UNIQUE IDENTIFIER NO: C-17-2008
EQUIP-2018-054
Review Date: August 2021
Review Lead: Infection Prevention & Control Doctor & Nurse

NHS
Calderdale and Huddersfield
NHS Foundation Trust

Section O - Creutzfeldt Jacob Disease (CJD) Transmissible Spongiform Encephalopathies

Version 8

Important: This document can only be considered valid when viewed on the Trust's Intranet. If this document has been printed or saved to another location, you must check that the version number on your copy matches that of the document online.

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Document Summary Table			
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Does this document map to other Regulator requirements?			
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DH TSE Guidance	Annex A1 – Distribution of TSE Infectivity in Human Tissues and Body Fluids Annex B – Diagnosis Annex E – Quarantining of surgical instruments Annex F – Endoscopy Annex H After Death Annex J – Assessment to be carried out before surgery and/or endoscopy Annex L – Managing CJD/vCJD risk in Ophthalmology Annex M Managing vCJD risk in general surgery and liver transplantation Part 4 – Infection control of CJD, vCJD and other human prion diseases in healthcare and community settings		

Document Version Control	
8	Routine review and update in line with national guidance.
7	Re-written into a new easier to understand format. All sections updated in line with national guidelines. A quick reference guide has been included.
Amendment July 2015	A new guideline has been added to the policy relating to Managing CJD/vCJD risk in neurosurgery, which has been added as Appendix 8 in this policy.

6	The document has been redesigned to incorporate changes to Annex F, J and Part 4 (all updated in Jan 2014) and to include a new section 'Frequently asked questions' which is around blood transfusion history. A new recently described human prion disease – Variably Protease-Sensitive Prinopathy (VPSPr) is also included. The annex's previously included in appendices have now been hyperlinked to the DH guidance and removed from the policy (they are available in the IPCT dept.)
Version 5	The document has been redesigned to incorporate changes to Annex J, F and Part 4 (all updated in Jan 2013) and to include a new Annex, Annex M which provides specific guidelines for managing vCJD risk in general surgery and liver transplantation (Jan 2013). The Trust Equalities Statement has been updated.
Version 4	The document has been redesigned to incorporate changes to Annex A1 (Jan 2012) and changes agreed by the TSE ADCP in 2011. It has also been updated to include updated local arrangements for the quarantine and decontamination of instruments following surgical and endoscopic procedures (see Appendix 12)
Version 3	The document has been redesigned to ensure that all new and revised procedural documents are set out to a Trust wide format and the content of which includes a minimum set of criteria which include: ▪ the training requirements for implementation ▪ monitoring arrangements for the document ▪ Equality Impact of the document In addition, the monitoring arrangements for this document have been included.

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Contents

Quick reference guide

The guide below is a summary of actions required. This does not negate the need for the document's author and others involved in the process to be aware of and follow the detail of the policy.

1. This policy provides guidance on safe working practices with the aim of preventing the transmission of sporadic CJD, genetic CJD, Fatal Familial Insomnia (FFI), Gerstmann-Straussler-Schneinker Disease (GSS), variant CJD (vCJD) and Variably Protease-Sensitive Prionopathy (VPSPr).

2. Immediately inform the Infection Prevention Control team of any patient admitted who fulfills the possible, definite/probable and ''at increased risk'' category of CJD/vCJD/TSE disease.

3. All patients about to undergo surgery, endoscopy or any other invasive clinical procedure must be assessed as to their risk of CJD or vCJD. See Appendix 2.

4. Specific precautions must be adopted for patients fulfilling the possible, definite/probable, and ''at increased risk'' category of CJD/vCJD/TSE disease who are about to undergo surgery, endoscopy or any other invasive clinical procedure (see section 7.4 of this policy).

5. There is no evidence that normal social or routine contact of a CJD/vCJD patient presents a risk to others. Isolation of a CJD/vCJD patient is not necessary and they can be nursed in an open ward using standard infection prevention control precautions.

6. Blood and body fluids from patients with, or ''at increased risk'' of CJD/vCJD should be treated the same as potentially infectious blood-borne viruses and handled with standard infection prevention control precautions.

7. Specific laboratory control measures must be adopted when working with tissues potentially containing TSE agents. Pathology staff must refer to this guidance when undertaking work with samples possible containing TSE agents (see section 8.2).

8. Specific guidance must be followed with the management of the deceased patient (see section 10)

1. Introduction/Background

Transmissible spongiform encephalopathies (TSEs), sometimes known as prion diseases, are rare, fatal degenerative brain diseases, which occur in humans and certain other animal species. The commonest human TSE is Creutzfeldt-Jacob Disease (CJD). The human TSEs can be divided into three groups:-

- Idiopathic diseases: Sporadic CJD and Sporadic familial insomnia
- Familial diseases: Familial CJD, Gerstmann Straussler Scheinker syndrome (GSS) and Fatal familial insomnia (FFI)
- Acquired diseases: From either human agents (Kuru and Iatrogenic CJD) or bovine agent Variant CJD (vCJD)

Classic (sporadic) CJD occurs worldwide with a frequency of approximately one per million population per annum. vCJD is thought to have resulted from oral exposure to the bovine spongiform encephalopathy (BSE) agent and is currently rare with approximately 178 cases in the UK (source NCJDRSU www.cjd.ed.ac.uk). The abnormal prion proteins are present in certain tissues before patients show any symptoms and some carriers may remain asymptomatic. Consequently there is a risk of contamination of instruments used during invasive procedures such as surgery and endoscopy.

Prions are highly resistant to standard methods of disinfection and sterilisation, and therefore a special approach must be adopted in the care of patients, disposal of clinical waste and handling of surgical instruments and other medical devices.

As non-CJD diseases are extremely rare this guidance will refer to CJD specifically. However the principles and guidance will be the same for other prion diseases.

For almost all routine clinical contact no special precautions are required for the care of patients with or identified as being at risk of developing CJD/vCJD.

However, because all TSEs including CJD and vCJD are resistant to conventional decontamination methods including sterilization, transmission may occur if a surgical instrument or flexible endoscopy, which has been in contact with infected tissues is subsequently reused on another patient. The level of infectivity of various tissues is outlined in Appendix 1.

2. Purpose

To ensure that appropriate procedures are in place to minimize the risk of transmission of CJD/vCJD and other human TSEs in healthcare settings, in line with national guidance.

This policy is based on national guidance from the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee.

3. Definitions

TSEs – Transmissible Spongiform Encephalopathies. This is the collective name for a group of degenerative diseases affecting the central nervous system.

CJD – Creutzfeldt-Jakob disease. The human form of transmissible spongiform encephalopathies, which causes a variety of neurological symptoms. The outcome is invariably fatal.

vCJD – variant Creutzfeldt-Jakob disease. First identified in 1986, thought to be linked to ingesting meat from cattle infected with Bovine Spongiform Encephalopathy (BSE)

Prions – Infectious proteins which do not share the normal properties of viruses or bacteria and are resistant to conventional chemical and physical decontamination methods.

Iatrogenic CJD – a form of CJD which occurs when CJD is accidently transmitted during medical or surgical procedures.

Further information can be found throughout this policy.

4. Duties

All clinical staff: should be aware of CJD/vCJD risk existence and be responsible for ensuring their own practice complies with this policy.

Pre-assessment staff: assessment should be carried out before surgery and/or endoscopy to identify a patient with or at increased risk of CJD/vCJD and inform the clinical team and Infection Prevention Control Team (IPCT) where a risk is identified.

Managers/Clinical Leads/Matrons/Senior Nurses/Nurses in Charge: will ensure **all** patients are assessed for risk of CJD/vCJD at the earliest opportunity as part of routine surgical/endoscopic assessment procedure.

The clinician in charge of the patient: is responsible for accessing the policy and the subsequent overall care and management of a patient with CJD/vCJD or deemed at risk of CJD/vCJD.

Theatre Staff: will ensure they comply with the precautions needed for prevention of iatrogenic CJD/vCJD. Will document in patient records if single use instruments have been used or if reusable instruments have been

incinerated/quarantined/or reused only on the same patient if a patient is either known, suspected or at increased risk of having CJD/vCJD, is operated on.

The Infection Prevention and Control Team: will advise and support clinical teams in taking appropriate infection control measures.

All staff: on wards or departments caring for a patient with CJD/vCJD or deemed at risk of CJD/vCJD have a duty to ensure that they are familiar with the policy.

The Decontamination Manager: is responsible for ensuring that processes around the decontamination and quarantining of instrumentation are effective and safe.

The Trust Decontamination Committee: is responsible for the development of high quality decontamination processes, policy and procedures to ensure that a safe, properly managed and effective decontamination & sterilisation process is adopted for all re-usable medical devices and equipment after and between each patient use. This is an essential element of routine infection control practice. The purpose of which is to provide a governance arrangement for the organisation to ensure effective and safe delivery of decontamination management and mitigation of risk through both internal and external review processes.

The Chief Executive: is responsible for ensuring that there are effective infection prevention and control arrangements in the Trust.

5. Method of Transmission

There are four types of CJD, not all types have the same characteristics and are necessarily transmitted in the same way. In addition, their infectivity varies at different phases of the disease. The risk of transmission is dependent on the type of procedure undertaken and the type of tissue involved.

- Classic or sporadic CJD – this is not thought to be found outside the brain. It is the most common type and its cause is unknown. Subsequent transmission of the prion is thought to be via instruments which have been contaminated by brain tissue or by the transplant of tissue itself e.g. dura mater
- Familial CJD – this type is very rare and is caused by an inherited abnormality in the gene that produces normal protein
- Iatrogenic CJD – can be caused by medical procedures and instruments. It has been shown to be transmitted between patients by procedures such as injections with human pituitary hormones, dura mater grafts, neurosurgical instruments and blood/bloods products

- Variant CJD (vCJD) – It is associated with the same transmissible agent that causes Bovine Spongiform Encephalopathy (BSE) in cattle. Primary infection is thought to be caused by consuming BSE contaminated food products. This prion is found throughout the body in lymphatic system and various organs e.g. tonsils, eyes

6. Diagnosis and Treatment

For symptomatic cases there are internationally accepted diagnostic criteria for definite, probable and possible CJD/vCJD. These are available at: www.advisorybodies.doh.gov.uk/acdp/tseguidance/tseguidance_annexb.pdf

Patients suspected of having CJD/vCJD must be referred to a neurologist or consultant with appropriate expertise for investigation.

The clinical presentation of prion disease includes dementia, personality disorders and neuromuscular symptoms e.g. unsteadiness, involuntary muscular jerking. Diagnosis is difficult and can only be confirmed by histological examination of the brain following brain biopsy or after death. There is currently no non-invasive test which can diagnose CJD during the incubation period and no effective treatment.

6.1 Notification

All cases of clinically suspected CJD of any type should be reported by the clinician caring for the patient to the local Consultant, Health Protection Unit **(Tel: 0113 386 0300)** and the National CJD Surveillance Unit:-

Director, National CJD Surveillance Unit,
Western General Hospital
Crewe Road
Edinburgh, EH4 2XUT
Tel: 0131 332 2117
Fax: 0131 343 1404

7. POLICY DETAILS/COURSE OF ACTION

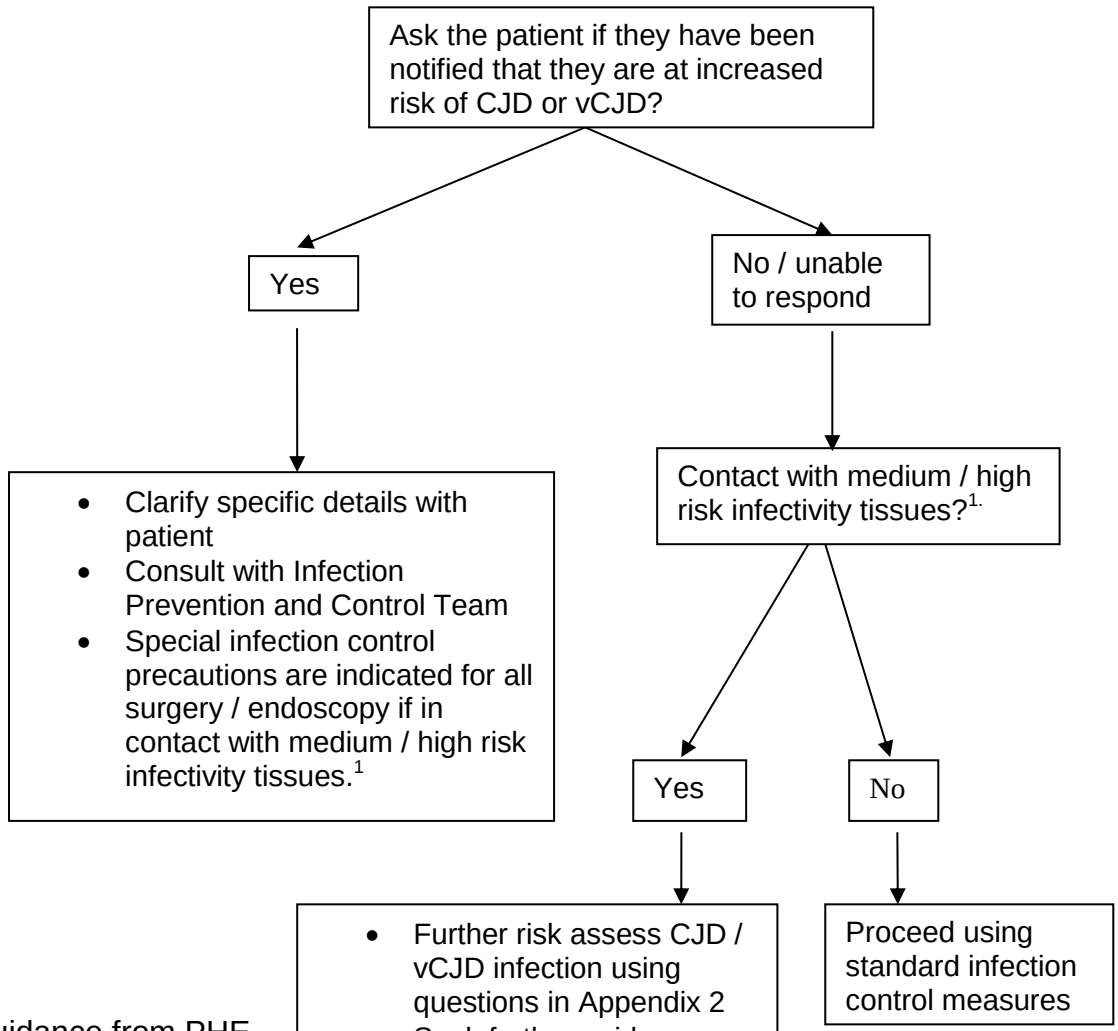
7.1 Patient risk assessment

Identifying patients with or at risk is important to minimize Iatrogenic transmission of these diseases. Risk is determined prior to surgery/endoscopy by either a single question (all patients) or a series of questions (for procedures involving high risk tissues). See Appendix 1.

7.2 Identification and management of patients at risk of TSE

All patients undergoing elective and emergency surgery or endoscopy must be asked whether they have been notified that they are at increased risk of vCJD or CJD see Appendix 2. The response must be documented in the patients' records on Electronic patient record (EPR).

Identification and management of patients at risk of TSE



Guidance from PHE informs us that for where there is no olfactory epithelium, doesn't need to be routine nasendoscopy risk of contact with the the CJD question asked.

7.3 Management of patients known, suspected or at risk of CJD/vCJD

If there is no evidence that TSEs have been spread from person to person by close contact or through occupational exposure, then:

- Inform the IPCT if the patient is going to be or has been admitted
- There is no need to isolate the patient provided standard precautions are followed

Surgical and Endoscopic procedures

The CJD incident panel has identified a number of individuals or groups who are at increased risk of CJD/vCJD. Arrangements should be in place to ensure that patients who have been notified that they are at increased irks 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 question below and reassure patients and provide further information if needed. Information for patients and healthcare professional is available from Public health England:
https://www.gov.uk/government/publications/cjd-information-leaflets-for-patients-and-healthcare-professionals

Also see:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/270735/Annex_J_Assessment_to_be_carried_out_before_surgery_and_or_endoscopy_to_identify_patients_with__or_at_risk_of__CJD_or_vCJD.pdf

7.4 Surgical procedures and instrument management

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

- IPCT must be informed before any surgical procedure is carried out
- Whenever possible the procedures should be carried out in an acute hospital theatre at the end of the list to ensure thorough cleaning of all surfaces before the next session
- Only the minimum number of healthcare personnel should be in the theatre
- Single use protective clothing should be used - a liquid repellent gown; gloves; masks and goggles or a full face visor
- Single use disposable surgical instruments and equipment must be used where possible and incinerated after use
- Where practical, expensive reusable equipment e.g. drills should be protected from contamination by using shields, guards or similar protective covering which should then be destroyed by incineration at the end of the operation. However in practice, effective protective covering may not be feasible and guidance should be sought from the manufacturer
- Drapes contaminated with CSF or other neural tissue from patients in the high and medium risk category should be incinerated

- Advice should be sought from the Decontamination Manager and IPCT on the management of the surgical instruments – see Appendix 3

Where single use instruments are not available, the handling of reusable instruments depends on:

- How likely the patient is to be carrying the infectious agent (the patients risk status)
- Whether the patient has, or is 'at increased risk' of CJD/vCJD

And

- 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

Appendices 1, 3 and 4 separately set out the actions to be taken for instruments/ endoscopes used on patients with, 'at increased risk' of CJD/vCJD. The differences in instrument management are due to differences tissue infectivity.

Ophthalmology

Please refer to specific pre-assessment questions for all ophthalmic patients and the standard operating procedures in Appendix 5 and 6 respectively.

High risk procedures and tissues have been defined as intra-dural operations on the brain and operations on the retina or optic nerve. Although we do not perform neurosurgery within the Trust, operations on the posterior eye are common and the following **must** be observed for all patients undergoing posterior eye surgery.

- Instruments used on the posterior eye must not move from one instrument set to another
- Supplementary instruments previously used in posterior eye procedures must be permanently kept with an instrument set, i.e. supplementary instruments are not acceptable for these procedures
- As a separate pool of new posterior segment surgical instruments should be used for children born since 1997, and who have not previously undergone high risk procedures, it is important to correctly identify patients born since 1st January 1997 and ensure they have had no previous high risk surgery which may have exposed them to the risk of CJD/vCJD
- Alternatively single-use instruments can be used providing they are equal in quality to re-usable instruments and do not pose any increased risk of complications. Single-use instruments which are not similar in quality should not be used

See also Annex L from the TSE guidance for further information on managing risk in ophthalmology:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209770/Annex_L_-_Managing_CJD_vCJD_risk_in_ophthalmology.pdf

Urology patients transurethral prostatic biopsy in men at risk of vCJD

This procedure should be performed using a single use needle with an ultrasound probe that runs alongside it. Under no circumstance should the single use needle be passed through the internal lumen of a reusable ultrasound probe as contamination of the probe would occur and there is no method of rendering this non-infectious.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/270732/Part4_Infection_control_of_CJD__vCJD_and_other_human_prion_diseases_in_healthcare_and_community_settings.pdf

7.5 Complex instrument

Some expensive items of equipment such as drills and operating microscopes, may be prevented from being contaminated by using shield, guards or coverings so that the entire item does not need to be destroyed if used on high risk or medium risk (for 'at increased risk'). However, in practice it may be difficult to ensure effective protective covering.

7.6 Quarantining of surgical instruments

Instruments that come into contact with tissues designated as high or medium infectivity should be kept separate from those that some into contact with tissue designated as low infectivity.

Re-usable instruments that only come into contact with tissues designated as being low infectivity may be decontaminated and returned to routine use.

Re-usable instruments that come into contact with high or medium infectivity should be managed in accordance with the **Quarantine and decontamination guidelines** Appendix 3 and 4.

7.7 Identification of possible CJD diagnosis after admission/treatment

Where it becomes know, after admission, that a patient may have CJD/vCJD, advice must be sought immediately from the ICD and IPCT and the patient's consultant.

Any reusable surgical instruments/endoscopes used for such a patient must be identified immediately and withdrawn and quarantined from use for other patients pending further guidance Appendix 4.

Having sought advice, there should be an agreement of a reasonable probability of diagnosis of CJD. Management of instruments should follow guidance given for 'at increased risk' patients.

7.8 Look-back exercise

Where there is a possibility that a patient could have been exposed to CJD/vCJD through contaminated surgical instruments that were previously used on a patient with or 'at increased risk' of CJD/vCJD, the IPCT must be informed. A look-back exercise may be required. Advice will be given by the ICD, the local Health Protection Unit; the National Incident Panel will also be contacted for advice.

7.9 Tracing of Instruments

To enable a 'look-back' to be effective, every individual instrument set must be uniquely numbered to enable it to be withdrawn from a cohort of sets of the same name. It is essential the tracing system is efficiently managed and easily interrogated; records should be retained for at least 11 years.

8. General Management of CJD Patient

There is no evidence to suggest that normal, social or routine clinical contact with a CJD/vCJD patient presents a risk to healthcare workers, relatives and others in the community. Isolation of patient with CJD/vCJD **is not** necessary, and s/he may be nursed in an open ward using standard infection control precautions.

8.1 Handling of Blood and Body Fluids

At present, there is no evidence of infectivity in saliva, body secretions or excreta. Any potential exposure to body fluids should be handled as for any other patient i.e. treated as potentially infectious in line with standard precautions.

Careful attention to standard infection control precautions will minimise any risk from blood and body fluids. Care must be taken to avoid sharps/splash injuries. If injury occurs, the normal procedure should be followed as in the Section M.
https://intranet.cht.nhs.uk/chft-documentation/view-document.php?docID=489

8.2 Sample taking and other invasive medical procedures

Blood, biopsy and lumbar puncture samples are classified as 'high risk' and must be performed using single-use equipment and performed only by personnel skilled in undertaking such procedures. Appropriate PPE must be worn and particular care should be taken with lymphoid tissue:

- Blood specimens should be collected using ANTT and standard precautions as for any patient; PPE - gloves and aprons
- All lumbar punctures should be carried out wearing disposable gloves and aprons: eye protection should be worn if there is a possibility of inoculation from splashing)
- Only single-use disposable instruments must be used
- Disposable drapes (to catch any blood spill)
- All waste to be disposed as clinical waste https://intranet.cht.nhs.uk/chft-documentation/view-document.php?docID=849
- Linen contaminated with CSF or neural tissue from patients in the high and medium risk category should be disposed of as clinical waste (as above)
- Samples from patients with or 'at increased risk' of CJD/vCJD should be classed as Hazard Group 3, should be labelled with an 'Infection Risk' label and the laboratory informed in advance of the sample being sent. Further details can be found in Section R. https://intranet.cht.nhs.uk/chft-documentation/view-document.php?docID=490

8.3 Inoculation injuries

For any incident involving 'sharps', or contamination of abrasions with blood or body fluids please follow Section M. https://intranet.cht.nhs.uk/chft-documentation/view-document.php?docID=489

8.4 Surface decontamination and spillages

Standard infection control precautions should be followed following a spillage of blood or body fluids occur which should be cleared up as quickly as possible. Spillage kits should be used rather than standard chlorine based solution. Wards or areas with suspected, confirmed or 'at increased risk' of CJD/vCJD should have the kits available. *Order details for spillage kits can be found on the Infection Control Consumables list in the IPC section of the Trust intranet.* Any waste, including cleaning materials such as disposable mop heads, should be disposed of as clinical waste (see waste policy).

8.5 Clinical waste

In the ward setting the majority of clinical waste will be low risk and can be disposed of according to standard Trust policy. High or medium risk tissues and objects contaminated with high or medium risk tissues should be bagged in yellow bags or placed in a rigid container with a yellow leak proof lid and sent for incineration in accordance with the Trust waste policy. https://intranet.cht.nhs.uk/chft-documentation/view-document.php?docID=849

Disposal of clinical waste from patients with, or ‘’at increased risk’’ of CJD/vCJD

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 **

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

*** ‘Normal Clinical waste disposal’ now would be disposed of as **’Orange’** waste*
Please refer to Annex A1 for tissue infectivity risk which can be found at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209759/Annex_A1_-_Distribution_of_TSE_infectivity.pdf

8.6 Bed linen

Used or foul linen (contaminated with blood or body fluids) – should be placed in a water soluble alginate bag (Red), then placed in a clear laundry bag. The linen can be washed in accordance with the linen & laundry management policy.
https://intranet.cht.nhs.uk/chft-documentation/view-document.php?docID=716

Linen contaminated with CSF or neural tissue from patients with suspected or confirmed CJD/vCJD or those ‘at increased risk’, must be disposed of a clinical waste.

8.7 Maternity 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.

8.8 Dental care

This should not be compromised. DH guidance is that endodontic reamers, files and other fine instruments which are difficult to clean are single use. This was endorsed by the chief Dental Office for England in April 2007.

8.9 Caring for the patient in the community

No special measures over and above standard infection control precautions are necessary.

9. Organ Transplants

To minimise the risk of transmission of CJD/vCJD, organ donations should be rejected from patients with definite, probable or possible CJD/vCJD; those with degenerative neurological conditions of unknown cause and patients classified as 'at risk' from CJD/vCJD.

10. Blood Transfusions

It is important to note that highly transfused patients (300+ donor exposures) are still considered 'at increased risk' of vCJD. If it is known that the patient has received blood from 300 or more donors then they should be considered 'at increased risk' of CJD. See appendix 7. However, if this information is not known at the time of surgery then there is no need to investigate any further.

11. Management of the Deceased Patient

If the patient is known or suspected of having a TSE the mortuary must be informed. The removal of the deceased to the mortuary should be carried out using normal infection control procedures. It is recommended that a body bag is used which should be labelled 'Infection risk' in line with guidance which can be found in Section P.
http://nww.cht.nhs.uk/fileadmin/uploads/divisions/diag_thera/infection_control/policies/Section_P_-_Care_of_the_Deceased_Version_7.pdf

For further information refer to Annex H After Death.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209766/Annex_H_-_After_death.pdf

12. Training and Implementation

Training will be carried out to all relevant Trust staff by the Infection Prevention and Control Team through targeted training sessions to key personnel, who will then cascade the information to appropriate colleagues within their area/department. Areas to include will be surgical pre-assessment, ophthalmic dept., endoscopy and acute surgical staff.

13. Trust Equalities Statement

Calderdale and Huddersfield NHS Foundation 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 placed at a disadvantage over others. We therefore aim to ensure that in both employment and services no individual is discriminated against by reason of their gender, gender reassignment, race, disability, age, sexual orientation, religion or religious/philosophical belief, marital status or civil partnerships.

This policy has been through the Trust's EQUIP (Equality Impact Assessment Process) to assess the effects that it is likely to have on people from different protected groups, as defined in the Equality Act 2010.

14. Monitoring Compliance with this Procedural Document

An annual audit of the policy will be undertaken by the IPCT. The results of this audit will be reported to the Infection, Prevention and Control Committee and subsequently to the Executive Board.

15. Associated Documents

This policy should be read in conjunction with the following policies:

Guidance from the ACDP TSE Risk Management Subgroup (formerly TSE Working Group) this can be found at:
https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group
In particular (all of the below Annexes are hyperlinked throughout the policy):
Annex A1 – Distribution of TSE Infectivity in Human Tissues and Body Fluids
Annex B – Diagnosis of TSEs
Annex E – Quarantining of surgical instruments
Annex F – Endoscopy updated October 2015
Annex J – Assessment to be carried out before surgery and/or endoscopy (revised and updated August 2017)
Annex H – After Death
Annex L – Managing CJD/vCJD risk in Ophthalmology
Annex M - Managing vCJD risk in General Surgery and liver transplantation)
Part 4 – Part 4 – Infection control of CJD, vCJD and other human prion diseases in healthcare and community settings (updated Jan 2014)
CHT guidance 'Procedure for the Quarantine of Medium/High Risk TSE Instrumentation' (Appendix 4 of this policy)
Frequently asked questions (related to blood transfusion history) (New Jan 2014)

16. References

Guidance from the ACDP TSE Risk Management Subgroup (formerly TSE Working Group) this can be found at:
https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

APPENDIX 1

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

	Status pof patient		
Tissue infectivity	**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) 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

APPENDIX 2

CJD risk assessment questions for patients about to undergo surgical or neuro-endoscopic procedures likely to involve contact with high risk tissue (including high risk posterior segment eye surgery)
The patient's response should be documented in their medical records (EPR) for future reference

1 *Have you any history of CJD or other prion disease in your family? If yes, please specify*	Notes to clinician Patients should be considered to be at risk from genetic forms of CJD if they have or have had 1. Genetic testing, which has indicated they are at significant risk of developing CJD or other prion disease 2. A blood relative known to have a genetic mutation indicative of genetic CJD or other prion disease 3. Two or more blood relatives affected by CJD or other prion disease If the patient answers No or Not certain to all 3 of these questions then surgery can proceed with normal infection prevention and control procedures.
2. *Have you ever received growth hormone or gonadotrophic treatment? If yes, please specify;* *i) Whether the hormone was derived from human pituitary glands* *ii) The year of the treatment* *iii) Whether the treatment was received in the UK or in another country*	Notes to clinician Recipients of hormone derived from human pituitary glands e.g. growth hormone or gonadtotrophin, are at increased risk of CJD. In the UK, the use of human growth hormone was stopped in 1985 but human-derived products may have been continued to be used in other countries. In the UK, the use of human-derived gonadotrophin was discontinued in 1973 but may have been continued in other countries after this time. Appendix ? J1 provides clarification of the actions needed if a patient is a recipient of growth hormone or gonadotrophin treatment.
3. *Have you ever had surgery on your brain or spinal cord?*	Notes to clinician Individuals who underwent intradural brain or intradural spinal surgery 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).

Quarantine and Decontamination guidelines for medium and high risk TSE Instrumentation

These guidelines are for medium and high risk tissue only (see Appendix 1). Please refer to the remainder of the TSE policy and follow normal infection prevention and control guidelines for low risk tissue infectivity.

1. Where possible the instruments should be single use.
2. A theatre should be allocated on the day (in the case of elective surgery) or prior to the procedure (in the case of an emergency) which, should where possible, be undertaken at the end of the list.
3. The allocated theatre must then not be used until the whole of the theatre has been terminally cleaned with a chlorine based solution (includes scrub room, setting up room, theatre and dirty utility room).
4. If a patient is suspected to have CJD/vCJD then the surgical equipment will need to be quarantined "dirty" post procedure until such time as a diagnosis is determined and, if the result is negative the equipment can be sent to B Braun and reprocessed in the normal way. If the results are positive, the equipment along with the container must be destroyed. For endoscopes these should be **cleaned prior to quarantining**
5. For quarantining of surgical instruments, the instruments should be placed in an impervious rigid plastic container with a close-fitting lid (TSE UN approved container). The TSE container is available from theatres on both sites and Endoscopy units on both sites. The TSE container must be labelled with a designated form (see appendix 11). The TSE container should be transferred and stored in a locked designated cupboard/room (HRI site) and should be kept until a decision has been made on the fate of the instruments.
9. Quarantining of endoscopes: these should be cleaned separately first via the normal procedures (see section 7.6 of this policy and Annex F of the TSE guidance and then stored **vertically in a cupboard in a locked room in theatre** until a decision has been made on the fate of the endoscope**.** The endoscope can be transported via the rigid TSE UN container and then be placed into the cupboard in the locked room in theatre HRI. Please ensure that the cupboard is cleaned prior to and on removal of the endoscope. The information about the patient and procedure etc. should be kept in the folder in the locked room (see appendix 11 for a copy of the form).
10. A record should be kept in the patients notes with all of the above information (see appendix 11). A copy of this form should also be kept with the infection prevention and control department.
11. For surgical instruments: if the diagnosis is "CJD or vCJD" or there is no definitive diagnosis possible but CJD or vCJD cannot be excluded, the instruments - including the container should be destroyed by incineration.
12. For endoscopes: if the diagnosis is "CJD or vCJD" or there is no definitive diagnosis possible but CJD or vCJD cannot be excluded, **further discussions are required with the Infection Prevention and Control team as to the fate of the endoscope.**
13. Any equipment destroyed should also be recorded and dated.
14. **Please note that during this current arrangement for quarantine and decontamination of surgical instruments, they cannot be reused on the same patient as they are unable to be re-processed. However this may not be the case for endoscopes – please see bullet point 12**
15. If a definite diagnosis of "**not** CJD or **not** vCJD" is made, the Decontamination Manager will be informed. The instruments and endoscope will then be made available for reprocessing and re-use and B Braun should be contacted to collect the instruments. In the case of endoscopes, they will then need to be reprocessed and the storage cupboard in the locked room in theatre cleaned following the removal of the endoscope.

APPENDIX 4

Possible risk of CJD/vCJD Quarantine of instruments form

Patient Name: …… Hospital Number: …….

Date of Admission:…… Hospital:……..Ward:……..

Status of patient (definite, possible, probable, at risk)…… …..

Date of Procedure: ……

Site (CRH/HRI)……..Theatre/Endoscopy …….

Theatre/Room number……

Name of lead nurse……Surgeon/Doctor…….....

Equipment quarantined: ……..

Date quarantined:…….

Equipment Tracking number:…….....
……..

Endoscopes should be stored vertically in designated cupboard in quarantine room in main theatre HRI

Form completed by:

Name: ……..... Signature: ……..

Date: ……..... Time: ……

Details entered into audit book in theatre Date……..

Please file original in patient notes; a sticky labeled copy on UN container (if theatre instruments); a copy in designated section of cupboard if endoscope
Copy in theatre quarantine room in folder and a copy to be sent to Infection Control

Infection Prevention and Control (IPCN) aware Yes/No

Name of IPCN…… Date notified……

Infection prevention and Control use only
Data entered onto data base (IPCT data base)……Name……..…
Eventual Outcome:
Quarantine discontinued
Equipment sent for incineration
Equipment kept for same patient use…….. Storage area……..
(Please indicate one of the above)
Reason for above decision…… ..
Theatre/Endoscopy aware Yes/No Date:……

APPENDIX 5

Questions to ask for all Ophthalmic surgery

CJD Risk Assessment questions for ophthalmic patients

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

For all ophthalmic surgery please also ask the following questions:

7. Have you a history of CJD or other prion disease in your family?

8. Have you ever received growth hormone or gonadotrophin treatment?

9. Have you ever had surgery on your brain or spinal cord?

If the answer is YES to any of these 4 questions please obtain further information and refer to the CJD (TSE) policy and Annex J and contact Infection prevention and control for further advice.

NB. There no longer is a 4th question asking about blood transfusion history in this second group of questions. However as of January 2014 the ACDP recommend that if patients present with a blood disorder history (information from patient notes or the patient themselves) then staff should ask about blood transfusion history. Please see 'frequently asked questions' from the ACDP in the CJD policy. Please contact Infection Prevention and Control for further advice if required.

Please also add a copy of this appendix into the patients notes once answered if not part of pre-assessment documentation

APPENDIX 6

Calderdale and Huddersfield NHS Foundation Trust

Standard Operating procedure for Ophthalmic pre-assessment in relation to CJD or vCJD whether this is via OPD or Pre-assessment

NB This is for both general and local anaesthetics as in terms of CJD/vCJD it is the instruments in relation to risk and not the type of anaesthetic

1. Please ask **all** of the questions set out below
2. If answers are no to all the questions – proceed with normal infection prevention and control precautions.
3. If the patient answers yes to any of the questions please clarify and obtain further information and then discuss with the Infection prevention and control team (IPCT).
4. If the decision from the IPCT is that there is no increased risk in terms of CJD or vCJD then the procedure can go ahead with normal infection prevention and control precautions
5. If there is deemed to be a risk, theatres need to be informed and single use items used where possible. If there is **any contact with posterior eye** during the procedure then the instruments will need to be **destroyed** - Currently instruments that are deemed medium or high risk re infectivity need to be destroyed as they **cannot** be reprocessed for use on the same patient. Please refer to the CJD policy for further information.
6. Please inform the IPCT if the instruments have to be destroyed and document in the notes that the instruments have been destroyed.

CJD Risk Assessment questions for ophthalmic patients

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

For all ophthalmic surgery please also ask the following questions:

10. Have you a history of CJD or other prion disease in your family
11. Have you ever received growth hormone or gonadotrophin treatment?
12. Have you ever had surgery on your brain or spinal cord?

If the answer is YES to any of these questions please obtain further information and refer to the CJD (TSE) policy and contact Infection prevention and control for further advice

NB. There is no longer a 4th question asking about blood transfusion history in this second group of questions. However as of January 2014 the ACDP recommends that if patients present with a blood disorder history (information from patient notes or the patient themselves) then staff should ask about blood transfusion history. Please see 'frequently asked questions' from the ACDP in the CJD policy. Please contact Infection Prevention and Control for further advice if required.