The Penrose Inquiry – Topic Statistics

Patients acquiring HIV from PFC product

Question

I refer to the above and to the various spreadsheets provided by the CLO on this matter:

It was previously discussed that the spreadsheets gave the impression that there must have been patients in addition to the Edinburgh Cohort who acquired HIV from the PFC product. We are aware of possibly two from Glasgow, but it now appears that there were other cases too.

I am now seeking the SNBTS position on these additional likely infections and looking forward to receiving same.

Yasmin Shepherd
18th April 2011

Response

To be certain that SNBTS product was the likely source of HIV infection in individual patients it would be necessary to have a high level of confidence that local treatment records are complete and that there were no episodes of treatment elsewhere in the UK or abroad.

The paper "HIV Statistics" (Ref SNBTS 2010-00013) submitted in June 2010, gave a figure of 18 patients likely to have been infected by SNBTS products, which was based upon reports received by the SNBTS in the mid 1980's. This paper included information on 16 patients who had been treated in Edinburgh (15 of whom had received Batch NY 3-009) and 2 from Glasgow.

On the basis of the information now available, including that provided to the Inquiry by the Haemophilia Directors, the SNBTS believes that 19 patients in Edinburgh (including one patient who did not receive Batch NY 3-009), 4 patients in Glasgow and 2 patients in Aberdeen were likely to have been infected by SNBTS product, giving a total figure of 25 patients. The basis for this conclusion is discussed below.

1. Edinburgh Patients

The original figure of 16 Edinburgh patients likely infected with HIV by SNBTS product was based on the information supplied to SNBTS in 1984 and on the subsequent publication of Ludlam et al, Lancet, 1985, where it was stated that 15 haemophiliacs had been infected who had all received a single batch of SNBTS product. However, there was a subsequent publication in 1988 from Steel et al in which it was recorded that 18 recipients of batch NY 3-009 had become infected with HIV. In addition, as referred to above, the SNBTS was also aware of one Edinburgh patient identified in 1984 who had not received the implicated batch. This total of 19 patients is consistent with the data provided to the Inquiry by Professor Ludlam. However, it is considered that the data in the spreadsheet provided by Prof Ludlam

could be open to other interpretations, based on exactly when individual patients received commercial product.

In summary, it is accepted that 19 patients in Edinburgh were most likely to have been infected by SNBTS products. [Refs: SNBTS paper Actions Surrounding FVIII Batch 023110090 (PEN.013.0192); Ludlam CA et al (1985), Human T-Lymphotropic Virus Type III (HTLV-III) Infection in Seronegative Haemophiliacs after Transfusion of Factor VIII. Lancet, August 3, 1985, 233-236 (SNB.008.3434); Steel CM et al (1988), HLA Haplotype A1 B8 DR3 as a Risk Factor for HIV-Related Disease. Lancet, May 28, 1988 (LIT.001.0894)].

2. Glasgow

From the details supplied to the SNBTS in the 1980s, the SNBTS was aware of two Glasgow patients with Haemophilia A who became infected with HIV and where it was thought likely that this was through use of SNBTS product. These 2 patients have now been identified in the Glasgow GRI list provided to the Inquiry as G5 and G9. In addition, the SNBTS was made aware of one patient with Haemophila B who had apparently only been treated with SNBTS product. This patient may have been G10 in the GRI list, but some of the details do not match with the information supplied to SNBTS in 1986 (ref letter from Dr C D Forbes to Dr J D Cash, 12 February 1986, attached). The SNBTS was also aware of the publication by Melbye et al, 1984 (Lancet ii, 1984, 1444-6), in which 2 patients were identified who had apparently only been treated with SNBTS product in Glasgow. Of note is the statement in this article that one of the patients had "travelled yearly throughout Europe and could have received unrecorded treatment: the other was a citizen of Pakistan and often visited his home country". Therefore the total provenance of these 2 patients is unclear. Exactly which patients were referred to in the Melbye publication is not known, but it seems likely that it was patients G5 and G8, based on the details of first positive HIV test results.

A review of the data supplied by the haemophilia directors to the Inquiry suggests that patient G8 is in the same category as patients G5 and G9, where the products administered during the likely time of seroconversion were stated to be exclusively SNBTS. The SNBTS had no prior knowledge of this patient in advance of the present Inquiry.

From the data currently available, it is accepted that 4 patients treated in GRI (3 Haemophilia A patients and one Haemophilia B patient) were likely to have been infected with SNBTS product. However it is not known if they received any treatment out with the Glasgow Centre – either in the UK or abroad. None of the patients treated at the RHSC appear to be candidates for infection by SNBTS products.

3. Aberdeen

Until very recently, the SNBTS was not aware of any HIV cases in Aberdeen associated with SNBTS product. However from the information provided through the Inquiry, it is accepted that there is 1 likely case and 1 possible case in Aberdeen as described in the paper "Aberdeen HIV Positive Haemophiliacs" (Ref SNBTS 2011-00079) submitted in April 2011. However, again, it is not known if these patients received any treatment out with their local treatment centre.

4. General Comments

The extra detail in the spreadsheets supplied by the Haemophilia Directors to the Inquiry is very helpful in identifying how many patients were infected with HIV. The data in these spreadsheets are also helpful in providing new information on the likelihood of patients being infected with SNBTS or commercial products. This information has suggested that more patients appear likely to have been infected with HIV through use of SNBTS product than was previously understood by the SNBTS, based on the details supplied by the Haemophilia Doctors in the mid 1980's when these infections were first detected.

The data are difficult to interpret, since it is not possible to unequivocally implicate either SNBTS or commercial products in the transmission of HIV for those patients who received a mix of SNBTS and commercial product. In addition, the SNBTS cannot tell whether or not individual patients received commercial products if treated out with the Scottish Haemophilia Centres. In the published literature, there is at least a suggestion from the publication of Melbye et al, that 2 patients may have received non-SNBTS product when travelling abroad. For those who were known to have received both SNBTS and commercial products, the assignment of probability will partly be determined by date of first detection of antibody to HIV and the date of the last negative HIV test result. For those patients who received both products within a time period consistent with HIV infection, it is more likely that the source of infection was the commercial product. This supposition is based on SNBTS current understanding of the frequency of HIV transmission by commercial and NHS products at that time, and is further supported by the much lower HIV infection rate in Scotland when compared with those haemophilia populations which were treated exclusively with commercial FVIII of US manufacture. This difference is found in many publications, including that from Moffat, Bloom and Mortimer, 1985 (Lancet 1, p935) who found a significant difference (p,0.001) between the infection rate in patients treated with US FVIII concentrate and those treated with UK Concentrate. Similarly, Kroner et al, 1994 (J Acquired Immune Deficiency Syndromes, 7: 279-286) reported that more than 90% of moderate and severe haemophiliacs treated with American product seroconverted to HIV.

If further information is required by the Inquiry at individual patient level, the SNBTS believes that this would have to be provided by more detailed analysis of data on treatment dates held by the Haemophilia Centres.

Bruce Cuthbertson
SNBTS Public Inquiry Team
5 June 2011

Attachments

1. Letter from Dr CD Forbes to Dr JD Cash, 12 February 1986
2. Melbye et al, 1984 Lancet ii, 1984, 1444-6
3. Moffat EH, Bloom AL and Mortimer PP, 1985 Lancet 1, 935
4. Kroner BL et al, 1994 Journal of Acquired Immune Deficiency Syndromes, 7: 279-286