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MEETING OF THE HAEMOPHILIA REFERENCE CENTRE DIRECTORS - 10 DECEMBER 1984

1. Background

So far three patients with haemophilia are known to have contracted AIDS, two of these have died. About twenty four other cases are known to have persistent generalised lymphadenopathy (PGL). Some eight hundred haemophiliac patients have now been tested for HTLV III antibody. The incidence of antibody to HTLV III in haemophiliac patients overall is of the order of thirty five per cent. However seventy five per cent of patients with severe haemophilia have the antibody. Of four thousand haemophiliac patients some two thousand can be considered to be severe the remainder being moderate and mild cases.

2. As you know I was invited to the above meeting held at CBLA headquarters and arranged to discuss the implications of AIDS for haemophilia patients. We can expect a letter from the Directors to the Department with a statement of their policy decisions. A letter will also be sent to all Haemophilia Centre Directors advising of the decisions taken by the Reference Centre Directors. The following main issues were discussed:

a. Testing haemophiliac patients for HTLV III antibody

Directors would like to test all haemophiliac patients in order to establish their antibody status. [REDACTED] (PHLS) thought that provided they were not overwhelmed by all specimens at once they could test most of these patients. They would need additional resources to do this.

Inconsistencies in the results of the tests reveal that a study of the haemophiliac population would provide the invaluable material to increase our knowledge of the disease. [REDACTED] at PHLS has developed the same test as [REDACTED] using the Gallo isolate obtained with his permission through [REDACTED]. I believe a study of haemophiliac patients could be regarded as a research project now and [REDACTED] could provide facilities for doing these tests. However I was told that little support has been given to the relevant section of the Virus Reference Laboratory while working on a shoe string. It may be appropriate to ask PHLS to treat testing as a priority.

b. Dealing with haemophiliac patients

It was agreed that all haemophiliac patients should be counselled to use barrier methods of contraception in order to protect their heterosexual contact. Patients who asked for their HTLV III antibody test results should be informed of them otherwise it is up to individual Directors to decide whether or not they wish to tell the patients their results.

(c) Use of heat treated Factor VIII

After prolonged discussion it was agreed that children should be treated with cryoprecipitate or if necessary with heat treated Factor VIII. New haemophiliac patients should be treated with heat treated Factor VIII. It was agreed that it was not proven that heat treatment inactivated HTLV III and that was essential for studies to be made of sero negative patients given heat treated material in order to monitor the efficacy of the heat treatment. Moreover the virologists considered that there was no evidence that haemophiliacs already HTLV III antibody positive would suffer if they received further doses of antigen (this view is based entirely on theoretical consideration). Nevertheless Directors felt that they should use commercial heat treated Factor VIII in preference to commercial non heat treated Factor VIII. Most agreed that untreated BPL Factor VIII could continue to be used until heat treated Factor VIII was available from Elstree. There will be some Directors who are not willing to do this, notably [redacted] of Newcastle who has declared that all patients will have 'safe' heat treated Factor VIII and has already had sanctioned by his District the extra money required to buy the heat treated product. He will therefore be prescribing commercial heat treated Factor VIII on a named patient basis until the Committee on Safety of Medicines have agreed to variations of license.

There was a little concern that a variation in license of all the commercial heat treated Factor VIII might result in a shortage of heat treated Factor VIII and the variations would prevent the usage of non-heat treated Factor VIII if necessary.

[redacted] is able to produce a certain amount of heat treated Factor VIII which he can release for children and new patients. He cannot greatly increase production until the two new ovens arrive. (Scotland have been able to produce the heat treated product because they are using a [redacted] method of heat inactivation, that is two hours at 68 degrees centigrade. The commercial companies and BPL are using 24 hours at 68 degrees centigrade).

(d) Handling of HTLV III antibody positive plasma samples

From information, mainly I understand gathered from their MLSO's who [redacted] presumably have had copies of drafts from ACDP members Directors were aware of the likely recommendation in the ACDP Interim Guidelines. They were much concerned at the implications for patient care once samples from haemophiliacs are known to be HTLV III antibody positive. It will mean that all coagulation testing will have to be carried out in containment level 3 laboratories. It seemed that in Scotland this would be impossible at the present time.

Directors consider that they should have been drawn into the discussion about the Guidelines and the Chairman intends to write to [redacted]

I attach a copy of the Newcastle policy developed following the death of a haemophiliac who had contracted AIDS. Directors agreed that they would recommend that patients relatives should not donate blood for the time being.

12 December 1984

MED SEB

copies

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