GUIDELINES FOR vCJD

1 **Red Book Edition 4 (2000) p 23 section 1.8**

"1.8 Prion associated diseases, Creutzfeldt-Jakob disease (CJD); classic, and 'variant' (vCJD)

1.8.1 Individuals at identifiable risk of developing a prion associated disease must be permanently excluded from donation.

1 People diagnosed as probably having CJD or vCJD must be permanently excluded as blood donors.

2 A person with a family history of CJD or related disorder, but who has been tested specifically for PrP genotype and found normal, may be accepted for donation upon confirmation of normality by the GP or consultant. A family history applies to parents, grandparents, siblings, children and grandchildren.

3 People who have received human derived pituitary hormones, or grafts of dura mater, cornea or sclera must be permanently excluded as blood donors. People who have had neurosurgical procedures before 1992 and for whom the possibility of receiving a graft of dura mater cannot be ruled out must also be excluded."

2 **Red Book Edition 5 (2001) p 24 section 2.8**

"2.8 Prion-associated diseases, including sporadic Creutzfeldt-Jakob Disease (CJD); and 'variant CJD' (vCJD)

Individuals who are identified as having an increased risk of developing a prion-associated disease must be permanently excluded from donation. This includes:

- Individuals who have received human pituitary-derived hormones
- Patients who have received human dura mater grafts or corneal grafts or scleral grafts
- Persons identified as being members of a family at risk of inherited prion diseases.

The current edition of the A-Z Guidelines provides detailed advice and should be consulted."

3 **MAD006 1/4/98 – 31/8/99 CJD entry p 22**

"CREUTZFELDT-JAKOB DISEASE (CJD)

Action: Permanently defer individuals with CJD or vCJD

All individuals who have been treated with extracts derived from human pituitary glands or who have a family history of CJD are permanently excluded from donating.

See Also: Brain Surgery
Corneal Transplant
Growth Hormone
Infertility
Pituitary Extract (Human)"

4 **Donor Selection Guidelines MAD 007 01/09/99 – 30/06/01**

CJD entry p20

Action: Permanently exclude individuals with CJD or vCJD
All individuals who have been treated with extracts derived from human pituitary glands or who have a family history or Creutzfeldt-Jakob Disease are permanently excluded from donating.

See Also: Brain Surgery
Cornea Transplant
Growth Hormone
Infertility
Pituitary Extract (Human)

Brain Surgery p15

Action: Permanently exclude if carried out before August 1992. Exception: Burr hole surgery only.

See Also: Creutzfeldt-Jakob Disease

Cornea Transplant p19

Action: Permanently exclude

See Also: Creutzfeldt-Jakob Disease

Growth Hormone p30

Action: Confirm type of growth hormone used by questioning the donor about their medical history.
Recipients of human growth hormone prior to 1987 are permanently excluded because of the risk of Creutzfeldt-Jakob Disease.
Accept donors treated with recombinant-derived growth hormone.

See Also: Creutzfeldt-Jakob Disease
Pituitary Extract (Human)

Infertility p40

Action: Defer if under investigation

Permanently exclude if on treatment with immuno-therapy, or recipients of Human Gonadotrophin of pituitary origin, available in injectable format between 1956-1985 in certain treatment centres.
Defer for 3 months following conclusion of therapy if on treatment with Clomid/clomiphene
Take care to exclude pregnancy

See Also: Creutzfeldt-Jakob Disease

Pituitary Extract (human) p51

Action: Permanently defer if received injection(s) of Human Pituitary Extract prior to 1985.

See Also: Creutzfeldt-Jakob Disease
Growth Hormone

5 **MAD 008 1/7/01 – CJD entry p 22**

Creutzfeldt-Jakob Disease (CJD)

Additional criteria: 31/07/01

Obligatory: Permanently exclude individuals with CJD, variant CJD (vCJD) or other Prion associated disorder.

Permanently exclude anyone identified at high risk of developing a prion associated disorder.

This includes: Recipients of dura mater grafts

Recipients of corneal or sclera grafts

Recipients of human pituitary derived extracts.

Individuals at familial risk of prion-associated diseases. This includes individuals who have had two or more blood relatives develop a prion-associated disease and individuals who have been informed they are at risk following genetic counselling.

Exceptions: Individuals who have had two or more blood relatives develop a prion-associated disease who, following genetic counselling, have been informed that they are not at risk. This requires confirmation by the Consultant with responsibility for donors.

"Lessons have been learnt with each notification. The first two major notifications involving patients potentially exposed to vCJD by blood transfusion and plasma products occurred during the winter of 2003/2004 (transfusion recipients) and during the summer of 2004 (plasma-product recipients). For the transfusion recipients, the notification was made by general practitioners with the aid of literature supplied by the HPA and support from the local Health Protection Unit (HPU). This notification was the first of its kind and had to be conducted in a short time frame over the Christmas holiday period, following the announcement of information into the public domain in December 2003. Criticisms of this notification included the need to communicate information to patients to tight deadlines, and during a holiday period, and that General Practitoners did not always feel that they had sufficient background knowledge to be comfortable with communicating the information, as requested. These lessons were applied to the next major notification exercise involving recipients of plasma products.

The majority of individuals identified as 'at-risk' of vCJD due to treatment with plasma products during the notification in September 2004 were patients with bleeding disorders, very many of whom were under ongoing care at a haemophilia centre. They were informed by haemophilia centre clinicians, by whom they were known. Staff in these centres had previously been involved in communicating information about previously unknown infective risks (HIV and HCV) associated with the use of plasma products when this became known. Such information introduces great uncertainty for the patients' future health. This previous experience was invaluable in addition to that gained with earlier CJD notifications in planning the notification of these patients. Furthermore this notification had the advantage of being able to work through clinicians who were well informed about both their individual patients and the issues relating to the notification information. Also, staff likely to be involved could be identified in advance (by association with defined patient groups) and invited to attend a training session to gain background information and given opportunities to provide input into the conduct of the exercise. Because of the patients' past experience of blood-borne infections there was the potential that the notification could be complicated by arousing individuals existing concerns for their health. For this reason the notification process was constructed so that patients would be given full information about vCJD, its risk of transmission by plasma products and then allowed to choose whether they wished to know or not know if they had received an implicated batch. The reason for allowing this choice by patients was so that they could determine the approach that would allow them to cope best with this further and new uncertainty. In addition they were informed that health precaution measures would need to be taken if instruments were used to conduct certain investigations or surgery on themselves. This would also have the advantage of limiting secondary spread should further patients be identified in the future as having received an implicated batch.