



16th April, 1984

Dear Director,

FUTURE PLANS FOR THE HAEMOPHILIA AIDS INVESTIGATION -
AN UPDATE

I enclose a cumulative list of batch numbers of factor VIII transfused to both cases within 5 years of the onset of AIDS (Appendix (i)). Unfortunately the total number of batches of commercial factor VIII to be included in the study have now increased to 15 for case A/1, and case A/4, the patient who died, received 5 batches. The increase in number is due to 2 factors. The first is that the latest information from CDC Atlanta, from studies on whole blood related transfusion AIDS, is that the maximum incubation period could be 5 years. This means that any batch of factor VIII transfused to cases A/1 and A/4 since 1.1.78 is now 'suspect'. We have also traced 2 further batches which were transfused to case A/4 in 1978 (Hemofil Batch 110477P1; Koate Batch M6375). These were overlooked in the first search of the transfusion records. If either or both of these additional batches were used by your Centre, would you please complete the enclosed form AIDS/10 and return it to Miss Spooner as soon as possible. I am sorry that it is necessary for me to send you yet another form regarding Case A/4:

On March 13th 1984, there were 29 cases of AIDS in the U.S.A. in haemophiliacs which fulfilled the CDC criteria, including 2 cases of Haemophilia B. Five patients had received only factor VIII or IX for the previous 5 years, and 3 patients had other 'high risk' association for AIDS.

There is at present no evidence that the rate of reporting new cases of AIDS in haemophiliacs is yet diminishing. Even if the current measures instituted by the blood collecting agencies in the U.S.A. are effective, there will be at least a 2-3 year period when patients who have received blood products manufactured before the screening of donors was introduced, might be at risk from a putative AIDS agent present in factor VIII concentrate. Of the 29 cases in the U.S.A., one was diagnosed in 1981; 8 in 1982; 12 in 1983 and to date 8 in 1984. Unfortunately, the cases in Europe outside the U.K. are difficult to evaluate, as the information is often incomplete, and in some instances contradictory. There are probably at least 5 cases in Europe including the U.K., but some do not fulfil the CDC criteria, owing to incomplete investigation.

Future Plan of Follow-up

Owing to the complex situation and the fact that other patients will have been exposed to a putative AIDS agent, I

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discussed the project with the persons concerned with AIDS in Haemophilia during a recent visit to the Centers for Disease Control, Atlanta. As a result of this I propose the following strategy:-

- 1) Follow up the batches of factor VIII related to case A/1 using a slightly modified protocol and fewer controls. This would include patients who had received the batches of NHS factor VIII but not the local controls. (These are patients receiving factor VIII not implicated in cases A/1 and A/4 matched for age, sex and severity of coagulation defect). Base line sera will be taken as in the protocol, and other investigations carried out, except that virus isolation specimens will not be taken unless wished by the Haemophilia Centre Director. Sera will be collected at 6 monthly instead of 3 monthly intervals. Please send sera to me at Manchester Public Health Laboratory as indicated in the protocol.
- 2) For the batches related to case A/4 the protocol should be followed as far as possible including the use of all control groups.

Yours sincerely,

GRO-C

J. Craske
Consultant Virologist

HAEMOPHILIA CENTRE DIRECTORS' AIDS INVESTIGATIONBatches of Factor VIII given to case A/1 since 1.1.78

| <u>Manufacturer</u> | <u>Brand</u> | <u>Batch</u> |
|-------------------------------|--------------|--------------|
| Armour | Factorate | T40405 |
| (Revlon Health Care) | " | R2709 |
| | " | R97906 |
| | " | R6511 |
| | " | R5910 |
| | " | S10101 |
| Travenol Lab Ltd. (Hyland) | Hemofil | 780411A028C |
| Immuno Lrd | Kryobulin | 09M12078 |
| | | 09M12378 |
| | | 09M00179 |
| | | 09M00679 |
| | | 09M10979 |
| | | 09M00980 |
| | | 09M04180 |
| | | 09M04980 |
| Blood Products Laboratory | | HL2621 |
| | | HL2632 |
| | | HL2730 |
| | | HL2766 |
| | | HL2833 |
| | | HL2879 |
| | | HL2893 |
| | | HL2894 |
| | | HL2914 |
| | | HL2958 |

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Batches of Factor VIII transfused to case A/4 since 1.1.78

| <u>Year</u> | <u>Manufacturer</u> | <u>Brand</u> | <u>Batch</u> |
|-------------|------------------------|--------------|--|
| 1978 | Travenol & Co Ltd | Hemofil | 110477P1 |
| " | Cutter | Koate | M6375 |
| " | Blood Products Lab. | NHS VIII | HL1390 |
| 1980 | Alpha Therapeutics Ltd | Profilate | A12780 A12710 |
| | Immuno Ltd | Kryobulin | 09M07980 |
| 1982 | Blood Products Lab. | NHS VIII | HLB2863 |
| 1983 | | | HLA2923 HLA2999 HLB3012 HLA3022 |