UKHCDO
UNITED KINGDOM HAEMOPHILIA CENTRES DOCTORS' ORGANISATION

Ref: GRO-C

Wednesday, 07 April 2010

To: All UKHCDO members and all Haemophilia Nurses

Dear Colleague,

Re: Mistaken notification of "at risk" status for vCJD

I have been told that a centre has mistakenly identified and notified a number of patients that they were at an increased risk of vCJD for public health purposes. These patients had, in fact, only been treated with BPL products manufactured from American sourced plasma. I am writing to all Haemophilia Centres asking that all past vCJD risk notifications are checked because I suspect that this error may have been repeated in other centres.

The context of this action is the history of the change from fractionation of UK to US plasma and the vCJD risk notification exercise that followed. The period of risk for vCJD from plasma products was considered 1980-2001.The end-date of 2001 was derived from the expiry date for the last batches of blood products manufactured by BPL from UK plasma. When UKHCDO and HPA wrote to all centres on 7/9/2004 asking them to identify all patients at increased risk of vCJD for public health purposes centres were told that *"all patients with bleeding disorders who have been treated with UK-sourced pooled factor concentrates or antithrombin between 1980 and 2001 should be considered "at risk" of vCJD for public health purposes and special precautions taken."* The letter went on *"The start date of 1980 is when BSE is thought to have entered the human food chain. The end date of 2001 is the last possible expiry date of any product manufactured by UK fractionators that was sourced from UK donors."* The letter was therefore quite explicit and unambiguous in its reference to "UK-sourced" products.

BPL ceased fractionating UK donor plasma in June of 1998. The plant was then stripped down, many parts replaced, and large vessels heat sterilised and treated with sodium hydroxide and other agents. Fractionation resumed, using American sourced donor plasma only, in September of 1998. The first three or so batches were used for quality control only and never issued to patients. Batches of US plasma derived concentrates were issued from early 1999 and in May of 1999 BPL offered to swap remaining UK-plasma derived products for US plasma-derived products. It is assumed that some UK plasma derived products remained in circulation but these were expired in 2001.

Between early 1999 and 2001 both UK-plasma and US-plasma derived concentrates were in use. These could be distinguished by their batch number.

All UK plasma derived products had a batch number made up of three letters followed by four digits always comprising a number *less than* 5000 e.g. FHB 4116.

All American plasma derived products had batch numbers starting with four letters, the last of which was always N, and then four digits always comprising a number *greater than* 5000 e.g. FGAN 5007.

The centre which mistakenly identified and notified patients as being "at risk" identified some infrequently treated patients, only treated with BPL products during the period 1999-2001 who had used only US-plasma derived products fractionated by BPL. Two thirds of these patients had factor XI deficiency. Across the UK, most patients who received BPL products during this period were frequently treated patients already at risk by virtue of prior treatment with BPL UK-plasma sourced products between 1980 and 1999. For this reason we suspect that a relatively small number of patients may have been misinformed of their vCJD "at-risk" status.

I ask that all centres review their records to ensure that they did not inadvertently notify patients, treated only with BPL products between early 1999 and 2001, without distinguishing between those treated with UK or US plasma derived products. The patients identified incorrectly as being "at risk" will ***only*** have been treated with US plasma derived BPL products between early 1999 and 2001 and will ***not*** have been treated with UK fractionated products between 1980 and 1999. If these patients have been treated in more than one centre during the period 1980-2001, it is important to cross-check with the other centre and with the National Haemophilia Database to make sure that they have not been treated with BPL products in the other centre between 1980 and 1999 before any notification of a change to their risk status is undertaken. It is important to avoid falsely reassuring patients who are still "at risk" by virtue of treatment given in another centre.

The patients identified are likely to be infrequently treated patients who have von Willebrand's disease, mild haemophilia A and B, factor XI, factor VII and Antithrombin deficiency.

The at-risk status of all patients suspected to have been mistakenly identified as "at risk" should be cross checked with the National Haemophilia Database before they are notified of the change in their "at risk"

status. Those then confirmed to have been told that they were "at risk " in error should then be contacted by their haemophilia centre and informed of the reassessment of their risk. They should also be informed of the reasons for the change and their other doctors (GPs, Gastroenterologists etc) should be formally notified and the patients offered the opportunity to discuss the matter with their centre doctor. The National Haemophilia Database should also be notified. To ensure that accurate records are held I would grateful if you could let me know by the end of July 2010 the results of your review, including nil returns as appropriate.

The keynote here is that this exercise should be done carefully rather than quickly. Patients requiring endoscopy or surgery should be checked first to ensure that this is not complicated unnecessarily. The "at risk" status of regularly treated patients can be quickly confirmed. Patients phoning the centre before the exercise is complete can be reassured that the "at risk" status will be correct in most cases, but that it will take some time to carefully check all the records and that they will be contacted if, on review, their status changes.

I will be consulting with colleagues in Scotland to find out if a similar situation may pertain there. My enquiries in Scotland have been hampered by the closure of PFC.

Yours sincerely,

GRO-C

Dr Charles RM Hay
Chairman UKHCDO