CJD INCIDENTS PANEL

20th July 2005

Assessment of the risk of variant Creutzfeldt-Jakob disease (vCJD) implied by donation of blood to a patient who later develops vCJD

Recommendations of the CJD Incidents Panel

This note outlines the key recommendations of the CJD Incidents Panel (the Panel)[1] for the assessment and management of individuals who have donated blood to patients who later develop vCJD. Specifically, the Panel considered whether these donors should be regarded as 'potentially at-risk of vCJD for public health purposes', and therefore subject to certain precautions to minimise any risk of infecting other patients.

The Panel recommendations are based on:

i) A Risk Assessment carried out by the Department of Health's Standards and Quality Analytical Team (http://www.dh.gov.uk/assetRoot/04/11/53/12/04115312.pdf) and reviewed by the CJD Incidents Panel and the Committee on Microbiological Safety of Blood, Tissues and Organs (MSBTO).

ii) Review by Panel members of the implications of this Risk Assessment for public health.

The Risk Assessment provides a method for calculating the chance of a blood donor being the source of vCJD infection, given that a recipient has been found to have vCJD. All such calculations are subject to a good deal of uncertainty, as much remains to be known about vCJD itself. However, it is clear that the chance of vCJD having come from any given donor will depend on two main factors:

- The probability that blood from an infected donor would, in fact, infect the recipient
- The number of donors whose blood had gone to the infected individual.

The Panel determined that the donors involved should be considered as 'potentially at-risk of vCJD for public health purposes' unless the probability of being infected with vCJD (implied by donation to a vCJD case) was clearly below 1%. This value is based on a) consistency with thresholds used for other assessments of individuals at increased risk of vCJD (e.g. patients exposed to potentially-contaminated surgical instruments or plasma products), and b) the Panel's opinion that on the basis of current knowledge, this threshold results in an appropriate response to the

situation under assessment. That is, it provides a balance between protecting other patients from any potential risk of vCJD being passed on and causing alarm to individuals to be considered as 'at-risk' of being infected.

The threshold is a guide for implementing special public health precautions to limit any possible human-to-human transmission of vCJD. The Risk Assessment only concerns the chance of a donor being *infected*, not the chance of their developing symptoms of vCJD. Even if a donor is infected, it is possible that they will never develop the disease. The risk of doing so is unknown. However, an infected donor may pose a risk to others via secondary transmission (e.g. via blood transfusion or surgery), even if they do not show vCJD symptoms themselves.

All cases where transfusion is suspected as a source of a patient's vCJD infection have been reviewed and the risk calculations carried out. New cases will be reviewed as they arise.

The Panel recommends the following action in relation to cases where transfusion is suspected as the source of a patient's vCJD infection:

Risk assessment: For each vCJD case where transfusion is suspected as a possible source of infection, the probability of each of the donors being themselves infected (i.e. the source of the recipient's vCJD infection) should be calculated using the method described in "Assessing the implications for blood donors if recipients are infected with vCJD" (http://www.dh.gov.uk/assetRoot/04/11/53/12/04115312.pdf). Unless there is evidence to the contrary, the assumptions for this calculation should be:

i) that an infected donation would certainly infect the recipient (the "worst case" assumption);

ii) that there is no way of distinguishing between the contributing donors (and recipient) in terms of risk of primary vCJD infection (e.g. that all had been resident in the UK during the BSE outbreak), and

iii) that there is no other significant secondary infection route for the recipient – e.g. having undergone "high risk" surgery.

Donors: Unless this calculation shows that the probability of their being the source of a recipient's vCJD infection is clearly less than 1%, such donors should be contacted, informed of the situation, and asked to take the following precautions to protect the health of others:

- **Not to donate blood;**
- **Not to donate organs or tissues;**
- **To tell whoever is treating them before they undergo medical, surgical or dental treatment, so they can then arrange any special procedures for the instruments used in their healthcare[2];**
- **To consider telling their family about all the above points. This is so that the family could pass on the information to doctors if the donor needed medical care in the future but was unable to pass on the information. (For example, this might happen if the donor needed emergency care following an accident).**

Neither the threshold, nor the exact risk estimate value for any individual donor should be considered useful as an indicator of a donor's risk of developing vCJD. This risk is unknown.

The clinical care of individuals identified as 'at-risk' due to donation to a vCJD case should not be compromised in any way.

Mr David Pryer
Chairman
CJD Incidents Panel

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[1] The CJD Incidents Panel (http://www.hpa.org.uk/infections/topics_az/cjd/incidents_panel.htm) is an expert committee established on behalf of the UK Chief Medical Officers in 2000. Its terms of reference include:

'To assist all those bodies responsible for the provision and delivery of healthcare to decide on the most appropriate action to take to handle incidents involving potential transmission of Creutzfeldt-Jakob Disease (CJD) and variant CJD (vCJD) between patients through clinical interventions, including via surgical instruments, tissues, organs and blood and to keep the relevant devolved administrations informed.

To consider what information should be collected on patients who may have been exposed; advise on what studies or follow-up may be needed; advise Directors of Public Health on patient tracing and notification exercises where these are indicated; and advise on whether any other measures are needed to protect the wider public health.'

[2] Transmissible spongiform encephalopathy agents: safe working and the prevention of infection. Guidance from the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee
http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/index.htm