

## ANNEX L

### **MANAGING CJD/vCJD RISK IN OPHTHALMOLOGY**

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## **Introduction**

- L1. This guidance has been produced by the ACDP TSE Working Group Ophthalmology subgroup (membership list included as [Appendix 5](#) of this document).
- L2. Creutzfeldt-Jakob Disease (CJD) is an invariably fatal human disease belonging to the Transmissible Spongiform Encephalopathies (TSEs). These conditions are caused by a pathological accumulation in the brain of an aberrant form (PrP<sup>Sc</sup>) of a normal cell surface glycoprotein, prion protein (PrP). CJD occurs in familial, sporadic and acquired (variant CJD and iatrogenic) forms. The familial forms of CJD are autosomal dominant traits associated with mutations in the prion protein gene (PRNP).
- L3. At present, sporadic CJD (sCJD) is the most commonly encountered form of the disease with an incidence of 1 case per million, thus giving approximately 60 new cases per year in the UK. Patients with sCJD are predominantly in their 60s and as such come into contact with ophthalmologists through a range of unrelated ophthalmic conditions or because of visual symptoms caused by their condition.
- L4. In the 1980s some British cattle developed bovine spongiform encephalopathy (BSE), probably from an altered form of the prion responsible for scrapie in sheep which had entered cattle feed. Human ingestion of BSE contaminated beef products is thought to have then led to the development of a new acquired form of the disease known as variant CJD (vCJD). The first case of vCJD was identified in the UK in 1994. Since then there have now been over 160 cases in the UK, typically in young adults.
- L5. Although the majority of the human population of the UK was exposed at one time or another until 1996 to PrP<sup>Sc</sup> by ingestion of contaminated beef products, the precise prevalence of preclinical infection of vCJD in the UK is unknown. The most reliable evidence we have to date is from the analysis of anonymised appendix and tonsil tissue taken from patients across the UK in 1995-1999. In this study, three positive samples were identified in the 12,674 samples tested, equating to a prevalence of approximately 1 in 4000 cases (237 per million). Although the infective risk of these preclinical cases is uncertain there is the obvious potential for iatrogenic transmission in a significant number of cases.

- L6. Iatrogenic CJD has been associated most recently with blood transfusion (3 clinical vCJD cases), and historically with human cadaveric growth hormone treatment (>190 cases), dura mater transplantation (>190 cases), contaminated neurosurgical instruments/EEG needles (6 cases) and corneal transplantation.
- L7. There has been one definite case of CJD transmission from corneal transplantation reported, in the US in 1974. The patient, a 55-year-old woman, received a cornea from a donor with biopsy-proven sCJD. She developed a neurologic illness eighteen months after surgery and died 8 months later. The recipient's autopsy was positive for CJD. A further probable case of CJD transmission reported in Germany in 1997 was that of a 45-year-old woman who developed clinical symptoms and EEG evidence of sCJD 30 years after keratoplasty. The donor had biopsy-proven CJD but an autopsy of the recipient was refused. Several further possible cases of CJD transmission from corneal transplantation have been reported over the past 2 decades but it is uncertain as to the significance of the corneal transplantation in their subsequent CJD disease development. There are no other known cases of ophthalmic surgery or diagnostic procedure having resulted in CJD transmission between patients.
- L8. Western blot analysis and immunohistochemistry of ocular tissues from sCJD and vCJD cases have found high levels of PrP<sup>Sc</sup> in the retina, comparable to levels with cerebral cortex, and lower levels in the optic nerve. However, no detectable levels of PrP<sup>Sc</sup> have been found in cornea, sclera, iris, lens, ciliary body vitreous or choroid. As prion proteins adhere strongly to materials including smooth metal surfaces and are not removed entirely by routine cleaning and autoclaving then there is the potential for iatrogenic transmission of PrP<sup>Sc</sup> particularly during surgery involving the retina and optic nerve. Although the fact that PrP<sup>Sc</sup> has not been found in other ocular tissues is reassuring, the demonstration of infectivity through transplantation suggests that practical precautions during diagnostic and surgical procedures are advisable to reduce the risk of iatrogenic transmission.
- L9. Guidance has been issued previously by the Medical Devices Agency, the College of Optometrists, the Association of British Dispensing Opticians, the Royal College of Ophthalmologists and the National Institute for Health and Clinical Excellence (NICE) to reduce the risk of iatrogenic CJD transmission in ophthalmic care. The purpose of this latest document is to consolidate and update the available guidance and offer pragmatic solutions to aid implementation of such guidance.

## **Definition of anterior segment and posterior segment eye surgery or procedure**

L10. Existing guidance has failed to clearly define anterior and posterior segment eye surgery or procedures for the purposes of CJD/vCJD risk. The ACDP TSE Working Group Ophthalmology Subgroup suggests the following definitions based on evidence of infectivity and presence of abnormal prion protein from animal and human studies:

- a) **Posterior segment eye surgery or procedure** is defined as any surgery or procedure that involves potential contact with the posterior hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve. Due to the high incidence of subretinal fluid drainage performed either intentionally or inadvertently during scleral buckling surgery, this form of surgery is considered as posterior segment surgery. See [Appendix 1](#) for a list of posterior segment surgeries.
  
- b) **Anterior segment surgery or procedure** is defined as any surgery or procedure involving ocular tissues other than those stated above, including:
  - Ocular adnexal tissue including eyelids, periorbital tissue and lacrimal system
  - Conjunctiva
  - Cornea and limbus
  - Iris
  - Crystalline lens
  - Anterior vitreous (excluding the posterior hyaloid face)
  - Anterior vitrectomy performed via the cornea
  - Extra-ocular muscle surgery
  - Ciliary body
  - Sclera (but not if allogeneic sclera used)
  - Tissues of the orbit except optic nerve

See [Appendix 2](#) for a list of anterior segment surgeries.

## **Definition of risk of surgical and diagnostic procedures**

L11. The risk of iatrogenic transmission of CJD/vCJD during a surgical or diagnostic procedure is dependent on the risk of tissue infectivity and the nature of the procedure itself.

- L12. **Any posterior segment eye surgery or procedure is considered high risk.**
- L13. **Any anterior segment eye surgery or procedure is considered low risk.**
- L14. The absence of any detectable abnormal prion protein in anterior segment tissue, the paucity of epidemiological evidence supporting iatrogenic transmission through anterior segment surgery and only a single definite case of iatrogenic transmission through corneal transplantation in 1974 (it is possible that the corneal tissue was contaminated by posterior segment tissue during processing) has led the ACDP TSE Working Group and its Ophthalmology Subgroup to propose anterior segment surgery or procedures as low risk for iatrogenic transmission.
- L15. The stratification of surgery and diagnostic procedures into high and low risk of infectivity has various implications for the management of patients and instruments. These implications are detailed in this guidance.

### **Assessment of CJD/vCJD risk**

- L16. A local level policy should be put in place to ensure that all patients with or at increased risk of CJD/vCJD are identified before ophthalmic surgery to allow the appropriate infection controls to be followed.
- L17. The ACDP TSE Working Group has issued advice for the assessment of patients' risk of CJD and vCJD before elective or emergency surgery and endoscopy in [Annex J](#) of their guidance. The following guidance for ophthalmic patients should be read in conjunction with [Annex J](#).
- L18. Any patient symptomatic of CJD/vCJD or considered at increased risk of CJD/vCJD should have their status recorded in their primary healthcare records. The GP should always include this information when referring patients for ophthalmic care. The clinical team undertaking pre-surgical assessment should check the patient's medical notes and/or referral information for any mention of CJD/vCJD status

### **Assessment for all elective and emergency ophthalmic surgery**

L19. [Annex J](#) recommends that all patients about to undergo any elective or emergency surgery should be asked the question:

**“Have you ever been notified that you are at increased risk of CJD or vCJD for public health purposes?”**

The actions to be taken following the patient’s response to the above question are outlined in paragraph J2 of Annex J.

Ophthalmic units should therefore ensure that all patients are asked this question prior to any elective or emergency ophthalmic surgery.

### **Additional assessment for posterior segment surgery**

L20. [Annex J](#) also recommends that those patients about to undergo surgery which may involve contact with tissues of potentially high level TSE infectivity (“high risk tissues”) should be assessed for CJD/vCJD risk through a set of detailed questions relating to possible exposure to CJD/vCJD outlined in Table J1 (see over). **For ophthalmic patients, only posterior segment eye surgery or procedures are defined as high risk**, as outlined in [section L3](#) of this document and listed in [Appendix 1](#). Ophthalmic units should therefore ensure that patients about to undergo a posterior segment eye procedure or surgery should be asked the CJD risk questions in Table J1 of Annex J (see over). [Paragraph J6 of Annex J](#) outlines the action to take based on the patient’s responses.

**Annex J Table J1 – CJD risk questions for patients about to undergo elective or emergency surgical or neuro-endoscopic procedures likely to involve contact with tissues of potentially high level infectivity**

	Question to Patient	Notes to clinician
1	Have you a history of CJD or other prion disease in your family? If yes, please specify.	Patients should be considered to be at increased risk from genetic forms of CJD if they have or have had: <ul style="list-style-type: none"> <li>i) Genetic testing, which has indicated that they are at significant risk of developing CJD or other prion disease;</li> <li>ii) A blood relative known to have a genetic mutation indicative of genetic CJD or other prion disease;</li> <li>iii) 2 or more blood relatives affected by CJD or other prion disease</li> </ul>
2	Have you ever received growth hormone or gonadotrophin treatment? If yes, please specify: <ul style="list-style-type: none"> <li>i) whether the hormone was derived from human pituitary glands</li> <li>ii) the year of treatment</li> <li>iii) whether the treatment was received in the UK or in another country</li> </ul>	Recipients of hormone derived from human pituitary glands, e.g. growth hormone or gonadotrophin, have been identified as at increased risk of sporadic CJD.  In the UK, the use of human-derived growth hormone was <b>discontinued in 1985</b> but human-derived products may have continued to be used in other countries.  In the UK, the use of human-derived gonadotrophin was <b>discontinued in 1973</b> but may have continued in other countries after this time.
3	Have you ever had surgery on your brain or spinal cord?	(a) Patients who underwent <b>intradural</b> neurosurgical or spinal procedures <b>before August 1992</b> may have received a graft of human-derived dura mater and should be treated as at increased risk, unless evidence can be provided that human-derived dura mater was not used. Patients who received a graft of human-derived dura mater <b>before 1992</b> are at increased risk of transmission of sporadic CJD, but <b>not</b> vCJD.  (b) <a href="#">NICE guidance</a> emphasises the need for a separate pool of new neuroendoscopes and reusable surgical instruments for high risk procedures on children born since 1 <sup>st</sup> January 1997 and <b>who have not previously undergone high risk procedures</b> . These instruments and neuroendoscopes should not be used for patients born before 1 <sup>st</sup> January 1997 or those who underwent high risk procedures using reusable instruments before the implementation of this guidance. [continued]

<p>4</p>	<p>Since 1980, have you had any transfusions of blood or blood components (red cells, plasma, cryoprecipitate or platelets*)?</p> <p>If yes, have you either:</p> <p>i) received more than 50 units of blood or blood components? <b>or</b></p> <p>ii) received blood or blood components on more than 20 occasions?</p> <p>Where possible, please provide the names of all the hospitals where you received blood or blood components.</p>	<p>Patients who have received blood from more than 80 donors have been identified as at increased risk of vCJD. Information on this notification is available from the HPA:  <a href="http://www.hpa.org.uk/vCJDpresurgicalassessment">http://www.hpa.org.uk/vCJDpresurgicalassessment</a></p> <p>* This does not include:</p> <ul style="list-style-type: none"> <li>• Autologous transfusion</li> <li>• Plasma products such as IVIG, albumin, coagulation factors and anti-D</li> </ul>
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L21. Ophthalmic units with a mixed case load of anterior and posterior segment surgeries and procedures may wish to ask the questions in Table J1 of Annex J to all their patients for practical reasons. This is a local decision.

L22. As a separate pool of new posterior segment surgical instruments should be used for children born since 1 January 1997, and who have not previously undergone high risk procedures (see [paragraph L38](#)), it is important to correctly and reliably identify patients born since 1 January 1997 and ensure that they have had no previous high risk surgery which may have exposed them to risk of CJD/vCJD.

### **Emergency surgery**

L23. Guidance on what to do if a patient about to undergo emergency surgery is physically or otherwise unable to answer any questions is included in [paragraphs J7-J10 of Annex J](#).

### **Diagnostic examination, instruments and contact lenses**

L24. There have been no known cases of iatrogenic transmission of CJD/vCJD resulting from diagnostic examination or contact lens wear. Although contact with the cornea is considered as low risk in terms of iatrogenic transmission of CJD/vCJD any steps that can further reduce potential risk of iatrogenic transmission are to be encouraged. A balance between pragmatism and a precautionary approach has been reached in the following advice.



- L25. Instruments and contact lenses considered within this section include:
- Soft refractive and therapeutic contact lenses
  - Rigid trial contact lenses, both corneal and scleral
  - Tonometer prisms (Goldmann) and other contact tonometry devices
  - Diagnostic contact lenses such as gonioscopes, fundus lenses, 3-mirror lenses
  - Contact lenses used in therapy, often in conjunction with laser treatment, for example in capsulotomy, iridotomy, trabeculoplasty, retinopexy
  - A- and B-scan ultrasound probes
  - Electronic pachymeters
  - Electrodes used in electrodiagnostic procedures such as electroretinography
  - Prosthetic devices including trial or temporary artificial eyes
- L26. The use of single-use instruments or contact lenses is recommended for use on those designated at increased risk of CJD or vCJD. Alternatively, the instruments or contact lenses should be quarantined and used solely on that individual patient. This latter approach could be problematic in ensuring mandatory sole use and thus the single-use instrument approach is considered more practical in these circumstances.
- L27. The practice of single-use instruments or contact lenses for examination should be encouraged for other patients where cost and quality are acceptable. Several examples already exist in practice where potential iatrogenic transmission is reduced:
- Many services have adopted the use of disposable tonometry systems for intraocular pressure measurements in general settings and reserving reusable Goldmann tonometry for glaucoma clinics
  - The use of non-contact biometry systems, for example IOLMaster
  - The widespread use of soft trial contact lenses and therapeutic lenses
- L28. This approach may not be practical for more specialised or complex instrumentation such as laser contact lenses and ultrasound probes.
- L29. If reusable instruments or contact lenses are to be used it is imperative that they are cleaned and decontaminated in an acceptable and consistent way. Previous guidance regarding cleaning and decontamination of lenses and tonometry prisms involving 20,000ppm sodium hypochlorite is poorly adhered to, practised incorrectly (for example keeping tonometers wet after decontamination, varying concentrations of hypochlorite,

not changing the hypochlorite frequently enough) and carries the added risk of corneal burns.

- L30. Generic guidance regarding cleaning, decontamination and storage of reusable instruments or contact lenses is outlined in [Appendix 3](#). This generic advice includes disinfection steps to reduce significantly the problem of cross infection by conventional organisms such as viruses and bacteria, and thorough washing steps to reduce the level of residual protein and possible prion infectivity. The combination of measures is designed to reduce possible prion load and be practical in terms of risk reduction rather than risk elimination. Further guidance is available in the Royal College of Ophthalmologists publication “Ophthalmic Instrument Decontamination”:

<http://www.rcophth.ac.uk/docs/profstands/ophthalmic-services/DecontaminationApril2008.pdf>

- L31. It is accepted that the guidance in [Appendix 3](#) may be difficult to adhere to in busy ophthalmic clinics. However it is important that it is followed, to reduce the risk of iatrogenic disease transmission. Pragmatic solutions to aid ophthalmic practitioners in this area include:

- Having a large subset of instruments (for example Goldmann tonometry prisms) which are used once each during a clinic, and following use are rinsed and kept wet. They can then be cleaned and decontaminated collectively at end of the clinic, according to the protocol in [Appendix 3](#)
- The possibility of using wholly disposable or non-contact systems for examination
- Encouraging procurement of non-contact or disposable covers for certain equipment, for example pachymeters or ultrasound probes
- Discussion with the local infection control team, decontamination team and/or microbiologist should be encouraged to promote best practice

- L32. The practice of decontaminating tonometers with alcohol wipes alone is not sufficient to remove prion material, and may in fact fix the prion protein to the surface of the instrument.**

## **Surgical management**

### **Posterior segment eye surgery**

#### **Posterior segment eye surgery on patients with, or at increased risk of, CJD or vCJD**

- L33. Where possible, procedures should be performed with the minimum number of healthcare personnel required and at the end of the list, to allow normal cleaning of theatre surfaces before the next session.
- L34. Single use instruments should be used if available provided they do not compromise the standard of clinical care. Following use, destroy all single-use items by incineration. This advice is also relevant to any instrument used during diagnostic procedures for such a patient.
- L35. If reusable instruments are used they may be quarantined strictly for repeated use on the same patient. Facilities must be stringent for storage, identification and isolation of such instruments. Detailed guidance on the procedure for quarantining instruments, including initial washing to remove gross soil is available in [Annex E](#) of this guidance. If such instruments are to be reused on the same patient, they should be kept separate from other instruments whilst being cleaned and decontaminated e.g. in a separate basket in the washer disinfectant. Alternatively the instruments must be disposed of by incineration.
- L36. In cases of suspected CJD/vCJD the instruments can be quarantined as outlined above and returned to use after standard decontamination if a definitive alternative diagnosis is confirmed.

#### **Posterior segment eye surgery on individuals not known to be infected and not at increased risk of CJD or vCJD**

- L37. The NICE interventional procedure guidance 196 “Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures”, published in November 2006, states several important interventions that are specific to high risk posterior segment surgery. The guidance can be accessed here: <http://www.nice.org.uk/nicemedia/pdf/ip/IPG196guidance.pdf>. Specifically, it states that, for high risk surgical procedures (intradural operations on the brain and operations on the retina or optic nerve – ‘high risk tissues’):

- “Steps should be taken urgently to ensure that instruments that come into contact with high risk tissues do not move from one set to another. Practice should be audited and systems should be put in place to allow surgical instruments to be tracked, as required by Health Service Circular 2000/032: ‘Decontamination of medical devices’ and described in the NHS Decontamination Strategy”
- “Supplementary instruments that come into contact with high risk tissues should either be single-use or should remain with the set to which they have been introduced. Hospitals should ensure without delay that an adequate supply of instruments is available to meet both regular and unexpected needs”

L38. Pragmatic advice with regard to implementation of the NICE interventional procedure guidance 196 is outlined below:

**a) Definition of the surgical set**

- i) The definition of a surgical set for posterior segment eye surgery is critical in implementing the NICE interventional procedure guidance 196. The greatest risk comes from instruments in contact with posterior segment tissues; however, splashes of vitreous or Hartmans’s solution could theoretically carry infectivity to more distant locations
- ii) **The surgical set is defined as any instrument that comes into contact with the eye during a procedure**
- iii) Cryoprobes are considered part of the surgical set, but it may not be feasible to have a separate cryoprobe for each set. A pragmatic approach to this problem would be to ally a cryoprobe to specific sets to limit migration. For example, cryoprobe A would be used with sets 1, 2 and 3; cryoprobe B would be used with sets 4, 5 and 6, and so on. Alternatively, the use of indirect laser or the use of single-use endo-laser probes may be recommended
- iv) Contact lenses used during surgery, irrigating or free standing, should also be defined as part of the set
- v) Microscope or other non-contact indirect viewing systems, for example EIBOS or BIOM, are not considered part of the surgical set

**b) Zero migration of instruments**

- i) Where reusable sets are used in high risk posterior segment surgery, zero migration of instruments must be adhered to and stringent tracking systems put in place
- ii) It is estimated that the incidence of at least one instrument migrating into or out of a surgical set is as high as 50%. This high level of migration of instruments during high risk posterior segment surgery has the potential to promote a self-sustaining epidemic of CJD or vCJD
- iii) Alternative pragmatic approaches to zero migration of instruments are outlined below:
  - Provision of large surgical sets covering all surgical eventualities
  - Provision of small surgical sets covering most surgical eventualities with the use of disposable instruments as supplements when required
  - Provision of small surgical sets covering most surgical eventualities with the use of reusable instruments as supplements when required which stay with the new surgical set. Sufficient quantities of additional instruments will need to be purchased to allow for immediate availability of supplementary instruments if required or if instruments in sets are found to be defective or become unsterile during procedures
  - Provision of small surgical sets covering most surgical eventualities with the use of clearly labelled reusable instruments as supplements, which are allied to a particular subset of surgical sets, and can be confidently tracked (e.g. cryoprobes)
  - Exclusive use of single-use instrumentation. This is now possible for most, if not all, posterior segment surgical cases including external buckling surgery. When procuring single-use instruments it is imperative that the quality and performance of these instruments be equivalent to those of reusable instruments with appropriate procurement, quality control and audit mechanisms in place. Further advice is found in [Appendix 4](#) of this document

**c) Posterior segment surgery on children born since 1 January 1997**

- i) The NICE interventional procedure guidance 196 specifically advises the following on this issue:

“A separate pool of new neuroendoscopes and reusable surgical instruments for high risk procedures should be used for children born since 1 January 1997 (who are unlikely to have been exposed to BSE in the food chain or CJD through a blood transfusion) and who have not previously undergone high risk procedures. These instruments and neuroendoscopes should not be used for patients born before 1 January 1997 or those who underwent high risk procedures before the implementation of this guidance.”

- ii) It is therefore important to identify patients born since 1 January 1997 and make sure that they have had no previous high risk surgery which may have exposed them to risk of CJD
- iii) A separate pool of new instruments should be used on this group of patients. However, it is important that this particular set does not become potentially infected through migration of other instruments into it, or its inadvertent use on patients born before 1 January 1997. This can be difficult to achieve confidently and thus it may be more practical in this group of patients to use single-use instruments. Where single-use alternatives are not practical, for example expensive instrumentation such as cryoprobes, mechanisms for the tracking, identification and storage of the new pool of reusable instruments should be stringent.

### **Anterior segment eye surgery**

#### **Low risk anterior segment eye surgery on individuals with, or at increased risk of, CJD or vCJD**

- L39. Although no special precautions such as quarantining or incinerating instruments is mandatory in these cases the general principles of reducing instrument migration and stringent tracking systems are encouraged.
- L40. Due to the uncertainties of potential inadvertent contamination with tissues of high risk status during surgery then individual case by case assessment is required. In some circumstances, it may be appropriate to follow the precautionary guidance outlined for high risk posterior segment eye surgery (see [paragraphs L33-37](#)).

#### **Low risk anterior segment eye surgery on individuals not known to be infected and not at increased risk of CJD or vCJD**

- L41. If any of the surgical procedures on low risk anterior segment eye tissues are complicated by surgery involving instruments coming into contact with the optic nerve or retinal tissue, the procedure should be considered as surgery on high risk posterior segment eye tissue.
- L42. Although NICE guidance 196 specifically refers to ensuring zero migration of instruments in high risk posterior segment eye surgery it is considered desirable and good practice to limit migration of instruments between sets for low risk anterior segment eye surgery.
- L43. Since Health Service Circular 2000/032: 'Decontamination of medical devices' all instrument trays must be identifiable and traceable. Tracking of all instruments or instrument trays is essential.
- L44. Cleaning and decontamination of re-useable instruments should follow the decontamination advice outlined in [paragraphs L54-55](#).

### **Ocular Tissue Transplantation**

- L45. The issue of ocular tissue transplantation is often confusing with regards to CJD risk assessment and actions required to reduce potential iatrogenic transmission. When assessing the risk, one must consider the nature of the surgical procedure (i.e. does the surgery involve high risk posterior segment surgery or low risk anterior segment surgery) and the potential infectivity of the donor material.

#### **Transplant surgical procedure**

- L46. If the transplant surgical procedure involves high risk posterior segment surgery as defined in [paragraph L10a](#) then the precautions for high risk posterior segment surgery outlined in [paragraphs L33-39](#) should be followed (e.g. potential future retinal pigment epithelium/retinal transplantation).
- L47. If the transplant surgical procedure involves low risk anterior segment surgery as defined in [paragraph L10b](#) then the precautions for low risk anterior segment surgery outlined in [paragraphs L40-45](#) should be followed (e.g. corneal transplantation).
- L48. If allogeneic sclera is used as part of a surgical procedure (e.g. glaucoma tube surgery), the procedure is considered to be high risk posterior segment surgery because the

donor allogeneic sclera may have been in direct contact with the retina and optic nerve during processing. Thus the precautions for high risk posterior segment eye surgery should be used as outlined in [paragraphs L33-39](#).

### **Potential infectivity of the donor material and recipient status**

L49. On the currently available evidence, the risk of an ocular tissue donor in the UK having CJD/vCJD lies between 1.3 and 6.0 per 45 000. This risk is far less than the 1% threshold level of risk used by the CJD Incidents Panel to determine whether an individual would be considered as at increased risk of CJD/vCJD. Therefore, transplant recipients of:

- cornea
- limbal tissue
- sclera
- amniotic membrane
- ocular stem cells

should **not** be designated as at increased risk of CJD/vCJD due to iatrogenic exposure. The same will apply to recipients of retina and retinal pigment epithelium allograft if and when such procedures become available.

**However, it must be noted that a recipient of any tissue or organ, including the above ocular tissues or cells, may not become a blood, tissue or organ donor. Organ donation from such individuals is not completely ruled out, but is considered on a case-by-case basis.**

### **Records management**

L50. Completion and return of the corneal, limbal and scleral transplant record and follow-up forms to NHSBT in a timely manner is a professional duty of ophthalmic surgeons, as stipulated by The Professional Standards Committee of the Royal College of Ophthalmologists.

L51. NHSBT, specifically the National Transplant Database maintained by ODT (Organ Donation and Transplantation), holds ocular tissue transplant records including donor and recipient details, the transplant record form and the transplant follow-up forms, which include the incidence of serious adverse reactions. If an ocular tissue transplant is not recorded on the National Transplant Database, the transplanting surgeon and the surgeon's hospital are legally responsible for ensuring the traceability of the tissue and maintenance of the two-way audit trail between donor and recipient.



- L52. It is a statutory requirement under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 for eye banks to maintain records for a minimum of 30 years.
- L53. A serious adverse events and reactions reporting mechanism has been developed by the Ocular Tissue Advisory Group (OTAG) and implemented by NHSBT for all ocular tissue transplants. This complements the statutory reporting mechanism for serious adverse reactions and events through the Human Tissue Authority. Forms are provided to the transplant surgeon with the tissue to be transplanted and should be retained in the patient's case notes. If at any stage a serious adverse reaction should occur (such as the development of CJD in the recipient) the reporting mechanism is commenced. The transplant follow-up forms also include a question regarding the occurrence of serious adverse reactions. Audit reports regarding issues of transplantation are reported to the Ocular Tissue Advisory Group.

### **Decontamination of surgical instruments**

- L54. Advice regarding decontamination of ophthalmic surgical instruments is available from the Royal College of Ophthalmologists publication "Ophthalmic Instrument Decontamination":  
<http://www.rcophth.ac.uk/docs/profstands/ophthalmic-services/DecontaminationApril2008.pdf>  
and from the forthcoming HTM01 01 series of documents (HTM01 01 A, B, C, D) which will cover, in detail, the decontamination of reusable medical and surgical devices.
- L55. The following key points are considered in the above guidance:
- a) Generic principles exist for the post-surgical handling/decontamination of ophthalmic instruments:
    - i) their fine fragile nature which makes them prone to damage during cleaning processes
    - ii) Fine bores which are difficult to clean
    - iii) Instruments from single sets often require separation for cleaning and decontamination
  - b) Generic advice for cleaning and decontamination includes:
    - i) Proper tracking systems for all ophthalmic instruments

- ii) Maintain integrity of sets throughout the cleaning and decontamination process
  - iii) Keep instruments moist following surgery and prior to washing (this can be achieved either by use of sprays, mists or immersion – each of these have their own logistic issues)
  - iv) Thorough cleaning in washer-disinfectors
  - v) Promote use of specific washer-disinfector systems for ophthalmic instruments
  - vi) Work closely with the decontamination manager within the unit to identify issues and highlight training for staff involved in cleaning and decontamination
  - vii) Validation of systems within the unit and off-site Central Sterile Services Department (CSSD)
- c) Good practice examples of cleaning and decontamination practices in UK and abroad should be highlighted

### **CJD incident management**

- L56. In relation to ophthalmology, a CJD incident occurs when there is a possibility that a patient or patients could have been exposed to CJD/vCJD through contaminated surgical instruments that were previously used on a patient with, or at increased risk of, CJD/vCJD. Such incidents occur 6-14 times per year (mean 9.7 times) in UK ophthalmic units.
- L57. The CJD Incidents Panel advises on how to manage these incidents, and how to manage patients who could have been exposed to CJD/vCJD. Local infection control teams and health protection teams should seek advice from the CJD Incidents Panel on how to manage these incidents. Information sheets for clinicians and patients on CJD/vCJD can be found at: <http://www.hpa.org.uk/CJD>
- L58. **All incidents should be reported to the CJD Incidents Panel secretariat:**  
The CJD Incidents Panel Secretariat, Health Protection Agency – Centre for Infections,  
61 Colindale Avenue, London NW9 5EQ  
Tel: 020 8327 6411, Email: [cjd@hpa.org.uk](mailto:cjd@hpa.org.uk),
- L59. The website <http://www.hpa.org.uk/CJDIncidentsPanel> includes the CJD Incidents Panel framework document which sets out the principles of managing CJD incidents, and also

describes the risk assessment models that underpin the risk management of surgical and blood incidents.

## Appendix 1

### Surgical procedures regarded as High Risk Posterior Segment Eye Surgery

#### Orbit (C01-C08)

- C01 Excision of eye
- C03 Insertion of prosthesis of eye
- C04 Attention to prosthesis of eye

These orbital operations are only included if the surgery or implant is likely to come into contact with the optic nerve or retinal tissue (for example, evisceration of the eye and intra-orbital implant)

#### Operations on Optic Nerve (A29.1–A36.4)

- A29.1 Excision of lesion of optic nerve
- A30.1 Repair of optic nerve
- A32.1 Decompression of optic nerve
- A34.1 Exploration of optic nerve
- A36.4 Radial Optic Neurotomy

#### Sclera and iris (C52-C65)

- C54 Buckling operations for attachment of retina

#### Retina, other parts of eye and anaesthetics (C79-C90)

- C79 Operations on vitreous body (only when this involves potential contact with the posterior hyaloid face). For example:
  - Codes C7910 for vitrectomy via anterior approach and C7923 for intravitreal injections are specifically excluded as they are unlikely to come into contact with posterior hyaloid face
  - Codes C7920 and C7922, which potentially could come into contact with hyaloid face, are included
- C80 Operations on retinal membrane
- C81 Photocoagulation of retina for detachment (only when the retina is handled directly)
- C82 Destruction of lesion of retina (only when retina is handled directly). For example:
  - Code C82.4 for insertion of radiotherapy plaques is specifically excluded
- C83 Translocation of retina
- C84 Other operations on retina

- C85 Fixation of retina
- C86 Other operations on eye
- C88 Destruction of subretinal lesion
- C89 Operations on posterior segment of eye

## Appendix 2

### Surgical procedures regarded as Low Risk Anterior Segment Eye Surgery

#### Orbit (C01-C08)

- C02 Extirpation of lesion of orbit
- C05 Plastic repair of orbit
- C06 Incision of orbit
- C08 Other operations on orbit

These orbital operations are only considered low risk if the surgery is unlikely to come into contact with the optic nerve (for example, drainage of orbit C0620 or retrobulbar injection C0840)

#### Eyebrow and eyelid (C09-C22)

- C09 Replacement of canthal tendon
- C10 Operations on eyebrow
- C11 Operations on canthus
- C12 Extirpation of lesion of eyelid
- C13 Excision of redundant skin of eyelid
- C14 Reconstruction of eyelid
- C15 Correction of deformity of eyelid
- C16 Other plastic repair of eyelid
- C17 Other repair of eyelid
- C18 Correction of ptosis of eyelid
- C19 Incision of eyelid
- C20 Protective suture of eyelid
- C22 Other operations on eyelid

#### Lacrimal apparatus (C24-C29)

- C24 Operations on lacrimal gland
- C25 Connection between lacrimal apparatus and nose
- C26 Other operations on lacrimal sac
- C27 Operations on nasolacrimal duct
- C29 Other operations on lacrimal apparatus

**Muscles of eye (C31-C37)**

- C31 Combined operations on muscles of eye
- C32 Recession of muscle of eye
- C33 Resection of muscle of eye
- C34 Partial division of tendon of muscle of eye
- C35 Other adjustment to muscle of eye
- C37 Other operations on muscle of eye

**Conjunctiva and cornea (C39-C51)**

- C39 Extirpation of lesion of conjunctiva
- C40 Repair of conjunctiva
- C41 Incision of conjunctiva
- C43 Other operations on conjunctiva
- C45 Extirpation of lesion of cornea
- C46 Plastic operations on cornea
- C47 Closure of cornea
- C48 Removal of foreign body from cornea
- C49 Incision of cornea
- C51 Other operations on cornea

**Sclera and iris (C52-C65)**

- C52 Excision of sclera
- C53 Extirpation of lesion of sclera
- C55 Incision of sclera
- C57 Other operations on sclera
- C59 Excision of iris
- C60 Filtering operations on iris
- C61 Other operations on trabecular meshwork of eye
- C62 Incision of iris
- C64 Other operations on iris
- C65 Operations following glaucoma surgery

**Anterior chamber of eye and lens (C66-C77)**

- C66 Extirpation of ciliary body
- C67 Other operations on ciliary body
- C69 Other operations on anterior chamber of eye
- C71 Extracapsular extraction of lens

- C72 Intracapsular extraction of lens
- C73 Incision of capsule of lens
- C74 Other extraction of lens
- C75 Prosthesis of lens
- C77 Other operations on lens



## Appendix 3

### **Guidance for the cleaning and disinfection (decontamination) of rigid contact lenses and ophthalmic medical devices which come into contact with the outer surface of the eye**

1. The lens or device should be decontaminated immediately after contact with the eye surface. It should not be allowed to dry at this stage.
2. It should be rinsed in Water for Irrigation BP for not less than 30 sec.
3. It should then be cleaned on all surfaces with a liquid soap or detergent, then rinsed in Water for Irrigation BP for a further 30 sec.
4. The lens or device should then be immersed in a freshly-prepared solution of sodium hypochlorite providing 10,000ppm of available chlorine for 10 min.
5. It should then be rinsed in three changes of Water for Irrigation BP for a total of not less than 10 min.
6. The device should then be shaken to remove excess water, dried with a disposable tissue, and stored dry in a suitable container.
7. Any further measure (such as autoclaving) can then be carried out, if this is necessary and if the device is designed to withstand such a process. Otherwise, it is ready for immediate re-use.
8. Other chemical agents should not be used unless the device manufacturer advises against the use of sodium hypochlorite. However, agents or procedures capable of binding proteins to surfaces (e.g. isopropyl alcohol, glutaraldehyde, autoclaving) should never be used, unless devices are first decontaminated according the above protocol.
9. The procedure described above is suitable for the great majority of devices manufactured from PMMA, glass or non-ferrous metals. Where other materials are used, the manufacturer's advice should be sought.

### **Notes on steps 1-6**

1. If circumstances do not permit the immediate decontamination of a contact lens or device, it should be immersed in Water for Irrigation BP contained in a disposable galley-pot, and decontaminated as soon as possible thereafter.
  
2. Most medical devices and instruments are decontaminated with the use of potable (drinking) water. However, this has not been recommended for contact lenses and ophthalmic instruments that come into contact with the ocular surface. This is because of the risk of contamination with *Acanthamoeba* spp. and is in line with the advice given to contact lens wearers, namely never to rinse their lenses or lens cases in tap water, and to avoid swimming and showering while wearing their lenses. The argument that rising mains water (as opposed to water from storage tanks) should be safe is not sustainable as it has been shown that rising mains pipework can become colonised by *Acanthamoeba* spp. even a short distance from its source. Moreover, in the clinical situation most people are unaware of the source of the water available to them at their workstations or in preparation rooms, or its distance from the mains supply. For these reasons, the use of tap water has not been recommended in this guidance.
  
3. The type of liquid soap or detergent is not specified. Unless the manufacturer publishes guidance, the advice of the local Sterile Services Department should be sought. Household detergents such as washing up liquid, and surgical scrub solutions, should not be used.
  
4. The sodium hypochlorite solution should be prepared immediately before the episode of decontamination. Such solutions are unstable and the concentration of available chlorine diminishes with time, especially in open containers. A recommended alternative to sodium hypochlorite solutions is NaDCC (sodium dichloroisocyanurate) which is available as tablets which are mixed just before use with a dedicated diluent or with Water for Irrigation BP. NaDCC, like sodium hypochlorite, is a source of hypochlorous acid and hence of available chlorine, and is widely used in healthcare environments; for example, dilutions giving 10,000 ppm available chlorine are recommended for the decontamination of blood spillages.  

The solution should be placed in a disposable plastic galley pot or similar disposable container. This should have a volume of not less than 50ml. (In the case of certain devices that cannot be wholly immersed, that part which comes into contact with the ocular surface must be so treated; the same consideration applies to Steps 2, 3 and 5.)

5. Starch iodide paper can be used to test the final rinse water. In the presence of residual hypochlorite or chlorine, the paper that is initially white will turn purple.
6. The lens or device will often have its own dedicated case for dry storage, but if not, a suitable case will have to be procured.

## Appendix 4

### Single-use instrumentation in ophthalmology

- The quality and performance of single-use instruments (SUI) should be equivalent to those of reusable instruments with appropriate procurement, quality control and audit mechanisms in place
- For reusable instruments there is an internal quality control, with instruments noted as faulty being either repaired or returned to the manufacturer. A similar process needs to be put in place for any SUI that is purchased
- A CE mark is not necessarily a mark of quality of instruments, and quality control of sub-contractors is often difficult when the number of instruments increases
- Manufacturers need to be encouraged to continue to produce high quality SUIs
- National contracts with manufacturers should be developed
- Quality control mechanisms for SUIs need to be developed which account for procurement, manufacturing and packaging. Evidence of this quality control must be clear, transparent and easily available to any individual using the SUIs
- A central reporting mechanism is to be encouraged to share information regarding the quality of instruments and to publicise this information nationally. This could be formally done through the Royal College of Ophthalmologists or via a website where the quality of instruments is constantly updated
- When considering the cost effectiveness of SUIs, appropriate costing is required not only for the purchase of the instruments but also their disposal. In addition, the potential cost savings of provision of reusable instruments and their subsequent decontamination and tracking should be taken into account

**Appendix 5****List of members of the ACDP TSE Working Group Ophthalmology subgroup**

<b>Name</b>	<b>Role</b>
<b>Mr Ian Pearce (Chairman)</b>	Consultant Ophthalmologist, Royal Liverpool University Hospital
<b>Professor John Armitage</b>	Professorial Research Fellow and Director of Tissue Banking, Bristol Eye Hospital
<b>Professor Roger Buckley</b>	Professor of Ocular Medicine, Anglia Ruskin University
<b>Ms Pat Cattini</b>	Infection Control Specialist, Royal Brompton Hospital
<b>Ms Cecilia Fenerty</b>	Consultant Ophthalmologist, Manchester Royal Eye Hospital
<b>Mr Allan Hilderley</b>	Medicines and Healthcare Products Regulatory Agency
<b>Mr Ken Holmes</b>	Northumberland and Tyne and Wear Mental Health Trust
<b>Professor James Ironside</b>	Professor of Clinical Neuropathology, University of Edinburgh Head of the Neuropathology Laboratories, National CJD Surveillance Unit
<b>Professor Don Jeffries</b>	Chair of the ACDP TSE Working Group
<b>Mr Stephen Kaye</b>	Consultant Ophthalmologist, Royal Liverpool University Hospital
<b>Professor John Lawrenson</b>	Professor of Optometry, City University, London
<b>Mr Raymond Lobo</b>	Associate Specialist in Ophthalmology, University College Hospital, London
<b>Ms Gwyneth Morgan</b>	Member of the College of Optometry
<b>Mr Andrew Morrell</b>	Consultant Ophthalmologist, St. James's University Hospital, Leeds
<b>Mr Richard Newsom</b>	Consultant Ophthalmologist, Southampton University Hospital

<b>Dr Mike Painter</b>	Chair, Engineering and Science Advisory Committee into the decontamination of surgical instruments including Prion Removal
<b>Mr David Pryer</b>	Chair, CJD Incidents Panel
<b>Professor Ian Rennie</b>	Consultant Ophthalmologist, Royal Hallamshire Hospital, Sheffield
<b>Dr Geoff Ridgway</b>	Consultant Microbiologist Department of Health Senior Medical Officer
<b>Professor Peter Shah</b>	Consultant Ophthalmologist, Birmingham and Midland Eye Centre
<b>Ms Jackie Shipley</b>	Senior Theatre Nurse, Royal Liverpool University Hospital
<b>Mr Alun Tomkinson</b>	Consultant ENT Surgeon, University Hospital of Wales
<b>Mr Barrie White</b>	Consultant Neurosurgeon, Queen's Medical Centre, Nottingham