Minutes of the Second Meeting of AIDG Group of Haemophillia Centre Directors held at the Royal Free Hospital on 19th February 1987

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 Assays:

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

i) The British isolates 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 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 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 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 licensing 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's 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. It was 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 PCL 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 all HTLV III+ patients showed brain atrophy on CAT scan. He would recommend the Reference Centre Directors to use the antigen 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. wondered 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 2-3 years before it was possible to monitor the virus in the patient. asked if high spin 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

1) I referred to F.2 of the MMWR 34:2 (1.4.89) regarding the time after exposure in respect of AIDS following needle stick injuries in the USA. The UK needle stick case remains unreported 7 months after the event.

1:2 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 DHET Guidelines should be followed as far as possible.
4. Clinical Trial Protocol

- Health Centre Coordinators referred to the
  minutes 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 I 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 names and the name of the hospital. After discussion ... DTG
agreed that the samples should be identified by the results,
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 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, codes, labels, forms, etc., for them to use to send samples to either 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.

It 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 back 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 M.8 (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
heterosexual females including 3 haemophilia contacts had AIDS. 25 children aged under 13 had AIDS; 67 were aged 13 years and had a parent or household contact with AIDS; one had a haemophilia contact.

asked if the Directors thought that family studies were viable and Professor Bloom replied that quite a lot of families would like it. He said that a protocol for family studies would need to go to local Ethical Committees for approval and asked if it was ethical to test small children. He thought it vital that children should be included in the studies. He 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 EIDC

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.

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 Haemopelias Centres should not be Blood Donors.

5. **Laboratory Precautions**

Notes on the precautions recommended locally were received from

reported on the SPL 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. **RCW 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+.** He was concerned about the clinical problems of labelling people "high-risk".

**said that 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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