was no treatment.

7. It was now necessary to reconsider these issues as the climate had changed with the passage of time and the Southwood Report on BSE had heightened public and media interest in slow viruses.

8. Dr Pickles questioned whether it was more ethical for recipients of hGH to learn of the risk from the media rather than from their doctor. Professor Preece's follow-up study had not been supported in 1986 as it had been considered unethical to ask recipients for information which would be of no benefit to those who had received the treatment.

9. Professor Zuckerman remarked that it might also be questioned whether action could have been taken to prevent contamination of plasma pools and this raised liability issues.

10. Dr Pickles reported that the Tyrrell group set up following the Southwood Report would be recommending additional studies into the transmissability of these sorts of infection by blood. There was no evidence of this at present.

11. Views were expressed that if blood did carry infection, the numbers of people at risk might be greater than had been estimated. Professor Preece had advanced the view in correspondence that recipients of hGH were more likely than the general population to donate blood. Whether or not this was the case, the 4 per cent figure for donors under-represented the proportion of the total population as donors lapsed and were replaced by others. It was also pointed out that contamination of a plasma pool could also spread infection to considerable numbers of recipients of blood products.

12. The Committee thought most recipients of hGH could be traced as they had been flagged on the national register. Professor Preece had been given permission in 1987 to do this. This work was likely to start shortly and could be supported. In addition to those patients treated at Great Ormond Street, hGH had been used in the West Midlands and some UK patients had been treated abroad. Pituitary material had also been used for treatment of deficiency of LH or FSH. Self-help groups might also be approached to identify other recipients.

13. It was recognised that not everyone could be traced by these means and measures to identify blood donors who had received hGH would need to be considered, possibly including a reference to this in the donor exclusion list. Dr Gunson pointed out potential problems for the NBTS in excluding hGH recipients as donors. Facilities were not available at donor sessions for confidential counselling to be done immediately on receipt of a positive response to exclusion questions. In reply to a suggestion, he said that it was debatable whether it would be ethical to take a unit of blood from such a donor, discard it and then counsel the donor at a later date. It was suggested that counselling could be done by GPs at a later stage but suitable literature on the lines prepared by the US National Institute of Health would be required. A study on CJD to validate diagnoses had been stopped 5 years before but was now to be reopened and history of blood transfusion could be included in data on clinical history.

14. It was thought it would be very difficult and was unnecessary to trace transfusion recipients, should any hGH recipients be found to have been blood donors.

15. The Committee concluded that its advice to the CMO's should be that:-

i) Recipients of hGH were not acceptable as blood donors because of the remote and theoretical risk of transfer of CJD. They were also not acceptable as donors for other tissues or organs.

ii) individual recipients of hGH should be approached and informed that they should not be donors. On balance it was considered that such approaches should not now be considered unethical; many recipients had already become aware of their potential for CJD and the current climate and media interest meant that an approach through their doctors was considered the least harmful of the options available.

iii) In addition, the NBTS should attempt to exclude hGH recipients as donors. This was needed to detect individuals who could not be traced by other means including those treated abroad.

16. Further action was considered appropriate as follows:-

i. Professsor Preece should be approached to assess the status of his study and should be offered all possible assistance.

ii. Transplant groups should be reminded about excluding people at risk of CJD from being potential donors.

Sent copy to BMA.

EC Directive on Blood Products (Papers ACVSB 1/3 and 1/6 (tabled))

17. The Directive provided a framework for harmonising the licensing requirements, and the technical specifications which would give it effect had still to be devised. This would be done in the EC Biotechnology Working Group but dates for its meetings have not yet been set. However the intention is that the UK should have its proposals ready by the end of 1989. Consultation on the draft texts would include this Committee and there would be the opportunity to contribute to the discussions in Europe. A progress report would be given to the ACVSB at each meeting.

18. The UK proposals could not be too specific otherwise they would simply become the focus of attack in the EC discussions. It was confirmed there would be full consultation in the process of devising texts and during the subsequent discussions on the technical specifications.

19. Also the NBTS would need to be involved in view of the currently different practices in EC countries with regard to source plasma for fractionation. The Directive did not apply where blood was obtained to be used as blood components. The same requirements were demanded of blood donors for whole blood or plasma.

20. The Chairman stressed it was important that all interests should be adequately consulted in view of the potentially major implications for the NBTS and CBLA.

HTLV1 (Papers ACVSB 1/4 and 1/8 (tabled))

21. The routine screening of donors for HTLV1 differed significantly from screening for HIV: HTLV1 did not cause AIDS, the risk of infection was very low in the general population and the risk of an infected person progressing to clinical disease was very low.

22. The US had decided to introduce HTLV1 screening as a public health measure to reduce transmission from high risk groups to the general population, rather than to prevent disease. The ethnic groups at higher risk of HTLV1 infection were present in much greater numbers in the US than in the UK but even so the cost/benefit of the US programme had been questioned.

23. The selective screening of the higher risk donor populations might be a rational and more economical approach. However as this would cover people of Afro-Caribbean or Japanese origin there could be accusations of racial discrimination. Also the risk of reducing much needed blood donations from these groups required careful consideration.

24. Dr Mortimer said that his paper (ACVSB 1/8) summarised the PHLS views on confirmatory testing for HTLV1 infection. At present such testing could only be done by special non-commercial assays in a very limited number of laboratories.

25. He also expressed the view that screening on a selective basis might be justified. He thought that information about the prevalence of infection might underestimate the problem as there had been no proper system for reporting, and the UK had a sizeable population of those ethnic groups who were at higher risk. He thought that the US precedent and the possibility of EC action might also create pressure to introduce screening.

26. Dr Gunson said that the selective screening carried out in a few Regional Transfusion Centres had identified a very small number of infected donors. No HTLV1 positive cases had yet been found among IV drug abusers in Scotland. His committee on transmitted disease had proposed screening 100,000 donors selected at random to establish the prevalence of infection, but this would require £100,000. This form of study was being adopted in other countries and he mentioned Canada and the Netherlands where so far one confirmed positive had been identified out of 20,000 random donors (but five had been initially positive and three repeat positive). However there were difficulties in the confirmatory testing and a good test was necessary. He understood that in the US, the move to universal screening had produced a large number of indeterminate cases.

27. Doubt was expressed that plasma fractionation inactivated any infection. This was thought to be the case but no-one could be certain at present. Differing views were put forward on the benefit or otherwise of selective racial screening.

28. The Chairman summarised the views. There was no justification for routine screening of all donors but Dr Gunson should consult within the NBTS on the practicality of selective screening of the Afro-Caribbean donors. The Committee supported the need for the NBTS study of 100,000 donors, for further development of confirmatory tests and for an experiment with spiked plasma.

Any Other Business

29. Dr Mortimer mentioned that Wellcome were expected to have a combined test for HIV1 and 2 available shortly and that Abbott were already producing such a test in small quantities. There could be pressure to introduce these tests into the NBTS but a proper evaluation seemed a necessary first step. The PHLS would be including some combination tests in its test of new products for which the Procurement Directorate of the Department was providing funds. The Chairman said that the Committee would await with interest the outcome of this evaluation.

Next Meeting

30. The Chairman said that Hepatitis could be in the agenda of the next meeting. Members were invited to submit papers.

31. The date was fixed for Monday 22 May at 10.30am. A subsequent meeting was set for Monday 3 July at 10.30am.