Report of possible transmission of vCJD through plasma products in a Haemophilia patient

1. Haemophilia patient population (Table 1)

There are 8,730 patients with bleeding disorders in the National Haemophilia Database (NHD)(data sent on 23 April 2008). Among them, 4140 patients have been designated as 'at risk' of vCJD for public health purposes ('at risk') for receiving UK sourced plasma products. Of these 4140 'at risk' patients, 802 have received plasma products sourced from known vCJD cases (implicated plasma products). These 802 patients were followed up for a median of 13 years after receiving the first dose of implicated clotting factors (range 2 days – 20 years; inter-quartile range 11 – 15 years).

2. Donors contributing to clotting factors (Table 2)

Clotting factors for 802 patients were sourced from 8 donors who went on to develop vCJD. Seven of the eight donors contributed to the production of more than one clotting factor (Factor VIII and Factor IX). The median interval between donation and onset of vCJD in these 8 donors was 7 years and 4 months (range 6 months - 11 years 11 months). Two hundred and twenty-eight patients received clotting factors sourced from more than one donor. The median infectivity of clotting factors received per patient from each donor ranged from ID_{50} 0.245 to 0.883.

3. Clotting factor batches (Table 3)

Twenty five batches of plasma products (all either Factor VIII or Factor IX) from seven products were administered to 802 patients. They received 1,146 treatments with 12,700,000 units of clotting factors over a period of 12 years from 1987 to 1999. The majority of patients (68%) received only one batch of a clotting factor. The median, lowest and highest infectivity-per-unit of batches used for these patients were ID_{50}s 0.0000584 (Factor VIII, Brand 8Y, Batch FHB4419), 0.0000199 (Factor VIII, Brand 8Y, Batch FHB4547) and 0.0009526 (Factor VIII, Brand Z8, Batch 0304-70510).

4. Case (Table 4)

A deceased haemophilia patient (index case) who underwent post mortem as part of a UKHCDO study has been found to have evidence of vCJD infection in his spleen. The spleen was examined at the NCJDSU, and $P^{r}P^{Sc}$ was detected by Western Blotting, but not by immunohistochemistry. The patient was 74 years when he died, and had not had any symptoms of vCJD.

4.1. Implicated Batches

The index case had been treated with an implicated batch of F-VIII (8Y) that had been sourced from plasma from a donor who later developed vCJD. The index case died nearly 11 years after being treated with this batch.

The implicated batch number of the Factor VIII was FHB4547. The patient received 8,025 units of this batch in December 1996. The patient had received no other plasma products sourced from donors who developed vCJD. The infectivity of the dose received has been calculated to be 0.16 ID_{50}.

A total of 63 haemophilia patients were treated with this batch of plasma product.

Draft 30.12.08

4.2. Donor *(TMER number 123)*

The donor developed symptoms of vCJD about six months after donating plasma that was used to manufacture this batch of clotting factor (Table 4). The donation for manufacturing this batch was made on 2 May 1996. The donor had also donated blood on 11 January 1993 and 17 August 1995. The latter donation was not used to produce any clotting factor.

In addition to the batch of Factor VIII (8Y) received by the index case, the donor's plasma was also used to produce Factor IX (9A) and Factor VIII (Replenate). Four batches of these 3 clotting factors were sourced from this donor. A total of 262 haemophilia patients received these batches. Of 262 patients, 19 received two different clotting factors sourced from the same donor.