TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (TSE): POLICY FOR INFECTION PREVENTION AND CONTROL

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Revision Date	Summary of changes	Author(s)	Version Number
March 2011	Updated in line with new HPA guidance issued January 2011	IPCT	2
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Approvals

This document requires the following approvals either individual(s), group(s) or board.

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1. Introduction

Transmissible Spongiform Encephalopathies (TSEs), sometimes known as prion disease, are rare but fatal degenerative brain diseases which occur in humans and certain other animal species. There are several recognised TSEs including Creutzfeldt-Jakob Disease (CJD) which can be classical, familial, iatrogenic and new variant; Gerstmann Sträussler Scheinker Syndrome (GSS); Fatal Familial Insomnia (FFI) and kuru.

TSEs are caused by unconventional infectious agents currently thought to be infectious proteins, known as prions. They do not share the normal properties of bacteria and viruses. TSE agents are not uniformly distributed in tissues of infected individuals, and infectivity varies at different stages of incubation. However, in general, neural tissue poses the greatest risk. Blood and other body fluids including dental pulp are assumed to have a low level of infectivity. TSE agents are unusual in that they exhibit resistance to conventional chemical and physical decontamination methods.

Whilst the evidence available to date does not suggest that CJD can be spread from person to person through close contact, it is known that transmission can occur in specific situations associated with medical interventions e.g. neurosurgical procedures.

2.Scope

The purpose of this policy is to provide concise guidance for all staff and to minimize the potential risks of infection and ensure prompt recognition of those patients who are at risk of infection. This document applies to all staff either employed or contracted within East Coast Community Healthcare CIC (ECCH).

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3. Policy Statement

This policy will be implemented to ensure adherence to safe practice.

4. Roles and responsibilities

It is the responsibility of all staff to ensure that they adhere to best practice.

5. Patient Risk Group

When considering measures to prevent transmission of TSE to patients or staff in the healthcare setting, it is useful to make a distinction between those patients who are ***known*** or ***suspected*** to have CJD or a related disorder and those who are at risk of the disease. This will include:

- Those with clinical symptoms
- Those who are potentially at risk of developing one of these diseases, i.e. someone who is asymptomatic but has a clinical or family history

The table below sets out these groups in more detail.

Table: PATIENT RISK GROUPS

Known Patients	Suspected Patients	At Risk Patients
Patients diagnosed as having a TSE, i.e. those who fulfil internationally accepted diagnostic criteria. Confirmation of a definite case (Post Mortem)	Patients suspected of having a TSE, i.e. those whose clinical symptoms are suggestive of TSE but where the diagnosis has not yet been confirmed.	Asymptomatic patients who are potentially at risk of developing a TSE. Recipients of hormone derived from human pituitary glands, e.g. growth hormone, gonadotrophin **before** 1989 Recipients of human dura mater grafts (not used after August 1992). Persons with a family history of CJD i.e. close blood line relatives (parents, siblings, children, grandparents and grandchildren).

6. Infection Control for Patients in Risk Groups

Current available evidence identifies that normal social or routine clinical contact with a TSE patient does **not** present a risk to healthcare workers, relatives or others.
Isolation of patients with TSE is not necessary. However, strict adherence to standard infection control procedures (as with all patients) is required.
Certain invasive interventions may potentially allow exposure to the infective agents of TSEs. The tissues that present the highest risk of exposure are:

- the brain;
- the spinal cord;
- Intracranial secretions of cranial nerves or procedures in which human dura mater was implanted in a patient prior to 1992
- the eye.

Body secretions, bodily fluids (including saliva, blood and cerebrospinal fluid (CSF) and excreta) are all low risk for TSE. There is currently no evidence of infectivity in saliva, body secretions or faeces. Therefore, it is likely that the majority of samples taken will be low risk.

Hand washing, as with all patient care remains of paramount importance.

All staff responsible for care of patients in any of the risk groups should be fully aware of the recommendations of the report of the Advisory Committee on Dangerous Pathogens – Spongiform Encephalopathy Advisory Committee (DoH 2003).

7. Minor Surgery, Dentistry, Podiatry and Other Minor Invasive Procedures
Tissue Infectivity

The following tissues have been categorised according to their CJD/vCJD infectivity:

- High risk – Brain, Spinal cord, Posterior eye, Intracranial secretions of cranial nerves;
- Medium risk – Olfactory epithelium plus gastro-intestinal Lymphoid tissue only in a case of vCJD
- Low / no detectable risk – Anterior eye and cornea and other tissues

It is considered that all procedures undertaken in Primary Care will fall into the low/no detectable risk category. However, if staff have a query about the risk category for **ANY** procedure that is undertaken they must contact the Health Protection Nurse/Consultant at the local Public Health England for further advice. 03003038537

Sample Collection and Labelling

Specimens containing potentially infectious TSE material (e.g. blood, CSF) should be labelled in accordance with your local trust policy. Samples must be securely sealed and the laboratory form completed with all the necessary patient details, including the patient's clinical history of their known, suspected or at risk TSE status. In the laboratory setting these specimens are dealt with in a level 2 cabinet.

Samples must be transported in a sealed plastic specimen bag.

The request form must accompany the specimen but must be placed within the appropriate separate pouch of the bag.

Care and Decontamination of Instruments

The risks of transmission of infection from minor surgical/dental/podiatry instruments are thought to be **very low** provided optimal standards of infection control and decontamination are maintained. This low risk will be the same for other minor invasive procedures undertaken by any other healthcare workers.
Such instruments used on patients can be handled in the same way as those used in any other low risk surgery i.e. taking a precautionary approach.
These instruments can be reprocessed according to best practice and returned to use. Optimal reprocessing standards must be observed.

Additionally, practitioners are reminded that any instruments labelled by manufacturers as "single use" should not be re-used under any circumstances

8. Categorisation of Patients by Risk for CJD/vCJD

Patients should be categorised as follows, in descending order of risk:

1. Symptomatic patients	1.1 Patients who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD. 1.2 Patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD or vCJD, but where the diagnosis of CJD is being actively considered.
2. Asymptomatic patients at risk from familial forms of CJD linked to genetic mutations	2.1 Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD or other prion disease. 2.2 Individuals who have a blood relative known to have a genetic mutation indicative of familial CJD. 2.3 Individuals who have or have had two or more blood relatives affected by CJD or other prion disease.
3. Asymptomatic patients at risk from iatrogenic exposure++	3.1 Recipients of hormone derived from human pituitary glands, e.g. growth hormone, gonadotrophin. In the UK, cadaver-derived human growth hormone was banned in 1989 but use of human-derived products may have continued in other countries. 3.2 Individuals who have received a graft of *dura mater*. (People who underwent neurosurgical procedures or operations for a tumour or cyst of the spine before August 1992 may have received a graft of *dura mater*, and should be treated as *at risk*, unless evidence can be provided that *dura mater* was not used). 3.3 Patients who have been contacted as potentially *at risk* including individuals considered to be: a) at risk of CJD/vCJD due to exposure to certain instruments used on a patient who went on to develop CJD/vCJD, or was at risk of vCJD, develop CJD/vCJD, or was at risk of vCJD. b) at risk of vCJD due to receipt of blood components or plasma derivatives. c) at risk of CJD/vCJD due to receipt of tissues/organs. d) at risk of vCJD due to the probability they could have been the source of infection for a patient transfused with their blood who was later found to have vCJD. 3.4 Individuals who have been identified prior to high risk surgery as having blood or blood components from 80 or more donors since January 1980.

The CJD Incidents Panel, which gives advice to the local team on what action needs to be taken when a patient who is diagnosed as having CJD or vCJD underwent surgery or donated blood, organs or tissues before CJD/vCJD was identified, will identify contacts who are potentially at risk.

9. Standard Precautions

CJD does not present a risk to others through routine clinical or normal social contact. Families and friends are not to be discouraged from ordinary contact.

Blood or Body Fluid Spillage

When dealing with blood / bodily fluids staff and carers should always wear protective clothing i.e. gloves and apron, as per standard precautions which should be discarded as clinical waste. Trust policy must be adhered to.

N.B. Standard infection control precautions should be used to clear up spillages as quickly as possible of all materials from patients with, or at "increased risk" of CJD/vCJD in a healthcare setting. 10,000ppm sodium hypochlorite is recommended

Spillages of blood and bodily fluids (faeces, vomit, pus, and urine)

Wearing appropriate personal protective equipment (disposable gloves and apron), absorb as much of the blood/ bodily fluids as possible using paper towels (e.g. kitchen roll) and discard in a orange clinical waste bag.

- Clean area thoroughly with hot soapy water and dry.
- Use disposable cloths and discard after use.
- Dispose of gloves, apron and used disposable equipment in an orange clinical waste bag.

Hand washing is very important after dealing with blood and/or bodily fluids

If there are any concerns regarding the risks and interventions required when caring for patients with CJD staff should contact the Infection Prevention and Control Team on 01502 445255.

Out of hours contact the on-call consultant microbiologist via James Paget University Hospital switchboard, 01493 452 452

10. References

Department of Health (2003. Revised 2015) Minimise transmission risk of CJD and vCJD in healthcare settings. (Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Part 4) DoH London. Available from https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

Transmissible Spongiform Encephalopathy (2011)(TSE / CJD) Guidance for Healthcare Workers Working in Primary Care & Community Settings

World Health Organisation 2010 Transmissible Spongiform Encephalopathy

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/260961/report.pdf

http://www.who.int/bloodproducts/tse/en/

11. Author

Infection Prevention and Control Team

12. Glossary of Terms

C.J.D. Creutzfeldt – Jacob Disease

Clinical Waste Waste from medical, nursing, dental, pharmaceutical and other clinical services or similar practice (e.g. podiatry, investigation, treatment, care. teaching or research), which by nature of its toxic infectious or dangerous content, may prove a hazard or give offence unless previously considered safe and inoffensive

C.O.S.H.H. Control of Substances Hazardous to Health

Dura mater The outer most, toughest, and most fibrous of the three membranes (meninges) covering the brain and spinal cord

Familial Occurring in or affecting members of a family more than would be expected by chance

F.F.I. Fatal familial insomnia

Gonadotrophin Any hormone having a stimulating effect on the gonads

Group E waste Items used to dispose of urine, faeces and other bodily secretions or excretions, which do not fall within Group A. This includes used disposable bedpans or bedpan liners, incontinence pads, stoma bags, and urine containers
(Defined in HSC 1999 ISBN Clinical Waste definitions)

G.S.S. Gerstmann Sträussler Scheinker Syndrome

Iatrogenic Resulting from the activity of a physician; said of any adverse condition in a patient resulting from treatment by a physician or surgeon

Kuru A chronic, progressive, uniformly fatal central nervous system disorder due to a slow virus and transmissible to subhuman primates; seen only in the Fore and neighbouring peoples of New Guinea

Prion Proteins A distinct group of micro-organisms **(PrP)**

Sporadic Occurring single; widely scattered; not epidemic or endemic

T.S.E. Transmissible Spongiform Encephalopathy

Variant C.J.D. Variant CJD **(vCJD)** (nvCJD) formerly known as New Variant CJD

EQUALITY AND DIVERSITY IMPACT ASSESSMENT

Impact Assessments must be conducted for:

- **All ECCH policies, procedures, protocols and guidelines (clinical and non-clinical)**
- **Service developments**
- **Estates and facilities developments**

Name of Policy / Procedure / Service	**TSE Policy**
Manager Leading the Assessment	**Teresa Lewis**
Date of Assessment	**December 2014**

STAGE ONE – INITIAL ASSESSMENT

Q1. Is this a new or existing policy / procedure / service?

☐ New

√ Existing

Q2. Who is the policy / procedure / service aimed at?

☐ Patients

√ Staff

☐ Visitors

Q3. Could the policy / procedure / service affect different groups (age, disability, gender, race, ethnic origin, religion or belief, sexual orientation) adversely?

☐ Yes

√ No

If the answer to this question is NO please sign the form as the assessment is complete, if YES, proceed to Stage Two.

Analysis and Decision-Making

Using all of the information recorded above, please show below those groups for whom an adverse impact has been identified.

	Adverse Impact Identified?
Age	No
Disability	No
Gender	No
Race/Ethnic Origin	No
Religion/Belief	No
Sexual Orientation	No

- Can this adverse impact be justified?
- Can the policy/procedure be changed to remove the adverse impact?

If your assessment is likely to have an adverse impact, is there an alternative way of achieving the organisation's aim, objective or outcome
What changes, if any, need to be made in order to minimise unjustifiable adverse impact?