Health Protection Agency

CJD Section
Centre for Infections
61 Colindale Avenue
London NW9 5EQ

Tel +44(0)20 8200 6868
Fax +44 (0)20 8200 7868
www.hpa.org.uk

With compliments

Health Protection Agency
Centre for Infections

CJD Section
Communicable Disease Surveillance Centre
61 Colindale Avenue
London NW9 5EQ

Professor Christopher A Ludlam,
Department of Clinical & Laboratory Haematology,
Royal Infirmary of Edinburgh,
The Lothian University Hospitals NHS Trust,
Laboratories 2nd Floor,
Little France Crescent,
Edinburgh.
EH16 4SA

Your ref: CAL/ajo
31st January 2005

Dear Christopher,

Re: vCJD risk categorisation for fibrinogen and factor XIII concentrate manufactured from UK-sourced plasma.

Thank you for your letter of 8th October 2004 to Professor Don Jeffries requesting guidance as to whether, with regard to vCJD risk categorisation, fibrinogen and factor XIII products should be considered in a similar way to factor VIII, factor IX and antithrombin. We have consulted with the product manufacturers and Professor Jeffries has asked me to reply to your query relating as it does to the HPA managed details of the risk assessments and patient notification.

As you are aware, all patients with bleeding disorders and congenital antithrombin III deficiency who have been treated with UK-sourced pooled factor concentrates or antithrombin between 1980 and 2001 (ie including implicated factor VIII, factor IX and antithrombin products and as yet non-implicated factor concentrates such as fibrinogen and factor XIII) should be considered 'at-risk' of vCJD for public health purposes. The decision to take this 'population approach' was made by the UKHCDO and endorsed by the UK CJD Incidents Panel and Department of Health.

The vCJD risk categorisation of implicated plasma products was based on the estimated batch specific infectivity (derived from fraction specific infectivity and manufacturing data) and typical doses patients were likely to have received in clinical practice. For batches of implicated factor VIII, factor IX and antithrombin, which were derived directly from cryoprecipitate and cryosupernatant, the estimated amount of potential vCJD infectivity in product batches was considered high enough for patients to be considered 'at-risk' of vCJD for public health purposes following the administration of a very small dose.

For some batches of other pooled factor concentrates that were made from fraction intermediates rather than directly from cryoprecipitate and cryosupernatant the likely risk categorisation may be uncertain. For fibrinogen and factor XIII experimental data do not provide a specific infectivity estimate for the intermediate fraction (fraction I) but available data indicate that this might be relatively high. Although these products are as yet un-implicated, further work may be needed to supplement the current risk assessment should these products become implicated in the future. For the time being, any patients in receipt of these products but not included in the population approach (as defined above) would NOT be considered 'at-risk'.

With best wishes
Yours sincerely

GRO-C

Anna Molesworth
Clinical Scientist
CJD Section

cc.
Professor Don Jeffries, Queen Mary's School of Medicine and Dentistry
Professor Frank Hill, UK Haemophilia Centre Doctors Organisation
Dr Kate Soldan, HPA Centre for Infections