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REVION HEALTH CARE (UK) LIMITED



INTER OFFICE MEMORANDUM

STRICTLY CONFIDENTIAL

TO : Dr P A Harris DATE: February 28, 1986
FROM : Mr R B Christie REF: RBC/EB/10177
SUBJECT : REPORT ON VISIT TO DR D N WHITMORE, LEWISHAM HOSPITAL - 27/2/1986

COPIES TO :

On 27 February 1986 I visited Dr D N Whitmore at Lewisham Hospital to follow up the history of two haemophiliacs who had sero-converted to HTLV-III positive following treatment with Heat Treated Factorate.

For reasons of confidentiality, I will refer to these patients as Patient 1 and Patient 2.

Patient 1

Patient 1 previously received Factorate Batch Y69402 which contained a known AIDS donor. My memo of February 25 refers.

I have looked at his records as far back as 1976. He had a lot of treatment in 1976, most of which was cryoprecipitate, but he also received 11 units of concentrate. He was not treated again until 1978 when he received 4 vials of NHS concentrate. His next treatment was in 1980 when he had four sets of treatment with cryoprecipitate. There was then a 5 year gap and he received no more treatment until 1985.

On 14 January 1985, he was HTLV-III Negative. He was treated on 5 February 1985 with 2 bottles of 540 units Batch Y69402. On 6 May 1985 he was HTLV-III positive. He was subsequently treated on 27 September 1985 with 2 bottles of Heat Treated Factorate Batch Y79805 and was re-tested on 4 November 1985 when he was confirmed as HTLV-III positive. He has received no treatment since that time and he is now due for a follow up to his HTLV-III status.

This patient is in no other risk group for AIDS and as far as is known is fit and well.

The antibody tests were done by the Lister Institute.

Patient 2 (Reported to me by Dr Whitmore by telephone on 26/2/86)

This patient is a 38 year old very severe haemophiliac. He is a recluse who lives with his mother and father and is an agoraphobic. He treats himself at home and is in no known risk category. He has been massively multiply treated and I went back over his records as far as 1983.

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STRICTLY CONFIDENTIALPatient 2 (cont'd)

He has mainly been treated with cryoprecipitate, but also received a few treatments of NHS concentrate, the odd Armour and Hyland batch between 1983 and 1985.

Over 1984 the patient received 260 units of cryoprecipitate, 11 bottles of various concentrates.

This may be significant - on 3rd, 5th and 12th October 1984, he received 1 bottle 245 units NHS each day. He then received 20 bottles of cryoprecipitate up to December 1984. On 9 December up to 17 December 1984 he had several infusions of NHS Batch HL3208. On 18 December 1984, he then received a further 10 bottles of cryoprecipitate and on 1st January 1985 he received 5 bottles of cryoprecipitate. Between 3 January and 19 January 1985 on each day he received 2 x 255 units of HL3208. On 20 January 1985 he received 10 bottles of cryoprecipitate.

On 22 January 1985 he was HTLV-III negative.

After this, the patient decided he wanted to change to Armour Heat Treated Factorate concentrate because he perceived that it was safer than anything he had had before. He was treated throughout 1985 with large quantities of the following batches: Y71103, X56910, A10801, A16702, X64212, X49808, A10590, Y91609.

On 12 December 1985 he was given NHS Factorate Y3295.

On 20 January 1986, he was re-tested and was found to be HTLV-III positive.

My interpretation is that as he had no HTLV-III test between January 1985 and January 1986, and as he was exposed to blood products in the period 3 or more months prior to his negative test, he could have sero-converted within the accepted time for sero-conversion. It could have been the NHS concentrate, or it could have been one of the bags of cryoprecipitate. It is unfortunate that he switched over to our Heat Treated material during that year and nobody knows quite when he sero-converted, but it is by no means an unequivocal relationship to our product.

Dr Whitmore had no objection to us discussing our summary conclusions with the DHSS, but asked that if they wished to know specific detail of treatment that we refer them to him. He was concerned that one of his patients could be suicidal if there was any leak of this information.

Full details of treatments are attached for our internal use only.

Cont'd. ...

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STRICTLY CONFIDENTIALCase Number 3

There is another case at Lewisham who was treated there and then transferred to another hospice - Dr Bolton-Maggs. He was tested by Dr Whitmore and found negative, was re-tested after receiving Batch Y69402 and was found to be still negative on two subsequent occasions. He was due for a further follow-up around January this year. I have to confirm with Dr Bolton-Maggs that he is still negative and will do so on 28/2/86 if possible.

Other Cases

There were three further cases in Swansea, one of which, on looking at the notes, looks a bit suspicious. I need to confirm previous treatment. These cases were sero-negative and then after receiving Y69402, one of the results was put down as "equivocal, possibly positive". I hope to follow this up with the clinician in Swansea on 28/2/86.

I have no information on timing and amounts or type of previous treatment for these cases.

GRO-C

R B Christie

NOTE

I have now followed up "Case Number 3" with Dr Bolton-Maggs. This patient did not come to the clinic for his December 1985 re-test for HTLV-III antibody. So far as Dr Bolton-Maggs knows, he is clinically well.

I also telephoned Swansea. Mr Al Ismail said that all patients who were negative prior to treatment with Y69402 are still negative but he would like to meet me as soon as possible for a discussion. A re-test of all these patients is due in about 1 month's time.

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PATIENT 1 - [REDACTED]

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<u>DATE</u>	<u>TREATMENT</u>
<u>1976</u>	
12/3	5 Cryoprecipitate
23/6	4 Cryoprecipitate
3/8	9 Cryoprecipitate
4/8	7 Cryoprecipitate
5/8	9 Cryoprecipitate
15/11	11 Cryoprecipitate
22/11	5 units AHF ? NHS
22/11	4 x 300 Profilate
23/11	4 Profilate
23/11 p.m.	12 Cryoprecipitate
24/11	17 Cryoprecipitate
25/11	20 Cryoprecipitate
26/11	15 Cryoprecipitate
27/11	15 Cryoprecipitate

1978

14/8 4 AHF x 245

1980

11/2	16 Cryoprecipitate
12/2	16 Cryoprecipitate
13/2	16 Cryoprecipitate
14/2	16 Cryoprecipitate

NOTE 5 YEAR GAP

1985

14/1/1985 = -Ve HTLV-III

5/2 2 x 540 Y69402

6/5/1985 = +Ve HTLV-III

27/9 2 x 470 Y79805

4/11/1985 = +Ve HTLV-III

Since 4/11/85 2 more Batches Y91609

12/12/85 10 x 250 8Y3298

Re-tested 20/1/86 = HTLV-III Positive

27/1/86 10 x 2258Y

ARMOUR002798

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Aged 38. Severe haemophiliac. Recluse. Lives with mother and father in Kidbrook. Agoraphobic. Treats himself at home. Mother collects treatment.

4/8/1984 Seen.

22/1/85 Tests were done. HTLV-III Negative

Low T4/T8 - 14/45

Lymphocytes - 1.6

20/1/86 HTLV-III Positive

T4/T8 - 10/48

Lymphocytes - 1.6

1983 - Multiply treated with Armour, Hyland, AHF & Cryoprecipitate, Lister, Elstree.

1984

3/1/ - 22/6 - 125 units of Cryoprecipitate

29/1/84 - 2 x 215 AHF = X21902 (Armour)

25/6 - 1 x 235 HLA3162 = Elstree

26 - 29/6/84 - 1 x 235 HLA3162 = Elstree (each day)

30/6/ - 26/9/84 96 units Cryoprecipitate

26/9 - 1 x 245 NHS

29/9 - 14 Cryoprecipitate

3/10, 5/10 &

12/10/84 - 1 x 245 NHS

21/11 - 1/12/84 20 Cryoprecipitate

9/12/84 - 1 x 255 HL3208 Elstree NHS

12/12 &

17/12/84 - 1 x 255 HL3208 Elstree NHS (each day)

18/12 - 10 Cryoprecipitate

1985

1/1/ - 5 Cryoprecipitate

3/1, 11/1, 17/1, 18/1 & 19/1/1985 on each day he received

2 x 255 HL3208 = Elstree NHS

20/1/85 - 10 Cryoprecipitate

22/1/85 - Tested = NEGATIVE

22/1, 23/1, 29/1, 31/1 - Y71103 - 1 unit on each day Factorate HT

15/2/85 - 1 x 240)

16/2/85 - 2 x 240) X56910 Factorate (HT ?)

25/2/85 - 1 x Y71103

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PATIENT 2 (continued)

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1985

TREATMENT

26/2, 1/3, 9/3 each day	1 x 240 X56910	
12/3, 15/3, 22/3, 27/3, 28/3, 13/4 each day	1 x 235 Y71103	
19/4	1 x 275)	
24/4	1 x 275)	
28/4	1 x 275)	
30/4	1 x 275)	A 10801
3/5	1 x 275)	Factorate HT
5/5	1 x 275)	
12/5	1 x 275)	
16/5	2 x 275)	
17/5	1 x 275)	
22/5	1 x 275)	
25/5	1 x 275)	
3/6	1 x 275)	A 16702
11/6	2 x 275)	
14/6	1 x 275)	
18/6	2 x 275)	
19/6	1 x 275)	
20/6	1 x 275)	
29/6	1 x 275 A16702	
30/6	2 x 240)	Factorate HT
1/7	1 x 240)	X64212
2/7	2 x 460	Factorate HT X49808
5/7	1 x 240)	
6/7	2 x 240)	
9/7	1 x 240)	X64212
12/7	1 x 240)	
17/7	2 x 240)	
19/7	1 x 240)	X64212
21/7	1 x 240)	

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PATIENT 2 (continued)

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1985 (cont'd)

TREATMENT

7/9	3 x 240)
9/9	1 x 240)
13/9	1 x 240) X64212
20/9	1 x 240)
24/9	1 x 240)
30/9	1 x 270)
2/10	1 x 270) Factorate HT
14/10	3 x 270) A10590
18/10	1 x 270)
25/10	3 x 270)
15/11	1 x 270 A10590
21/11	1 x 495)
23/11	1 x 495) Y91609 Factorate
2/12/85	1 x 495)

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