

0045

SNBTS - CONFIDENTIALHIV SEROCONVERSIONS RELATED TO SNBTS FVIII1. INTRODUCTION

This updates an earlier (interim) report dated 28/6/86 which summarised available information on FVIII batches administered to 18 Scottish haemophiliacs believed to have seroconverted to HIV following receipt only of SNBTS FVIII. The contents of this report only relates to information received by the manufacturer (PFC). Other clinical information may be available from Regional Transfusion Directors or Haemophilia Directors.

2. SUMMARY OF DATA ON BATCHES ADMINISTERED

- 2.1 16 Haemophiliacs in the South-East of Scotland were found to have seroconverted to HIV at some stage during 1984. 15 of the 16 haemophiliacs received a common batch (023110090) and it has been concluded that this batch was infective.
- 2.2 Follow-up of West of Scotland haemophiliacs, has revealed two patients receiving SNBTS FVIII who seroconverted in 1984 and 1985 respectively.

PATIENT 1

Incomplete details available as no written report ever received from reporting clinician (Dr Maddock, GRI).

Sample	1.7.82	Negative
Sample	12.12.83	Positive

PATIENT 2

Seroconverted between 5.10.84 and 25.10.85. At least five years since previous Commercial FVIII.

- 2.3 The batches of product received by the South-East and West of Scotland seroconverters are summarised in Table 1. The following should be noted:
- Neither of the West of Scotland patients received the batch (023110090) implicated in the South-East Scotland seroconversions.
 - No batch is common to the two West of Scotland seroconversions.
 - If SNBTS FVIII was responsible for each of the 18 seroconversions, then at least three infective batches must have been issued.

7
Cryo

SNBTS - CONFIDENTIAL

- d. Seven batches were common to West of Scotland and South-East Scotland seroconversions. These batches were:

	<u>Batch</u>	<u>Number of Seroconversions</u>
	756	8/18
	762	10/18 *
	780	2/18
	784	13/18
	797	10/18 *
	3-003	15/18 *
	3-016	4/18
c.f.	3-009 (South-East Implicated batch)	15/18 *

HH has conc. samples.

The batches marked * were tested for HIV antibody using a sensitive variant of the Wellcozyme assay. No trace of antibody was found in any of these batches.

3. RETROSPECTIVE DETECTION OF HIV POSITIVE DONATIONS USED IN THE MANUFACTURE OF SNBTS FVIII

The introduction of HIV antibody testing led to the discovery of several donors who were HIV antibody positive. When positive, library samples of previous donations were also tested. Where HIV positive library samples were detected, the fate of the donation was traced.

- 3.1 Seven batches of FVIII have been identified which were derived from confirmed HIV positive donations. These are listed in Table 2, only one of these batches was in the group of batches listed in Table 1 which had been potentially implicated in the seroconversions. This batch (No. 797) had been administered to 8 of the Edinburgh seroconversions and could have been implicated in their seroconversion. However, 19 patients in the West of Scotland received this batch. Of these, 12 were already HIV positive prior to receiving it. The remaining 6 recipients remained seronegative. It does not therefore, appear to be a good candidate batch for any of the Edinburgh seroconversions.
- 3.2 A further group of FVIII batches have been derived from donations for which there was no library sample remaining but where a subsequent donation was found HIV-antibody positive. It is likely that many of these donations were seronegative but their infectivity cannot be completely excluded. Of these 10 batches, only one (3-015) was included in Table 1. Whether this batch was genuinely infective cannot be concluded, although it should be noted that only 8 of the Edinburgh and neither of the Glasgow seroconverters received this batch.

SNBTS - CONFIDENTIAL

3.3 Follow up of retrospective donor testing has not, therefore, been of any significant value in pinpointing the infective batches responsible for these 18 seroconversions.

4. COMMENTS

At least 3 batches of SNBTS FVIII were infective and led to seroconversions to HIV in 18 recipients of SNBTS FVIII. The precise number of implicated batches may be defined more precisely as a result of PCR studies on the HIV isolated from these patients. Such studies are being carried out by other bodies at the present time.

One batch (3-009) remains the main candidate for 15 of the 18 seroconversions but the other candidate batches have not been identified.

B CUTHBERTSON
5/1/91

UPDATED 20/2/92

0046

SNBTS - CONFIDENTIALTABLE 1

FVIII. BATCHES OF PRODUCT RECEIVED IN 12 MONTH PERIOD BEFORE EARLIEST POSSIBLE TIME OF SEROCONVERSION

<u>Batch</u>	<u>South-East</u> (n = 16)	<u>West</u> (n = 2)	<u>Total</u> (n = 18)
666	0	1	1
681	0	1	1
682	0	1	1
692	0	1	1
699	0	1	1
700	3	0	3
708	2	0	2
711	8	0	8
715	0	1	1
721	6	0	6
724	9	0	9
727	5	0	5
728	8	0	8
733	8	0	8
746	7	0	7
749	0	1	1
750	6	0	6
756	7	1	8
757	0	1	1
759	0	1	1
762	9	1	10
766	0	1	1
768	12	0	12
773	10	0	10

SNBTS - CONFIDENTIALTABLE 1 CONTINUED

<u>Batch</u>	<u>South-East</u> (n = 16)	<u>West</u> (n = 2)	<u>Total</u> (n = 18)
775	0	1	1
776	5	0	5
780	1	1	2
781	6	0	6
782	0	1	1
784	12	1	13
785	0	1	1
786	5	0	5
787	8	0	8
791	13	0	13
797	9	1	10
799	11	0	11
800	5	0	5
802	10	0	10
803	0	1	1
3-003	14	1	15
3-004	0	1	1
3-005	0	1	1
3-010	2	0	2
3-013	0	1	1
3-014	6	0	6
3-015	8	0	8
3-016	3	1	4
3-017	14	0	14
3-019	10	0	10

SNBTS - CONFIDENTIALTABLE 1 CONTINUED

<u>Batch</u>	<u>South-East</u> (n = 16)	<u>West</u> (n = 2)	<u>Total</u> (n = 18)
3-009	15	0	15
4-006	0	0	1
4-005-1*	0	0	1
4-022-1*	0	0	1
4-055-1*	0	0	1

NOTE: * = Heat Treated 2hrs at 68°C.

0044

SNBTS - CONFIDENTIAL

TABLE 2

BATCHES OF FVIII DEFINITELY KNOWN TO
 HAVE INCLUDED AN HIV-POSITIVE DONATION

<u>BATCH</u>	<u>PFC INCIDENT REFERENCE NUMBER</u>	<u>YEAR OF MANUFACTURE</u>	<u>HEAT TREATMENT CONDITIONS</u>
797	7	1983	NONE
4-021	21	1984	68°C/2h
4-027-1	4	1984	68°C/2h
4-047-1	4	1984	68°C/2h
4-072-1	11	1984	68°C/2h
5-003	17	1985	68°C/24h
5-014	4	1985	68°C/24h

HH has samples

NOTE: All of the batches in this table were derived from donations retrospectively found to be HIV-antibody positive.

0048

SNBTS - CONFIDENTIALBATCHES OF FVIII WHICH POSSIBLY CONTAINED
AN HIV-POSITIVE DONATION

<u>BATCH</u>	<u>PFC INCIDENT REFERENCE NUMBER</u>	<u>YEAR OF MANUFACTURE</u>	<u>HEAT TREATMENT CONDITIONS</u>
495	10	1979	NONE
540	10	1980	NONE
599	1	1981	NONE
657	1	1982	NONE
680	10	1982	NONE
702	1	1982	NONE
735	2	1982	NONE
3-015	2	1983	NONE
4-017	9	1984	NONE
4-019	22	1984	NONE
5-003	17	1985	68 °C/24h

NOTE: All of the batches in the table were derived from donations for which there are no library samples but who were found to be HIV-antibody positive on testing subsequent donations.