THE ROYAL FREE HAMPSTEAD NHS TRUST

The Katharine Dormandy Haemophilia Centre & Thrombosis Unit

FINAL DRAFT

Report on vCJD "lookback" exercise

26th March 2010

Background
In September 2004 all patients with inherited bleeding disorders who received UK-sourced pooled factor concentrates between 1980-2001 were classified as **"at risk of vCJD for public health purposes"**. The risk assessment was carried out on behalf of the vCJD Incidents Panel and accepted by the Spongiform Encephalopathy Advisory Committee (SEAC), the Committee on the Microbiological Safety of Blood and Tissue(MSBT) and the Committee on the Safety of Medicines. In England, Wales and N. Ireland the notification of patients and their GPs was instituted by the Health Protection Agency's Communicable Disease Surveillance Centre. On 9th September a letter was sent by the Chair of UKHCDO (United Kingdom Haemophilia Centre Doctors Organisation) to all Haemophilia Centres informing them that patients must be identified and notified. The notification documents for patients and their GPs had to be posted on 20th September.

In 2004 there were 512 patients notified by the Royal Free. There are currently 555 patients registered at the Royal Free who have been classified as "at risk". The number has increased due to transfers from other haemophilia centres.

Documentation is held in individual patient notes, including an "Exposure Assessment Form" which indicates "at risk" status and also whether the patient was treated with 'implicated' batches that are known to include donations from individuals who developed vCJD. All "at risk" patients are flagged on CRS. Hard copy lists of all "at risk" patients are held in the Haemophilia Centre and in the Endoscopy Department

Incident triggering "lookback"
On 3rd March 2010 a patient attended the haemophilia centre for a pharmacokinetic study of a factor VIII concentrate. In the course of reviewing the medical notes for past treatment, Debra Pollard, clinical nurse specialist, noticed that the patient appeared to have only been exposed to 8Y, a UK manufactured product that had an "N" in the batch number indicating that the plasma source was the US. She realised that the patient may have been wrongly identified as "at risk of vCJD for public health purposes as she had not had UK plasma-derived product. The error was confirmed by further investigation. The patient's mother was informed on the day and both parents were seen by Professor Tuddenham and Debra Pollard on the following day. An apology was made to them for the error in process and the distress caused to them. The patient was a child at the time of the notification and was not told of her "at risk" status. The decision was made to inform these parents immediately as the patient is about to reach the age of 18 and there had been several discussions with the parents around informing her.

A new vCJD risk assessment form indicating that the patient is "not at risk of vCJD for public health purposes" was completed and put in the patient's notes. Warning labels were removed from the notes and the haemophilia data manager has removed the vCJD risk flag from CRS and removed the patient's name from the "at risk" register on the haemophilia database.

An incident form was completed and has been forwarded to the clinical governance facilitator for the haematology directorate.

An investigation was instigated into whether any other patients were placed on the vCJD "at risk" list in error for the same reasons as this patient.

Methods of examination
Confirmation of "N" in batch numbers denoting US plasma derived product was sought from Dr Clive Dash the Medical Director of BPL.

The following searches of the Haemophilia database were performed:

- All patients who only received "N" batch products between 1st Jan 1980 and 31st Dec 2001 (n.43)
- All recipients of "N" batches during this period (n157).

The database treatment records for all patients who received "N" batches were manually examined (114,057 records). This list revealed a further 4 patients who appeared to have only received "N" batch UK manufactured products.

Medical notes, where available, were examined:

- to confirm database treatment records
- for evidence of treatment at other hospitals and vCJD "at risk" status

Results
Confirmation was received from BPL that US plasma was used for the manufacture of their products from late 1998. The "N" in a batch number was used exclusively to denote US plasma-derived products. No discussion of this issue has been found to date in the correspondence and toolkit accompanying the 2004 notification instructions and documents.

46 patients were only treated with "N" batches of UK products at the Royal Free.
Of these, there is clear evidence that 9 patients have been treated with products elsewhere that place them in the "at risk" category.
The medical records for 4 patients could not be found.
2 patients who are probably not "at risk" live abroad. Their addresses were not traced in 2004 and they therefore would not have received the notification documents.
1 further patient has no current address on record.
1 patient's status is unclear as it is highly likely that he was treated elsewhere.

32 patients have been identified to have only ever had treatment with "N" batch/batches. These patients do not therefore fulfil the criteria for being "at risk of vCJD" for public health purposes. There are contact details for 29 of these patients.

Conclusion
32 (+ 1 patient who was the subject of the original incident) have been incorrectly informed that they are "at risk of vCJD for public health purposes". Whilst they had received UK manufactured clotting factor concentrate between 1980 and 2001, the batches they were exposed to were made from US plasma. It seems clear that at the time of the 2004 Notification the haemophilia database search identified all UK products received by patients regardless of plasma-source.

Actions necessary

1. Actions to be agreed with the Trust.
2. Informing 29 patients that they are not "at risk" under the terms of the Notification. Letter to be drafted by Professor Tuddenham to include circumstances leading to their incorrect identification and the offer of a consultation.
3. Haemophilia MDT to discuss strategy for handling telephone calls and providing support where necessary to respond to possible impact.
4. Make further efforts to source missing notes and check status of remaining patients who appear to only have had US plasma derived product.
5. Remove these patients from the "at risk" register, remove CRS flags and replace the Exposure Assessment Forms with corrected versions.
6. Professor Tuddenham to inform the Chair of UKHCDO who it is anticipated will liaise with the HPA and decide on actions to be taken to ascertain whether similar incorrect identification of "at risk" patients has occurred at other haemophilia centres. **(Dr Charles Hay, UKHCDO Chair, informed by Professor Tuddenham on 26th March 2010)**
7. Further investigation of the circumstances leading to the incorrect identification of patients.