

IN CONFIDENCE

EXPERT ADVISORY GROUP ON AIDS

MINUTES OF THE FIFTH MEETING HELD ON 30 JULY 1985

Present: Dr E D Acheson - Chairman DHSS

Professor M Adler	Dr E L Harris	(Chairman pm)
Dr J D Cash	Dr Ower	
Dr N S Galbraith	Dr A Smithies	
Professor A Geddes	Dr W Miller	
Dr H Gunson	Dr D Holt	
Miss E Jenner	Mr C Howard	
Dr D B L McClelland	Miss B Weller	
Dr P Mortimer	Mr A Williams	
Dr D Pereira-Gray	Dr M Sibellas	(Medical Secretary)
Dr A J Pinching	Mr T Murray	(Secretary)
Dr R Tedder	Mrs R C Gorvin	(Minutes)
Dr N Thin	Dr R G Covell	SHHD
Dr D A J Tyrell	Dr S N Donaldson	DHSS NI
Professor R Weiss	Dr Ferguson-Lewis	WO
Mr R Wells		
Dr J E M Whitehead		
Professor A J Zuckerman		

1. Apologies for Absence

Apologies were received from Professor Bloom and Dr Contreras.

2. Chairman's Announcements

The Chairman welcomed Dr Thin as a new member to the Group.

3. Minutes of the Last Meeting on 29 May 1985

3.1 Dr Gunson's name should be added to the apologies for absence.

3.2 Dr Pereira Gray said that he would send in a suggested amendment to paragraph 3.3.

4. Matters Arising

4.1 Resource implications of AIDS [item 14 on the agenda].

The Chairman said that since the Group had last met, the Department had provided £750,000 to the PHLS for its programme to provide facilities for HTLVIII antibody tests and Reference Centres for confirmatory tests, plus £58,000 for the evaluation of the test in this financial year. £50,000 was being allocated to St Mary's Hospital to support training courses in counselling. In addition, £80,000 was being provided to the Blood Transfusion Service for field trials on the tests. He said that the problem of AIDS was well understood in the Department and was being given high priority. With regard to the resource implications of treating AIDS patients and those with AIDS related conditions, discussions had been held with the Thames Regional Health Authorities and bids for future resources put forward in the Government's Public expenditure exercise (PESC).

4.2 CNO Letter on AIDS Guidance for Community Nursing Staff
[Item 6 of the minutes]

Miss Weller said that the CNO had issued a letter on 15 July to Regional Nursing Officers and the professional associations drawing attention to Miss Jenner's paper on infection control guidelines for the community care of AIDS patients and other HTLVIII positive clients. Mr Wells reported that the Royal College of Nursing had welcomed the paper and recommended that it should be widely distributed.

5. 5.1 AIDS Surveillance Update CDR 85/26 28 June 1985 - EAGA(5)1

5.1.1 Dr Galbraith reported that the number of cases at the end of July totalled 196 with 110 deaths.

5.1.2 The Chairman drew attention to a paper produced by Dr Sencer on AIDS surveillance in New York City. This included the numbers and proportions of AIDS cases by sex and at-risk group. 195 cases had been reported in heterosexual women, who were mostly prostitutes and drug abusers. The proportion of males not in any risk group had not changed, which suggested that the spread from females to males was slow. The quarterly figures from New York seemed to indicate that numbers were flattening out. It was agreed that Dr Sencer's paper would be circulated to members with the minutes.

5.1.3 Dr Tyrrell said that community surveillance should be seen against the background of family studies of patients with haemophilia. These suggested that wives were becoming infected, indicating that transmission did occur. Professor Weiss said that in African countries, the male to female spread was 1.2 to 1. The Chairman said that he would like to see a sound scientific study which analysed the African situation.

5.2 Revision of the Case Definition of AIDS for National Reporting, United States. MMWR June 28 1985/Vol 134/No 25 - EAGA(5)2

Dr Galbraith said that the effect of the revised case definition of AIDS would be minimal in the UK. Applied retrospectively, it would probably exclude two cases and add four. The definition remained one for surveillance purposes and did not include other clinical conditions caused by HTLVIII infection. The CDSC would be publicising the revision of the case definition in the Communicable Disease Report and would also write to genito-urinary physicians, with the aim of implementing the change from 1 September. An item in the BMJ would also be considered.

6. HTLVIII Infection, the AIDS Epidemic and the Control of its Spread in the UK - Paper by the Chief Medical Officer - EAGA(5)3

The Chairman said that his paper had been circulated for information and in confidence. He welcomed any comments in writing.

7. 7.1 Serological Tests for Antibodies to HTLVIII

Professor Zuckerman reported that Professor Grob of the University of Zurich and Professor Deinhardt of the University of Munich used Western Blot routinely as confirmatory tests. He recommended their use as a validation test in the evaluation of the test kits. Professor Deinhardt had offered to do the validation tests and this might be less expensive than having them done commercially. Dr Smithies said that arrangements were being made for the sera in the PHLS evaluation to be tested by the Western Blot method and

Professor Deinhardt's offer was an alternative that would be investigated. Dr Mortimer did not envisage any difficulty in using the confirmatory tests already readily available, and Western Blot might also be used in 2 or 3 laboratories in this country.

7.2 Evaluation of AIDS Screening Tests

7.2.1 Paper EAGA(5)11 was tabled. Dr Smithies said that this would be issued to health authorities as a report on the evaluation of the kits. The kits had been tested against a panel of sera from unselected blood donors, from groups of patients with AIDS or AIDS-related diseases, and from groups of patients in which false positive results were a possibility. The kits recommended as most suitable for use in diagnostic laboratories were Vironostika anti-HTLVIII (Organon Teknika Ltd), Wellcozyme anti-HTLVIII (Wellcome Diagnostics) and HTLVIII BioEnza Bead (Ortho Diagnostic Systems Ltd). These kits provided a clear distinction between positive and negative results, a low rate of false positives and gave reliable results with heat-treated sera. Wellcozyme anti-HTLVIII and Vironostika anti-HTLVIII were considered to be particularly suitable for use in blood transfusion centres and were easy to use. Both these kits would be the first to be investigated in the second stage of the evaluation which was designed to investigate performance in large scale screening of blood donors. The Chairman congratulated all those concerned with the development of this work, particularly for the speed with which it had been achieved.

7.2.2 Dr Pinching questioned the way in which the data would be presented. The Expert Advisory Group had not been given the raw data to consider, only assumptions, and could not judge on that basis whether the three tests indicated were the best. Dr Mortimer said that a full report, including data, would be available to the Health Service in about a month's time. A summary of the data would be considered for publication in a medical journal. Professor Weiss said that it would be a useful exercise to confirm this set of sera using the Western Blot and it would also serve to evaluate the Western Blot technique. Dr Smithies agreed that this was being arranged. Members agreed that the most important factor was to achieve an effective and reliable test.

7.3 Introduction of AIDS Screening tests - Paper by the Department EAGA(5)4

7.3.1 Dr Smithies said that the purpose of this paper was to inform doctors about the AIDS screening test, and the intention was to issue it as an appendix to a CMO letter. The Department had received assurances from the commercial companies involved that sufficient supplies of the two tests recommended for the BTS would be available. Dr Whitehead said that twenty two PHLS laboratories were lined up for the ELISA testing and seven laboratories were ready to the confirmatory tests.

N 7.3.2 Members agreed that the timing of the introduction of the tests was crucial. It would be tragic to expose the BTS to the risk of being the only free access testing point and it was essential to have sufficient counselling arrangements set up by the time the tests were introduced. A synchronised introduction of testing arrangements was therefore required in the BTS, in GUM clinics and elsewhere. The Chairman took note of this point and said that a letter had been sent out by the Department that day to Regional General Managers asking them to provide testing facilities outside the BTS and to plan for the counselling of people found to be antibody positive.

7.3.3 The question of patient consent to HTLVIII testing was discussed. A positive test result could be serious for an individual patient and the implications of tests taken as an infection control measure for staff and not for the benefit of the individual's diagnosis and treatment should be carefully considered. The BTS would be informing blood donors, who were volunteers, that the test was being done on their blood donation. However, in the context of the diagnosis and treatment of a patient it was agreed that a general clinical approach should be adopted. Patient's permission for hepatitis B testing was not always sought and, with a variety of tests being taken, it should not be necessary to inform the patient in all cases that these included a test for HTLVIII antibody. It was also agreed that the result of the HTLVIII antibody test should not be awaited before undertaking other tests which might be critical in the treatment of a patient. Professor Zuckerman said that with hepatitis B it was now accepted that other tests should be done while the result of the hepatitis B test was awaited. These tests should be handled in a high risk laboratory and no additional precautions were required.

7.3.4 Specific points on the text of the paper would be made direct to Dr Smithies. It was suggested that the term 'genito/urinary medicine clinic' should be used in preference to 'sexually transmitted disease' clinic, and Paragraph 10 concerning the employment of HTLVIII antibody positive individuals needed to be strengthened. The Chairman said that the covering letter would include a statement that the test would be available to doctors generally.

7.4 Screening of blood donations for anti HTLVIII in Regional Blood Transfusion Centres - report by the Working Party of Regional Transfusion Directors - EAGA(5)6

7.4.1 Dr Gunson tabled an amendment to item 3 on page one of the report. The working party of the Regional Transfusion Directors Committee recognised the pressure to introduce routine screening in the BTS as soon as possible. Regional Transfusion Directors were therefore being advised to make arrangements with their respective RHAs for the introduction of routine screening, and familiarising themselves with the kits recommended by the PHLS study, whilst the NBTS evaluation was proceeding. The evaluation within the BTS had begun, 6000 specimens were being tested each in two centres, at the rate of 600 tests a day. An analysis should be available in September which would give estimates of the specificity of the kits and their ease of use. The working party considered it possible to commence screening of blood donations in October 1985 and recommended that the introduction of the tests should take place throughout the UK over the shortest period practicable. On receipt of a confirmed positive result for HTLVIII antibody, the donor would be sent a letter by the Centre and an appointment arranged for the donor to be interviewed by a doctor trained in counselling. The donor would be asked for the name and address of his family doctor and efforts made to ensure that the donor received further medical advice and obtaining his consent for the results of the test to be reported to his family doctor.

7.4.2 Mr Williams said that the Department would be writing to Regional Transfusion Directors asking them to make arrangements for screening with RHAs. The exact introduction of testing would be a matter of co-operation between Regional Transfusion Directors, but some pressure might need to be brought to bear where Regions were not making the necessary funds available. Members agreed that the screening test should be introduced simultaneously throughout the BTS and that a date for the introduction should be set for all centres to work to. This would also provide an opportunity for publicity, which could be linked with advice to blood donors and the general public.

7.4.3 Follow up of blood donations previously given by donors who are identified as positive for HTLVIII - paper by the Department

Dr Smithies said that the Screening Sub-Committee had recommended that the haematologist in charge of the hospital blood bank should be informed if it was believed that an earlier donation could have transmitted HTLVIII infection. The haematologist would be asked to identify the recipient of the suspect donation and to inform the clinician in charge of the case when the blood had been transfused. The BTS was aware of the importance of good record keeping to enable the follow up of donations. It was suggested that these follow up investigations would provide a good opportunity to check on the transmission of the virus between spouses and from female to male, and a national registry would be useful. Members agreed with the Sub-Committee's recommendations and considered that it would be up to the clinician in charge of the patient to decide on what subsequent investigations should be made. It was also agreed that, although there might be practical difficulties, the follow up for donations should go back a minimum of five years from the date of the donation.

8. HTLVIII is non-human primates

Professor Zuckerman reported that a simian retrovirus had been identified which cross reacted with HTLVIII; this potentially had implications for the safety of vaccines, such as poliomyelitis vaccine, prepared from non-human primates. Several species of monkeys and apes were infected and at least 50% of healthy African Green monkeys were infected with the virus STLVIII. African Green and Rhesus monkeys were relevant to vaccines; kidneys from Rhesus monkeys were used for vaccine production in some countries but not in the UK. The simian virus could infect human T lymphocytes but it was not known if it could infect man. In July, WHO had held an informal consultation to advise member states on the significance of these findings, and had recommended the continued monitoring of vaccines using kidney culture. The Chairman said that about two thirds of the UK's live poliomyelitis vaccine was based on human diploid cell culture. He thanked Professor Zuckerman for his report and noted its significance. The Committee on Safety of Medicines and the Biological Sub-Committee were considering the problem and NIBSC was setting up retrovirus testing. They would be looking at the implications of these findings. The Department would keep the matter under close review.

9. AIDS and Renal Dialysis Units: Comments from Dr Polakoff EAGA(5)5

Members agreed that a Sub-Group should be set up and should include a clinician experienced in treating AIDS patients as well as Dr Polakoff, two expert virologists and a renal dialysis consultant. The aims of the Sub-Group would be as suggested by Dr Polakoff, plus the implications for a patient found to be HTLVIII positive and the wider issues concerning transplantation policy.

10. Draft guidance for surgeons, anaesthetists and dentists dealing with patients infected with HTLVIII - EAGA(5)7

Dr Ower said that this guidance had been drafted on the basis of advice from from the Sub-Group and some further editing was now required, in particular to take on board comments from the dentists. Members commented on paragraphs 2.6, 5.1 and 9.5 and it was agreed that these should be looked at again. Miss Jenner said that she would comment in writing about the

disinfection and sterilisation procedures recommended in the paper. The problem of obtaining dental treatment for HTLVIII positive patients, was discussed, and some members felt that special centres should be set up where patients could be referred for treatment. It was generally felt however that the emphasis should be on influencing the dental profession to improve their practices. The guidance should reflect this but in recognition of present realities, it should say that in some areas there might be resistance to treating HTLVIII positive patients and therefore centres might need to be designated temporarily to give dental treatment to these patients. Provision would be up to local arrangements. The dental profession would be consulted on this issue. In conclusion, it was agreed that the guidance would be revised to take into account these further comments and would be issued in booklet form under cover of a Chief Medical Officer/Chief Dental Officer letter.

11. Health Education Group - report of preliminary meeting

11.1 The note of an informal meeting on AIDS health education held on 9 July was tabled. The Chairman said that it had been agreed at that meeting that options for conducting a health education programme about safer sexual practices and the use of condoms, directed at the gay community, should be put in motion. A meeting had been arranged to discuss this with the HEC and an advertising agency at the end of August. The Health Education Group would be meeting again in September and would be considering the questions of confidentiality in HTLVIII testing and how to get information to those involved in male prostitution. A second group involving those concerned with the care of drug addicts had met on 10 July and had agreed that it was essential to get the message about AIDS across to drug abusers.

11.2 Dr Tyrrell said that it would be essential to define what the health education should achieve - the protection of communities from transmission of the virus, the protection of homosexuals outside spheres of known homosexual influence and drug abusers. The impact of the campaign should be monitored to ensure that it was effective. There was a practical difficulty in putting over unpalatable truths and the content and message needed very careful consideration. The HEC leaflet had been widely distributed and the Terrence Higgins Trust had distributed 100,000 AIDS leaflets. The problem was to reach those who did not see themselves as being at risk, bisexuals who were married and homosexuals who did not go out to gay clubs or read the gay press. There was no information about the potential size of this clientele.

11.3 It was suggested that with testing becoming available, policy decisions needed to be made on whether to encourage homosexuals to check their antibody status. In Copenhagen where kits were freely available, a large number of people had been identified who were not in the recognised groups and were not represented by homosexual organisations. Broad strategic principles needed to be established on the use of free access testing. Evidence suggested that a personal health education approach was more effective than broad brush advertising. It was possible that GPs might become a focal point and it was necessary to consider what advice to offer to GPs about the kind of service they could provide. Another suggestion was that a secret telephone number facility might be provided for those who did not wish to consult their GP. This would need a back up counselling service and could be very labour intensive. It might be possible to give the STD clinic telephone number in some areas, but clinics were unlikely to welcome this system because of existing pressures on their services. It was agreed that advice would be sought from Dr Farthing, who had been providing free access testing for two months as part of the monitoring study, and that these issues would be discussed at the next meeting of the Health Education Group.

12. AIDS Counselling course at St Mary's Hospital

A paper by the Department [EAGA(5)10] was tabled. Dr Holt reported that the Department was providing financial support to St Mary's to extend their counselling training courses. A clinical psychologist, a health adviser and a secretary were being recruited and the NHSTA would select applicants for the courses giving preference to personnel from the BTS and STD clinics on a regional basis initially. About 160 people would be trained prior to the introduction of the HTLVIII antibody test and it was therefore hoped that there would be several individuals in each region who had attended a counselling course by the time the test came into use. Any one who was suitable could apply to come on a course and it was expected that courses would be set up regionally in the future. It was agreed that an evaluation of the counselling courses was an important part of this service and a revised proposal was awaited from St Mary's. Arrangements would be made to let Dr Tyrrell see the programme of study.

13. AIDS and Confidentiality - paper by the Department EAGA(5)8

13.1 Mr Murray said that Departmental guidance to health authorities contained in HM(56)58 suggested procedures for dealing with press inquiries about the condition of individual patients and recommended that personal health information should not be made public without the consent of the patient. AIDS was also covered by the National Health Service (Venereal Diseases) Regulations 1974 which imposed an obligation on health authorities to ensure that information about sexually transmitted diseases should be treated as confidential. Regional General Managers had been reminded of these Regulations in the Department's letter of 30 July.

13.2 Members agreed that information concerning an HTLVIII positive patient should only be passed on within a hospital on a 'need to know' basis and in order to instigate infection control measures. Ideally HTLVIII positives should be seen in the same light as hepatitis B carriers and the same infection control precautions taken. Only personnel directly caring for patients needed to know the specific diagnosis. Other staff needed only to know that the patient belonged to an infectious risk group. The Hospital Infection Society had also taken this line. The question of seropositive health care personnel was discussed. In America, such staff were counselled and allowed to continue in their employment. The RCN knew of nine cases of HTLVII positive staff, two of whom had been dismissed by their private employers. Guidance for employers was needed on this issue. The view was that the guidance on the employment of hepatitis B carriers could be adopted in general terms to HTLVIII sero positive staff. There was a need to avoid compulsory screening and to concentrate on those involved in invasive procedures because of blood to blood contact. The question whether AIDS should become a prescribed disease also needed to be considered. In conclusion, it was agreed to set up a Sub-Group to consider these issues and to prepare guidance for the field.

14. Resource Implications of AIDS

This was dealt with under Matters Arising.

15. AIDS: Recommendations of a Working Party of the Hospital Infection Society - EAGA(5)9

This paper was for the information of members. It was still at draft stage and comments to Professor Speller would be welcome. The intention was to publish it in the Journal of Hospital Infection. BTS centres needed advice at an early stage about the handling of suspected samples. It was pointed out that the literature put out by the commercial companies

recommended that the test agents should be treated as if infective despite being exposed to inactivating agents. This would be pursued by the Department with the companies concerned. It was also hoped that the ACDP guidelines, which were being revised, would cover these issues and be published at an early date.

16. Any other business

Dr Tedder referred to the concern among prison officers about the transmission of HTLVIII in penal institutions. The Chairman said that discussions about this problem were in progress with the Home Office.

17. Date of next meeting

It was agreed that the next meetings should be held on 1 October and 26 November 1985 commencing at 10.30.