Infection Prevention and Control

Transmissible Spongiform Encephalopathies (TSE’s), Including Creutzfeldt-Jakob Disease (CJD) Policy
Policy Title: Transmissible Spongiform Encephalopathies (TSE’s) including Creutzfeldt-Jakob Disease (CJD)

Executive Summary: This policy details the actions to be followed when caring for a patient with known or suspected TSE/ CJD, and thereby ensure appropriate procedures are in place to minimise the risk of transmission within the Trust.

Supersedes: Acute - Transmissible Spongiform Encephalopathies (TSE’s) including Creutzfeldt-Jakob Disease (CJD)V3 2009 – Community Transmissible Spongiform Encephalopathy (TSE / CJD)

Description of Amendment(s): Updated to reflect National guidelines and Organisational changes

Financial Implications: Increased Screening due to identification of new cases

Policy Area: Infection Prevention and Control Trust Wide

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Policy Area: Infection Prevention and Control Trust Wide

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Authors: Anita Swaine
Lead Nurse Infection Prevention and Control

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This policy will impact on: Clinical Staff

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Directorate SQS Groups

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<table>
<thead>
<tr>
<th>CONTENTS</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Introduction</td>
<td>4</td>
</tr>
<tr>
<td>2 Purpose</td>
<td>4</td>
</tr>
<tr>
<td>3 Roles and Responsibilities</td>
<td>4</td>
</tr>
<tr>
<td>4 Definitions</td>
<td>6</td>
</tr>
<tr>
<td>5 Types of CJD</td>
<td>6</td>
</tr>
<tr>
<td>6 Diagnosis, Treatment and Medical staff CJD reporting contacts</td>
<td>7</td>
</tr>
<tr>
<td>7 Risks of transmission for CJD / vCJD to healthcare workers</td>
<td>8</td>
</tr>
<tr>
<td>8 Patient Categorisation</td>
<td>8</td>
</tr>
<tr>
<td>9 General management of CJD patients in Community and Hospital Settings</td>
<td>10</td>
</tr>
<tr>
<td>10 Identification of possible CJD diagnosis after admission / treatment</td>
<td>17</td>
</tr>
<tr>
<td>11 Management of CJD/VCJD in Childbirth</td>
<td>18</td>
</tr>
<tr>
<td>12 Death of a Patient with CJD/vCJD</td>
<td>18</td>
</tr>
<tr>
<td>13 Look back exercises</td>
<td>18</td>
</tr>
<tr>
<td>14 Occupational Health and exposure of healthcare workers to CJD</td>
<td>19</td>
</tr>
<tr>
<td>15 Training</td>
<td>20</td>
</tr>
<tr>
<td>16 Monitoring Compliance</td>
<td>20</td>
</tr>
<tr>
<td>Legislation, Guidance and References</td>
<td>21</td>
</tr>
<tr>
<td>Equality and Human Rights Policy Screening Tool</td>
<td>22</td>
</tr>
</tbody>
</table>
1. Introduction

Transmissible spongiform encephalopathies (TSEs) are a rare group of uniformly fatal diseases caused by unconventional agents and prions, the most common of which is Creutzfeldt Jakob disease (CJD) which accounts for 95% of all TSE’s.

All TSE’s are invariably progressive and fatal once clinical symptoms appear, and there is no known treatment or prophylaxis. Confirmation of diagnosis can only be made at post mortem. Human TSE’s have a pre-clinical phase which may last for many years during which time no symptoms of the disease are evident.

To prevent transmission of TSEs in medical practice it is necessary to take a two stage risk approach:

   i. Patients affected with, or at risk of, developing a TSE must be reliably identified

   ii. Measures must be taken to ensure that any invasive device used on such patients are not used on other patients this includes all surgical equipment, flexible endoscopes.

Despite the diagnosis of CJD it is essential that patient experience is not compromised and they receive all care in line with the relevant clinical pathways and in collaboration with the Consultant Microbiologist.

Patient’s identified as having CJD/vCJD or as being “at increased risk” of developing the disease must undergo further assessment. This will be co-ordinated by the Infection Prevention and Control Team in conjunction with Public Health England.

2. Purpose

The purpose of this policy is to ensure that all staff within East Cheshire NHS Trust (ECNHST) understand the risks associated with TSE’s (including CJD/vCJD).

This will enable staff to ensure appropriate procedures are in place to minimise the risk of transmission within the Trust as a consequence of healthcare delivered to the patient (including but not limited to surgical and endoscopic procedures).

3. Roles and Responsibilities

3.1 Responsibilities

- **The Chief Executive:** has ultimate responsibility for the implementation and monitoring of the policies in use in the Trust. This responsibility may be delegated.

- **The Director of Nursing, Performance and Quality, Director of Infection Prevention and Control (DIPC):** has strategic responsibility for Infection Prevention and Control within the Trust and will take the lead responsibility for the development and implementation of this policy with support of the Lead Nurse - Infection Prevention and Control, and the Infection Prevention and Control Doctor. Providing assurance to the board that systems and process are in place to ensure compliance with agreed standards.
- Consultant Microbiologist, Infection Control Dr: Will advise on the management of individual cases who are confirmed or “at increased risk” of CJD/vCJD infection, including appropriate instrument management.

- Consultant in Communicable Disease Control (Public Health England): Will liaise with the Infection control Doctor in the case of an incident and work with the relevant teams to ensure all necessary steps are followed as laid down in the national guidance on management of a suspected case of CJD/vCJD.

- The Infection Prevention and Control Team (IPCT): Will have responsibility for ensuring the policy is implemented and monitored across the Trust; in addition they will ensure compliance with any national initiatives or directives.

  Provide support and advice to clinical areas on the management of patients with suspected or confirmed CJD / vCJD, ensuring that controls are in place to minimise risk of transmission to other patients, staff or general public. Obtaining further advice as required from Public Health England.

  Provide and support a sustainable programme of audit and education across the health economy.

- Managers/Clinical Leads/ Matrons/Senior Sisters/ Charge Nurses: Will ensure that the policy is implemented and complied with within their areas of responsibility.

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

- Admitting Clinician / Consultant: Will consider the possibility of CJD / vCJD for all patients undergoing surgery or endoscopy involving high or medium risk tissue and check medical notes / referral letter for any documentation of a patient’s CJD/vCJD status.

- Theatre Staff: Will ensure that instrument identification labels are placed in all patients records following surgical procedures.

  Will document in each patient’s records if single use instruments have been used, or reusable instruments have been incinerated if a patient being operated on is either known, suspected, or at increased risk for public health purposes of having CJD/vCJD.

- All Employees: Must ensure they are compliant with Infection Prevention and Control Policies, training and standards which are monitored through the appraisal process and are responsible for reporting known or suspected cases to the department.

- Occupational Health: Are responsible for providing confidential advice and support to staff relating to the implementation of Infection Prevention and Control including screening and treatment, consulting with the Consultant Microbiologist as appropriate.
### 4. Definitions

<table>
<thead>
<tr>
<th>TSE</th>
<th>Transmissible spongiform encephalopathies (TSEs) also known as prion diseases. A group of rare, fatal, degenerative brain diseases that affect humans and some animals. Prion diseases exist in different forms, all of which are progressive, currently untreatable and ultimately fatal.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prions</td>
<td>Infectious proteins which do not share the normal properties of viruses or bacteria and are resistant to conventional chemical and physical decontamination methods.</td>
</tr>
<tr>
<td>CJD</td>
<td>CJD (Creutzfeldt-Jakob Disease) is one of the TSEs. It is a rare illness and one of a group of prion diseases which affect humans and animals e.g. BSE (Bovine spongiform encephalopathy) in cattle and scrapie in sheep.</td>
</tr>
<tr>
<td>Iatrogenic CJD</td>
<td>CJD arising from contamination with tissue from an infected person, usually as the result of a medical procedure. Transmission has occurred following procedures such as injection with human pituitary hormones, dura mater grafts, neurosurgical instruments and blood / blood products.</td>
</tr>
<tr>
<td>Variant CJD</td>
<td>vCJD first described in the United Kingdom in March 1996, linked with exposure to a TSE of cattle called Bovine Spongiform Encephalopathy (BSE), also known as Classical BSE1.</td>
</tr>
</tbody>
</table>

### 5. Types of CJD

#### 5.1 CJD

CJD is one of the TSEs, a group of rare, fatal, degenerative brain diseases that affect humans and some animals, e.g. BSE (Bovine spongiform encephalopathy) in cattle and scrapie in sheep. Human TSEs occur in 3 groups:

- **Idiopathic diseases**: Sporadic CJD and sporadic fatal insomnia
- **Familial diseases**: Familial CJD, Gerstmann-Straussler-Scheinker syndrome (GSS) and fatal familial insomnia
- **Acquired diseases**: Human agents: Kuru and iatrogenic CJD
  Bovine agent: Variant CJD

A minority of TSEs appear to have a genetic origin and therefore run in families.
TSEs are caused by infectious agents known as TSE agents or prions which are unlike bacteria or viruses in that they are:

a) Not uniformly distributed in the tissues and body fluids of infected individuals and infectivity levels vary at different stages of the disease incubation. In general, during the clinical disease, central nervous system (CNS) tissues including the retina pose the highest risk, lymphoid tissues, cornea and dura mater are lower risk and most body fluids and other tissues negligible risk.


b) Resistant to standard methods of disinfection and sterilisation used in hospitals.

c) Not readily transmissible, although there have been cases of transmission to patients through contaminated medical instruments, hormone injections and tissue transplants.

<table>
<thead>
<tr>
<th>5.2 Variant CJD (vCJD)</th>
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<tbody>
<tr>
<td>Key differences between CJD and vCJD include:</td>
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<tr>
<td>• Patients affected are generally younger (mean age at onset = 28 years)</td>
</tr>
<tr>
<td>• The appearance of affected brain tissue is different</td>
</tr>
<tr>
<td>• The vCJD agent is concentrated in other tissues in addition to neural tissue, e.g. tonsils, spleen, lymph nodes.</td>
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</tbody>
</table>

The Government’s expert committee concluded that the most likely explanation for the emergence of vCJD was that it had been transmitted to humans via exposure to BSE. As a result, additional safeguards have been put in place to protect the population from the theoretical risk of vCJD being transmitted from people who are infected but asymptomatic. These include:

- Leucodepletion (removal of white cells) from blood destined for transfusion
- Using non-UK sourced plasma for the production of certain blood products
- Excluding certain individuals with identifiable risk factors as potential organ/blood donors
- Withdrawing or recalling blood components, plasma products or tissues from any individuals who later developed CJD.

It is still too early to tell how many cases of vCJD there will eventually be but up to the end of 2011 there had been over 176 cases in the UK and some experts are predicting a second wave of cases over the next two or three decades.

<table>
<thead>
<tr>
<th>6 Diagnosis, Treatment and Medical staff CJD reporting contacts</th>
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<tbody>
<tr>
<td>• Clinicians caring for a patient can contact Edinburgh University to discuss a CSF sample (which would need to be frozen) and to obtain the request form which would need to be sent to:</td>
</tr>
<tr>
<td>The National Creutzfeld Jacob Disease Surveillance Unit</td>
</tr>
<tr>
<td>Western General Hospital</td>
</tr>
<tr>
<td>Crewe Road</td>
</tr>
</tbody>
</table>
A definitive diagnosis requires examination of brain tissue, usually at post-mortem. Diagnosis of CJD/vCJD is therefore usually based on medical history, symptoms and diagnostic tests e.g. MRI scans, EEGs. There are no proven specific treatments available but it may be possible to reduce some symptoms such as pain and jerky movements

Medical staff must report all cases of confirmed or suspected CJD or vCJD to the following:

i. National CJD Research & Surveillance Unit (CJDSU) at the Western General Hospital, Crewe Road, Edinburgh, EH4 2XUT
ii. The National Prion Clinic, London - see Public Health England (PHE) website; CJD section; “Guidance on Reporting and Infection Control”
iii. Consultant Microbiologist/ Infection Control Doctor
iv. Local Consultant in Communicable Disease Control at Public Health England

<table>
<thead>
<tr>
<th>Patient Groups</th>
<th>Categories of patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic (definite, probable or possible CJD or vCJD)</td>
<td>• Patients who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD</td>
</tr>
<tr>
<td></td>
<td>• Patients with neurological disease of unknown aetiology, who do not fit the criteria for possible CJD or vCJD, but were the diagnosis of CJD is being actively considered</td>
</tr>
</tbody>
</table>

Patients “at increased risk” from genetic forms of CJD
- Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD
- Individuals who have a blood relative known to have a genetic mutation indicative of genetic CJD
- Individuals who have or have had two or more blood relatives affected by CJD or other prion disease.

Patients identified as at “increased risk” of vCJD through receipt of blood from a donor who later developed vCJD
- Individuals who have received labile blood components (whole blood, red cells, white cells or platelets) from a donor who later went on to develop vCJD.

Patients identified as “at increased risk” of CJD/VCJD through iatrogenic exposure
- Recipients of hormone derived from human pituitary glands e.g. growth hormone, gonadotrophin, are “at increased risk” of transmission of sporadic CJD. In the UK the use of human derived gonadotrophin was discontinued in 1973, and the use of cadaver-derived human growth hormone was banned in 1985. However, use of human-derived products may have continued in other countries after these dates.
- Individuals who underwent intradural 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 dura mater was not used).
- Individuals who have had surgery using instruments that had been used on someone who went on to develop CJD, or was at increased risk of CJD.
- Individuals who have received an organ or tissue from a donor infected with CJD or “at increased risk” of CJD.
- Individuals who have been identified as having received blood or blood components from 300 or more donors since January 1990.
- Individuals who have given blood to someone who went on to develop vCJD.
- Individuals who have received blood from someone who has also given blood to a patient who went onto develop vCJD.
- Individuals who have been treated with certain implicated UK source plasma products between 1990 and 2001.

ACDP document Part 4, Table 4a and sections 4.16-4.20 in available from:
General management of CJD patients in Community and Hospital Settings

9.1 How do I manage Patient in the community setting?

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.

For more information relating to Infection Prevention and Control of CJD in healthcare and community setting, please refer to: https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

| GP patient notes | Must be annotated to reflect the confirmed or “at increased risk” status of the patient to inform future case management |
| Spillages | It is assumed that all spillages in the patient's own home 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 |
| 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 domestic bin. |
| Laundry | Laundry e.g. bed linen and bed clothes can be washed in a domestic washing machine. It may be preferable to wash them separately to other household items. Any soiled items should not be washed by hand |

9.2 managing a patient with CJD, vCJD in clinical environment
### General clinical area

For routine clinical management, no additional infection control precautions are needed for patients in either the “symptomatic” or “at increased risk” groups. See Table 4a: Categorisation of patients by risk in Part 4 – Infection Prevention and Control of CJD in healthcare and community settings. However high standards of Infection Control must be practiced to minimise the risk of exposure, in particular the avoidance of inoculation injury and the safe disposal of sharps and contaminated waste.

**Available via:**

### Pathology Specimens

Due to the unusual resistance of the TSE agent, single use disposable equipment should be used wherever practicable when obtaining specimens and all other items of equipment contaminated whilst obtaining specimens should normally be destroyed by incineration. Discussion with Consultant Microbiologist IPCT/ should occur prior to any invasive procedure for example obtaining a biopsy especially if expensive equipment which is not normally single use is involved.

Biopsy and lumber puncture samples should only be taken by trained personnel who are aware of the hazards involved.

The collection of blood specimens should involve the same precautions normally used for venepuncture. Particular care should be taken while obtaining and handling CSF. And lymphoid tissue specimens. Standard Practice should be to use disposable gloves and aprons. Eye protection should be worn for procedures where splashing may occur.

The agents of CJD/vCJD are classified as Hazard Group 3 pathogens by the Advisory Committee on Dangerous Pathogens (ACDP). Therefore all specimens from known or at risk patients **MUST** be labelled with “Danger of Infection” stickers. Specimens of cerebrospinal fluid, tissues and biopsies should be marked with a Biohazard label. The laboratory should be informed in advance that a sample is being sent. High risk material including from the eye, olfactory epithelium or lymphoid tissue must only be submitted for examination after prior consultation with the lab.

### Patient notes

Must be annotated to reflect the confirmed or “at increased risk” status of the patient

### Isolation

Patients with CJD or vCJD may be nursed in open bays using standard infection prevention and control
<table>
<thead>
<tr>
<th>Precautions</th>
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<tbody>
<tr>
<td><strong>Linen</strong></td>
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<tr>
<td>Used linen, or linen soiled with bodily fluids must be returned for laundry as per the Trust linen policy. No further handling or processing is required.</td>
</tr>
<tr>
<td><strong>Personal Protective equipment</strong></td>
</tr>
<tr>
<td><strong>Spillages</strong></td>
</tr>
<tr>
<td>When a spillage of any fluid (including blood and CSF) from a patient with, or “at increased risk” of, CJD occurs in a healthcare setting, the main defence is efficient removal of the contaminating material and thorough cleaning of the surface. See Infection Prevention and Control Standard Precautions policy. A 10,000 ppm chlorine releasing agent must be used to decontaminate the area, after the spillage has been removed any waste generated e.g. gloves, aprons; mop heads etc. must be disposed of as “clinical waste”. See ACDP document Part 4 sections 4.30 – 4.34 available from: <a href="https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group">https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group</a></td>
</tr>
<tr>
<td><strong>Clinical waste</strong></td>
</tr>
<tr>
<td><strong>Invasive procedures on wards</strong></td>
</tr>
<tr>
<td>During certain invasive procedures there is potential for exposure and transmission of TSE agents. Special precaution must be taken for all symptomatic and at increased risk patients:</td>
</tr>
<tr>
<td>- Only trained staff must perform invasive procedures on patients deemed “symptomatic” or “at increased risk”.</td>
</tr>
<tr>
<td>- Single use disposable equipment must be used wherever possible. After use this equipment must be disposed of. Other small items of equipment which may become contaminated during use may also need to be destroyed.</td>
</tr>
<tr>
<td>- Disposable instruments must be used when undertaking lumbar puncture, bone marrow aspirations and biopsies for other invasive procedures wherever practicable.</td>
</tr>
<tr>
<td>- Appropriate PPE must be worn following assessment of the risk from exposure e.g. apron, gloves, eye protection, mask etc.</td>
</tr>
<tr>
<td>- During beside procedures e.g. lumbar puncture care must be taken to avoid environmental contamination</td>
</tr>
</tbody>
</table>
e.g. spillages. Blood, CSF and tissue biopsy specimens sent for laboratory testing must be labelled with “Danger of infection” stickers

9.3 Management of Patients with known or suspected CJD/v who require Surgical Procedure

- **Pre-operative assessment:** ALL patients undergoing surgery or endoscopy (elective or emergency) especially those that may involve contact with tissues considered to have high or medium levels of infectivity for CJD / vCJD must be assessed for risk factors for CJD / vCJD and other TSEs

  see appendix’s J (Assessment to be carried out before surgery and/or endoscopy to identify patients with, or at increased risk of, CJD or vCJD) and M (Managing vCJD risk in general surgery and liver transplantation) available from: https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

Patients considered as being “symptomatic” or “at increased risk” must be managed in line with ACDP guidance and this policy.

Invasive procedures for this patient group must be carefully planned and consideration taken surrounding:

- Instrument choice and handling – preferable the use of single use equipment.
- Decontamination
- Environmental cleaning
- Waste disposal
- The patient must be placed last on the theatre list.
- Sterile services must be informed in advance by the user regarding the following:

  i. Selection of appropriate equipment for the procedure i.e. if single use equipment is not available, it may be appropriate to use old sets which may be disposed of after use.
  ii. The return of instruments for reprocessing see section Sterilisation and decontamination

9.4 Management of patients requiring Ophthalmology

**Ophthalmic Instruments and Contact lenses**

Patients undergoing ophthalmic surgery must be pre-operatively assessed for risk factors for CJD and vCJD and any patients deemed as symptomatic or “at increased risk” managed in accordance with ACDP annex J **Assessment to be carried out before surgery and/or endoscopy to identify patients with, or at increased risk of, CJD or vCJD and Annex L – Managing CJD/vCJD risk in ophthalmology** available from https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

9.5 Management of patients requiring Urology investigations/ surgery

9.6 Specific precautions for symptomatic (definite, probable and possible) and “at increased risk” patients undergoing surgical procedures

Particular concerns exist regarding surgical and other invasive procedures performed upon symptomatic and/or at increased risk patients. This is due to the potential for transmission of TSE agents via contaminated surgical and other invasive instruments. Effective decontamination or use of disposable instruments is central to reducing the risk of transmission:

- Where possible, all invasive procedures should be undertaken in an operating theatre
- Patients should be placed at the end of the theatre list to allow time for cleaning etc
- Single use protective clothing must be worn as a minimum Plastic apron under a liquid repellent operating gown, gloves, mask, Visor / goggles
- The minimum number of healthcare personnel required should be involved
- Use single use equipment or disposable instruments were possible these should then be disposed of by incineration
- Maintain a one-way flow of instruments
- If procedure is to be performed at the patient’s bedside e.g. lumbar puncture, care should be taken to clear the environment from all none essential equipment and ensure the space is readily cleanable. Full PPE must be worn by the healthcare staff involved in the procedure.

9.7 Handling of equipment not designated as single use

The management of reusable instruments after surgery depends on a combination of factors, the risk status of the patient, the organ(s) / tissue(s) involved the procedure and the type of CJD suspected or confirmed.

Effective decontamination is the key to reducing transmission of TSE risk therefore any decontamination must be undertaken in line with the Trust Decontamination policy.

Expensive items of equipment such as drills can have the risk of contamination reduced by the use of shields, guards or coverings, this reduces the elements requiring disposal. The drill and shield/guard will need to incinerated.

Reusable surgical instruments including endoscopes must be managed using a robust tracking and traceability procedure. Tracking of equipment facilitates a permanent record to indicate which instrument has been used on which patient; in addition it provides validation on the decontamination process. Tracking of surgical instruments may work in two ways, firstly to identify specific equipment used on particular patients but also on the patients the equipment has subsequently been used on. Surgical instruments may be tracked as individual items or alternatively as a specific set.

9.8 Controls for patients with CJD, vCJD undergoing endoscopes

Flexible endoscopes and their accessories are expensive pieces of equipment therefore the guidance must be followed to minimise the necessity to quarantine or destroy them.

Current guidance is detailed in ACDP annexes F (endoscopy), and J (assessment to be carried out before surgery and/or endoscopy to identify patients with, or at increased risk of, CJD or vCJD). These are accessible via the following link: https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

There is currently no reliable method to decontaminate a fibreoptic endoscope after use on a symptomatic or at “increased risk patient”. Patients undergoing endoscopic procedures must be assessed for risk factors for CJD / vCJD (and other TSE’s) before the procedure is conducted. Patients identified as symptomatic or at “increased risk patient” and the endoscopic equipment and accessories used on them must be managed in accordance with ACDP advice.

Gastrointestinal endoscopy performed on patients with known or suspected CJD/vCJD will not involve high risk tissues, therefore the scopes must be managed in accordance with usual decontamination process.

If nasal endoscopy is being undertaken then the risk is increased due to the contact with the olfactory epithelium where prion protein has been detected in sporadic CJD patients. If this procedure is to be undertaken then further advice should be obtained from the Consultant Microbiologist and the IPCT. This will involve a risk assessment with the medical staff performing the procedure and the potential contamination levels of the scope with olfactory epithelium. This may result in the scope being destroyed, or implementing the use of a single use scope.

Patients with definite or probable CJD should only undergo flexible endoscopy if it is deemed a clinical necessity by their Consultant. This procedure may require the loaning of a dedicated kit by the National CJD surveillance unit; the IPCT will contact Public Health England for further advice.

If a patient with probable or confirmed CJD/vCJD requires a tissue biopsy or other invasive procedure including ERCP or diathermy, the endoscope must be considered as contaminated. Therefore endoscopic biopsies must only be performed if the results are diagnostically required and warrant quarantine of the endoscope.

Disposable forceps (i.e. for single patient usage) must be used on all cases with definite or probable CJD, vCJD. The biopsy channel brushes and the valve on the biopsy/instrument channel port should be disposed of as clinical waste. If reusable accessories have to be used these must be dedicated to the identified scope.

It is essential that the unique identifier for the endoscope is recorded in the patient’s notes as this may be required in the event of any lookback exercise.

<table>
<thead>
<tr>
<th>9.9 Sterilisation and Decontamination</th>
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<tbody>
<tr>
<td>TSE agents are resistant to most standard methods of sterilization and disinfection used in healthcare. The following are <strong>INNEFFECTIVE:</strong></td>
</tr>
<tr>
<td>• Standard autoclaving cycles (as used in hospital Sterile Services departments)</td>
</tr>
<tr>
<td>• Gases e.g. ethylene oxide and formaldehyde</td>
</tr>
<tr>
<td>• Most chemical disinfectants e.g. alcohol, formalin, glutaraldehyde and phenolics</td>
</tr>
<tr>
<td>• Dry heat and UV radiation</td>
</tr>
<tr>
<td>• Prolonged or repeated autoclaving in porous-load (vacuum) autoclave is no-longer considered to be effective</td>
</tr>
<tr>
<td>• Concentrated hypochlorite and sodium hydroxide are (partially) effective</td>
</tr>
<tr>
<td>• Thorough cleaning is essential to remove as much of the TSE agents as possible before sterilisation or disinfection is attempted. This must be followed by an appropriate heat or chemical treatment. Manual cleaning must be kept to a minimum.</td>
</tr>
<tr>
<td><strong>Under no circumstances should attempts be made to sterilise instruments in a benchtop autoclave.</strong></td>
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<tr>
<th>9.10 Return of instruments to HSDU</th>
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<tbody>
<tr>
<td>Re-useable lumbar puncture sets MUST NOT be used on ANY patient. Single use instruments must be used to undertake this procedure.</td>
</tr>
<tr>
<td>HSDU must be informed in advance of the return of any instruments from an at risk patient. These instruments must be securely contained and appropriately labelled, see surgical procedures section and ACDP annex E (Quarantining of surgical instruments) available from: <a href="https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group">https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group</a></td>
</tr>
<tr>
<td>HSDU will reprocess these instruments following guidelines issued by expert advisory bodies e.g. the advisory committee on dangerous pathogens and the NHS executive. However, HSDU may refuse to reprocess any instruments or components which they feel they are unable to adequately clean or sterilise. In these instances the instrument(s) may be destroyed following discussion between the HSDU manager (or deputy) and the appropriate theatre manager (or deputy).</td>
</tr>
<tr>
<td>It may be appropriate to quarantine instruments used on a possible CJD or vCJD patient rather than destroying them. They must be stored in a rigid sealed</td>
</tr>
</tbody>
</table>

16
container after use, until the diagnosis is confirmed. Items must be clearly identified as being removed from circulation and recorded at the Trust Decontamination group.

10 Identification of possible CJD diagnosis after admission / treatment
Where it becomes known, after admission, that a patient may have CJD/vCJD, advice must be sought immediately from the Consultant Microbiologist / Infection Prevention and Control and the patients Consultant.

Any non-disposable surgical instruments / endoscopes used to examine or treat the patient must be identified immediately and withdrawn from use pending further guidance.

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

Non disposable instruments / flexible endoscopes must be quarantined pending confirmed diagnosis. Instruments must be washed to remove gross soil. PPE must be worn and care taken to avoid splashing. Surfaces where instruments are sorted should be covered with disposable drape or similar and all surfaces cleaned with hypochlorite. All disposable drapes and clothing sealed in an orange clinical waste bag and sent for incineration.

11 Management of CJD/VCJD in Childbirth
In the event that a patient with, or at increased risk of, CJD becomes pregnant, it is important to ensure that patient confidentiality is properly maintained, and that any action taken to protect public health does not prejudice individual patient care.

Childbirth should be managed using standard infection prevention and control procedures. The placenta and other associated material and fluids are considered low risk tissues, and should be disposed of as clinical waste, unless they are needed for investigation; in which case see ACDP Part 4 – Infection prevention and control of CJD and variant CJD in healthcare and community settings parts 4.24 – 4.29. Instruments management should be undertaken as per points 4.46 – 4.56 available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/427854/Infection_controlv3.0.pdf

12 Death of a Patient with CJD/vCJD
Care of the deceased person will continue to adhere to standard infection prevention and control procedures. Patients deemed "symptomatic", or "at increased risk" at time of death must be placed in a body bag and labelled as “Danger of Infection” prior to transportation to the mortuary.

12.1 Mortuary Precautions for Patient with CJD/vCJD
Post-mortem examination is required to confirm the clinical diagnosis of CJD, VCJD. However, this has the potential to expose the Pathologist and Mortuary
staff to tissues with high infectivity therefore it is likely that the patient will be transferred to a regional neuropathology centre. This will be undertaken in consultation with the National CJD surveillance unit and the Histopathologist.

- Relatives of the deceased may wish to view or have some final contact with the patient superficial contact such as touching or kissing need not be discouraged
- Information for Funeral directors, relatives and others following a CJD death can be found at the following link.

*ACDP Annex H (after death, and Funeral arrangements after a CJD death)*

*Answers to some commonly asked questions:*


### 13 Look-back Exercises

The infection prevention and control team must be informed of any case where there is a possibility that a patient could have been exposed to CJD/vCJD via contaminated surgical instruments which had previously been used on a patient with, or at increased risk of, CJD/vCJD.

A “look-back” exercise may be required. Advice will be provided by the Consultant Microbiologist and the local Health Protection Unit and the National CJD Incident Panel will be also be contacted for advice.

- **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.

- **Quarantining of surgical instruments:** Instruments that come into contact with tissues designated as high or medium infectivity should be kept separate from those that come into contact with tissues designated as low infectivity.

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

Re-usable instruments that come into contact with tissues designated as being of high or medium infectivity should be washed to remove gross soiling. Care should be taken to avoid splashing and aerosol generation, by holding the instruments below the surface of the water. Instruments should not be held underneath a flowing tap as this is likely to generate splashes. Operatives must wear protective gloves and either a visor or goggles.

- After washing, instruments should be placed on a disposable instrument tray and allowed to dry
- They should then be placed in an impervious rigid plastic container with a close fitting lid
- The container must be sealed with heavy duty tape and labelled with the patient’s details (name, date of birth, hospital number)
• The label should also state the surgical procedure performed and the name of the theatre manager
• The disposable instrument tray should be disposed of with normal clinical waste.

If diagnosis of CJD of any type is confirmed, the bin and contents should be incinerated as “Hazardous Waste” without further examination. Only if a definitive alternative diagnosis is confirmed may the instruments be decontaminated following the usual routine procedures and returned to use.

On rare occasions, it may be necessary to consider the re-use of a quarantined set of instruments on the same patient. In these circumstances the instrument set should be reprocessed through a sterile services department in the usual manner. No special precautions are necessary due to the high dilution factor involved in the decontamination process.

14 Occupational Health and exposure of healthcare workers to CJD

All incidences which result in a clinical, laboratory of research worker being significantly exposed to a TSE agent of any type MUST be reported to the Occupational Health Service. For practicality purposes this means following the Sharps, Needle stick Injury and Body Fluid Exposure Management Policy and Procedure

• A list of individuals exposed or potentially exposed to the TSE agents may have to be kept in accordance with instructions contained within Annex B of HSC1999/178. This may include:
  – Those performing invasive clinical procedures on patients suspected to be suffering from CJD of any type, particularly where there is a risk of exposure to central nervous tissue, eye tissue or other tissue known to contain CJD infectivity.
  – Laboratory staff handling tissue specimens from patients with CJD of any type.
  – Staff undertaking post-mortem examinations of patients who have died of CJD of any type or where CJD of any type is suspected.
  – In cases of unintentional or accidental exposure where risk assessment shows there is a significant risk.

The information that should be recorded includes the type of work done and where known, any specific exposure, accident or incident. Due to the long latency of TSE the list must be kept for a period of 40 years.

15 Training

All clinical staff must undertake Trust infection control mandatory training annually. Additional training on VRE management will be provided by the IPCT

16 Monitoring Compliance

The infection prevention and control team will review and investigate incidents reported relating to this policy and audit departments compliance as part of the annual audit programme.

Failure to follow the guidance in this policy will be reviewed as part of the Post Infection Review process and consideration given if this constitutes a Lapse in
Care contributing to the development of an infection. This will be monitored through the Infection Prevention and Control Committee.

Non-compliance with the policy will be managed via the staff disciplinary route; this will be supported by the Director of Nursing, Quality, Performance, DIPC, and the Medical Director.

This policy should be read in conjunction with (but not exclusively):

- Standard Precautions policy
- Isolation Policy
- Decontamination of Medical Devices Policy
Legislation, Guidance and References


Health and Safety Legislation

• Health and Safety at Work etc. Act 1974
• Management of Health and Safety at Work Regulations (MHSWR) 1999
• Control of Substances Hazardous to Health (COSHH) Regulations 2002

Guidance

• Decontamination of surgical instruments (HTM 01-01)
• East Cheshire NHS Trust Decontamination of re-usable medical devices policy.
• Prevention of CJD and vCJD by Advisory Committee on Dangerous Pathogens’ Transmissible Spongiform Encephalopathy (ACDP TSE) Subgroup.

Current guidance regarding prevention of CJD and vCJD by the Advisory Committee on Dangerous Pathogens’ Transmissible Spongiform Encephalopathy (ACDP TSE) Subgroup can be found at the below link. This link is used frequently throughout this document and includes up-to-date advice regarding the minimisation of transmission risks related to CJD and vCJD in the healthcare settings. The link must be used in association with this policy. 

Available at: https://www.gov.uk/dh

NICE quality standard (2014) Guidelines for Infection Prevention and Control

Department of Health (DOH 2013) - Environment and sustainability Health Technical Memorandum 07-01: Safe management of healthcare waste. DOH. London. Available from

Equality Analysis (Impact assessment)

Please START this assessment BEFORE writing your policy, procedure, proposal, strategy or service so that you can identify any adverse impacts and include action to mitigate these in your finished policy, procedure, proposal, strategy or service. **Use it to help you develop fair and equal services.** Eg. If there is an impact on Deaf people, then include in the policy how Deaf people will have equal access.

1. What is being assessed?

Transmissible Spongiform Encephalopathies (TSE’s) including Creutzfeldt-Jakob Disease (CJD)

Details of person responsible for completing the assessment:

- Name: Anita Swaine
- Position: Lead Nurse Infection Prevention and Control
- Team/service: Infection Prevention and Control

State main purpose or aim of the policy, procedure, proposal, strategy or service: *(usually the first paragraph of what you are writing. Also include details of legislation, guidance, regulations etc which have shaped or informed the document)*

This policy details the actions to be followed when caring for a patient with known or suspected TSE/CJD, and thereby ensure appropriate procedures are in place to minimise the risk of transmission within the Trust.

2. Consideration of Data and Research

To carry out the equality analysis you will need to consider information about the people who use the service and the staff that provide it. **Think about the information below – how does this apply to your policy, procedure, proposal, strategy or service**

2.1 Give details of RELEVANT information available that gives you an understanding of who will be affected by this document

Cheshire East (CE) covers Eastern Cheshire CCG and South Cheshire CCG. Cheshire West & Chester (CWAC) covers Vale Royal CCG and Cheshire West CCG. In 2011, 370,100 people resided in CE and 329,608 people resided in CWAC.

**Age:** East Cheshire and South Cheshire CCG’s serve a predominantly older population than the national average, with 19.3% aged over 65 (71,400 people) and 2.6% aged over 85 (9,700 people).

Vale Royal CCGs registered population in general has a younger age profile compared to the CWAC average, with 14% aged over 65 (14,561 people) and 2% aged over 85 (2,111 people).

Since the 2001 census the number of over 65s has increased by 26% compared with 20% nationally. The number of over 85s has increased by 35% compared with 24% nationally.
Race:
- In 2011, 93.6% of CE residents, and 94.7% of CWAC residents were White British
- 5.1% of CE residents, and 4.9% of CWAC residents were born outside the UK – Poland and India being the most common
- 3% of CE households have members for whom English is not the main language (11,103 people) and 1.2% of CWAC households have no people for whom English is their main language.

Gender:
- In 2011, c. 49% of the population in both CE and CWAC were male and 51% female. For CE, the assumption from national figures is that 20 per 100,000 are likely to be transgender and for CWAC 1,500 transgender people will be living in the CWAC area.

Disability:
- In 2011, 7.9% of the population in CE and 8.7% in CWAC had a long term health problem or disability
- In CE, there are c.4500 people aged 65+ with dementia, and c.1430 aged 65+ with dementia in CWAC. 1 in 20 people over 65 has a form of dementia
- Over 10 million (c. 1 in 6) people in the UK have a degree of hearing impairment or deafness.
- C. 2 million people in the UK have visual impairment, of these around 365,000 are registered as blind or partially sighted.
- In CE, it is estimated that around 7000 people have learning disabilities and 6500 people in CWAC.
- Mental health – 1 in 4 will have mental health problems at some time in their lives.

Sexual Orientation:
- CE - In 2011, the lesbian, gay, bisexual and transgender (LGBT) population in CE was estimated at 18,700, based on assumptions that 5-7% of the population are likely to be lesbian, gay or bisexual and 20 per 100,000 are likely to be transgender (The Lesbian & Gay Foundation).
- CWAC - In 2011, the LGBT population in CWAC is unknown, but in 2010 there were c. 20,000 LGB people in the area and as many as 1,500 transgender people residing in CWAC.

Religion/Belief:
The proportion of CE people classing themselves as Christian has fallen from 80.3% in 2001 to 68.9% In 2011 and in CWAC a similar picture from 80.7% to 70.1%, the proportion saying they had no religion doubled in both areas from around 11%-22%.

- Christian: 68.9% of Cheshire East and 70.1% of Cheshire West & Chester
- Sikh: 0.07% of Cheshire East and 0.1% of Cheshire West & Chester
- Buddhist: 0.24% of Cheshire East and 0.2% of Cheshire West & Chester
- Hindu: 0.36% of Cheshire East and 0.2% of Cheshire West & Chester
- Jewish: 0.16% of Cheshire East and 0.1% of Cheshire West & Chester
- Muslim: 0.66% of Cheshire East and 0.5% of Cheshire West & Chester
• Other: 0.29% of Cheshire East and 0.3% of Cheshire West & Chester
• None: 22.69% of Cheshire East and 22.0% of Cheshire West & Chester
• Not stated: 6.66% of Cheshire East and 6.5% of Cheshire West & Chester

Carers:
• In 2011, nearly 11% (40,000) of the population in CE are unpaid carers and just over 11% (37,000) of the population in CWAC.

2.2 Evidence of complaints on grounds of discrimination: (Are there any complaints or concerns raised either from patients or staff (grievance) relating to the policy, procedure, proposal, strategy or service or its effects on different groups?)

None

2.3 Does the information gathered from 2.1 – 2.3 indicate any negative impact as a result of this document?

None

3. Assessment of Impact

Now that you have looked at the purpose, etc. of the policy, procedure, proposal, strategy or service (part 1) and looked at the data and research you have (part 2), this section asks you to assess the impact of the policy, procedure, proposal, strategy or service on each of the strands listed below.

**RACE:**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, racial groups differently?

Yes ☐ No √

Explain your response: For any patient whose first language is not English, as information needs to be provided and understood, staff will follow the trust interpretation policy.

___________________________________________________________________

**GENDER (INCLUDING TRANSGENDER):**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, different gender groups differently?

Yes ☐ No √

Explain your response: No impacts identified.

___________________________________________________________________
DISABILITY
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, disabled people differently?

Yes √ No ☐

Explain your response: Clinical staff will need to implement support for patients in isolation as this is a mandatory requirement of this policy. Staff should follow the trust interpretation policy for people who are Deaf and involve the health facilitators for people with learning disabilities.

AGE:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, age groups differently?

Yes ☐ No √

Explain your response: Visitors at the extremes of the age range should be discouraged from visiting as they may be more susceptible.

LESBIAN, GAY, BISEXUAL:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, lesbian, gay or bisexual groups differently?

Yes ☐ No √

Explain your response: No impacts identified.

RELIGION/BELIEF:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, religious belief groups differently?

Yes ☐ No √

Explain your response: No impacts identified.

CARERS:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, carers differently?

Yes √ No ☐

Explain your response: May need to be involved in the support of the patient during admission and post discharge. Therefore staff must ensure they receive the appropriate information on management of Isolation precautions and the management of a particular organism. On occasions language may be a barrier to the information required therefore Clinical staff should access interpreter services as per Trust guidelines.

OTHER: EG Pregnant women, people in civil partnerships, human rights issues.
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect any other groups differently?

Yes ☐ No √

Explain your response: No other impacts identified.
4. Safeguarding Assessment - CHILDREN

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes □ No □</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Is there a direct or indirect impact upon children?</td>
<td></td>
</tr>
<tr>
<td>b. If yes please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; competing / conflicting impact between different groups of children and young people:</td>
<td></td>
</tr>
<tr>
<td>c. If no please describe why there is considered to be no impact / significant impact on children. This policy applies the same as for adult patients. If any concerns are noted with any child these would be escalated via the appropriate channels. Information would be provided to relatives to ensure they understand VRE, the need for screening and isolation.</td>
<td></td>
</tr>
</tbody>
</table>

5. Relevant consultation

Having identified key groups, how have you consulted with them to find out their views and that the made sure that the policy, procedure, proposal, strategy or service will affect them in the way that you intend? Have you spoken to staff groups, charities, national organisations etc?

This policy has been ratified by the ICG which includes a member of the public. As with the majority of IC policies it is acknowledged that staff need to support individuals who require Isolation, any variance to this must be clearly documented in the patients notes as part of their clinical care.

6. Date completed: 27/2/2017 Review Date: 27/2/2020

7. Any actions identified: Have you identified any work which you will need to do in the future to ensure that the document has no adverse impact?

<table>
<thead>
<tr>
<th>Action</th>
<th>Lead</th>
<th>Date to be Achieved</th>
</tr>
</thead>
</table>

8. Approval:

At this point, you should forward the template to the Trust Equality and Diversity Lead lynbailey@nhs.net

Approved by Trust Equality and Diversity Lead:

Head of Safety Risk and Resilience

Date: 8/3/17