Leicestershire Partnership NHS Trust

Transmissible Spongiform Encephalopathy (TSE) including Creutzfeldt-Jacob Disease (CJD) variant CJD Policy (vCJD).

This policy describes the process for managing patients with suspected TSE including CJD & vCJD within Leicestershire Partnership NHS trust.

Key Words:	Infection Prevention and Control, Transmissible Spongiform Encephalopathy, Creutzfeldt-Jacob Disease, Variant Creutzfeldt-Jacob Disease.	
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Type of Policy	Clinical *V*	Non-Clinical

Contents

1.0 Quick Look Summary

The aim of the policy is to give direction to staff within LPT with regards to caring for patients with suspected Transmissible Spongiform Encephalopathy (TSE), including Creutzfeldt-Jacob Disease (CJD) and Variant Creutzfeldt-Jacob Disease (vCJD).

The transmission risks and diagnosis of the disease are identified, including the necessary infection prevention and control precautions with the overall aim being to reduce the risk of transmission.

This policy sets out to ensure that all staff employed by LPT provide evidence-based care which is in accordance with the health & social care act (2008) updated (2015).

1.1 Version Control and Summary of Changes

Version number	Date	Comments
Version 1	May 2014	Review of national guidelines for policy relevant to LPT. Infection Prevention and Control advice pertaining to theatres, day surgery and endoscopy departments is currently provided by UHL infection prevention and control team. Therefore, staff are directed to this team for advice pertaining to these services. Circulated for comments to relevant parties within LPT and outside organisations.
Version 2	July 2017	Clarification that no new national guidelines available. Policy updated in line with the latest LPT template for policies. Information relating to UHL services removed as not relevant to LPT.
Version 3	November 2019	Clarification that no new guidelines available Policy updated in line with the latest LPT template for policies.
Version 4	December 2020	Clarification that no new guidelines available Policy updated in line with the latest LPT template for policies.
Version 5	August 2023	Clarification that no new guidelines available Policy updated in line with the latest LPT template for policies.

1.2 Key individuals involved in developing and consulting on the document.

Name	**Designation**
Accountable Director	Dr Anne Scott
Author(s)	Reviewed by Claire King Infection prevention and control nurse.
Implementation Lead	Amanda Hemsley Lead for infection prevention and control.
Core policy reviewer group	Infection prevention and control assurance group.
Wider consultation	Infection prevention and control assurance group members. Trust Policy expert group.

1.3 Governance

Level 2 or 3 approving delivery group	**Level 1 Committee to ratify policy**
Infection prevention and control assurance group	Quality and safety committee

1.4 Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population, and workforce, ensuring that none are placed at a disadvantage over others. It takes into account the provisions of the Equality Act 2010 and promotes equal opportunities for all. This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy, and maternity.

1.5 Due Regard

LPT will ensure that Due regard for equality is taken and as such will undertake an analysis of equality (assessment of impact) on existing and new policies in line with the Equality Act 2010. This process will help to ensure that:

- Strategies, policies and procedures and services are free from discrimination.
- LPT complies with current equality legislation.
- Due regard is given to equality in decision making and subsequent processes.
- Opportunities for promoting equality are identified.

Please refer to due regard assessment (Appendix 4) of this policy

1.6 Duties within the Organisation

Duties in regard to this policy can be located in the LPT infection prevention and control assurance framework policy.

Consent

- Clinical staff must ensure that consent has been sought and obtained before any care, intervention or treatment described in this policy is delivered. Consent can be given orally and/ or in writing. Someone could also give non-verbal consent as long as they understand the treatment or care about to take place. Consent must be voluntary and informed, and the person consenting must have the capacity to make the decision.
- In the event that the patient's capacity to consent is in doubt, clinical staff must ensure that a mental capacity assessment is completed and recorded. Someone with an impairment of or a disturbance in the functioning of the mind or brain is thought to lack the mental capacity to give informed consent if they cannot do one of the following:

  - *Understand information about the decision.*
  - *Remember that information.*
  - *Use the information to make the decision.*
  - *Communicate the decision.*

1.7 Definitions that apply to this Policy.

Transmissible Spongiform Encephalopathy (TSE)	Transmissible Spongiform Encephalopathy (TSE) is a group of diseases that are caused by the build-up of an abnormal form of the naturally occurring prion protein in the brain.
Creutzfeldt-Jacob Disease (CJD)	Creutzfeldt-Jacob Disease (CJD) is a form of TSE
Variant Creutzfeldt-Jacob Disease (Vcjd)	Variant Creutzfeldt-Jacob Disease (vCJD) is a prion disease that was first described in 1996 in the United Kingdom, there is now strong scientific evidence that the agent responsible for the outbreak of prion disease in cows' bovine spongiform encephalopathy (BSE or 'Mad cow' disease) is the same agent responsible for the outbreak of vCJD in humans.
Classical CJD	Classical CJD is a human prion disease, it is a neurodegenerative disorder with characteristic clinical and diagnostic features. This disease is rapidly progressive and always fatal, Infection with this disease leads to death usually within 1 year of onset of illness.
Healthcare Acquired Infection (HCAI)	HCAI are infections that are acquired as a result of healthcare interventions.
Iatrogenic	Brought about by surgical or medical treatment
Infection	Invasion of the body by organisms causing disease
Prion	A small infectious particle composed of abnormally folded protein that causes progressive neurodegenerative conditions. These abnormally folded proteins do not multiply in the host organism that they infected. Instead they affect the brain structure by acting as a template, inducing proteins with normal folding to convert to the abnormal prion form.
Standard Precautions	The precautions taken by all staff for all patients all of the time based on risks identified.

2.0. Purpose and Introduction

The aim of this policy is to give direction to staff within LPT with regards to caring for patients with suspected Transmissible Spongiform Encephalopathy (TSE), including Creutzfeldt-Jacob Disease (CJD) and Variant Creutzfeldt-Jacob Disease (vCJD).

The transmission risks and diagnosis of the disease are identified, including the necessary infection prevention and control precautions with the overall aim being to reduce the risk of transmission.

This policy sets out to ensure that all staff employed by LPT provide evidence-based care which is in accordance with the health & social care act (2008) updated (2015).

3.0 Policy requirements

There is currently no known cure for TSE, CJD or vCJD, nor is there currently and formal means of diagnosis except following the death of a patient. Therefore, it is imperative that staff are aware of signs and symptoms of the disease and of the necessary precautions they need to take when TSE, CJD or vCJD is suspected.

Patients with TSE, CJD, vCJD **are not an infection risk to other patients or staff and therefore will not require source isolation precautions.**

This disease is thought to be caused by the build-up of an abnormal form of prion proteins that are found in the brain: and can be transferred by medical equipment following certain procedures which are deemed to be high risk. None of these 'high risk' procedures are currently undertaken in within LPT services.

The emergence of covid-19 has not had an impact on the measures to be taken with a patient who is known to have TSE, CJD or vCJD.

The purpose of this policy is to provide information with regards to the transmission of TSE, CJD or vCJD.

TSE is a group of disease that affects both humans and animals, it is thought to be caused by the build-up of an abnormal form of the naturally occurring 'Prion' protein in the brain. CJD is a form of TSE and is a rare and ultimately fatal degenerative disease.

CJD can be classed as classical or sporadic, it can also be generic or a form of inherited prion disease and these are associated with mutation in the prion protein gene. Rarer forms of human prion disease included acquired diseases such as iatrogenic CJD. Iatrogenic CJD is very rare and occurs when CJD is transmitted as a result of medical or surgical exposures. To reduce this risk precautionary measures have been taken to improve the standards of surgical instruments and endoscope decontamination.

vCJD is thought to be most likely acquired through ingestion of meat contaminated with a bovine spongiform encephalopathy agent.

3.1 The management of patients with transmissible Spongiform Encephalopathy (TSE) including Creutzfeldt-Jacob Disease (CJD) variant Creutzfeldt-Jacob Disease (vCJD

This policy covers all healthcare settings within LPT.

3.2 Diagnosis

Diagnosis is usually made on a clinical basis, there are currently no widely available laboratory tests for human TSE'S. At present diagnosis can only be confirmed by examination of the brain tissue after death (Postmortem), Brain biopsy may be used in investigating cases of suspected TSE buy may not be definitive in establishing a diagnosis.

3.3 Treatment

There are currently no cures available, any treatment given would be to alleviate any symptoms if possible.

3.4 Screening

There is currently no screening process available that can give a conclusive diagnosis.

3.5 Infection prevention and control measures

A patient with suspected TSE is not an infection risk, therefore any patient who has been clinically 'provisionally' diagnosed with TSE does not require source isolation precautions. Standard precautions such that are applicable to all patients at all times should be undertaken.

- Effective hand hygiene before and after each patient contact and contact with their environment is of paramount importance in reducing spread of all infections (Please refer to the LPT hand hygiene policy).
- Antibiotics must be prescribed according to the antibiotic guidance for primary care.
- Personal protective equipment (PPE) must be worn where there is a risk of exposure to blood or body fluids (Please refer to the LPT personal protective policy).
- Cleaning and decontamination of equipment must be undertaken as per the LPT cleaning and decontamination policy.

There have been 4 cases of presumed person-person transmission vCJD infection via blood transfusion reported within the United Kingdom (UK) since 2003 (3 clinical & 1 asymptomatic) and a further probable vCJD infection via plasma products has been reported in a haemophiliac person.

Since 1997 when the theoretical risk of vCJD transmission through blood was first considered, the UK blood services have taken a number of precautionary measures to protect the blood supply and associated plasma products, these include:

- Blood components, plasma products or tissues obtained from any person who later develops vCJD are withdrawn or recalled preventing their use.
- Since 1998 plasma for the manufacture of plasma products, such as clotting factors has been obtained from non-UK sources.
- Since 1998 synthetic (Recombinant) clotting factors for treatment of haemophilia has been provided to those under the age of 16 and for all patients in whom it is suitable since 2005.
- Since 1999 white blood cells (Which may carry a significant risk of transmitting vCJD) have been removed in all blood used for transfusion, a process known as leucodepletion.
- Since 2002 fresh frozen plasma for treating babies and young children born on or after 1st January 1996 has been obtained from the USA, IN 2005 it's use was extended to all children up to the age of 16.
- Since 2004 individuals who have received a transfusion of blood components since January 1980 or are unsure if they have had a blood transfusion are excluded form donating blood or platelets.

- Since 2009 cryoprecipitate a special cold-treated plasma preparation has been imported form the USA for children up to the age of 16.

Even though the risk of obtaining CJD through blood and body fluids is very low samples from patients with suspected of having or at increased risk of CJD should be treated as potentially infectious and any samples sent to the laboratory should indicate that the patient from the whom sample is taken is suspected of having TSE, CJD or vCJD should this be the case.

When patients suspected of TSE, CJD vCJD have certain procedures undertaken in theatres, including day surgery and endoscopy then the equipment used may need to be quarantined until a diagnosis can be made and ultimately disposed of if a positive diagnosis is made. However, LPT do not currently support these services and therefore this is not pertinent to LPT.

3.6 Movement and transport of patients

There are no infection prevention and control requirements to be implemented, other than standard precautions that are required for all patients when patients are being moved from one area to another or transported in vehicles, including volunteer cars, private cars or ambulance transportation.

3.7 Caring for patients within the community setting.

People should not be dissuaded from routine contact with patients with TSE, CJD or vCJD as they 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 patients with TSE, CJD or vCJD patients in the community as it is unlikely that procedures will be adopted that will lead to contact with high or medium risk.

3.8 Deceased patients

After the patient has died, staff will need to contact the mortuary for the up-to-date protocols, any the following must be followed:

- The patient must be placed in a body bag prior to transporting to the mortuary.
- Normal procedures for bodies where there is a known infection risk must be followed.
- Embalming should be avoided in confirmed/suspected cases.

In all cases discuss with a consultant histopathologist regarding postmortem examinations, postmortems on diagnosed or suspected TSE patients are to be carried out at the Queen Medical Centre (QMC) Nottingham.

4.0 References and Bibliography

Advisory Committee on Dangerous Pathogens-Spongiform Encephalopathy (1998) Revised and updated 2009

Department of health Control of Substances Hazardous to Health (COSHH) regulations (2002) (as amended).

Department of health Creutzfeldt-Jacob Disease: Guidance for healthcare workers (2000)

Department of health Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection: part 4 (2003, revised and updated 2015)

Department of health: The health and social care act code of practice for health and adult social care on the prevention of infections and related guidance (2008) updated 2015.

Department of health: Health, and safety at work act (1974)

Department of health: Management of health and safety at work regulations (MHSWR) (1999)

Department of health and social care: Infection prevention and control of Creutzfeldt-Jacob Disease (CJD) in healthcare and community settings part 4 (2003) updated (2021)

LPT Hand hygiene including bare below the elbows policy (2022)

LPT Management of a patient requiring source isolation precautions policy (2022)

LPT Personal protective equipment for use in health care policy (2022)

Medical devices agency: Devices bulletin, single use medical devices implications and consequences of reuse (MDA DB2006 04) (2006)

National Institute for Health and Clinical Excellence (NICE): Patients safety and reduction of risk of transmission of Creutzfeldt-Jacob Disease (CJD) via interventional procedures (2006)

NHS England: National infection prevention and control manual for England (2023)

Public Health England (PHE) Patients at increased risk of Creutzfeldt-Jacob Disease Background information (2016)

5.0 Monitoring Compliance and Effectiveness

Compliance with this policy is outlined in LPT'S infection prevention and control assurance framework policy.

Appendix 1 Training Requirements

Training Needs Analysis

Training topic:	Transmissible spongiform encephalopathy (TSE) including Creutzfeldt-Jacob Disease (CJD) variant CJD (vCJD)
Type of training: (see study leave policy)	☐ Mandatory (must be on mandatory training register) x Role specific ☐ Personal development
Directorate to which the training is applicable:	x Mental Health x Community Health Services x Enabling Services x Families Young People Children / Learning Disability Services x Hosted Services
Staff groups who require the training:	All clinical staff must undertake trust infection prevention and control mandatory training, Additional training on TSE will be provided by infection prevention and control team as required.
Regularity of Update requirement:	Bi-annually
Who is responsible for delivery of this training?	Learning and development teams' delivery IPC level 1 & 2 e-learning packages. Infection prevention and control team delivery of additional training as required.
Have resources been identified?	Yes, delivered by e-learning training package
Has a training plan been agreed?	Yes
Where will completion of this training be recorded?	x U-Learn ☐ Other (please specify)
How is this training going to be monitored?	Trust monthly reporting systems

Appendix 2 The NHS Constitution

- The NHS will provide a universal service for all based on clinical need, not ability to pay.
- The NHS will provide a comprehensive range of services.

Shape its services around the needs and preferences of individual patients, their families and their carers	☐
Respond to different needs of different sectors of the population	☐
Work continuously to improve quality services and to minimise errors	☐
Support and value its staff	☐
Work together with others to ensure a seamless service for patients	☐
Help keep people healthy and work to reduce health inequalities	☐
Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance	☐

Appendix 3 Due Regard Screening Template

Section 1	
Name of activity/proposal	Transmissible spongiform encephalopathy (TSE) including Creutzfeldt-Jacob Disease (CJD) variant CJD (vCJD).
Date Screening commenced	08-08-2023
Directorate / Service carrying out the assessment	Enabling Infection prevention and control team
Name and role of person undertaking. this Due Regard (Equality Analysis)	Claire King
Give an overview of the aims, objectives and purpose of the proposal:	
AIMS: To provide staff with a guide to the process to follow for managing patients with suspected TSE including CJD and vCJD within LPT.	
OBJECTIVES: For the policy to clearly identify the aims and goals for infection prevention and control within LPT and provide a coherent strategic objective. This policy should be reviewed whenever there is a need to adapt to the changing regulatory/environment or in response to ongoing risk assessment to ensure a safe environment for all patients, visitors and staff.	

Section 2	
Protected Characteristic	If the proposal/s have a positive or negative impact please give brief details
Age	No Impact
Disability	No Impact
Gender reassignment	No Impact
Marriage & Civil Partnership	No Impact
Pregnancy & Maternity	No Impact
Race	No Impact
Religion and Belief	No Impact
Sex	No Impact
Sexual Orientation	No Impact
Other equality groups?	No Impact

Section 3	
Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please tick appropriate box below.	
Yes	No x
High risk: Complete a full EIA starting click here to proceed to Part B	Low risk: Go to Section 4.

Section 4
If this proposal is low risk please give evidence or justification for how you reached this decision:

Signed by reviewer/assessor	Claire King	Date	08-08-2023
Sign off that this proposal is low risk and does not require a full Equality Analysis			
Head of Service Signed		Date	

Appendix 4 Data Privacy Impact Assessment Screening

Data Privacy impact assessment (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet Individual's expectations of privacy.
The following screening questions will help the Trust determine if there are any privacy issues associated with the implementation of the Policy. Answering 'yes' to any of these questions is an indication that a DPIA may be a useful exercise. An explanation for the answers will assist with the determination as to whether a full DPIA is required which will require senior management support, at this stage the Head of Data Privacy must be involved.

Name of Document:	**Transmissible Spongiform Encephalopathy (TSE) including Creutzfeldt-Jacob Disease (CJD) variant CJD (vCJD)**	
Completed by:	**Claire King**	
Job title	**Infection prevention and control nurse**	**Date08-08-2023**

Screening Questions	**Yes / No**	**Explanatory Note**
1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.	No	
2. Will the process described in the document compel individuals to provide information about them? This is information in excess of what is required to carry out the process described within the document.	No	
3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document?	No	
4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?	**No**	
5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.	No	
6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them?	No	
7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.	No	
8. Will the process require you to contact individuals in ways which they may find intrusive?	**No**	

If the answer to any of these questions is 'Yes' please contact the Data Privacy Team via Lpt-dataprivacy@leicspart.secure.nhs.uk
In this case, ratification of a procedural document will not take place until review by the Head of Data Privacy.

Data Privacy approval name:	
Date of approval	

Acknowledgement: This is based on the work of Princess Alexandra Hospital NHS Trust