9.14 Screening for HBV infection includes testing for HBsAg, anti-HBc and NAT tests for HBV DNA. Samples giving repeat reactivity for HBsAg should undergo confirmatory testing by neutralisation as soon as possible. The detection of confirmed HBsAg and/or HBV DNA indicates current infection;

9.15 Hepatitis B has been contracted from contaminated liquid nitrogen tanks. If cells, gametes or tissues requiring long term cryopreservation from an unscreened donor or an HBV-infected donor are to be stored or processed, see paragraph 6.14 onwards on storage. A donor whose serum contains anti-HBc alone is unlikely to contain HBV DNA at a level which could cause contamination of the storage facility (see the need for risk assessment in paragraph 6.16);

9.16 NOTE: The availability of active and passive immunisation and effective anti-viral therapy allows consideration of departure from these recommendations under circumstances of clinical need and with expert advice.

**Table 7 – The interpretation of a repeatably-reactive serological and/or positive NAT result in an ALLOGRAFT donor – HBV**

| Test result(s) suggesting possible donor HBV infection | Organs | Tissues | HPC and TC | Reproductive cells | Human embryonic stem cells |
|---|---|---|---|---|---|
| **HBsAg** | Contraindication to donation* | Contraindication to donation | Contraindication to donation | Contraindication to donation | Contraindication to donation***** |
| **HBV DNA NAT** | Contraindication to donation* | Contraindication to donation | Contraindication to donation | Contraindication to donation | Contraindication to donation***** |
| **Anti-HBc alone and anti-HBs < 100IU/L** | Donation permitted** | Contraindication to donation | Permissible for life-preserving transplant | Contraindication to donation | Contraindication to donation***,**** |
| **Anti-HBc alone and anti-HBs ≥ 100IU/L** | Donation permitted*** | Donation permitted | Donation permitted | Donation permitted | Donation permitted |

*Transmissible Spongiform Encephalopathies (TSEs)*

9.32 TSEs (otherwise known as prion diseases) are a group of fatal transmissible neurodegenerative disorders that in humans occur in sporadic, genetic and acquired forms. The commonest human TSE, Creutzfeldt-Jakob disease, occurs in both sporadic (sCJD) and acquired (vCJD) forms. The transmissible agent (or prion) is composed principally of a misfolded host protein, the prion protein, that accumulates at high levels in the brain.

9.33 Over past decades, sCJD has been transmitted from one patient to another through medical or surgical procedures involving neurosurgical instruments, brain electrodes, tissue (human cornea and dura mater grafts) and tissue extracts (human pituitary hormones). There have been no known transmissions of vCJD via surgery or use of tissues or organs to date; however there has been transmission of vCJD infection via transfusion of red blood cells (4 cases) and UK plasma used to produce Factor VIII (1 case).

9.34 Donor deferral issues centre around the potential for transmitting TSEs during organ and tissue transplantation. Deferral of donors is complex. An effective screening test for the detection of misfolded prions in donor blood is not available at present, and the prevalence of asymptomatic infected persons in the UK is uncertain.

9.35 However, there are a number of risk factors for human TSEs that have been identified, including prior exposure to human blood, dura mater grafts, pituitary-derived hormones and contaminated surgical instruments. In addition, a number of individuals have been notified that they are at increased risk of CJD/vCJD for public health purposes, due to their exposure to one or more risk factors. Guidance from the Advisory Committee on Dangerous Pathogens' TSE Working Group is available from their website and information on notifications is on the CJD Incidents Panel website.

9.36 Individuals with a confirmed or suspected TSE, a neurological disease of unknown aetiology or those who are blood relatives of persons with familial CJD cannot be accepted as donors of organs or tissues. However, if a donor has had two or more blood relatives develop a prion-associated disease and, following genetic counselling, they have been informed they are not at risk, they may be accepted for donation.

9.37 Pre-exposure to human dura mater grafts, human pituitary-derived growth hormone and/or gonadotrophin excludes the donation of tissues, and should be taken into account when assessing any donor for their suitability for organ donation. There is no good evidence of transmission by organs or tissues other than by those of the central nervous system.

9.38 For lifesaving organ and bone marrow transplantation only, donor exposure to risk factors for CJD and vCJD should be taken into account in the risk assessment, but does not necessarily preclude donation.

9.39 Table 14 gives a summary of the exclusions from organ and/or tissue donation, based on possible TSE exposure.

**Table 14 – Exclusions from organ and/or tissue donation based on possible TSE exposure**

| | LIVE TISSUE DONORS | | CADAVERIC TISSUE DONORS | | | | SOLID ORGAN DONORS |
|---|---|---|---|---|---|---|---|
| | **Bone** | **HSC** | **Musculoskeletal (ligaments, tendons & cartilage)** | **Bone and processed bone** | **Ocular** | **Skin/ Heart Valves** | |
| **Definite, probable or possible case of human TSE, including CJD and vCJD** | Exclude | Exclude | Exclude | Exclude | Exclude | Exclude | Exclude |
| **Individual with a neurological disease of unknown aetiology** | Exclude | Exclude | Exclude | Exclude | Exclude | Exclude | Exclude |
| **Individual whose blood relatives have had familial CJD [1]** | Exclude | Exclude | Exclude | Exclude | Exclude | Exclude | Exclude |
| **Individual "presumed infected" with vCJD [2]** | Exclude | Exclude | Exclude | Exclude | Exclude | Exclude | Exclude |
| **Individual "at increased risk of CJD/vCJD" (for public health purposes) [3]** | Exclude | Individual assessment required [4] | Exclude | Exclude | Exclude | Exclude | Individual assessment required [4] |
| **History of definite [5] or probable [6] blood transfusion since 1980** | Exclude | Individual assessment required [4] | Exclude<br>Do not exclude if transfusion is within 1 week prior to death | Exclude | Do not exclude [7] | Do not exclude | Individual assessment required [4] |
| **History of receipt of *dura mater* graft** | Exclude | Individual assessment required [4] | Exclude | Exclude | Exclude | Exclude | Individual assessment required [4] |
| **History of definite receipt of tissue since 1980** | Exclude | Individual assessment required [4] | Exclude | Exclude | Exclude | Do not exclude | Individual assessment required [4] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **History of receipt of pituitary derived growth hormone and/or gonadotrophin** | Exclude | Individual assessment required [4] | Exclude | Exclude | Exclude | Exclude | Individual assessment required [4] |
| **History of receipt of organ** | Exclude | Exclude | Exclude | Exclude | Exclude | Exclude | Individual assessment required [4] |

[1] However, if a donor has had two or more blood relatives develop a prion-associated disease and, following genetic counselling, they have been informed they are not at risk, they may be accepted for donation

[2] Donors who have received blood components, tissues and/or organs from donors who have gone on to develop vCJD.

[3] Donors who have been notified that they are at increased risk of vCJD (for public health purposes) due to possible exposure.

[4] Level of risk or exposure should be clarified and weighed, on an individual basis, against the expected benefit of the transplant and the availability of alternative donors. The recipient (and/or relatives) should be informed of the nature of the estimated risk of vCJD transmission.

[5] Definite transfusion is defined as at least one of the following:

- Recorded in medical notes available to clinical staff at time of donation;
- Documented during interview;
- Reported by GP;

[6] For tissue and organ donors, probable transfusion is defined as:

- previous major surgery; and/or
- previous major accident.

[7] Ocular donors should not be excluded if they have a history of definite or probable transfusions, in view of supply issues. However it is essential that:

- information is provided to recipients;
- wherever possible donor and recipients are age matched;
- efforts are made to increase yields of ocular tissues;
- donors excluded on the basis of public health measures are not accepted as ocular donors.