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Dear Dr Dolan,

Re-assessment of vCJD risk from UK produced plasma products and de-notification of certain recipients

In 2012 the Health Protection Agency reviewed the risk assessment for variant CJD transmission through the receipt of UK sourced plasma products. This has led to the recommendations that:

i) individuals who received Factor VIII and Factor IX between 1990 and 2001 should remain notified as "at increased risk of vCJD for public health purposes"

ii) Individuals who only received plasma products between 1980 and 1989 should now have their treatment history re-assessed to confirm this fact and if it is confirmed, they should be de-notified.

Background

In 2004, patients with bleeding disorders who had been treated with UK sourced plasma products manufactured between 1980 and 2001 were contacted, on the recommendation of the CJD Incidents Panel, and informed that they were at increased risk of variant CJD for public health purposes. These individuals have been asked to take certain precautions to reduce the risks of passing on any infection to other people. This includes informing those who provide their healthcare prior to any invasive medical, dental or surgical procedures so that special arrangements can be made for the instruments used.

The decision to notify these individuals followed a risk assessment based on the understanding of the evidence at the time and taking a precautionary view.

Revised risk assessment

In 2011 a re-examination of the risks of blood borne transmission of vCJD took account of new evidence on infectivity and of the limited number of cases seen to date that could be attributed to blood. This work was carried out by the DH Health Protection Analytical Team and considered three main changes:

- A hundred-fold reduced estimate of infectivity per unit of non-leucodepleted blood;

- Confirmation, and more precise estimates, of asymptomatic population prevalence of abnormal prion protein (1 in 2,000) – and the assumption that this translates to a prevalence of potentially infective blood donors;
- A smaller window of recipient-exposure to potentially infective blood -1990 to 2001.

The effect of these three changes on the risk assessment for plasma product recipients was then examined by the Health Protection Agency and the following conclusions and recommendations reached:

- The revised calculation did not affect the risk assessment for some products, specifically Factor VIII and Factor IX. For most recipients the maintenance of the notified at increased risk of vCJD status should continue;
- The reduced window period of exposure did have an effect. Notified patients who only received plasma products outside of the new window period (ie during 1980 to 1989 but not during 1990 to 2001) should have their treatment history re-assessed to confirm this, and if it is confirmed they should be denotified.
- Reassessment and denotification should also be considered for (the very few) individuals who received other plasma products and were notified in 2004, some of whom are also no longer at risk following the re-assessment.

The ACDP TSE Risk Management Subgroup[1] was asked to consider the re-assessment methodology and the recommendations. At their meeting of the 8th November 2012 the subgroup members agreed with the recommendations and asked the HPA to inform the UKHCDO of this decision and work together on the process of denotifying patients where appropriate.

The minutes from that meeting will be agreed in March when the subgroup reconvenes and will be available shortly afterwards on the ACDP webpages.

Yours sincerely,

GRO-C

Dr Katy Sinka

Head CJD Section

Tel: GRO-C

[1] Advisory Committee on Dangerous Pathogens. Transmissible Spongiform Encephalopathy Risk Management Subgroup