



# Variant Creutzfeldt-Jakob Disease (vCJD) and Transmissible Spongiform Encephalopathy Agents (TSE): Minimising the Risks of Transmission

This procedural document supersedes: Variant Creutzfeldt-Jakob Disease (vCJD) and Transmissible Spongiform Encephalopathy Agents (TSE): Minimising the Risks of Transmission – PAT/IC 4 v.4



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### Amendment Form

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5	26 June 2018	<ul style="list-style-type: none"> <li>• Updated all hyperlinks</li> <li>• Added Executive Sponsor on front page</li> <li>• Removed audits ward round by Matrons</li> <li>• Added Standard statement from the Educational Department to the training Section</li> </ul>	Dr K Agwuh
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3	October 2010	All sections re-written in line with National Guidelines	Dr C M Hoy
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## 1. INTRODUCTION

Transmissible spongiform encephalopathies (TSEs) are rare, fatal degenerative diseases affecting the central nervous system. The human TSEs are:

- Idiopathic diseases: sporadic Creutzfeldt Jakob disease (CJD) and sporadic fatal insomnia
- Familial diseases: familial CJD, Gerstmann-Sträussler-Scheinker (GSS) disease and fatal familial insomnia
- Acquired diseases: Human agents: Kuru and iatrogenic CJD  
Bovine agent: variant CJD

TSEs are caused by unconventional infectious agents, currently thought to be infectious proteins known as prions. The world-wide incidence of TSEs is about 1 per million people each year. The most common form is sporadic CJD, the cause of which is unknown, although genetic factors influence disease susceptibility. Around 10% of cases occur as inherited familial diseases, which have a genetic origin associated with mutations in the prion protein gene.

It is known that transmission of CJD can occur in specific situations associated with medical interventions (known as iatrogenic infections). Worldwide, cases of iatrogenic CJD have been associated with administration of hormones prepared from human pituitary glands and *dura mater* preparations and one definite case has been associated with a corneal graft (it is possible that corneal tissue was contaminated with posterior segment tissue during processing). Iatrogenic transmission has also been identified following neurosurgical procedures with inadequately decontaminated instruments.

Variant CJD (vCJD) was first recognised in 1996 and the agent responsible is biologically indistinguishable from that responsible for Bovine Spongiform Encephalopathy (BSE) in cattle. Since 2003, four cases of presumed person-to-person spread of vCJD infection via blood transfusion of non-leucodepleted red blood cells have been reported in the UK and a probable case via plasma products.

In sporadic CJD, most patients present in late middle age with rapidly progressive dementia and focal neurological signs including ataxia, myoclonus, visual disturbances and rigidity. Variant CJD generally affects young adults, with initially psychiatric and sensory abnormalities followed by ataxia, myoclonus and dementia.

TSE agents exhibit an unusual resistance to conventional chemical and physical decontamination methods, including disinfectants, standard autoclaving and ionising and UV irradiation. Effective cleaning is therefore of great importance in the removal of these agents.

## 2. PURPOSE

To provide advice on safe working practices to minimise the risk of transmitting transmissible spongiform encephalopathies (TSEs) in a healthcare setting.

### 3. DUTIES AND RESPONSIBILITIES

This policy covers infection prevention and control management issues for Trust staff this includes:-

- Employees
- Volunteers
- Agency/Locum/Bank Staff
- Contractors whilst working on the Trust premises

**All staff** working on Trust premises, outreach clinics and community settings, including Trust employed staff, contractors, agency and locum staff are responsible for adhering to this policy, and for reporting breaches of this policy to the person in charge and to their line manager.

**Chief Executive:** To ensure that infection control is a core part of clinical governance and patient safety programmes. Promote compliance with infection control policies and national standards in order to ensure low levels of health care associated infections.

**Board of Directors:** The Board of Directors and executives, through the Chief Executive, is ultimately responsible for ensuring that systems are in place that effectively manage the risks associated with Infection Control. Their role is to support the implementation of a Board to Ward culture to support a Zero Tolerance approach to Health Care Associated Infections

The **Director of Infection Prevention and Control** will provide assurance to the board that effective systems are in place.

**Director of Infection Prevention and Control:** Is responsible for the development of infection prevention and control strategies throughout the Trust to ensure best practice

**The Infection Prevention and Control Team:** is responsible for providing expert advice in accordance with this policy, for supporting staff in its implementation, and assisting with risk assessment where complex decisions are required.

**Microbiologists:** As part of their role provide expert advice to CSM / senior staff out of hours. They will also be responsible in alerting the IPC team of any new alert organisms and difficulties in isolation out of hours.

**Senior Nurses:** are responsible for ensuring implementation within their area by undertaking regular audits in ward rounds activities. Any deficits identified will be addressed to comply with policy.

**Ward and Department Managers:** are responsible for ensuring implementation within their area, and for ensuring all staff who work within the area adhere to the principles at all times.

**Consultant Medical Staff:** are responsible for ensuring their junior staff read and understand this policy, and adhere to the principles contained in it at all times.

**Chief operating officer / On-call Managers:** are responsible for providing senior and executive leadership to ensure implementation of this policy, and for ensuring infection risks are fully considered and documented when complex decisions need to be made regarding capacity and patient flow.

#### 4. HOSPITAL CARE OF PATIENTS

There is no evidence that normal social or routine clinical contact of a CJD/vCJD patient presents a risk to healthcare workers, relatives and others. Isolation of patients with CJD/vCJD is not necessary, and they can be nursed in an open ward using standard infection control precautions (PAT/IC 19)

In sporadic CJD, abnormal prion protein appears to be restricted to the central nervous system in patients with clinical disease. However, in patients with clinical vCJD, abnormal prion protein has been detected in various lymphoid tissues including tonsils, spleen, gastrointestinal lymphoid tissue (appendix and rectum), lymph nodes, thymus and adrenal glands. Abnormal prion protein has also been detected in lymphoid tissue within the appendix prior to clinical onset of vCJD.

Although cases of CJD/vCJD have been reported in healthcare workers, there have been no confirmed cases linked to occupational exposure. However, it is prudent to take a precautionary approach. The highest potential risk is from exposure to high infectivity tissues through direct inoculation, for example as a result of sharps injury, puncture wound or contamination of broken skin, and mucous membrane exposure. Healthcare personnel who work with patients with definite/probable/possible CJD/vCJD, or with potentially infected tissues should be appropriately informed about the nature of the risk and relevant safety procedures. Compliance with standard infection control precautions will help to minimise risks from occupational exposure. ([PAT/IC 19](#))

When considering measures to prevent transmission in a healthcare setting, it is useful to distinguish between **symptomatic** patients, who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD and patients with no clinical symptoms, who are **“at increased risk”** of developing one of these diseases. A number of patients have been identified as “at increased risk” of CJD or vCJD on the recommendation of the CJD Incidents Panel due to their medical or family history - the patient groups are outlined in Table 1. Recipients of ocular transplants, including corneal transplants, are not considered to be “at increased risk” of CJD/vCJD.

All people who are “at increased risk” of CJD/vCJD are asked to help prevent any further transmission to other patients by:

- Not donating blood
- Not donating organs or tissues including bone, marrow, sperm, eggs or breast milk
- If undergoing medical, dental or surgical procedures – tell whoever is treating them beforehand so appropriate arrangement can be made for instruments

GPs are asked to record their patient's CJD/vCJD risk status and should include this information in any referral letter should the patient require invasive medical, surgical or dental procedures.

**Table 1. Categorisation of patients by risk**

<p><b>Symptomatic patients</b></p>	<ul style="list-style-type: none"> <li>• Patients who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD (cases are classified by a neurologist from the National CJD Surveillance Unit – see <a href="#">Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection – Annex B</a>)</li> <li>• Patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD or vCJD but where the diagnosis of CJD is being actively considered</li> </ul>
<p><b>Patients “at increased risk” from genetic forms of CJD</b></p>	<ul style="list-style-type: none"> <li>• Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD</li> <li>• Individuals who have a blood relative known to have a genetic mutation indicative of genetic CJD;</li> <li>• Individuals who have had two or more blood relatives affected by CJD or other prion disease.</li> </ul>
<p><b>Patients “at increased risk” of vCJD through receipt of blood from a donor who later developed vCJD</b></p>	<ul style="list-style-type: none"> <li>• Individuals who have received labile blood components (whole blood, red cells, white cells or platelets) from a donor who later went on to develop vCJD</li> </ul>

<p><b>Patients identified as “at increased risk” of CJD/vCJD through iatrogenic exposures</b></p>	<ul style="list-style-type: none"> <li>• Recipients of hormone derived from human pituitary glands, <i>e.g.</i> growth hormone, gonadotrophin. In the UK, the use of human-derived gonadotrophin was discontinued in 1973 and use of cadaver-derived human growth hormone was banned in 1985. However, use of human-derived products may have continued in other countries after these dates.</li> <li>• Individuals who underwent intradural brain or spinal procedures before August 1992 who received (or might have received) a graft of human-derived dura mater are “at increased risk” of transmission of sporadic CJD (unless evidence can be provided that human-derived dura mater was not used).</li> <li>• Individuals who have had surgery using instruments that had been used on someone who went on to develop CJD/vCJD, or was “at increased risk” of CJD/vCJD</li> <li>• Individuals who have received an organ or tissue from a donor infected with CJD/vCJD or “at increased risk” of CJD/vCJD</li> <li>• Individuals who have been identified as having received blood or blood components from 300 or more donors since January 1990</li> <li>• Individuals who have given blood to someone who went on to develop vCJD</li> <li>• Individuals who have received blood from someone who has also given blood to a patient who went on to develop vCJD</li> <li>• Individuals who have been treated with certain implicated UK sourced plasma products between 1990 and 2001</li> </ul>
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## 5. SAMPLE TAKING AND OTHER INVASIVE PROCEDURES

When taking samples or performing other invasive procedures, the possible infectivity of the tissue(s) involved must be considered, and if necessary, suitable precautions taken. It is important to ensure that only trained staff, who are aware of the hazards, carry out invasive procedures that may lead to contact with medium or high risk tissue. Body secretions, body fluids (including saliva, blood, CSF and excreta) are all low risk for CJD/vCJD. It is therefore likely that the majority of samples taken or procedures performed will be low risk. Contact with small volumes of blood (including inoculation injury) is considered low risk, though it is known that transfusion of large volumes of blood and blood components may lead to vCJD transmission.

Blood and body fluid samples from patients with or “at increased risk” of CJD/vCJD should be handled with standard infection control precautions as for any other patient *i.e.* use of disposable gloves and eye protection where splashing may occur, avoidance of sharps injuries and the safe disposal of sharps ([PAT/IC 8](#)) and contaminated waste ([CORP/HSFS 17 \(B\)](#)). Single use disposable equipment should be used wherever practicable.

Samples from patients with or “at increased risk” of CJD/vCJD should be marked with a “Biohazard / Danger of Infection” label and the laboratory informed in advance that a sample



is being sent. TSE agents are classified as Hazard Group 3 and considered at Category B for transport– see [\(PAT/IC 11\)](#) for appropriate packaging and transport of pathology samples.

Blood and CSF are classified as low risk tissue and do not require special precautions for biochemical or cytological investigations. Guidance for pathologists and pathology laboratories handling tissues from patients with, or at risk of, CJD or vCJD can be found at [“Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection” - Annex K. Department of Health. March 2009](#)

## 6. SPILLAGES

Standard infection control precautions should be followed for any spillages (including blood and CSF), which should be cleared up as quickly as possible, keeping contamination to a minimum. Disposable gloves and an apron should be worn. For spillages of large volumes of liquid, absorbent material should be used to absorb the spillage. Standard disinfection for spillages (e.g. 10,000ppm chlorine-releasing agent) should be used to decontaminate the surface after the spillage has been removed. It should be noted that none of the methods currently suggested by WHO for prion inactivation are likely to be fully effective.

Any waste (including cleaning tools such as mop heads and PPE worn) should be disposed of as clinical waste – see below and [\(CORP/HSFS 17 \(A\)\)](#).

## 7. CLINICAL WASTE

Tissues, and contaminated materials such as dressings and sharps, from patients with, or “at increased risk” of CJD/vCJD should be disposed of as in the following table:

Diagnosis of CJD	High or medium risk tissue*	Low risk tissue and body fluids**
<b>Definite</b>	Incinerate	Normal clinical waste disposal
<b>Probable</b>	Incinerate	Normal clinical waste disposal
<b>“At increased risk”</b>	Incinerate	Normal clinical waste disposal

\* - See Table 3 below and [Transmissible Spongiform Encephalopathy Agents: Safe working Practice and the Prevention of Infection - Annex A1](#)

\*\* - Tissues and materials deemed to be low risk include body fluids such as urine, saliva, sputum, blood and faeces. Blood from vCJD patients is considered low risk except when transfused in large volumes.

## 8. CHILDBIRTH

In the event that a patient with, or “at increased risk “of CJD or vCJD becomes pregnant, it is important to ensure that patient confidentiality is properly maintained, and that any action taken to protect public health does not prejudice individual patient care.

Childbirth should be managed using standard infection control precautions. The placenta and other associated materials and fluids are designated as low risk tissues, and should be disposed of as clinical waste, unless they are needed for investigation.

## 9. SURGICAL AND ENDOSCOPIC PROCEDURES

The CJD Incidents Panel has identified a number of individuals or groups who are at increased risk of CJD or vCJD. Arrangements should be in place to ensure that patients who have been notified that they are at increased risk of CJD/vCJD are identified before surgery or endoscopy to allow appropriate infection control procedures to be followed.

Healthcare staff conducting pre-surgery assessments should receive instruction and/or training necessary to understand the reasons for answering the questions below and reassure patients and provide further information if needed. Information for patients and healthcare professionals is available from Public Health England:

<https://www.gov.uk/government/publications/cjd-information-leaflets-for-patients-and-healthcare-professionals>

Also see [“Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection” - Annex J. Appendix B. Department of Health](#)

### 9.1 Assessment of CJD/vCJD risk

**All** patients about to undergo **any** elective or emergency surgical or endoscopic procedure should be asked the question:

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

Patient's response	Action
<b>No</b>	Surgery or endoscopy should proceed using normal infection control procedures unless the procedure is likely to lead to contact with high risk tissue.
<b>Yes</b>	Ask the patient to explain further – response should be recorded in medical notes. Special infection control precautions should be taken for all surgery or endoscopy involving contact with medium or high infectivity tissues (see below) and the Infection Prevention and Control team consulted for advice.
<b>Unable to respond</b>	Surgery or endoscopy should proceed using normal infection control procedures <b>unless</b> the procedure is likely to lead to contact with high risk tissue. If this is the case, follow additional recommendations for high risk procedures – see below

## 9.2 Additional recommendations for surgery and neuroendoscopy which may involve contact with high risk tissue

These additional recommendations are only applicable to those assessing patients for intradural and posterior ophthalmic surgical procedures and intradural neuro- endoscopic procedures.

- 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 or 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 [Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection” - Annex L](#), for a list of posterior segment eye surgeries.

As well as asking patients whether they have been notified as being at increased risk of CJD/vCJD, clinicians assessing patients for procedures that involve contact with high risk tissues should ask supplementary questions outlined in Table 2 below. Tissues assumed or proven to have high level infectivity for CJD or vCJD are:

- Brain, spinal cord, implanted dura mater grafts prior to 1992, cranial nerves (entire optic nerve but only intracranial component other cranial nerves), cranial nerve ganglia, posterior eye (specifically, posterior hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid, optic nerve) and pituitary gland.

Ophthalmic units with a mixed case load of anterior and posterior segment surgeries and procedures may wish to ask the questions in Table 2 to all their patients for practical reasons – this is a local decision.

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, it is important to correctly and reliably identify these patients and ensure they have had no previous high risk surgery which may have exposed them to a risk of CJD/vCJD.

**Table 2. CJD Risk Questions for patients undergoing 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.	<p>Patients should be considered to be at risk from genetic forms of CJD if they have or have had:</p> <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) Two or more blood relatives affected by CJD or other prion disease</li> </ul>
2	<p>Have you ever received growth hormone or gonadotrophin treatment? If yes, please specify:</p> <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>	<p>Recipients of hormone derived from human pituitary glands e.g. growth hormone or gonadotrophin, have been identified as at increased risk of sporadic CJD.</p> <p>In the UK the use of human-derived growth hormone was discontinued in 1985 but human-derived products may have continued to be used in other countries.</p> <p>In the UK, the use of human-derived gonadotrophin was discontinued in 1973 but may have continued in other countries after this time.</p>
3	Have you ever had surgery on your brain or spinal cord?	<ul style="list-style-type: none"> <li>a) Patients who underwent intradural brain or spinal procedures before August 1992 who received (or might have received) a graft of human-derived dura mater, are “at increased risk” of transmission of sporadic CJD (unless evidence can be provided that human-derived dura mater was not used).</li> <li>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 1st January 1997 and who have not previously undergone high risk procedures. These instruments and neuroendoscopes should not be used for patients born before 1st January 1997 or those who underwent high risk procedures using reusable instruments before implementation of this guidance</li> </ul>

**Actions to be taken following the patients response to the above questions:**

Patient's response	Action
No to all questions	Surgery or neuro-endoscopy can proceed using normal infection control procedures.
Yes to any of questions 1,2 or 3	<p>Further investigation should be undertaken to assess the nature of the patient's CJD risk – and this assessment recorded in the patient's notes.</p> <p>If the patient is found to be at increased risk of CJD or vCJD, or the risk status is unknown, special infection control precautions should be taken, including quarantining of instruments (see below) and the Infection Prevention and Control team consulted for advice.</p> <p>Also see <a href="#">“Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection” - Annex J. Department of Health</a> for further advice.</p>
Unable to respond	See below

In the event that a patient about to have emergency surgery or neuro-endoscopy is unable to answer any questions, a family member or someone close to the patient should be asked the CJD risk questions set out in Table 2.

If the family member is not able to provide a definitive answer to the CJD risk questions, the surgery or neuro-endoscopy should proceed but all instruments should be quarantined (see below) following the procedure. The patient's GP should be contacted after the surgery or neuro-endoscopy and asked as to whether the patient is at increased risk of CJD or vCJD according to the questions set out in Table 2.

See [“Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection” - Annex J. Department of Health](#) for further advice.

In addition to asking the CJD/vCJD risk questions, before any surgical or endoscopic procedure involving contact with high risk tissue, the clinician undertaking the pre-surgery assessment should:

- Check the patient's medical notes and/or referral letter for any mention of CJD or vCJD.
- Consider whether there is a risk that the patient may be showing early signs of CJD or vCJD i.e. consider whether the patient may have an undiagnosed neurological disease involving cognitive impairment or ataxia.

### 9.3 Surgical procedures and instrument management

For all patients with or “at increased risk” of CJD or vCJD, the following precautions should be taken for surgical procedures:

- Wherever appropriate and possible the intervention should be performed in an operating theatre
- Where possible, procedures should be performed at the end of a list to allow normal cleaning of theatre surfaces before the next session
- Only the minimum number of healthcare personnel required should be involved
- Protective clothing should be worn i.e. liquid repellent operating gown, over a plastic apron, gloves, mask and goggles or full-face visor:
  - For symptomatic patients, this protective clothing should be single use and disposed of in line with Trust waste policy ([CORP/HSFS 17 \(A\)](#))
  - For patients “at increased risk” of CJD/vCJD, this protective clothing need not be single use and may be reprocessed.
- Single-use disposable surgical instruments and equipment should be used where possible, and subsequently be destroyed by incineration
- Effective tracking of re-usable instruments should be in place, so that instruments can be related to use on a particular patient.

#### 9.4 Single Use Instruments

The following should be taken into account when using single-use instruments:

- The quality and performance of single-use instruments should be equivalent to those of reusable instruments, with appropriate procurement, quality control and audit mechanisms in place
- Procurement should be quality, not cost based, with the minimum safe functional requirements of each instrument purchased being understood by the purchaser
- An internal quality control process for faulty single use instruments, similar to that for reusable instruments, needs to be put in place
- A CE mark is not necessarily a mark of quality of instruments

#### 9.5 Handling of instruments not designated single-use

Where single-use instruments are not available, the handling of re-usable instruments depends on:

- How likely the patient is to be carrying the infectious agent (the patient’s risk status)
- Whether the patient has, or is “at increased risk” of CJD/vCJD
- How likely it is that infection could be transmitted by the procedure being carried out i.e. whether there is contact with tissues of high or medium infectivity.

Table 3 sets out the actions to be taken for instruments used on patients with, or “at increased risk” of CJD/vCJD. These are also summarised in the algorithm in Appendix 1.

**Table 3. Handling of instruments – patients with or “at increased risk” of CJD/vCJD** From  
 “Transmissible spongiform encephalopathy agents: Safe working and the prevention of  
 infection” –Department of Health

Tissue infectivity	Status of patient		
	Definite or probable	Possible	At increased risk
<b>High</b>			
Brain	Single use	Single use	Single use
Spinal cord	or	or	or
Cranial nerves, specifically the entire optic nerve and the intracranial components of the other cranial nerves	Destroy	Quarantine for re-use exclusively on the same patient pending diagnosis	Destroy
Cranial ganglia	or	or	or
Posterior eye, specifically the posterior hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve	Quarantine for re-use exclusively on the same patient	Quarantine for re-use exclusively on the same patient pending diagnosis	Quarantine for re-use exclusively on the same patient
Pituitary gland			
<b>Medium</b>			
Spinal ganglia	Single use	Single use	Single use
Olfactory epithelium	or	or	or
Tonsil (vCJD only)	Destroy	Quarantine for re-use exclusively on the same patient pending diagnosis	Destroy
Appendix (vCJD only)	or	or	or
Spleen (vCJD only)	Quarantine for re-use exclusively on the same patient	Quarantine for re-use exclusively on the same patient pending diagnosis	Quarantine for re-use exclusively on the same patient
Thymus (vCJD only)			
Adrenal gland (vCJD only)			
Lymph nodes and gut associated lymphoid tissues (vCJD only)			
<b>Low</b>	No special precautions	No special precautions	No special precautions

## 9.6 Quarantining of surgical instruments

Instruments may be quarantined if used for procedures involving tissues designated as high or medium infectivity on patients either;

- with, or at increased risk of CJD/vCJD, for use exclusively on the same patient; or
- with a *possible* CJD/vCJD diagnosis pending confirmation

Instruments should be kept separate from those that only come into contact with tissues designated as low infectivity, rinsed to remove gross soil, taking care to avoid splashing and generating aerosols. Operatives should wear protective gloves and a visor or goggles. Reusable instruments should be allowed to air-dry then placed in an impervious, rigid plastic container, sealed and labelled with the patient's details, surgical procedure and the name of the responsible person (HSDU manager) and the box stored in a suitable designated place.

Detailed guidance on the procedure is set out in [“Transmission spongiform encephalopathy agents: Quarantining of surgical instruments” - Annex E](#). If a possible case is confirmed as CJD or vCJD, the box and its contents should be disposed of by incineration. If a definitive alternative diagnosis is confirmed and CJD/vCJD positively excluded, the instruments may be removed from the box by the responsible person and reprocessed according to best practice and returned to use.

## 9.7 Decontamination of instruments

Effective decontamination is key to reducing the risk of transmission of CJD/vCJD through surgery. TSE agents are particularly resistant to standard physical and chemical methods of inactivation and decontamination. Therefore, effective cleaning is of great importance in the removal of these agents. Most chemical disinfectants are ineffective at reducing infectivity and some, acting as protein fixatives, may stabilise the agent. Incineration is effective at removing the infective agent and eliminating infectivity. Autoclaving remains an important method of reducing infectivity, but cannot be relied upon to completely eliminate infectivity. For further information see [“Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection – Annex C”](#).

Some complex and expensive equipment such as drills and operating microscopes may be prevented from being contaminated by using shields, guards or coverings, so that the entire item does not need to be destroyed. In this case, the drill bit, other parts in contact with high or medium risk tissues, and the protective coverings would need to be incinerated. However, in practice, it may be difficult to ensure effective protective covering and advice should be sought from clinical staff and the manufacturer to determine practicality.

## 9.8 Managing CJD/vCJD risk in ophthalmology

There has been one definite case of CJD transmission from corneal transplantation, and other probable or possible cases reported over the past two decades. There are no other known cases of ophthalmic surgery or diagnostic procedure having resulted in CJD transmission



between patients. No detectable levels of abnormal prion protein have been found in cornea, sclera, iris, lens, ciliary body, vitreous or choroid.

All patients should be assessed for risk of CJD or vCJD before elective or emergency surgery – see sections 9.1 and 9.2. Any posterior segment eye surgery or procedure is considered high risk. Any anterior segment eye surgery or procedure is considered low risk – see [Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection – Annex L](#) for list of procedure.

NICE guidance <https://www.nice.org.uk/guidance/ipg196/resources/patient-safety-and-reduction-of-risk-of-transmission-of-creutzfeldtjakob-disease-cjd-via-interventional-procedures-pdf-1899863525353669> states that for high risk surgical procedures:

- Steps should be taken to ensure that instruments that come into contact with high risk tissues do not move from one set to another.
- 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.
- A separate pool of new neuroendoscopes and reusable surgical instruments for high risk procedures should be used for children born since 1 January 1997 and who have not previously undergone high risk procedures.

For further advice on handling of instruments used in posterior segment eye surgery see [“Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection” – Annex L](#).

There have been no known cases of iatrogenic transmission of CJD/vCJD resulting from diagnostic examination or contact lens wear, however any steps that can further reduce the potential risk are to be encouraged. The use of single use instruments (e.g. tonometer prisms) or contact lenses is recommended for use on those designated “at increased risk” of CJD or vCJD. The practice of single-use instruments or contact lenses for examination should be encouraged for other patients where cost and quality are acceptable. If re-usable instruments or contact lenses are used, it is imperative that they are cleaned and decontaminated in an acceptable and consistent way, in accordance with [“Transmission spongiform encephalopathy agents : safe working and the prevention of infection” - Annex L](#). The practice of decontaminating tonometers with alcohol wipes is not sufficient and may, in fact, fix prion material to the surface of the instrument.

### 9.9 Use of laser for tonsillectomy - smoke plumes

Some ENT surgeons may use laser techniques for tonsillectomy. There is no evidence of transmission of TSEs by the respiratory route. Any risk from smoke plumes is thought to be very low, but there are no data on vCJD.

### 9.10 Decontamination of Endoscopes

The general procedures set out in [Choice Framework for Local Policy and Procedures 01-06 – Decontamination of flexible endoscopes: Policy and Management \(CFPP 01-06\)](#) and the

updated [BSG Guidelines for Decontamination of Endoscopes for Gastrointestinal Endoscopy](#), should be followed. Additional precautions for the decontamination of flexible endoscopes used in all patients with definite, probable or possible CJD/vCJD and those identified as “at increased risk” are recommended – see tables 5 and 6 below.

Channel cleaning brushes and, if biopsy forceps or other accessories have been passed, the rubber valve on the biopsy/instrument channel port should be disposed of as clinical waste after each use. Single-use (disposable) biopsy forceps should be used routinely in all patients. BSG guidelines advice that endoscope accessories should be single-use wherever possible. It is essential to have systems that enable endoscopes, together with all their detachable components and any re-used accessories, to be traced to the patients on whom they have been used.

Endoscopes used for certain procedures in the CNS and nasal cavity in individuals with CJD/vCJD, or in whom the diagnosis is unclear, should be removed from use or quarantined pending diagnosis.

Endoscopes, other than those used in the CNS and nasal cavity, which have been used for **invasive** procedures in most individuals designated as “at increased risk” of vCJD can be decontaminated to the standards set out in CFPP 01-06 and the BSG guidelines and returned to use. The endoscope should be put through all the normal stages of cleaning and be disinfected separately from other equipment in an automated endoscope washer disinfectant (EWD).

Aldehyde disinfectants with fixative qualities (such as glutaraldehyde and OPA) tend to stabilise rather than inactivate prions and are no longer recommended for use in the UK.

When decontaminating the endoscope cleaning equipment the EWD should be put through an “empty” self-disinfection cycle. Provided the cleaning equipment is decontaminated as indicated, there is no known risk of transmission of TSE agents via this route.

Following use in patients at risk of vCJD endoscopic accessories (including normally reusable devices such as heater probes) and cleaning aids such as brushes should be disposed of by incineration.

**Table 4. Summary of precautions advised for use of endoscopes – CJD other than vCJD**

Tissue infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/ probable	Possible/ diagnosis unclear <sup>1</sup>	At risk iatrogenic/inherited
<b>High</b> <ul style="list-style-type: none"> <li>• Brain</li> <li>• Spinal cord</li> </ul>	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re-use exclusively on the same patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re-use exclusively on the same patient

<b>Medium</b> <ul style="list-style-type: none"> <li>Olfactory epithelium<sup>3</sup></li> </ul>	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re-use exclusively on the same patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re-use exclusively on same patient
<b>Low/none detectable</b> <ul style="list-style-type: none"> <li>All other tissues</li> </ul>	No special precautions	No special precautions	No special precautions

**Table 5. Summary of precautions advised for endoscopes – vCJD and CJD type uncertain**

Tissue infectivity	Status of patient			
	Symptomatic		Asymptomatic	
	Definite/ probable	Possible vCJD, possible sCJD or diagnosis unclear <sup>1</sup>	At risk (blood recipient <sup>4</sup> from a donor who later developed vCJD)	At risk – other iatrogenic
<b>High</b> <ul style="list-style-type: none"> <li>Brian</li> <li>Spinal cord</li> </ul>	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re-use exclusively on same patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re-use exclusively on same	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re- use exclusively on same
<b>Medium</b> <ul style="list-style-type: none"> <li>Olfactory epithelium<sup>3</sup></li> </ul>	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re-use exclusively on same	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re-use exclusively on same	No special precautions unless contaminated with olfactory epithelium <sup>3</sup> when: Single use OR Destroy after use OR Quarantine <sup>2</sup> for re- use exclusively on same

<b>Medium</b> <ul style="list-style-type: none"> <li>Lymphoid tissue<sup>5</sup></li> </ul>	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re-use exclusively on same	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine <sup>2</sup> for re-use exclusively on same	No special precautions
<b>Low/none detectable</b> <ul style="list-style-type: none"> <li>All other tissues</li> </ul>	No special precautions	No special precautions	No special precautions	No special precautions

<sup>1</sup>This includes patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD but where a diagnosis of CJD is being actively considered.

<sup>2</sup>Quarantined endoscopes may be re-used exclusively on the same individual patient if required. The endoscope should be fully cleaned and decontaminated (alone using an automatic EWD) immediately after use and quarantined as for surgical instruments (see above).

<sup>3</sup>The advice of the consultant carrying out endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination with olfactory epithelium can be excluded with confidence. If such contamination cannot be excluded, take precautions appropriate for medium infectivity tissue.

<sup>4</sup>A small number of individuals are known to have received labile blood components from a donor who later developed vCJD.

<sup>5</sup>Lymphoid tissue refers to spleen, thymus, tonsils, adenoids, lymph nodes, appendix and gastro- intestinal tract sub-mucosa.

See [“Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection” – Annex F](#). Department of Health for further advice and details of common flexible endoscopic procedures classified as invasive or non-invasive.

### 9.11 Transrectal prostatic biopsy in men at risk of variant CJD

Patients at risk of vCJD requiring transrectal biopsy should have the procedure performed by means of single use equipment that runs alongside (rather than through) the ultrasound probe. If the procedure is undertaken with equipment that has internal biopsy channels, the reusable components should be quarantined after decontamination. It must be accepted that this equipment would be unlikely to return to general use, except for dedicated re-use in the same

patient. For further advice see [“Alert to Urological Surgeons: Transrectal Prostatic Biopsy in Men at Risk of variant CJD”](#)

### 9.12 Dental treatment of patients with, or at risk of CJD or vCJD

The risks of transmission of infection from dental instruments, used for routine dental treatment, are thought to be very low provided optimal standards of infection control and decontamination are maintained. Information for dentists about the management of patients with, or “at increased risk” of CJD/vCJD can be found in [Decontamination Health Technical Memorandum 01-05: Decontamination in primary care dental practices \(March 2013\)](#). This also includes advice for dentists on the re-use of endodontic instruments and vCJD.

### 9.13 List of workers exposed to TSE agents

Control of Substances Hazardous to Health (COSHH) regulations require employers to keep a list of employees who work with TSE agents, such as:

- Staff performing invasive clinical procedures on patients suspected to be suffering from CJD of any type, particularly where there is a risk of exposure to central nervous tissue, eye tissue or other tissues known to contain CJD infectivity.
- Laboratory staff handling tissue specimens from patients with CJD.
- Staff undertaking post-mortem examinations of patients who have died of CJD/vCJD or where CJD/vCJD is suspected.

The information recorded should include the type of work done and, where known, any specific exposure, accident or incident. The list must be kept for 40 years after the last known exposure and may be kept with the individual’s occupational health record.

## 10. AFTER DEATH

On the death of a patient defined in Table 1, the removal of the body from the ward to the mortuary should be carried out using standard infection control measures. A body bag is recommended for transportation to the mortuary, in line with normal procedures where there is a known infection risk, and mortuary staff notified of this risk.

Post-mortem examination may be required to confirm a clinical diagnosis and cause of death in patients with suspected CJD or vCJD. Such procedures have the potential to expose mortuary staff to tissues containing high levels of infectivity and must be discussed with the Consultant Histopathologist and Infection Prevention and Control Team. Detailed guidance is available in [“Minimise transmission risk of CJD and vCJD in healthcare settings” – Annex H. Department of Health; May 2010](#)

The undertakers should be notified of the infection control risk. When the diagnosis of CJD or vCJD is known or suspected it is advisable to avoid embalming procedures. Viewing the deceased, and superficial contact, need not be discouraged even if a post-mortem has taken place. See [\(PAT/T 60 v.1 \(amended\)\)](#).

## 11. TRAINING/ SUPPORT

The training requirements of all staff will be identified through a training needs analysis. Role specific education will be delivered by the service lead or nominated person.

Infection Prevention and Control must be included in individual Annual Development Appraisal and any training needs for IPC addressed.

## 12. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
The policy will be reviewed in the following circumstances:-	APD Process Group  IPCT	Every three years routinely, unless: <ul style="list-style-type: none"> <li>• When new national or international guidance are received.</li> <li>• When newly published evidence demonstrates need for change to current practice.</li> <li>• Action required from Root Cause Analysis Serious Incident Investigation Report.</li> </ul>	Approved Procedural Document (APD) database.  Policy will be approved and ratified by the Infection Prevention and Control Committee.
Compliance with policy to negate cross-infection.	The Infection Prevention and Control Practitioners	Weekly	"Alert organism review" to monitor adherence with the policy.
Training needs for infection prevention and control	Ward and Department Managers  Training and Education Department.	Annually	Staffs Professional Development Appraisal.  Attendance will be captured by the via OLM system.

## 13. DEFINITIONS

- **'at risk'** at increased risk of CJD and vCJD
- **Decontamination** a process which removes or destroys contamination and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response.

- **Definite CJD** an international definition used by the NCJDRSU that refers to the diagnostic status of cases. In definite cases the diagnosis will have been pathologically confirmed, in most cases by post mortem examination of brain tissue (rarely it may be possible to establish a definite diagnosis by brain biopsy while the patient is still alive).
- **Iatrogenic CJD** infection with CJD that occurred as the result of a medical procedure.
- **Standard precaution** underpin all infection prevention and control practice. The precautions must be used for all patients whether they are known to have an infection or not. Universal/standard precautions are a collection of essential practices that when used together will reduce the risk of patients, visitors and staff from developing transmissible infections.
- **Personal Protective Equipment (PPE)** is the equipment that must be worn by HCWs to protect patients and staff against the risk of infection.

## 14. EQUALITY IMPACT ASSESSMENT

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4). (See Appendix 2).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified.

## 15. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

**This policy should be read in conjunction with other Trust Policies and protocols for the prevention and control of HCAI in line with the Health and Social Care Action 2008. In particularly:**

- Hand Hygiene Policy – PAT/IC 5
- Glove usage – CORP/HSFS 13
- Spillages of Blood and Other Body Fluids Policy – PAT/IC 18
- Collection and Handling of Pathology Specimens – PAT/IC 11
- Laundry Policy – PAT/IC 21
- Waste Disposal Policy CORP/HSFS 17
- Trust Mental Capacity Act - PAT/PA 19
- Privacy and Dignity Policy – PAT/PA 28

## 16. REFERENCES

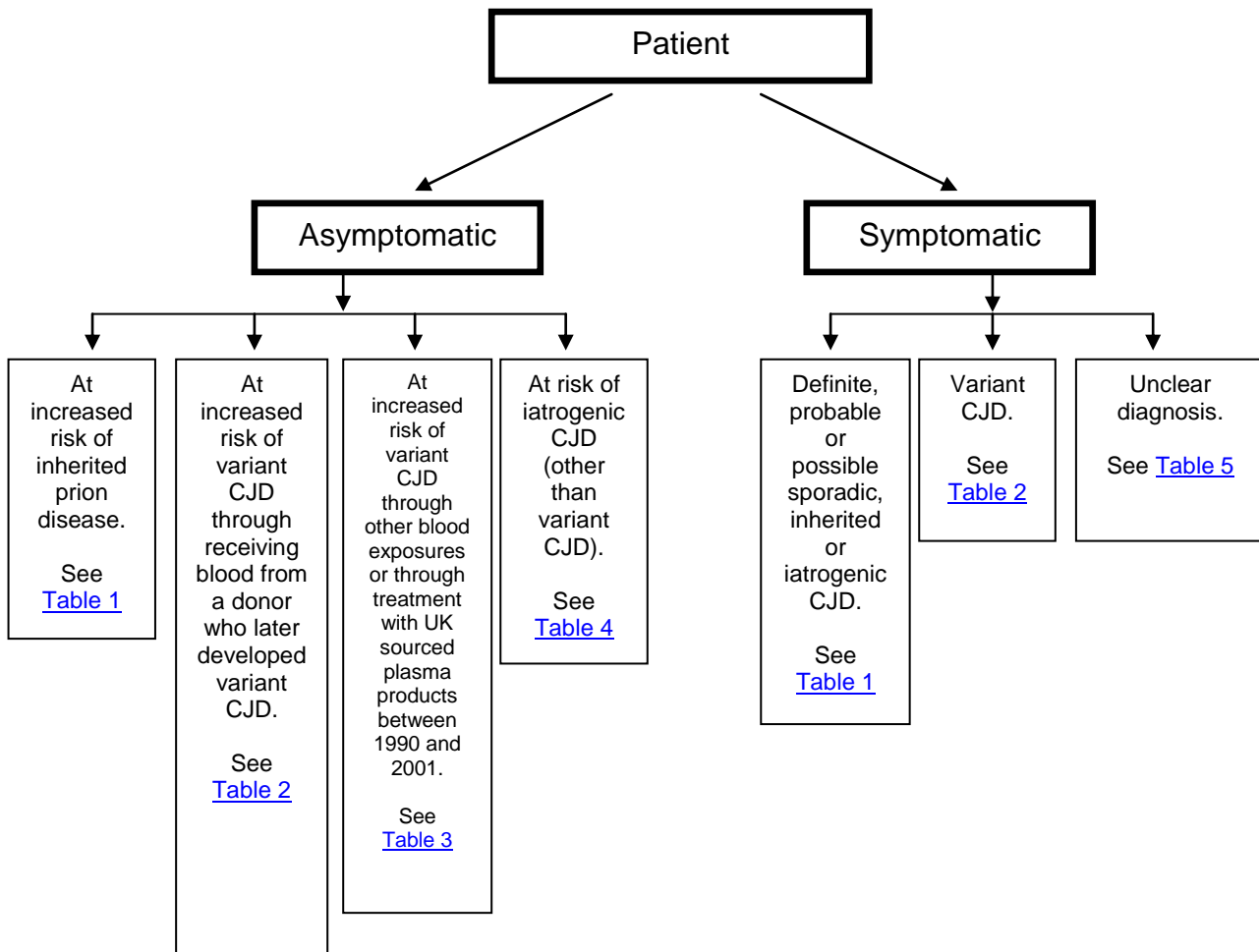
Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection.

Guidance from the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee. Department of Health

TSE guidance: Department of Health - Advisory Committee on Dangerous Pathogens (ACDP)

## APPENDIX 1

Public Health action following a report of a new case of CJD or a person at increased risk of CJD



Information given by:

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/367797/Public\\_health\\_action\\_following\\_a\\_report\\_of\\_a\\_new\\_case\\_of\\_CJD\\_or\\_a\\_person\\_at\\_increased\\_risk\\_of\\_CJD.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/367797/Public_health_action_following_a_report_of_a_new_case_of_CJD_or_a_person_at_increased_risk_of_CJD.pdf)



**APPENDIX 2 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING**

<b>Policy</b>	<b>Care Group/Executive Directorate and Department</b>	<b>Assessor (s)</b>	<b>New or Existing Service or Policy?</b>	<b>Date of Assessment</b>
Variant Creutzfeldt-Jakob Disease (vCJD) and Transmissible Spongiform Encephalopathy Agents (TSE): Minimising the Risks of Transmission – PAT/IC 4 v.5	Corporate Nursing, Infection Prevention & Control	Dr Kenneth Agwuh	Existing policy	05.06.2015
<b>1. Who is responsible for this policy? Infection Prevention &amp; Control</b>				
<b>2. Describe the purpose of the policy? To provide advice on safe working practices to minimise the risk of transmitting transmissible spongiform encephalopathies (TSEs) in a healthcare setting.</b>				
<b>3. Are there any associated objectives? No</b>				
<b>4. What factors contribute or detract from achieving intended outcomes?</b>				
<b>5. Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? No</b>				
<ul style="list-style-type: none"> <li><b>If yes, please describe current or planned activities to address the impact</b></li> </ul>				
<b>6. Is there any scope for new measures which would promote equality? N/A</b>				
<b>7. Are any of the following groups adversely affected by the policy? N/A</b>				
<b>a. Protected Characteristics</b>	<b>Affected?</b>	<b>Impact</b>		
b. Age	No	Neutral		
c. Disability	No	Neutral		
d. Gender	No	Neutral		
e. Gender Reassignment	No	Neutral		
f. Marriage/Civil Partnership	No	Neutral		
g. Maternity/Pregnancy	No	Neutral		
h. Race	No	Neutral		
i. Religion/Belief	No	Neutral		
j. Sexual Orientation	No	Neutral		
<b>8. Provide the Equality Rating of the service/ function/policy /project / strategy</b>				
<b>Outcome 1 ✓</b>	<b>Outcome 2</b>	<b>Outcome 3</b>	<b>Outcome 4</b>	
<b>9. Date for next review June 2021</b>				
<b>Checked by: Beverley Bacon IPCP</b>			<b>Date: 07.06.2018</b>	