Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

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

This procedural document supersedes: Varient Creutzfeldt-Jakob Disease (vCJD) and Transmissible Spongiform Encephalopathy Agents (TSE): Minimising the Risks of Transmission – PATIC 04 v.5

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Amendment Form

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6	October 2022	• Change of terminology from "CJD or vCJD" to "CJD" • Inclusion of proteopathic seed information • Removed reference to CJD Incidents Panel reference due to dissolution	Dr P Morris
5	June 2018	• Updated all hyperlinks • Added Executive Sponsor on front page • Removed audits ward round by Matrons • Added Standard statement from the Educational Department to the training Section	Dr K Agwuh
4	June 2015	• Re-written in new APD format • All sections updated in line with national guidelines	Dr K Agwuh Dr C M Hoy
3	October 2010	• All sections re-written in line with National Guidelines	Dr C M Hoy
2	April 2007	• Policy re-written in conjunction with National Guidelines	Infection Control Team

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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.

Proteins other than prion protein, termed “prion-like,” “prionoid,” or “proteopathic seeds”, can adopt abnormal confirmations, self-propagate, and cause transmissible pathologies and diseases in humans. There are no documented animal or human epidemics or established occupational risks. Examples of “proteopathic seeds” known to associate with human neurodegenerative disease are amyloid-beta peptide and microtubule-associated protein tau.

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.

The use of the term "CJD" in this guidance encompasses sporadic CDJ, sporadic fatal insomnia, variable protease-sensitive prionopathy, vCJD, iatrogenic CJD, genetic CJD, Fatal Familial Insomnia and Gerstmann-Straussler-Scheinker Disease, on order to assist readability.

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 PROCEDURE

There is no evidence that normal social or routine clinical contact of a CJD patient presents a risk to healthcare workers, relatives and others. Isolation of patients with CJD 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 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, 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 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 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.

All people who are "at increased risk" of CJD 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 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

Symptomatic patients	• Patients who fulfil the diagnostic criteria for definite, probable or possible CJD (cases are classified by a neurologist from the National CJD Surveillance Unit – see Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection – Annex B) • Patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD but where the diagnosis of CJD is being actively considered
Patients "at increased risk" from genetic forms of CJD	• Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD • Individuals who have a blood relative known to have a genetic mutation indicative of genetic CJD; • Individuals who have had two or more blood relatives affected by CJD or other prion disease.
Patients "at increased risk" of vCJD through receipt of blood from a donor who later developed vCJD	• 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

Patients identified as "at increased risk" of CJD **through iatrogenic exposures**	• Recipients of hormone derived from human pituitary glands, *e.g*. 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. • 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). • Individuals who have had surgery using instruments that had been used on someone who went on to develop CJD, or was "at increased risk" of CJD • Individuals who have received an organ or tissue from a donor infected with CJD or "at increased risk" of CJD • Individuals who have been identified as having received blood or blood components from 300 or more donors since January 1990 • Individuals who have given blood to someone who went on to develop vCJD • Individuals who have received blood from someone who has also given blood to a patient who went on to develop vCJD • Individuals who have been treated with certain implicated UK sourced plasma products between 1990 and 2001

4.1 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. 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 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 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 can be found at: "Prions and proteopathic seeds: Safe Working and the Prevention of Infection; Laboratory containment and control measures (update November 2021)".

4.2 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)).

4.3 Clinical waste

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

Diagnosis of CJD	High or medium risk tissue*	Low risk tissue and body fluids**
Definite	Incinerate	Normal clinical waste disposal
Probable	Incinerate	Normal clinical waste disposal
"At increased risk"	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 CJD patients is considered low risk except when transfused in large volumes.

4.4 Childbirth

In the event that a patient with, or "at increased risk" of, CJD 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.

4.5 Surgical and endoscopic procedures

A number of individuals have been identified as "at increased risk" of CJD due to a medical or family history conferring increased risk of developing CJD. Arrangements should be in place to ensure that patients who have been notified that they are at increased risk of CJD 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. Department of Health

4.6 Assessment of CJD 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 for public health purposes?"

Patient's response	**Action**
No	Surgery or endoscopy should proceed using normal infection control procedures unless the procedure is likely to lead to contact with high risk tissue.
Yes	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.
Unable to respond	Surgery or endoscopy should proceed using normal infection control procedures **unless** 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

*Refer to explanatory diagrams in Figures J1 & J2 within "Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection" - Annex J. Department of Health

4.7 Additional recommendation 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, 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 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.

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-levels of 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 risk from genetic forms of CJD if they have or have had: i) Genetic testing, which has indicated that they are at significant risk of developing CJD or other prion disease ii) A blood relative known to have a genetic mutation indicative of genetic CJD or other prion disease iii) Two or more blood relatives affected by CJD or other prion disease

2	Have you ever received growth hormone or gonadotrophin treatment? If yes, please specify: i) whether the hormone was derived from human pituitary glands ii) the year of treatment iii) whether the treatment was received in the UK or in another country	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 discontinued in 1985 but human-derived products may have continued to be used in other countries. In the UK, the use of human-derived gonadotrophin was discontinued in 1973 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 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). b) NICE guidance 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

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**	Further investigation should be undertaken to assess the nature of the patient's CJD risk – and this assessment recorded in the patient's notes. If the patient is found to be at increased risk of CJD, 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. If the patient is found to be at increased risk of CJD they should also be referred to their GP, who will need to inform them of their increased risk of CJD and provide them with further information and advice. This is available from the PHE website. Also see "Transmissible spongiform encephalopathy agents : Safe working and the prevention of infection" - Annex J. Department of Health for further advice.
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 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 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.
- Consider whether there is a risk that the patient may be showing early signs of CJD i.e., consider whether the patient may have an undiagnosed neurological disease involving cognitive impairment or ataxia.

4.8 Surgical procedures and instrument management

For all patients with or "at increased risk" of CJD, 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, 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.

4.9 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

4.10 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
- 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. These are also summarised in the algorithm in Appendix 1.

Table 3. Handling instruments – patients with or "at increased risk" of CJD 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**
High Brain Spinal cord Cranial nerves, specifically the entire optic nerve and the intracranial components of the other cranial nerves Cranial ganglia Posterior eye, specifically the posterior hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve Pituitary gland	Single use or Destroy or Quarantine for re-use exclusively on the same patient	Single use or Quarantine for re-use exclusively on the same patient pending diagnosis	Single use or Destroy or Quarantine for re-use exclusively on the same patient
Medium Spinal ganglia Olfactory epithelium Tonsil (vCJD only) Appendix (vCJD only) Spleen (vCJD only) Thymus (vCJD only) Adrenal gland (vCJD only) Lymph nodes and gut associated lymphoid tissues (vCJD only)	Single use or Destroy or Quarantine for re-use exclusively on the same patient	Single use or Quarantine for re-use exclusively on the same patient pending diagnosis	Single use or Destroy or Quarantine for re-use exclusively on the same patient
Low	No special precautions	No special precautions	No special precautions

4.11 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, for use exclusively on the same patient; or
- with a *possible* CJD diagnosis pending confirmation

Single-use instruments should be separated and disposed of by incineration with normal clinical waste. Re-usable instruments that have only come into contact with tissues designated as low infectivity may be decontaminated and returned to routine use.

Instruments that have come into contact with tissues designated as high or medium infectivity 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. The sink does not require high level decontamination afterwards on basis that water has continuously been draining out.

After washing, reusable instruments should be reprocessed through the Sterile Services Department in the usual manner before being quarantined. The reusable instrument set must be tracked though the entire decontamination cycle. 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 indefinitely 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, the box and its contents should be disposed of by incineration. If a definitive alternative diagnosis is confirmed and CJD positively excluded, the instruments may be removed from the box by the responsible person and reprocessed according to best practice and returned to use.

4.12 Decontamination of instruments

Effective decontamination is key to reducing the risk of transmission of CJD 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 "Transmissable 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.

4.13 Managing CJD 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 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 Transmissable 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-1899863525353669states 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 ofinfection" – Annex L.

There have been no known cases of iatrogenic transmission of CJD 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. 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

4.14 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.

4.15 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 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, 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 disinfector (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 edoscopes – CJD other than vCJD

Tissue infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/ probable	**Possible/ diagnosis unclear[1]**	**At risk iatrogenic/inherited**
High • Brain • Spinal cord	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same patient
Medium • Olfactory epithelium[3]	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on same patient
Low/none detectable • All other tissues	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[1]**	**At risk (blood recipient[4] from a donor who later developed vCJD)**	**At risk – other iatrogenic**
High • Brian • Spinal cord	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on same patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on same	Single use OR Destroy after use OR Quarantine[2] for re- use exclusively on same
Medium	Single use OR	Single use OR	Single use OR	No special precautions
• Olfactory epitheliu m3	Destroy after use OR Quarantine2 for re-use exclusively on same	Quaranti ne pending diagnosis	Destroy after use OR Quarantine2 for re-use exclusively on same	contaminate d with olfactory epithelium3 when: Single use OR Destroy after use OR Quarantine2 for re- use exclusively on same
Medium • Lymphoid tissue5	Single use OR Destroy after use OR Quarantine2 for re-use exclusively on same	Single use OR Quaranti ne pending diagnosis	Single use OR Destroy after use OR Quarantine2 for re-use exclusively on same	No special precautions

Low/none detectable • All other tissues	No special precautions	No special precautions	No special precautions	No special precautions

[1]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

[2]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).

[3]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.

[4]A small number of individuals are known to have received labile blood components from a donor who later developed vCJD.

[5]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.

4.16 Transrectal prosatic biopsy in men at risk of 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 samepatient. For further advice see "Alert to Urological Surgeons: Transrectal Prostatic Biopsy in Men at Risk of variant CJD"

4.17 Transrectal prosatic biopsy in men at risk of CJD

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 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.

4.18 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 or where CJD 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.

4.19 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. 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 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)).

PATIENTS LACKING CAPACITY

Sometimes it will be necessary to provide care and treatment to patients who lack the capacity to make decisions related to the content of this policy. In these instances staff must treat the patient in accordance with the Mental Capacity Act 2005 (MCA 2005).

- A person lacking capacity should not be treated in a manner which can be seen as discriminatory.
- Any act done for, or any decision made on behalf of a patient who lacks capacity must be done, or made, in the persons Best Interest.
- Further information can be found in the MCA policy, and the Code of Practice, both available on the Extranet.

There is no single definition of Best Interest. Best Interest is *determined on an individual basis. All factors relevant to the decision must be taken into account, family and friends should be consulted, and the decision should be in the Best interest of the individual. Please see S5 of the MCA code of practice for further information.*

5 TRAINING/SUPPORT

Please note: The training requirements of staff will be identified through a learning needs analysis (LNA). Role specific education will be co-ordinated/ delivered by the topic lead. Alternatively, training may be accessed via an approved e-learning platform where available.

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

6 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: • When new national or international guidance are received. • When newly published evidence demonstrates need for change to current practice. • Action required from Root Cause Analysis Serious Incident Investigation Report.	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.

7 DEFINITIONS

- **'at risk'** at increased risk of CJD
- **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.

8 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

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).

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. (See Appendix 2)

9 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

This policy should be read in conjunction with other Trust policies and protocls for the prevention and control of HCAI in line with the Health and Social Care action 2008. In particulary:

- 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

10 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

11 REFERENCES

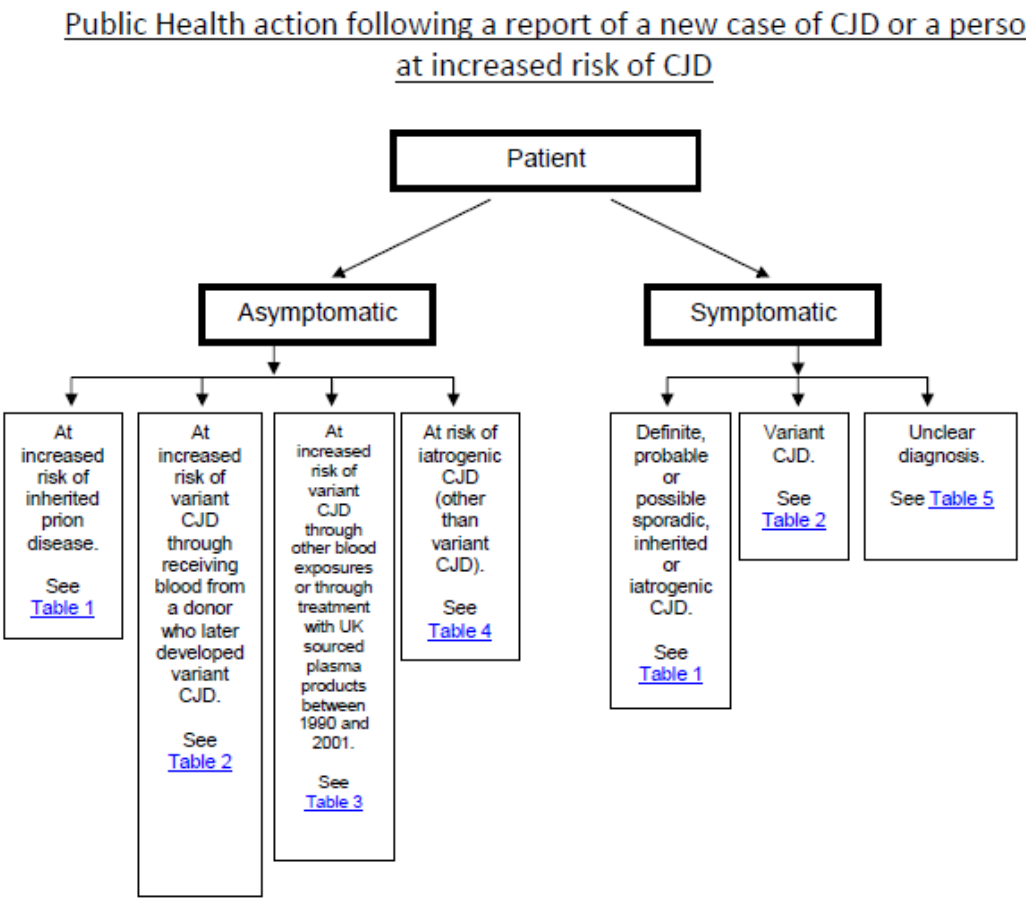
Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection.

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)

Department of Constitutional Affairs Mental Capacity Act (2005): Code of Practice, 2007 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/497253/Mental-capacity-act-code-of-practice

APPENDIX 1 – FLOW CHART FOR NEW CJD CASE



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

APPENDIX 2 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/Strategy	Division	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
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 Paul Morris	Existing policy	18/10/2022

1) **Who is responsible for this policy? Infection Prevention & Control**

2) **Describe the purpose of the service / function / policy / project/ strategy? To provide advice on safe working practices to minimise the risk of transmitting transmissible spongiform encephalopathies (TSEs) in a healthcare setting.**

3) **Are there any associated objectives?** Legislation, targets national expectation, standards: No

4) **What factors contribute or detract from achieving intended outcomes?** – N/A

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

6) **Is there any scope for new measures which would promote equality? N/A**

7) **Are any of the following groups adversely affected by the policy?**

Protected Characteristics	Affected?	Impact
a) Age	No	Neutral
b) Disability	No	Neutral
c) Gender	No	Neutral
d) Gender Reassignment	No	Neutral
e) Marriage/Civil Partnership	No	Neutral
f) Maternity/Pregnancy	No	Neutral
g) Race	No	Neutral
h) Religion/Belief	No	Neutral
i) Sexual Orientation	No	Neutral

8) **Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box**

Outcome 1 (✓)	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form – see CORP/EMP 27.

Date for next review: **October 2025**

Checked by: **Carol Scholey** **Date:** **09/11/2022**