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3						

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1 Introduction

Transmissible spongiform encephalopathies (TSEs) also known as prion diseases, are rare, fatal, degenerative diseases affecting the central nervous system of humans and other mammals. Human TSEs include Creutzfeldt-Jacob Disease (CJD) and variant CJD. They are caused by unconventional infectious agents known as prions, which are highly resistant to conventional decontamination processes.

The Health and Social Care Act (2008) Code of Practice on the prevention and control of infections and related guidance requires all Trusts to have clear arrangements for the effective prevention, detection and control of Healthcare Associated Infection (HCAI), including TSE.

National guidance on safe working and the prevention of infection by TSE is regularly updated on the Department of Health (DH) website. This policy is based upon this guidance which can be found at

Guidance to Minimise transmission risk of CJD and vCJD in healthcare settings.

2 Purpose

The purpose of this policy is to ensure effective arrangements are in place for the management of patients in risk groups for TSE and care of patients with known or suspected TSE to reduce the risk of transmission of the infection.

3 Definitions

TSE – a group of rare, degenerative and fatal brain diseases which occur in humans and some other animal species.

CJD – a human form of TSE causing a variety of neurological symptoms including dementia and personality changes among other. At present the outcome is invariably fatal; only limited symptomatic treatment is currently available.

vCJD – a form of CJD first identified in 1996, initially thought to be linked to ingestion meat from cattle infected with Bovine Spongiform Encephalopathy [BSE].

Familial CJD – a form of CJD with confirmed abnormality in the gene that produces normal prion protein; often with a family history of a degenerative central nervous system disease.

latrogenic CJD – a form of CJD which occurs when CJD is accidentally transmitted during surgical/medical procedures – could be both classic CJD and vCJD.

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

4 Duties

4.1 Responsibility for Infection Prevention and Control (IPC) outside the immediate scope of this policy

For duties and responsibilities for IPC practices outside the specific scope of this policy, please refer to the IPC Arrangements and Responsibilities Policy on the Staff Zone SCHT Staff Zone (shropcom.nhs.uk).

4.2 IPC Duties specific to this policy

4.2.1 Clinical Staff

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

4.2.2 Pre-Assessment Staff

Assessment should be carried out before surgery and/orendoscopy to identify a patient with or at increased risk of CJD/vCJD and inform the clinical team and Infection Control Team where a risk is identified.

4.2.3 The admitting clinician/Consultant

Will consider the possibility of CJD/vCJD in all patients undergoing surgery or endoscopy involving high or medium risk tissue and check medical notes/referral letter for any mention of CJD/vCJD status. The consultant carrying out the endoscopic procedure in the nasal cavity should determine whether a risk of contamination of the endoscope with olfactory epithelium can be excluded with confidence.

4.2.4 Theatre and Dental staff

Will ensure they comply with the precautions needed for prevention of iatrogenic CJD/vCJD. Will ensure that instrument documentation labels are placed in the patient's records following all surgical procedures. Will document in patients' records if single use instruments have been used or reusable instruments have been incinerated/or reused only on the same patient if a patient who is either known, suspected or at increased risk for public health purposes of having CJD/vCJD, is operated on.

4.2.5 Managers/Clinical Leads/Seniors Sisters/Nurses in charge

Will ensure all patients are assessed for risk of CJD/vCJD at the earliest opportunity as part of the routine surgical / endoscopic assessment procedure.

4.2.6 Infection Prevention and Control Team

Will advise and support clinical teams in taking appropriate infection control measures

5 Patient Risk Assessment

Identifying patients with or at risk of TSE is important to minimise iatrogenic transmission of these diseases.

5.1 Patients with suspected CJD/vCJD

A definitive diagnosis of TSE/CJD can only be made by brain biopsy, usually post-mortem. For this reason, patients with neurological symptoms resembling TSE are classified as probable or possible CJD or vCJD. The diagnosis of CJD/vCJD is beyond the scope of this policy, case definitions only are provided inAnnex B of the national guidance Annex B (publishing.service.gov.uk) Patients suspected of having CJD or vCJD must be referred to a neurologist, or consultant with appropriate expertise for investigation.

All cases of confirmed or suspected CJD must be notified to the Infection Control Doctor or Consultant Microbiologist (via switchboard). The clinical team and microbiologist must also ensure that both the National CJD Surveillance Unit and local Health Protection Unit are notified. Invasive procedures should not be carried out on such patients until prior discussion with the IPCT has taken place.

5.2 Risk assessment before surgical procedure or endoscopy

Identifying patients with or at risk of TSE is important to minimise iatrogenic transmission of these diseases.

5.2.1 All patients undergoing surgery or endoscopy

ALL patients about to undergo any surgery or endoscopy should be asked if they have ever been notified as at increased risk of CJD or vCJD; See annex J of the national guidance

ANNEX J - PRE-SURGERY ASSESSMENT TO IDENTIFY PATIENTS WITH, OR AT RISK OF, CJD (publishing.service.gov.uk).

The response should be documented in the patients' notes.

If the patient:

- has NOT been notified as at increased risk of CJD or vCJD
- AND is NOT suspected of having a Transmissible Spongiform Encephalopathy
- AND is NOT undergoing a procedure on high risk tissue (see Table 1)

then no further investigations or specific precautions are indicated.

If the patient HAS been notified as at increased risk of CJD or vCJD:

- Ask the patient to explain further the reason they were notified.
- At risk patients will require special infection control precautions to be taken for surgery or endoscopy involving contact with medium or high risk tissues (See annex F <u>Annex F: Endoscopy (publishing.service.gov.uk)</u>).
- It should be noted that surgical procedures undertaken with the community trust are unlikely to be classified as at High risk.
- Endoscopy procedures which may involve contact with high risk tissues may be performed within the Trust (see annex F of the national guidance <u>Annex F:</u> <u>Endoscopy (publishing.service.gov.uk)</u>
- The IPCT and Microbiologist should be consulted for advice.

Appendix B in the above annex contains information which can be given to these patients to explain why these questions are being asked.

5.3 Infection prevention and control precautions

In most routine clinical contact, no additional precautions are needed for the care of patients in the "increased risk" patient groups. However, when certain **invasive** interventions are performed, there is the potential for exposure to the agents of TSEs. In these situations it is essential that control measures are in place to prevent iatrogenic CJD/vCJD transmission. All people who are "at increased risk" of CJD/vCJD are asked to help prevent any further possible transmission to other patients by following this advice:

- Do not donate blood. No-one who is "at increased risk" of CJD/vCJD, or who has received blood donated in the United Kingdom since 1980, should donate blood.
- Do not donate organs or tissues, including bone marrow, sperm, eggs or breast milk.
- If you are going to have any medical, dental or surgical procedures, tell whoever is treating you beforehand so they can make special arrangements for the instruments used to treat you if you need certain types of surgery or investigation.
- You are advised to tell your family about your increased risk. Your family can tell the
 people who are treating you about your increased risk of CJD/vCJD if you need
 medical or surgical procedures in the future and you are unable to tell them yourself.

Annex B - Diagnostic Criteria

This guidance categorises CJD patients in descending order of risk, distinguishing between symptomatic and asymptomatic patients. Symptomatic patients are those who fulfil the internationally accepted diagnostic criteria, set out below, for definite, probable and possible CJD or vCJD.

Click here for link to Annex B

Annex L – Managing CJD/vCJD in Ophthalmology

This link contains advice on the precautions to be taken for ophthalmic procedures on patients with, or "at increased risk" of, CJD.

Click here for link to Annex L

6 Hospital care of CJD/vCJD patients

There is no evidence to suggest that CJD/vCJD are spread from person-to-person by close contact. Isolation of patients with CJD/vCJD is not necessary; they can be nursed in an open ward using standard infection control precautions in line with those used for all other patients.

7 Diagnostic samples

Body secretions, body fluids (including saliva, blood, CSF and excreta) are all low risk for CJD/vCJD. It is therefore likely that the majority of samples taken or procedures performed will be low risk. Contact with small volumes of blood (including inoculation injury) is considered low risk, though it is known that transfusion of large volumes of blood and blood components may lead to vCJD transmission.

Blood and body fluid samples from patients with, or "at increased risk" of, CJD/vCJD, should be treated as potentially infectious for blood-borne viruses and handled with standard infection prevention and control precautions as for any other patient, i.e.:

- Use of disposable apron, disposable gloves and eye protection where splashing may occur.
- Avoidance of sharps injuries and other forms of parenteral exposure.
- Safe disposal of sharps by incineration in a yellow lidded sharps container. It
 is best if a separate container is kept for the patient.
- Contaminated waste disposed of in line with Waste Management Policy (see section 6.2.4).
- Single-use disposable equipment should be used wherever practicable.

Specimens must be placed in leak-proof containers and securely capped. The container must be placed in the sealed compartment of a double-compartment plastic bag, with the form in a separate pocket. The form must be labelled 'Danger of Infection' and the diagnosis of CJD or "at increased risk of CJD/vCJD" must be clearly indicated.

The laboratory MUST be informed in advance before a sample is sent.

Annex D – Transport of TSE Infected Material

Click here for link to Annex D

8 Spillages

When a spillage of any fluid (including blood and CSF) from a patient with, or "at increased risk" of, CJD/vCJD occurs in a healthcare setting, the main defence is efficient removal of the contaminating material and thorough cleaning of the surface.

Standard infection prevention control precautions should be used to clear up spillages of any fluid (including spillages of blood and CSF) from a patient with, or "at increased risk" of, CJD/vCJD. Disposable gloves and an apron should be worn when removing such spillages and eye protection, if there is a risk of splashes.

Potentially infectious materials should be removed using absorbent material and any waste (including used cleaning equipment e.g. mop heads, gloves and aprons) disposed of as clinical waste.

Standard disinfection for spillages (e.g. 10,000ppm chlorine-releasing agent) should be used to decontaminate the surface after the spillage has been removed. A full risk

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assessment may be required. It should be noted that none of the methods currently suggested by World Health Organisation (WHO) for prion inactivation are likely to be fully effective.

9 Clinical waste

General guidance on the safe management of clinical waste is given in the Department of Health's guidance document 'Health Technical Memorandum (HTM) 07-01: Safe Management of Healthcare waste": This Guidance can be found at

NHS England » (HTM 07-01) Management and disposal of healthcare waste

According to this guidance, "Waste known or suspected to be contaminated with transmissible spongiform encephalopathy (TSE) agents, including CJD, must be disposed of by high temperature incineration in suitable authorised facilities." Additional guidance on the management of TSE-infected waste is given in the Department of Health's 'Transmissible spongiform encephalopathy: Safe working and the prevention of infection.'

The Advisory Committee on Dangerous Pathogens (ACDP) TSE Working Group have considered the disposal of clinical waste, and have agreed that tissues and contaminated materials such as dressings and sharps, from patients with, or "at increased risk" of, CJD/vCJD, should be disposed of as in the following table:

Table: Disposal of clinical waste from patients with, or "at increased risk" of, CJD or 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 patients is considered to be low risk except when transfused in large volumes.

Annex C contains advice on the general principles of decontamination and waste disposal for transmissible spongiform encephalopathies.

Click here for link to Annex C

10 Sharps and inoculation injuries

Although cases of CJD/vCJD have been reported in healthcare workers, there have been no confirmed cases linked to occupational exposure. However, it is prudent to take a precautionary approach.

The highest potential risk in the context of occupational exposure is from exposure to high infectivity tissues through direct inoculation, for example as a result of sharps injuries, puncture wounds or contamination of broken skin, and exposure of the mucous membranes.

Healthcare personnel, who work with patients with definite, probable or possible CJD/vCJD, or with potentially infected tissues, should be appropriately informed about the nature of the risk and relevant safety procedures.

For any accident involving sharps or contamination of abrasions with blood or body fluids, wounds should be gently encouraged to bleed, gently washed (avoid scrubbing) with warm soapy water, rinsed, dried and covered with a waterproof dressing, or further treatment given appropriate to the type of injury. Splashes into the eyes or mouth should be dealt with

by thorough irrigation. Such accidents must be reported immediately and the Prevention and Management of Needlestick Injuries: including Inoculation Incidents and Exposures to Blood Borne Viruses (BBV) Policy followed. This can be found on the Trust's Staff Zone.

Consultant Occupational Health physicians and microbiologists should be informed and will assist in counselling the staff member.

11 Linen, laundry and Patients' personal laundry

Linen and laundry should be handled and segregated as per the SCHT Linen Handling and Laundry Policy. Any soiled items MUST NOT be manually sluiced. Patients/ relatives/ carers should be encouraged to wash personal laundry at home. The laundering of patients' own clothes in community hospitals should be done by exception only.

12 Infection prevention and control precautions in patient's own home

12.1 Standard Precautions

People should not be dissuaded from routine contact with CJD patients as both CJD and vCJD are not thought to present a risk through normal social or routine clinical contact. No special measures over and above standard infection prevention and control precautions are generally required for caring for CJD patients in the community, as it is unlikely that procedures will be adopted that will lead to contact with high or medium risk tissues. Normal standard infection prevention and control procedures should be used as for any other patient. Any exposure to bodily fluids must be treated as potentially infectious in line with standard infection prevention and control precautions including hand hygiene and the wearing of personal protective equipment.

12.2 Spillages

It is assumed that all spillages in patients' own homes will be of low risk material e.g. blood and urine. Standard infection prevention and control precautions should be followed to clear up spillages of material from patients with, or "at increased risk" of, CJD/vCJD in the community. Spillages of body fluids should be removed using disposable paper towel and the surface washed thoroughly with detergent and warm water using disposable apron, disposable gloves and eye protection where splashing may occur.

12.3 Clinical waste

Any clinical waste generated in a patient's own home is unlikely to contain high risk material. Continence products and wound dressings should be double bagged and disposed of in the patient's wheelie bin or clinical waste stream if available. Where appropriate, arrangements should be made with the local authority for removal of clinical waste.

12.4 Linen

Used or fouled bed linen (contaminated with body fluids or excreta), should be washed and dried in accordance with current standard practice. No further handling or processing is necessary.

13 Care of the deceased patient

Standard infection control precautions need to be observed; national guidelines recommend that patients with CJD or at risk of CJD need to be placed in a body bag and have to have labels attached to both the deceased and the outside of the bag stating "Danger of infection". Viewing of patients can take place.

14 Occupational exposure

Although cases of CJD/vCJD have been reported in healthcare workers, there have been no confirmed cases linked to occupational exposure. The highest potential risk in the context of occupational exposure is from exposure to high infectivity tissues through direct inoculation, for example as a result of sharps injuries, puncture wounds or contamination of broken skin, and exposure of the mucous membranes.

Healthcare personnel who work with patients with definite, probable or possible CJD/vCJD, or with potentially infected tissues, should be appropriately informed about the nature of the risk and relevant safety procedures. Compliance with standard infection control precautions will help to minimise risks from occupational exposure.

For any accident involving sharps or contamination of abrasions with blood or body fluids, wounds should be gently encouraged to bleed, gently washed (avoid scrubbing) with warm soapy water, rinsed, dried and covered with a waterproof dressing, or further treatment given appropriate to the type of injury. Splashes into the eyes or mouth should be dealt with by thorough irrigation. The incident should be reported via the electronic Datix system.

15 Dentistry

The risks of transmission of infection from dental instruments are thought to be very low provided satisfactory standards of infection prevention and control and decontamination are maintained. There is no reason why any patient with, or "at increased risk" of CJD or vCJD, should be refused routine dental treatment.

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) at: Decontamination in Primary Care Dental Practices. This also includes advice for dentists on the re-use of endodontic instruments and vCJD.

Dental instruments used on patients with, or "at increased risk" of CJD or vCJD can be handled in the same way as those used in any other low risk surgery i.e. these instruments can be reprocessed following SCHT Decontamination of Reusable Surgical and Dental Instruments Policy and returned to use.

16 Consultation

This policy has been developed by the IPC team in consultation with appropriate Locality Clinical Managers, advisors/specialists (e.g., Medical Advisor, Specialist Nurses, Medicine Management), PHE and IPC Governance Meeting members.

A total of three weeks consultation period was allowed and comments incorporated as appropriate.

16.1 Approval Process

The IPC Committee members will approve this policy and its approval will be notified to the Quality and Safety Committee.

17 Dissemination and Implementation

This policy will be disseminated by the following methods:

- Managers informed via Datix who then confirm they have disseminated to staff as appropriate
- · Staff via IPC newsletter
- Awareness raising by the IPC team
- Published to the StaffZone of the Trust website

The web version of this policy is the only version that is maintained. Any printed copies should therefore be viewed as 'uncontrolled' and as such, may not necessarily contain the latest updates and amendments. When superseded by another version, it will be archived for evidence in the electronic document library.

18 Training

Managers and service leads must ensure that all staff are familiar with this policy through IPC induction and update undertaken in their area of practice.

In accordance with the Trust's mandatory training policy and procedure the IPC team will support/deliver training associated with this policy. IPC training detailed in the core mandatory training programme includes Standard Infection Control Precautions and details regarding key IPC policies. Other staff may require additional role specific essential IPC training, as identified between staff, their managers and / or the IPC team as appropriate. The systems for planning, advertising and ensuring staff undertake training are detailed in the Mandatory Training Policy and procedure. Staff who fail to undertake training will be followed up according to the policy.

Further training needs may be identified through other management routes, including Clinical Case Review (CCR), Root Cause Analysis (RCA) and Post Infection review (PIR), following an incident/infection outbreak or following audit findings. Additional ad hoc targeted training sessions may be provided by the IPC team.

19 Monitoring Compliance

Compliance with this policy will be monitored as follows:

- Environmental and patient equipment cleaning will be monitored as part of local routine cleanliness audits.
- Dentistry audit to include decontamination processes and use of single-use devices to ensure compliance against HTM0501.
- Medical notes of patients who undergo theatre or endoscopic procedures will be audited to ensure the paperwork is completed.

Numbers of staff undertaking IPC training, which includes Standard Infection Control Precautions will be monitored by the Organisational Development and Workforce Department

As appropriate the IPC team will support Services' Leads to undertake IPC CCRs/RCAs/PIRs. Managers and Services' Leads will monitor subsequent service improvement plans and report to the IPC Operational Group meeting.

Knowledge gained from CCR/RCA/PIR and IPC audits will be shared with relevant staff groups using a variety of methods such as reports, posters, group sessions and individual feedback.

The IPC team will monitor IPC related incidents reported on the Trust incident reporting system and, liaising with the Governance team, advise on appropriate remedial actions to be taken.

20 References

Department of Health 2012 (Updated 2021) Minimise transmission risk of CJD and vCJD in healthcare settings - GOV.UK (www.gov.uk) [Accessed 12.12.23]

NHS England. 2022 (updated October 2023) NHS England » National infection prevention and control manual (NIPCM) for England [Accessed 12.12.23]

NHS England NHS England » (HTM 01-05) Decontamination in primary care dental practices [Accessed 12.12.23].

21 Associated Documents

This policy should be read in conjunction with the SCHT's:

- Cleaning and Disinfection Policy
- Decontamination and Storage of Flexible Endoscopes Policy
- Decontamination of Reusable Surgical and Dental Instruments Policy
- Hand Hygiene Policy
- Linen and Laundry Policy
- Prevention and Management of Needlestick Injuries: including Inoculation Incidents and Exposures to Blood Borne Viruses (BBV) Policy
- Standard Precautions Policy
- Waste Management Policy

22 Annex

Annex A1 – Distribution of TSE Infectivity in Human Tissues and Body Fluids

Click here for link to Annex A1

Annex A2 - Distribution of Infectivity in Animal Tissue and Body Fluids

Click here for link to Annex A2

Annex B – Diagnostic criteria

Click here for link to Annex B

Annex C – Decontamination and Waste Disposal

Click here for link to Annex C

Annex D – Transport of TSE Infected Material

Click here for link to Annex D

Annex E – Quarantining of surgical instruments

Click here for link to Annex E

Annex F - Endoscopy

Click here for link to Annex F

Annex H – Funeral arrangements after a CJD death

Click here for link to Annex H

Information sheet for funeral directors, relatives and others following a CJD death

Click here for link to Funeral Arrangements following a CJD Death

Annex I – Outline Protocol for Management of Instruments and Tissues from Brain Biopsy Procedures on Patients with Progressive Neurological Disorders

Click here for link to Annex I

Annex J – Assessment to be carried out before surgery and endoscopy to identify patients with, or at risk of, CJD and vCJD

Click here for link to Annex J

Annex L – Managing CJD/vCJD in Ophthalmology

This link contains advice on the precautions to be taken for ophthalmic procedures on patients with, or "at increased risk" of, CJD.

Click here for link to Annex L

Annex M – Managing vCJD Risk In General Surgery and Liver Transplantation Click here for link to Annex M