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Draft
Minutes of the Second Meeting of AIDS Group of Haemophilia Centre Directors, held at the Royal Free Hospital on 19th February 1985

Present:

(Chairman)

(Secretary)

1. Apologies for absence:

2. Minutes of the First Meeting were approved and signed by the Chairman. All matters arising from the Minutes were covered by the Agenda for the Second Meeting.

3a) Availability of HTLV III Ab Assays:

said that it was hoped that a routine HTLV III assay service could be provided for Haemophilia Centres by several laboratories when they had secured financial support. The Haemophilia Society had agreed to assist with the funding of the service provided by (CPHL, Colindale) and (Middlesex Hospital). There were, however some technical difficulties:-

i) The British isolate and cell line appeared to be unstable and it was likely to be some time before it could be the basis for a general test available commercially

ii) Data from the USA trials were worrying. There appeared to be very many false ~~negative~~ positive results. The Western blotting

technique was not as specific as one would think; there were problems at present with all 5 USA test kits. There were plans for a UK laboratory of one of the US companies to produce a kit. recommended that the Haemophilia Centre Directors should not rush into using unvalidated test systems. The systems and had set up appeared to be more reliable than the US systems, though they had some difficulties.

iii) and were scaling up their systems but there were difficulties over the laboratory facilities available to them and staffing problems. and should soon be able to handle a reasonable number of samples (2-500 per week) from Haemophilia Centres.

iv) asked what service the Haemophilia Centre Directors wanted. Routine screening of patients would not give the scientific information and would like. There was the problem of false negative results and also special problems with tests on haemophiliacs because of the blood products they received.

v) The testing of blood donors was discussed briefly and the question of licencing of test systems.

The problem regarding HTLV III tests for pregnant wives of haemophiliacs was discussed. It was emphasised that these tests needed to be done urgently as there was the possibility of termination being requested if the woman was found to be HTLV III positive. asked that requests for urgent tests should be sent to the laboratory separately from routine specimens, with full details of the patient: coded specimens without the patient's name gave rise to problems for him in identifying the patient clearly. Ideally he would

like repeat samples for testing from the pregnant women to confirm the results.

In reply to a query regarding the status of virus antigen testing, said that no test was at present available for routine use. Reference was made to the paper by Gallo et al in The Lancet (Lancet II, 1418-1420 (1984)), which was worrying. hoped to get some of Gallo's sera next week. In reply to the question for information on evidence as to how many HTLV III + patients had the virus, said that the virus could be got very easily from all AIDS patients, those with PGL and sometimes from others. The picture seemed to change when multiple tests were done. Most of the work had been done by Levi's group and the data had not yet been published.

More data was needed than that published in the Lancet paper. There was a lengthy discussion of published work on the virus. ..... said that 2/3 of the HTLV III+ patients (AIDS patient) showed brain atrophy on CAT scan. said he would recommend the Reference Centre Directors to use the antibody test for the time being, but expressed concern about this as he would prefer an antigen test as a measure of the infectivity of the patients. said the HTLV III virus was more like CMV than Hepatitis and was difficult to detect.

was asked if it was correct that Ab+ patients would "recover" and he said that he would think that if the patient was relatively well after 5 years he was unlikely to develop AIDS. It would be 3-4 years before it was possible to monitor the virus in the patient. asked if high spun plasma was safer than blood samples. and said they would think so;

the risk was still there but was probably less. In reply to a query said he did not know if the virus would affect platelets in stored samples.

3b) MMWR

i) referred to P.2 of the MMWR 34,2 (11.1.85) regarding the time after exposure in respect of AIDS following needle stick injuries in the USA. The UK needle stick case remains well 5 months after the event.

ii) P.3 Confidentiality and coded samples:

There was discussion regarding the system of naming/coding/numbering of samples from Centres. said he would prefer, indeed find it invaluable, to have the name of the patient as he wanted to set up a register of the patients tested. was worried about the names of sexual contacts of haemophilia patients being given and thought there was especially a problem with patients who had many sexual contacts. also saw problems with giving names on samples and was worried about confidentiality: he would much prefer samples to be identified by number only. said his staff found it very unsatisfactory to handle samples which were not clearly identified with the patient's name.

and said they would only be using a desk-top, not main-frame, computer and would devise a scheme to ensure confidentiality of the data. It was suggested that only summarised results should be forwarded to Concern was expressed regarding the delays at present experienced over results being reported to clinicians. After further discussion it was agreed that confidentiality was very important at all levels and that the DHSS Guidelines should be followed as far as possible.

4) Clinical Trials Protocols

a) Heat-treated Concentrates referred to the Minutes he had circulated of the meeting held on 3rd January between , and . The London laboratories would send computer discs of data to and he would try to fill in gaps in the information. He asked for comments on the form which had prepared to go to the laboratories with samples. The patients would be identified by letters and numbers. It was suggested that, for the time being, participation in the trial should be restricted to Reference Centres plus Alton.

said he would prefer the patients to be identified by their name and the name of the hospital. After discussion it was agreed that the samples should be identified by the hospital, patient's name (if possible) or a unique code and specimen number.

agreed to provide NCR forms to Reference Centre Directors for both the survey of heat-treated materials and for general use. A query was raised as to whether the system would cause delays in the reporting back of results to Centres and it was agreed that one copy of the report form would be sent back to the patient's Centre, with a copy sent to Concern was expressed about the increase in the work-load at Centres which would result from their agreeing to participate in the clinical trials. It was suggested that individual Centres should look at only one brand of heated product but some Directors thought this might be difficult. was asked to specify the type of tube he would recommend for samples to be sent in. After discussion agreed to send each Reference Centre

Director 'kits' of tubes, packaging, boxes, labels, forms, etc. for them to use to send samples to either or Dr. Tedder for testing; the two laboratories used identical assay methods. said although he did not expect every Reference Centre to take part in the trials he hoped they would do so if at all possible. To be worthwhile it was important that the trials should be undertaken Nationally rather than limited to 1-2 Centres. The number of patients likely to be included in the trials of heat-treated materials was assessed. suggested that the Directors should use the protocols prepared by the commercial firms where these were relevant.

suggested that an A4-sized data collection form should be used for the Group's trials and that this should be kept quite separate from BPL's data collection form. Concern was expressed regarding the large number of clinical trial forms Directors were being asked to complete, e.g. BPL's form a different form from each of the commercial companies and a separate form for the Group's trial. It was suggested that should check on all the forms to see if one form could be used for all the trials. After discussion it was agreed that and should look at all the protocols and ensure that the Group's protocol was designed to answer the questions posed. The seven Reference Centres in England and Wales had each received 100 vials of NHS (BPL) heat-treated concentrate for trial.

4b) Family Studies

thought it very important for family studies to be undertaken by the UK Haemophilia Centres. In the USA 54

heterosexual females including 3 haemophilia contacts had AIDS. 95 children aged under 13 had AIDS; 87 were aged <3 years and had a parent or household contact with AIDS: one had a haemophilia contact.

[redacted] asked if the Directors thought that family studies were viable and Professor Bloom replied that quite a lot of families would like it. [redacted] said that a protocol for family studies would need to go to local Ethical Committees for approval and [redacted] asked if it was ethical to test small children. [redacted] thought it vital that children should be included in the studies. [redacted] wondered if family studies should be regarded as 'research' or as part of general comprehensive care of haemophiliacs and their families: he was very concerned about the practicalities (staffing etc.) of embarking on these studies.

4c) Staff at Risk

[redacted] referred the Group to the new HSAC document on "Safety in Health Service Laboratories: Hepatitis B" which he had distributed. It was agreed that Directors should send their comments to the DHS and that the subject would be discussed again at the next meeting of the AIDS Group.

[redacted] said that at St. Thomas's Hospital the venepuncturing staff now wore gloves, gowns, visors etc. and he had been advised that the Haemophilia Centre staff should do likewise. He asked if other hospitals were adopting policies similar to STH's. It did not seem from the ensuing comments that any other Centres were in a similar situation to St. Thomas's.

4d) Blood Donors

After discussion it was agreed that staff at Haemophilia Centres should not be Blood Donors.

5. Laboratory Precautions

Notes on the precautions recommended locally were received from , and _ .

reported on the BPL trials in Oxford. There were serious problems with samples which had been treated. A cabinet was ordered for the laboratory and would be arriving soon. An area of the laboratory would be sealed off and reserved as a "designated area".

emphasised that the instructions he had presented applied to his Coagulation Laboratory only and were not used by the General Haematology Department.

said her document summarised the precautions taken in her Department. She was encountering problems with getting a suitable cabinet.

There was discussion of the problems staff encountered in using gloves while assaying and about the way "high-risk" samples were identified and which patients were "high-risk". Some Centres used "Bio-hazard" labels on high risk samples, others marked appropriate samples "HTLV III risk" or "dangerous specimen". preferred "Bio-hazard" to "AIDS Risk" labels. It was appreciated that each Centre had to deal with local policies and problems regarding labelling of specimens. In Glasgow a local AIDS Advisory Panel had been set up, with representatives from all departments involved e.g. Virology.

6. RCN Report

said the forecast figures for the number of AIDS cases in the UK had been refuted. It was agreed that the Group should take away copies of the report to read before the next meeting, when it would be discussed further, along with the document from San Francisco General Hospital.

The problem of hospital staff who contracted AIDS continuing to be employed was discussed. The preliminary draft of a questionnaire for reporting needle-stick injuries was distributed for discussion at a later date.

7. Dental Aspects

Two documents on the dental situation in Glasgow were presented. said that in Cardiff all high-risk patients go to a Special Dental Clinic. He had told his patients if they were HTLV III+. was concerned about the clinical problems of labelling people "high-risk".

said the Oxford dental surgeons had drawn up a document very similar to the Glasgow one. The dentists in Belfast and at St. Thomas's Hospital did not appear to be worried about AIDS. Further discussion was deferred until the next meeting.

8. Blood Transfusion and Concentrates

A paper from the Genito-Urinary Medicine and Blood Transfusion Departments at Glasgow Royal Infirmary was presented. The results of testing stored plasma samples from Glasgow patients showed that HTLV III+ results first appeared in 1981.

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