## Summary

The purpose of this protocol is to provide guidance to staff on the precautions necessary to minimise the risk of occupational exposure to CJD and to prevent transmission of CJD between patients.

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<table>
<thead>
<tr>
<th>Owner</th>
<th>Name</th>
<th>Hazel Gray, John Harrison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job Title</td>
<td>Senior Infection Control</td>
<td></td>
</tr>
<tr>
<td>Sister. TSSU Manager</td>
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<tr>
<td>Final approval committee</td>
<td>Name</td>
<td>Infection Control Committee</td>
</tr>
<tr>
<td>Date of meeting</td>
<td>19 May 2009</td>
<td></td>
</tr>
<tr>
<td>Authoriser</td>
<td>Name</td>
<td>Dr Fatima El Bakri</td>
</tr>
<tr>
<td>Job title</td>
<td>Director of Infection</td>
<td></td>
</tr>
<tr>
<td>Prevention and Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signature</td>
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<td></td>
</tr>
<tr>
<td>Date of authorisation</td>
<td>19 May 2009</td>
<td></td>
</tr>
<tr>
<td>Review date</td>
<td>(maximum 3 years from date of authorisation)</td>
<td>May 2012</td>
</tr>
<tr>
<td>Audience</td>
<td>(tick all that apply)</td>
<td>Trust staff ✓ NHS ✓</td>
</tr>
<tr>
<td>Standards</td>
<td>Standards for Better Health</td>
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</tr>
<tr>
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<td>NHSLA, Health Act,</td>
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</tbody>
</table>
Implementation Plan

Summary of changes

This document has been revised prior to its review date in response to Annexe J of CJD guidance which was published in May 2008 and requires pre surgery questions to be asked.

www.advisorybodies.doh.gov.uk/acdp/tseguidance/index.htm

Action needed and owner of action

The prevention of transmission of infection and the provision of safe instruments are fundamental for patient care. Incorrect procedures for the handling or reprocessing of instruments used on patients infected with any form of Transmissible Spongiform Encephalopathy (TSE), namely Creutzfeldt- Jakob Disease (CJD) or Variant Creutzfeldt-Jakob Disease (vCJD) can present an infection risk to patients on whom instruments are subsequently used.

This protocol describes the steps, which must be taken by all staff to manage patient treatment in order to minimise risk, and is based on national guidelines for preventing the transmission of TSEs.
1.0 Rationale

The prevention of transmission of infection and the provision of safe instruments are fundamental for patient care. Incorrect procedures for the handling or processing of instruments used on patients infected with any form of Transmissible Spongiform Encephalopathy (TSE), namely Creutzfeldt-Jakob Disease (CJD) or Variant Creutzfeldt-Jakob Disease (vCJD) can present an infection risk to patients on whom instruments are subsequently used.

This protocol describes the steps, which must be taken to manage patient treatment in order to minimise risk, and is based on national guidelines for preventing the transmission of TSEs.

2.0 Aim

The purpose of this protocol is to provide guidance to staff on the precautions necessary to minimise the risk of occupational exposure to CJD and to prevent transmission of CJD between patients.

3.0 Objectives

To describe safe working practices to prevent the transmission of CJD and related disorders

To protect staff and patients from any infection risk from instruments used on patients known, suspect or at risk of possible CJD.

4.0 Legal framework

Health and Safety at Work etc Act, 1974

Control of Substances Hazardous to Health (COSHH) Regulations, 2002

Management of Health and Safety at Work Regulations, 1999
5.0 Roles, Responsibilities and Education

All staff dealing with patients who are symptomatic (known, suspect or at risk of TSE will comply with this protocol and the procedures laid down in this document.

Clinical and Service Managers will:

- Ensure that all staff responsible for the management of patients with CJD comply with the policy and procedures laid down in this document and have the necessary resources.
- Ensure that their staff receive appropriate support and training in the management of CJD and vCJD.

The consultant responsible for the patient will:

- Ensure that the Infection Control Team is informed of any patient in any of the above categories of CJD & vCJD
- Ensure appropriate departments are informed before any invasive procedures are carried out.
- Ensure that any case where TSE/CJD & vCJD of any type is a possible diagnosis is reported to the National CJD Surveillance Unit (CJDSU) (Tel: 0131 537 2128) so that necessary action can be taken particularly with regards to making or excluding the diagnosis.

The Infection Control Team will:

- Provide guidance and support on the practical application of this protocol.
- Monitor, evaluate and review the policy in the light of new evidence.

The Occupational Health Department will:

- Record any significant exposure to Health Care Workers from blood or CSF & other source.
6.0 Introduction

The term Transmissible Spongiform Encephalopathy (TSE) describes a group of rare and fatal degenerative conditions of the central nervous system, which are transmissible. TSEs are currently thought to be caused by infectious proteins known as prions (see Appendix 1).

TSEs occur in both man and certain animal species. There is currently no known treatment vaccine or prophylaxis for TSEs.

6.1 The human TSEs are very rare. They occur in 3 groups:

1. Idiopathic diseases: Sporadic Creutzfeldt–Jakob Disease (CJD) and Sporadic Fatal Insomnia

2. Familial diseases: Familial CJD, Gertsmann-Sträussler-Scheinker Disease (GSS), Familial Fatal Insomnia

3. Acquired diseases:
   - Human agents: Kuru and Iatrogenic CJD
   - Bovine agent: Variant CJD (vCJD)

CJD is a fatal brain disease first classified in the 1920s. In 1996, doctors reported a variant of the disease, vCJD. Research suggests that vCJD results from exposure to the agent that causes Bovine Spongiform Encephalopathy (BSE) in cattle.

6.2 Diagnosis and treatment

Diagnosis is usually made clinically; there are currently no widely available laboratory tests for human TSEs. CSF samples can be tested at the National Reference Laboratory but the definitive diagnosis can only be made by examination of brain tissue after death. Brain biopsy may be used in investigating cases of suspected TSE but may not be definitive in establishing a diagnosis. Reaching a clinical diagnosis of TSE may take a period of months as some patients may have an atypical presentation and this may not have been taken into consideration during the initial investigation. There are no proven specific treatments available.
7.0 Categorisation of patients by risk Table 1

Taken and adapted from ‘Transmissible Spongiform Encephalopathy agents: safe working and the prevention of infection’ Department of Health June 2003

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

<table>
<thead>
<tr>
<th>Known Symptomatic patients</th>
<th>1.1 Patients who fulfill the diagnostic criteria for definite, probable or possible CJD or vCJD, TSE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.2 Patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD or vCJD, TSE but where the diagnosis of TSE is being actively considered</td>
</tr>
<tr>
<td>Suspect Asymptomatic patients at risk familial forms of CJD linked to genetic mutations</td>
<td>2.1 Individuals who have or have had two or more blood relatives affected by CJD or other prion disease, or a relative known to have a genetic mutation indicative of familial TSE.</td>
</tr>
<tr>
<td></td>
<td>2.2 Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD or other prion disease</td>
</tr>
<tr>
<td>At Risk Asymptomatic patients potentially at risk from iatrogenic exposure##</td>
<td>3.1 Recipients of hormone derived from human pituitary glands, e.g. growth hormone, gonadotrophin.</td>
</tr>
<tr>
<td></td>
<td>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 a risk, unless evidence can be provided that dura mater was not used).</td>
</tr>
<tr>
<td></td>
<td>3.3 Patients who have been contacted as potentially at risk because of exposure to instruments used on, or receipt of blood, plasma derivatives, organs or tissues donated by, a patient who went on to develop CJD or vCJD*.</td>
</tr>
</tbody>
</table>

## NB: A decision on the inclusion of corneal graft recipients in the “iatrogenic at risk” category is pending completion of a risk assessment.

* If an invasive procedure is planned for a patient who is known to have received a blood product or plasma derivative that may have been contaminated by a TSE agent -
Inform the Infection Control Team who will obtain advice from the CJD incident panel on an individual patient basis. The CJD Incidents Panel was identified; to give 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.

It is the responsibility of the referring doctor to notify clinicians if any patients are considered to fall into any of the above categories.

If any patient is assessed to fall within any of the above categories, the Infection Control Team must be informed as soon as possible, prior to any clinical procedures being carried out.

8.0 Transmission of CJD

There is no evidence of direct person to person spread even by close contact. However, nervous tissue from affected patients is a source of infection as is corneal transplantation and human growth hormone. Iatrogenic transmission has also been identified following neurosurgical procedures with inadequately decontaminated instruments. In vCJD it is likely that there is more involvement of lymphoreticular tissues, tonsils, appendix and spleen. Four cases of probable human transmission of vCJD via non-leucocyte depleted blood transfusion have been reported. There is no current evidence of infectivity in saliva, body secretions and excreta. There is no evidence of transmission by the respiratory route. Any risk to surgeons from smoke plumes during laser tonsillectomy is thought to be very low. The risk of transmission via dental instruments is also thought to be low.

8.1 Distribution of TSE infectivity in Human Tissues and Body Fluids

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Level of Infectivity</th>
<th>CJD other than vCJD</th>
<th>vCJD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assumed level of infectivity</td>
<td>Assumed level of infectivity</td>
<td></td>
</tr>
<tr>
<td>Brain</td>
<td>High</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Spinal cord</td>
<td>High</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Spinal ganglia</td>
<td>High</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Dura mater</td>
<td>High</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Cranial nerves</td>
<td>High</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Cranial ganglia</td>
<td>High</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Posterior eye</td>
<td>High</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Anterior eye and cornea</td>
<td>Medium</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Olfactory epithelium</td>
<td>Medium</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Tonsil</td>
<td>Low</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Appendix</td>
<td>Low</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Spleen and thymus</td>
<td>Low</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Other lymphoid tissues</td>
<td>Low</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Peripheral nerve/ skeletal muscle</td>
<td>Low</td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>
9.0 Risk assessment

Prior to invasive procedures/surgery clinicians must consider the possibility of risk factors for TSEs in the patient groups identified in above categories and it is the responsibility of the referring doctor to notify clinicians if any patients are considered to fall into any of the above categories.

The Infection Control Team must be informed if there is any suspicion that a patient is in any of the patient risk groups described above.

Any investigation or procedure where TSE (of any type) is a differential diagnosis (no matter how unlikely), Infection Control must be informed immediately.

If a patient has had a procedure/surgery performed and is subsequently found to be in the above-mentioned patient groups, the instruments used must be tracked, traced and quarantined.

9.1 Dental Instruments

The likelihood of transmission of CJD or vCJD via dental instruments or contact with tonsillar tissue during dentistry is considered remote. See British Dental Association “Infection Control in dentistry” on www.bda-dentistry.org.uk. Patients from any of the risk groups (see Section 5) should not be refused dental treatment and should be treated as any member of the general public.

The English Chief Dental Officer sent a letter to all dentists in England, in February 2005 to give advice about treating patients with (or at risk of) vCJD. This letter can be found at www.hpa.org.uk/infections/topics_az/cjd/incidents_panel.htm

9.2 Infection control measures

Normal social or routine clinical contact with a patient with CJD or related disease, does not present a risk to health care workers, relatives or the community (DH, 2003). Isolation of patients with such diseases is therefore not necessary. They can be nursed on the open ward or at home.

The following infection control measures apply to patients in all 3 risk categories defined above:

9.3 Protective Clothing
As for all other patients, health care staff must wear protective clothing when in contact with body fluids, i.e. gloves and aprons, plus mask and eye protection when there is a risk of splashing to the face. This should be single use wherever possible.

9.4 Spillages of Blood and Body Spillages (See SOP CJD 002)

All spillages should be cleaned up promptly, to minimise the risk of transmission of blood-borne viruses and other pathogens.

If there is any delay in dealing with a spillage, e.g. staff with appropriate training is not readily available, the spillage must be safely cordoned off and/or the room locked. If in a public area, it must not be left unattended by staff.

**Spillage of blood and blood stained body fluid on impervious flooring**
- Wear protective clothing (gloves, apron, goggles, footwear)
- Cover spillage with Actichlor add conc 10,000 ppm
- Leave for 5 minutes (prepare bucket with hot water and detergent solution)
- Scoop up the spillage with paper towels and discard as clinical waste into yellow bag
- Clean area with hot water and detergent using disposable cloths, rinse and dry
- Clean bucket in fresh water and detergent, rinse and dry
- Dispose of protective clothing and cloths as clinical waste and wash hands

N.B. If a spill contains glass or other sharps, these should be picked up with forceps and disposed of carefully into a sharps bin. Use single use forceps wherever possible and dispose of in the clinical waste. See SOP / CJD 001/002 (appendix 5 and 6)

**Spillage of low-risk body fluids, e.g. urine, vomits, onto any flooring or Blood spillage on carpet**
- Wear protective clothing (gloves, apron, goggles and footwear)
- Use paper towels to absorb as much of the spillage as possible
- Clean area thoroughly using hot water and detergent and disposable cloths, rinse and dry
- **Impervious flooring:** wipe over the area with chlorine solution, e.g. Actichlor tablets made up to 10,000 ppm strength, and paper towels
- Dispose of all materials as clinical waste
- Clean the bucket in fresh water and detergent, rinse and dry
- Dispose of protective clothing as clinical waste and wash hands
- **Carpet:** arrange for the carpet to be steam

9.5 Laundry

Patients’ clothes and linen can be washed as normal. Foul linen should be washed separately and be sent to the linen room in a red alginate bag before placing into a red plastic bag for linen. Linen for any surgical procedures should be single use and disposed of as clinical waste. Any re usable linen must also be disposed of as clinical waste following a procedure involving any category of CJD

9.6 Clinical Waste

All clinical waste should be double bagged and disposed of by incineration.
9.7 Accidental Inoculation Injuries
For any accident involving "sharps", or contamination of abrasions with blood or body fluid(s), wounds should be gently encouraged to bleed, gently washed (avoid scrubbing) with warm soapy water, rinsed, dried and covered with a waterproof dressing, or further treatment given appropriate to the type of injury. Splashes into the eyes or mouth should be dealt with by thorough irrigation. The accident should be reported to the line manager, and an incident form completed and then the Trust procedure for dealing with a sharps injury followed. (See Sharps policy)

9.8 Laboratory investigations
All samples from patients suspected of having CJD or nv CJD should be very clearly labelled to alert laboratory staff to this possibility.

9.9 Invasive medical procedures and sample labeling
Because of the unusual resistance of the TSE agents, single-use disposable equipment should be used wherever practicable, and all other small items of equipment contaminated whilst obtaining specimens should be destroyed by incineration. Where this is not possible, the advice in Annex C on decontamination should be followed.

Blood, biopsy and lumbar puncture samples from patients defined in Table 4a should only be taken by trained personnel who are aware of the hazards involved. Under health and safety at work legislation (see Part 2), employers have a legal obligation to provide information, instruction and training for staff involved in potentially hazardous tasks. The collection of blood specimens should involve the same precautions used for all work of this type with any patient, i.e. avoidance of sharps injuries and other forms of parenteral exposure, and the safe disposal of sharps and contaminated waste in line with locally approved arrangements. The 1998 Guidance recommended incineration of this waste. Discussions are currently in progress to determine whether this requirement can be modified for low risk clinical waste. Disposable gloves and eye protection should be worn where splashing may occur. Particular care should be taken with lymphoid tissue specimens from patients defined in Table 4a. Standard practice should be to use disposable gloves, aprons and single-use disposable instruments when performing a lumbar puncture for the collection of cerebrospinal fluid.

NB: HSC 1999/178, on “vCJD: Minimising the risk of transmission”, issued by the Department of Health in August 1999, specifically states that lumbar punctures should always be carried out using single-use equipment. It also stresses that devices labelled as “single use” by the manufacturer should not be re-used under any circumstances.

10.1 Last offices
On the death of a patient defined in Table 1, the removal of the body from the ward to the mortuary should be carried out using normal infection control measures. It is recommended that the deceased patient be placed in a body bag prior to transportation to the mortuary, in line with normal procedures for bodies where there is a known infection risk. The body should be labeled with a ‘danger of infection’ sticker.
10.2 Post Mortem

A post mortem is usually essential in order to confirm clinical diagnosis and the cause of death in patients with suspected CJD or vCJD. BNHFT mortuary currently does not perform examination in patients suspected of having a TSE. The responsible histopathologist will determine the need for further investigations and where they should be undertaken based on risk assessment above.

10.3 Post Mortem Precautions

Follow protocol for infectious cases.

11.0 Organ donations and transplantation

Blood donation, organs or tissue for transplantation must not be taken from definite, probable, possible or at risk CJD or vCJD patients.

In addition, members of ophthalmic teams must make specific enquiries to exclude patients with definite, probable, possible or at risk of CJD or vCJD before taking corneas from demented or psychiatric patients, or those who die from obscure undiagnosed neurological disease.

12.0 Occupational health records

It is recommended that healthcare workers who perform invasive procedures on, or handle potentially infectious material from any category of TSE patient in Table 1(pg4), have this recorded in their confidential occupational health clinical record.

Exposure to handling contaminated or potentially contaminated medical devices or equipment must be minimized and all equipment used should be quarantined or contained for incineration by theatre staff, pathology staff or mortuary staff immediately after use.

This can be done by management discussing the process with the healthcare worker and then writing to occupational health service giving the name, job title and date of birth of each healthcare worker.

For example such record keeping is needed in the following situations (for healthcare workers who perform invasive procedures on, or handle potentially infectious material from any category of TSE patient in Table 1.)

- All surgical procedures.
- Processing of tissue specimens
- Post mortem

If a healthcare worker needs occupational health advice regarding TSE the healthcare worker contacting the occupational health department can achieve this.

In the above situations the manager of the department involved must:

- Send to Occupational Health a list of all staff directly involved, along with the nature of the procedure and each staff member’s involvement.
- Inform each member of staff that they may attend Occupational Health for advice if needed.
13.0 Surgical Procedures

(See, Algorithm charts for precautions for surgical procedures on definite, probable, possible and at risk category patients)

Due to the unusual resistance of TSE agents to decontamination there are particular concerns regarding surgical and other clinical procedures because of the potential for onward transmission of CJD to other patients via contaminated surgical instruments. These guidelines refer to surgical procedures on patients where CJD is known or suspected, or the patient is at risk; they do not refer to surgery on patients where there is no known risk of CJD.

13.1 Precautions during all clinical procedures/surgery for all symptomatic patients (definite, probable or possible CJD or vCJD) (Risk Group 1 see page 7):

- Whenever appropriate and possible, the intervention should be performed in an operating theatre or designated clinical area.

- Perform the procedure at the end of the list to allow for cleaning of theatre surfaces before the next session (see Management of spillages, ).

- Involve minimum numbers of staff.

- Care should be taken with procedures performed at the bedside e.g. lumbar puncture, chest drain insertion, to ensure the environment may be readily cleaned should a spillage occur (see Spillages, page ). Protective clothing should be worn.

- Staff should wear single-use protective clothing:
  - liquid repellent gown over plastic apron
  - gloves (double gloving at surgeons’ discretion)
  - mask (fluid repellent)
  - visor or goggles

- Maintain a one-way flow of instruments.

- Use single-use disposable instruments and equipment where possible. Destroy by incineration.

- Incinerate all single-use used instruments, drapes, dressings and protective clothing.

- Instruments for incineration must be placed in a sharps bin, sealed, clearly identified with date, theatre/ward and hospital and removed as soon as possible.

- Expensive equipment e.g. drills may be protected from contamination by using guards etc. so that entire items do not require incineration. The drill bit and other parts in contact with high-risk tissue and the protective covering must be incinerated.
14.0 Identification of a case of known or suspected TSE in a patient who has previously undergone invasive/surgical procedures.

In the event of the above happening the Infection Control Team should be informed immediately.

It is essential that sets of instruments and any additional items that were used are identified and held immediately in quarantine until a decision is made on how to proceed.

**Known patients**, with a definitive diagnosis will need to have any equipment used for their procedure to be destroyed by incineration. Surgery should be avoided wherever possible for this category of patients. **See SOP / CJD 001/002 (appendix 5 and 6)**

**Suspect patients** surgery on suspect patients should be avoided apart from life threatening situations. In the eventuality of such a patient needing surgery the following guidance must be followed: **See SOP / CJD 001/002 (appendix 5 and 6)**

**At risk patients**

*Sterile Services must not under any circumstances process any equipment that has been used on a known or suspected CJD case.*

15.0 **Re-usable Instruments**

This refers to instruments and equipment not designated as single-use or disposable. Where single-use instruments are not available ‘reusable’ instruments may have to be used. These cannot just be decontaminated and reused in the usual way: they must be either destroyed or quarantined pending classification of the diagnosis, if there is any risk they may have come into contact with infectious tissue. The following table defines the action to be taken.

<table>
<thead>
<tr>
<th>Tissue infectivity (See table page 6 Patient Risk Groups)</th>
<th>Risk Group of Patient</th>
<th>Definite/Probable (Group 1)</th>
<th>Possible/Uncertain (Group 1)</th>
<th>At risk (Groups 2 &amp; 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High&lt;br&gt;• brain&lt;br&gt;• spinal cord&lt;br&gt;• posterior eye</td>
<td>genetic</td>
<td>Incinerate</td>
<td>Quarantine pending diagnosis</td>
<td>Incinerate</td>
</tr>
<tr>
<td></td>
<td>iatrogenic</td>
<td></td>
<td></td>
<td>Incinerate</td>
</tr>
<tr>
<td>Medium</td>
<td>Incinerate</td>
<td>Quarantine pending diagnosis (See below: sub section 8)</td>
<td>Incinerate</td>
<td>Incinerate</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>------------</td>
<td>----------------------------------------------------------</td>
<td>------------</td>
<td>------------</td>
</tr>
<tr>
<td>• anterior eye</td>
<td>Incinerate</td>
<td>Incinerate pending diagnosis (See below: sub section 8)</td>
<td>Incinerate</td>
<td>Incinerate</td>
</tr>
<tr>
<td>• olfactory epithelium</td>
<td>Incinerate</td>
<td>Incinerate pending diagnosis (See below: sub section 8)</td>
<td>Incinerate</td>
<td>Incinerate</td>
</tr>
</tbody>
</table>

Low/none detectable | No special precautions | No special precautions | No special precautions | No special precautions |

### Variant CJD

<table>
<thead>
<tr>
<th>High</th>
<th>Incinerate</th>
<th>Quarantine pending diagnosis</th>
<th>(Not applicable)</th>
<th>Incinerate</th>
</tr>
</thead>
<tbody>
<tr>
<td>• brain</td>
<td>Incinerate</td>
<td>Quarantine pending diagnosis</td>
<td>(Not applicable)</td>
<td>Incinerate</td>
</tr>
<tr>
<td>• spinal cord</td>
<td>Incinerate</td>
<td>Quarantine pending diagnosis</td>
<td>(Not applicable)</td>
<td>Incinerate</td>
</tr>
<tr>
<td>• posterior eye</td>
<td>Incinerate</td>
<td>Quarantine pending diagnosis</td>
<td>(Not applicable)</td>
<td>Incinerate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medium</th>
<th>Incinerate</th>
<th>Quarantine pending diagnosis</th>
<th>(Not applicable)</th>
<th>Incinerate</th>
</tr>
</thead>
<tbody>
<tr>
<td>• lymphoid tissue</td>
<td>Incinerate</td>
<td>Quarantine pending diagnosis</td>
<td>(Not applicable)</td>
<td>Incinerate</td>
</tr>
<tr>
<td>• anterior eye</td>
<td>Incinerate</td>
<td>Quarantine pending diagnosis</td>
<td>(Not applicable)</td>
<td>Incinerate</td>
</tr>
<tr>
<td>• olfactory epithelium</td>
<td>Incinerate</td>
<td>Quarantine pending diagnosis</td>
<td>(Not applicable)</td>
<td>Incinerate</td>
</tr>
</tbody>
</table>

Low/none detectable | No special precautions | No special precautions | (Not applicable) | No special precautions |
### CJD Tissue Infectivity

<table>
<thead>
<tr>
<th>Definite / Probable</th>
<th>Possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH: Brain, Spinal Cord, Posterior Eye</td>
<td>Destroy</td>
</tr>
<tr>
<td>MEDIUM: Anterior Eye, Olfactory Epithelium</td>
<td>Destroy</td>
</tr>
<tr>
<td>MEDIUM / LOW Other Low risk tissues</td>
<td>Destroy</td>
</tr>
</tbody>
</table>

### vCJD Tissue Infectivity

<table>
<thead>
<tr>
<th>Definite / Probable</th>
<th>Possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH: Brain, Spinal Cord, Posterior Eye</td>
<td>Destroy</td>
</tr>
<tr>
<td>MEDIUM: Lymphoid Tissue, Anterior Eye, Olfactory Epithelium</td>
<td>Destroy</td>
</tr>
<tr>
<td>MEDIUM / LOW Other Low Risk tissues</td>
<td>Destroy</td>
</tr>
</tbody>
</table>

**NOTE:** IT IS IMPERATIVE THAT INSTRUMENTS KNOWN TO BE OR POTENTIALLY BE CONTAMINATED BY CJD ARE NOT RETURNED TO TSSU. See SOP / CJD 001/002 (appendix 5 and 6)

Forward planning of any procedure and adherence to this protocol is required to ensure that staff and patient safety can be maintained.

Any sharps injury or personal contamination **must** be reported according to the Trust’s policies. (Sharps Policy)

Equipping levels in the Theatre will be kept to a minimum safe level with all unnecessary items removed prior to the procedure commencing.

Staffing levels in the theatre will be kept to a minimum level appropriate to the procedure.

TSSU staff to be notified
16.0 Theatre Procedure

16.1 Introduction

This section identifies the procedure for handling cases of known or suspected CJD cases within the operating theatres and has been formulated with the sole intention of managing the risks associated to exposure to known or suspected contaminants. This section is divided into 4 sections, dealing with “No Risk”, “Possible Medium Risk tissue”, “Possible High Risk Tissue” and Probable Medium/High Risk Tissue however standard universal precautions regarding Protective equipment apply under each section.

(No individual theatre is designated to carry out known suspect or at risk procedures).

16.2 No Risk

The routine procedure for the disposal of waste and reusable instrumentation via the Sterile Services Department is followed.

16.3 Possible Risk - Low Risk Tissue

The routine procedure for the disposal of waste and reusable instrumentation via the Sterile Services Department is followed.

16.4 Possible Risk - High/Medium Risk Tissue

Instruments

a) Wherever possible disposable instruments and medical devices should be used.
b) All non-disposable instruments must be handled as “normal” except that they must not be sent to SSD for reprocessing. Similarly no attempt must be made to reprocess or decontaminate any instrument(s) within the theatre environment,
c) All used instruments must be wrapped in their original packing drape and tray and then placed into two appropriately sized yellow clinical waste bags (double bag).
d) The container’s lid must be fully secured and be labelled correctly with a Biohazard label (see Appendix 3).

Once contained and sealed the container will be quarantined in an appropriate area. See SOP / CJD 001/002 (appendix 5 and 6)

17.0 Storage

17.1 Quarantine of Instruments

Instruments used for procedures involving tissues designated as high or medium infectivity on a possible CJD or possible vCJD patient must not be re-used but may be quarantined pending clarification of the diagnosis.

Instruments for quarantine must be labelled as such and washed to remove gross soiling. Those undertaking washing of instruments must be informed of the possible diagnosis and hazards. Care must be taken to avoid splashing and generation of aerosols. Instruments should therefore be held below the surface of the water in a sink into which water is running and draining out continually. Do not hold instruments under
a flowing tap as this is likely to generate splashes. Gloves, apron, visor/goggles and mask should be worn. Do not decontaminate in an automated washer disinfecter.

Full boxes will be stored and secured in the quiet room of Sterile services. Equipment stored in these circumstances will only be released from quarantine under the following circumstances:

Following a **NEGATIVE** pathological test result, in which case the equipment will be processed by the Sterile Services Department in line with policy and returned to circulation.

Following a **POSITIVE** or **PROBABLE** pathological test result, in which case the container with the contaminated equipment will be removed and placed into the contaminated waste container trolley and incinerated in its entirety.

**Clinical Waste**

All clinical waste will be bagged according to Trust policy for destruction by incineration. All "sharps" will be placed in a new sharps bin, which will be sealed and removed for incineration along with the other clinical waste.

**18.0 Specimens for Laboratory Investigations**

All clinical specimens from **definite**, **probable**, **possible** or **at risk** patients should initially be sent to microbiology laboratory and handled at Containment Level 3. Samples should be marked with a “Biohazard” label.

It is essential that the diagnosis or suspected diagnosis of CJD is clearly stated on the form. **The laboratory must be informed in advance that samples are being sent.**

**18.1 Transport of pathology specimens**

All specimens must initially be sent to microbiology laboratory.

The transport of specimens from **definite**, **probable**, **possible** or **at risk** patients should fulfil the requirements for classification, packaging, labelling and transporting.

**19.0 Ward Guidelines**

A patient with CJD does not routinely require isolation as CJD is not transmissible from person to person by 'normal' social contact or routine clinical contact. However, if heavy environmental contamination with blood is likely patients must be nursed in a side-room. No particular precautions, beyond routine infection control as used for all other patients i.e. Universal Precautions, are necessary, unless there is bleeding from the mouth, in which case disposable cutlery should be provided. There is no evidence of infectivity in saliva, body secretions or excreta.

For invasive procedures e.g. chest drain insertion or lumbar puncture, carried out on the ward for **definite**, **probable**, **possible** or **at risk** CJD or vCJD patients follow the above guidelines of this protocol.
20.0 Linen

All items of theatre linen including clothes and shoes will be treated as clinical waste. Single use linen should be used wherever possible. See SOP / CJD 001/002 (appendix 5 and 6)

21.0 Record keeping

An inventory (appendix 4) of any equipment destroyed will be maintained to assist prompt replacement and ensure that items have been removed from use.

A logbook will be maintained by the Theatre Co-ordinator noting the date, theatre used, patient details and ALL those staff involved with the patient’s procedure. This file is located in the Theatre Co-ordinator’s Office.

22.0 At Risk/Definite/Probable - High/Medium Risk Tissue

Surgery on known risk patients should be avoided apart from in life threatening situations. In the eventuality of such a patient needing surgery the following guidelines are to be followed.

22.1 Instruments

a) Wherever possible disposable instruments and medical devices should be used.

After washing place instruments in a disposable instrument tray and allow to air dry. They should then be placed in an impervious rigid plastic container with a close-fitting lid that can be re-opened. The lid must be sealed with heavy-duty tape and labelled with the patient’s details. The label must state the surgical procedure in which the instruments were used and the name of the person in charge at the time. Dispose of the instrument tray by incineration. The sealed container must then be kept in a locked cupboard until diagnosis.

b) All non-disposable instruments and medical devices must be handled as “normal” except that they must not be sent to SSD for reprocessing. Similarly no attempt must be made to reprocess or decontaminate any instrument(s) within the theatre environment, which includes the use of a Bench-top steriliser (e.g. Little Sister) or cold sterilising solution.

If the case is confirmed CJD or vCJD, or if after testing, the diagnosis is inconclusive instruments must be incinerated. These instruments must not be removed from their container. Only if a definitive alternative diagnosis is confirmed may instruments be decontaminated using routine procedures and re-used. Areas quarantining instruments must be informed as soon as possible after confirmation of diagnosis or testing, death or post-mortem. A logbook of possible CJD patients, who have been operated on (as well as a record of quarantined instruments), must be kept in theatres and their case reviewed 6 monthly. This review must be initiated by a designated member of the theatre team appointed by theatre management.

c) All used instruments must be wrapped in their original packing drape and tray and then placed into two appropriately sized yellow clinical waste bags (double bag). All used instruments must be wrapped in their original packing drape and tray and then placed into two appropriately sized yellow clinical
waste bags (double bag). This will then be placed in a clinical waste box of appropriate size and sealed.

d) The container’s lid must be fully secured and be labelled correctly with a Biohazard label (see Appendix 3).

22.2 Storage

Full clinical waste boxes will be taken to the holding area for clinical waste and placed into the clinical waste trolley for incineration.

22.3 Clinical Waste

All clinical waste will be double bagged in yellow clinical waste bags and removed straight away for destruction by incineration.
All “sharps” will be placed in a new sharps bin, which will be sealed and placed in a double yellow clinical waste bag and removed for incineration along with the other clinical waste.
It is essential to ensure that the waste is disposed of for incineration and not autoclaving.

22.4 Linen

All items of theatre linen including clothes and shoes will be treated as clinical waste.

22.5 Record Keeping

An inventory of all equipment destroyed will be maintained to assist prompt replacement and to ensure that items have been removed from use.

A log book will be maintained by the Theatre Co-ordinator noting the date, theatre used, all patient details and ALL staff involved with the patient procedure. This will be issued to Occupational Health Department

23.0 Clinical procedures (surgical and other invasive interventions):

Further precautions may be required during surgical or other invasive procedures on patients placed in known, suspect or at Risk category) whose invasive procedure involves tissues listed in the distribution of tissue infectivity (appendix1) in order to prevent cross infection; if in doubt as to what constitutes “invasive” contact the Infection Control Team for advice.

To initiate these further precautions, the clinician caring for the patient or the person in charge of the ward/department:

- Must inform the Infection Control Team, of the proposed procedure/operation. As much notice as possible must be given. Or planned procedures this means no less than 24 hours.
- Must inform the person in charge of the appropriate receiving theatre/department.
23.1 When handling high/medium risk tissue (see appendix 1):

- The nurse in charge of the relevant theatre/department will inform Theatre Sterile Service Unit (TSSU) of the proposed invasive/surgical procedure on the patients in category 1, 2 and 3 (Table 1).
- Single use instruments must be used wherever possible.
- Where single use instruments are not available the TSSU will wrap each instrument, that need to be identified and specifically requested by theatre, separately in peelable packaging. These may then be contained and wrapped in a tray so that they are all together. Instruments so wrapped can be opened and used as required. Any unopened instruments should be returned to TSSU.
- Following a risk assessment by the above a decision will be taken to incinerate or quarantine instruments.
- The TSSU department will be informed of the need to decontaminate, destroy or quarantine instruments, before the user department undertakes the procedure so that a list of devices destroyed can be identified and replaced.

23.2 Intra-operative procedures:

- The procedure should be performed by experienced staff who understand the nature of the risk.
- Wherever possible the intervention should be performed in an operating theatre.
- If a procedure is performed in another clinical area (e.g. at the bedside), the environment must be readily and easily cleanable should a spillage occur.
- Perform the procedure at the end of a list or session; disinfect blood and body fluid spillage as in standard infection control precautions with a detergent solution followed by an hypochlorite solution. This should be performed immediately after the case leaves theatre using single use cleaning equipment where possible.
- Involve only the minimum required number of health care personnel.
- Wear the following single use protective clothing:
  - Liquid repellent gown over a plastic apron
  - Gloves
  - Mask
  - Goggles or visor
  - Footwear should be worn (i.e. surgical boots) and disposed of after case by incineration.
- Maintain a one way flow of instruments.
- Use single use disposable instruments and equipment (if single use items are not available the instruments used should under no circumstances be reused on another patient).
- Where practicable, expensive reusable equipment (e.g. drills) should be protected from contamination by using shields, guards or covering, any protective coverings used should be destroyed by incineration.

23.3 Post operative instrument decontamination:

- Instruments will not be returned to sterile services/TSSU without prior contact/consultation.
- After the procedure the person in charge of the theatre will arrange for the management and storage of the items according to TSSU procedures.
The Director of Infection Prevention and Control (or nominated deputy) will be responsible for following up patients with a differential diagnosis. He/she will be responsible for informing the TSSU manager when written confirmation of a diagnosis of “TSE” or “not TSE” is made and the action to be taken.

If a definite diagnosis of “not TSE” is made the TSSU manager will be informed. The instruments will then be made available for reprocessing and reuse.

If the diagnosis is “TSE” or there is no definitive diagnosis possible, but TSE cannot be excluded, then the instruments **MUST** be destroyed by incineration.

- All contaminated instruments should be covered with instrument holding fluid (pre klenze gel). Personnel carrying out this procedure must wear personal protective clothing as listed above paragraph 7.2

23.4 When handling low risk tissue (see appendix 1):

Continue to use Standard infection control precautions

23.5 Quarantining of instruments:

After completion of a surgical procedure on a possible CJD or vCJD patient, single-use instruments should be separated and disposed of by incineration.

Any re usable medical devices (surgical instruments) must be sprayed with a holding solution of Pre Klenze Gel. These will be wrapped in the original wrapping, placed into double yellow clinical waste bags. Sealed and then placed into a clinical waste bin and adequately sealed and labeled as per **See SOP / CJD 001/002 (appendix 5 and 6)**

The sealed box can be stored indefinitely in a suitable designated place until the outcome of any further investigations is known. If the patient is confirmed as suffering from CJD or vCJD, the box and its contents should be incinerated without any further examination.

If an alternative diagnosis is confirmed, the instruments may be removed from the box by the responsible person (or a named deputy) and reprocessed according to best practice and returned to use. Additional decontamination procedures are not required.

Records must be kept of all decisions, and the Theatre Sterile Service Unit (TSSU) must be informed about the decision before the instruments are sent for routine reprocessing.

23.6 Labeling of specimens

TSEs are categorised as hazard group 3 organisms. All pathology including all CNS specimens from patients who are in categories 1, 2 and 3 of table 1 must be labeled as “danger of infection”. Contact the laboratory for advice before submitting specimens.
24.0 Childbirth

In the event that a patient defined in Table 1 (pg 4) above 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 control procedures. See SOP / CJD 001/002 (appendix 5 and 6).

The placenta and other associated material and fluids should be treated as if infected, and disposed of by incineration in double clinical waste bags.

25.0 Endoscopy

In order to decrease the risk of transmission of TSEs through endoscopic procedures, additional precautions for the decontamination of flexible endoscopes are recommended.

Channel cleaning brushes used in the biopsy/instrument channel port used with flexible endoscopes should be disposed of as clinical waste after each use. Single use, disposable biopsy forceps should be used routinely in all patients with known, suspect or at risk of CJD, and in those identified as at risk of developing CJD. No biopsies should be taken from any category of risk patient and single use brushes and cleaning materials must be used when cleaning any equipment. This must be disposed of as clinical waste and incinerated.

Where single use items are not used, they must be kept together with the endoscope, forming a unique set, until the accessories are disposed of. It is essential to have systems in place that enable endoscopes, together with all re-usable accessories, to be traced to the patients on whom they have been used.

Endoscopes used for certain procedures in individuals with possible CJD, or in whom the diagnosis is unclear should be removed from use or quarantined pending diagnosis or exclusion of CJD. Endoscopes other than those used in the CNS and nasal cavity, which have been used for invasive procedures in individuals designated as at risk of vCJD should be removed from use or quarantined to be re-used exclusively on the same individual patient if required.

The endoscope should be fully cleaned and then placed in quarantine.

Aldehyde disinfectants with fixative qualities (such as glutaraldehyde and OPA) tend to stabilise rather than inactivate prions. The use of non-fixative disinfectants, if this is in accordance with the manufacturers’ instructions, is therefore preferable. Disinfectants with fixative properties should not be used on flexible endoscopes used for any procedure on patients with a diagnosis of definite, probable or possible CJD or where the diagnosis of CJD is unclear or the patient is at risk of developing CJD.

25.1 Summary of precautions advised for the use of endoscopes

<table>
<thead>
<tr>
<th>CJD other than vCJD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tissue Infectivity</strong></td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Symptomatic</th>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definite/probable</strong></td>
<td><strong>Possible/diagnosis unclear</strong></td>
</tr>
<tr>
<td><strong>High:</strong></td>
<td>Single use OR Destroy after use</td>
</tr>
<tr>
<td></td>
<td><strong>Medium:</strong></td>
</tr>
<tr>
<td></td>
<td>Single use OR Destroy after use</td>
</tr>
<tr>
<td></td>
<td><strong>Low/none detectable:</strong></td>
</tr>
<tr>
<td></td>
<td>All other tissues</td>
</tr>
</tbody>
</table>

The advice of the consultant carrying out the endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination of the endoscope with olfactory epithelium could be excluded with confidence. If such contamination cannot be excluded, take precautions appropriate for medium infectivity tissues.

1. This includes patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD but where a diagnosis of CJD is being actively considered.

2. This advice refers to the use of flexible endoscopes in patients at risk of developing CJD. For guidance on the use of rigid endoscopes that can be autoclaved,

3. Instruments that are destined for disposal may be collected for use in research. Anyone considering such a course of action should contact the Surgical Instrument Store (contact: Dr. James Walker), Health Protection Agency, Porton Down on 01980 612643 (answer phone on out-of-hours).

4. Quarantined endoscopes may be re-used exclusively on the same individual patient if required. The principles behind the procedures recommended for quarantining of surgical instruments should be followed except the endoscope should be fully cleaned and decontaminated immediately after use, before being quarantined. The endoscope should be decontaminated alone using an Automatic Endoscope Reprocessor (AER). The AER should be decontaminated as per section F.1 (d) of this guidance.

5. For some procedures, the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. However, this does not obviate the need for routine decontamination following use on a patient.
Additionally, in practice, it may be difficult to ensure effective protection and advice should be sought from the surgical staff carrying out the procedure and the manufacturer of the endoscope to determine practicality.

The decontamination procedures advised in this guidance, taken together with the MDA Device Bulletin MDA DB2002(05), (available from the MHRA website), should be followed.

**vCJD**

<table>
<thead>
<tr>
<th>Tissue Infectivity</th>
<th>Status of patient</th>
<th>Symptomatic</th>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definite/probable</td>
<td>Possible/diagnosis unclear</td>
<td>Single use OR Destroy after use</td>
<td>Single use OR Quarantine pending diagnosis</td>
</tr>
<tr>
<td>High:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Brain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Spinal cord</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medium:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Olfactory epithelium*</td>
<td></td>
<td>Single use OR Use dedicated endoscope OR Destroy after use</td>
<td>Single use OR Quarantine pending diagnosis</td>
</tr>
<tr>
<td>• Lymphoid tissue**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low/none detectable 8</td>
<td>No special precautions</td>
<td>No special precautions</td>
<td>No special precautions</td>
</tr>
</tbody>
</table>

*The advice of the consultant carrying out the endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination of the endoscope with olfactory epithelium can be excluded with confidence. If such contamination cannot be excluded, take precautions appropriate for medium infectivity tissues

**For the purposes of this Annex, lymphoid tissue refers to the spleen, thymus, tonsils and adenoids, lymph nodes, the appendix and the gastro-intestinal tract submucosa.

1 This includes patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD but where a diagnosis of CJD is being actively considered
This advice refers to the use of flexible endoscopes in patients at risk of developing CJD. For guidance on the use of rigid endoscopes that can be autoclaved, refer to the guidance for the use of all surgical instruments in at risk patients.

Instruments that are destined for disposal may be collected for use in research. Anyone considering such a course of action should contact the Surgical Instrument Store (contact: Dr. James Walker), Health Protection Agency, Porton Down on 01980 612643 (answer phone on out-of-hours).

Quarantined endoscopes may be re-used exclusively on the same individual patient if required. The principles behind the procedures recommended for quarantining of surgical instruments should be followed except the endoscope should be fully cleaned and decontaminated immediately after use, before being quarantined. The endoscope should be decontaminated alone using an Automatic Endoscope Reprocessor (AER). The AER should be decontaminated as per section.

For some procedures, the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. However, this does not obviate the need for routine decontamination following use on a patient. Additionally, in practice, it may be difficult to ensure effective protection and advice should be sought from the surgical staff carrying out the procedure and the manufacturer of the endoscope to determine practicality.

The decontamination procedures advised in this guidance, taken together with the MDA Device Bulletin MDA DB2002(05), (available from the MHRA website), should be followed.

The NCJDSU holds a few flexible endoscopes dedicated for use on probable CJD cases. If these are suitable for the clinical purpose intended, they may be borrowed from the Unit. They should not be used on patients with possible CJD, patients for whom the diagnosis of CJD is unclear or patients at risk of CJD.

All endoscopes used for invasive procedures must be removed from use or quarantined.
References


### Appendix 1 Distribution of Tissue infectivity

**CJD. Risk categories**
*(FEB Note: is this for vCJD? Need to specify)*

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Presence of abnormal Prion Protein and assumed level of infectivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain</td>
<td>High</td>
</tr>
<tr>
<td>Spinal Cord</td>
<td>High</td>
</tr>
<tr>
<td>Spinal ganglia</td>
<td>High</td>
</tr>
<tr>
<td>Dura mater</td>
<td>High</td>
</tr>
<tr>
<td>Cranial nerves</td>
<td>High</td>
</tr>
<tr>
<td>Cranial ganglia</td>
<td>High</td>
</tr>
<tr>
<td>Posterior eye</td>
<td>High</td>
</tr>
<tr>
<td>Anterior eye and cornea</td>
<td>Medium</td>
</tr>
<tr>
<td>Olfactory epithelium</td>
<td>Medium</td>
</tr>
<tr>
<td>Tonsils</td>
<td>Medium</td>
</tr>
<tr>
<td>Appendix</td>
<td>Medium</td>
</tr>
<tr>
<td>Spleen and thymus</td>
<td>Medium</td>
</tr>
<tr>
<td>Other lymphoid material</td>
<td>Medium</td>
</tr>
<tr>
<td>Peripheral nerve</td>
<td>Low</td>
</tr>
<tr>
<td>Dental Pulp</td>
<td>Low</td>
</tr>
<tr>
<td>Gingival Tissue</td>
<td>Low</td>
</tr>
<tr>
<td>Blood and bone marrow</td>
<td>Low</td>
</tr>
<tr>
<td>CSF</td>
<td>Low**</td>
</tr>
<tr>
<td>Placenta</td>
<td>Low</td>
</tr>
<tr>
<td>Urine</td>
<td>Low</td>
</tr>
<tr>
<td>Other tissues</td>
<td>Low</td>
</tr>
</tbody>
</table>

** Although designated low risk tissue infectivity further precautions are advised in certain situations

*Take from 'Transmissible spongiform encephalopathy agents: safe working and the prevention of infection' Department of Health June 2003*
# Appendix 2 Common flexible endoscopic procedures classified as invasive or non-invasive

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Contamination of biopsy channel</th>
<th>Mechanism</th>
<th>Invasive (+) or Non-Invasive (-)</th>
<th>Notes/Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 ARTHROSCOPY, BRONCHOSCOPY AND CYSTOSCOPY</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a All arthroscopy procedures</td>
<td>This procedure will not involve contact of the endoscope with any infectious tissue.</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1b Diagnostic Cystoscopy or bronchoscopy</td>
<td>Providing no biopsy is taken it is very unlikely that the endoscope will become contaminated.</td>
<td>None. Tissue contamination would not result from a straightforward diagnostic procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1c Cystoscopy with biopsy to obtain fixed lymphoid tissue</td>
<td>When a biopsy is taken of lymphoid tissue, there is a risk that the suction/biopsy channel could become contaminated with potentially infectious tissue</td>
<td>Lymphoid tissue could come into contact with the lining of the biopsy channel. Tissue may be deposited in the biopsy channel</td>
<td>+</td>
<td>Biopsy of the bladder can be considered non-invasive (-) if it can be determined with confidence that there has been no contact with, or invasion of, lymphoid tissue.</td>
</tr>
<tr>
<td>1d Bronchoscopy with biopsy to obtain fixed lymphoid tissue</td>
<td>When a biopsy is taken of lymphoid tissue, there is a risk that the suction/biopsy channel could become contaminated with potentially infectious tissue</td>
<td>Lymphoid tissue could come into contact with the lining of the biopsy channel. Tissue may be deposited in the biopsy channel</td>
<td>+</td>
<td>Bronchoscopy with biopsy can be considered non-invasive (-) if it can be determined with confidence that there has been no contact with, or invasion of, lymphoid tissue.</td>
</tr>
<tr>
<td>1e Transbronchial biopsy</td>
<td>There is a risk that the biopsy channel may become contaminated with lymphoid tissue during transbronchial biopsy.</td>
<td>Lymphoid tissue could come into contact with the lining of the biopsy channel. Tissue may be deposited in the biopsy channel</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>Contamination of biopsy channel</td>
<td>Mechanism</td>
<td>Invasive (+) or Non-Invasive (-)</td>
<td>Notes/Exceptions</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------------------------</td>
<td>-----------</td>
<td>---------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>2 ENDOSCOPIC ULTRASOUND (EUS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2a Diagnostic EUS</td>
<td>Providing no biopsy is taken it is very unlikely that the endoscope will become contaminated.</td>
<td>None. Tissue contamination would not result from a straightforward diagnostic ultrasound procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2b EUS with biopsy</td>
<td>Biopsy utilises a needle that may result in contamination of the suction/channel with lymphoid tissue.</td>
<td>Lymphoid tissue may contain prions, which then come into contact with the lining of the biopsy channel. Tissue may be deposited in the biopsy channel. Decontamination may be sub-optimal.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 UPPER GI ENDOSCOPY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3a Diagnostic gastroscopy</td>
<td>Providing no biopsy is taken it is very unlikely that the endoscope will become contaminated.</td>
<td>None. Tissue contamination would not result from a straightforward diagnostic endoscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3b Gastroscopy with biopsy</td>
<td>Even with efficient disposable biopsy forceps contamination of the suction/channel with submucosal lymphoid tissue is likely.</td>
<td>Submucosal lymphoid tissue may contain prions, which then come into contact with the lining of the biopsy channel. Tissue may be deposited in the biopsy channel. Decontamination may be sub-optimal.</td>
<td></td>
<td>Cytology should be used as an alternative technique for assessing gastric ulcers if malignancy is suspected.</td>
</tr>
<tr>
<td>3c Gastroscopy with brush cytology</td>
<td>The instrument is sheathed and therefore there is low risk of the biopsy channel becoming contaminated with lymphoid tissue</td>
<td>No contact of lymphoid tissue with the biopsy channel.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3d Gastroscopy and balloon dilatation of stricture (oesophagus or pylorus)</td>
<td>Balloon dilatation may disrupt submucosal lymphoid tissue which could be transferred to the suction/biopsy channel as the balloon is retracted back into this channel</td>
<td>Contamination would be through 'contact' and would be lower than biopsy. Modifying the technique to include removing the endoscope and used balloon as one (without retracting it back into the channel) would minimise the risk</td>
<td></td>
<td>This technique should be considered non-invasive ONLY if the endoscope and balloon are withdrawn from the patient as one (i.e. without retracting the balloon into the suction/biopsy channel) and the balloon is cut-off and destroyed by incineration.</td>
</tr>
<tr>
<td>Procedure</td>
<td>Contamination of biopsy channel</td>
<td>Mechanism</td>
<td>Invasive (+) or Non-Invasive (-)</td>
<td>Notes/Exceptions</td>
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<tr>
<td>3e Gastroscopy and bougie dilatation of oesophagus</td>
<td>Bougie dilatation over a guide wire involves disruption of submucosal tissue only when he endoscope has been withdrawn</td>
<td>No contamination of the biopsy channel with lymphoid tissue.</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>3f Gastroscopy and Polypectomy</td>
<td>Polypectomy snare use diathermy, which coagulates tissue and this adheres to the snare. Although the snare is sheathed it is possible for lymphoid tissue to contaminate the biopsy channel.</td>
<td>The snare is retracted into the endoscope before retracted into the sheath and tissue, adheres to the snare. Therefore it is possible that the biopsy channel will be contaminated with lymphoid tissue.</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>3g Gastroscopy and endoscopic mucosal resection</td>
<td>The risks are the same as for Polypectomy but the disruption of submucosal lymphoid tissue ill be greater. A diathermy current is used and tissue will adhere to the snare.</td>
<td>The snare is retracted into the endoscope before retracted into the sheath and tissue, adheres to the snare. Therefore it is possible that the biopsy channel will be contaminated with lymphoid tissue.</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>3h Gastroscopy and argon plasma coagulation</td>
<td>In theory the technique involves no contact with the mucosa and no risk. However contact frequently occurs and tissue adheres to the catheter</td>
<td>Tissue is likely to enter the suction/biopsy channel. Uncertain risk associated with vaporisation of tissue and smoke</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>3i Gastroscopy and use of heater probe</td>
<td>May be used to arrest bleeding but tissue may adhere o the probe and contaminate the biopsy channel</td>
<td>Lymphoid tissue contamination of the biopsy channel is possible</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>3j Gastroscopy and injection of ulcer</td>
<td>This may be a necessary procedure and haemostasis may be achieved through a variety of methods. Injection of adrenaline would not disrupt submucosal lymphoid tissue but there is contact between the needle and the submucosal tissue.</td>
<td>Good technique would minimise risk. The needle is sheathed and therefore not in contact with the suction/biopsy channel. Poor technique might result in the unsheathed needle coming into contact with the channel.</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>Contamination of biopsy channel</td>
<td>Mechanism</td>
<td>Invasive (+) or Non-Invasive (-)</td>
<td>Notes/Exceptions</td>
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<tr>
<td>3k</td>
<td>Gastroscopy and injection of varices</td>
<td>This may be a necessary procedure and haemostasis may be achieved through a variety of methods. Injection of sclerosing agent would not disrupt submucosal lymphoid tissue but there is contact between the needle and the submucosal tissue.</td>
<td>Good technique would minimise risk. The needle is sheathed and therefore not in contact with the suction/biopsy channel. Poor technique might result in the unsheathed needle coming into contact with the channel.</td>
<td>—</td>
</tr>
<tr>
<td>3l</td>
<td>Gastroscopy and banding of varices</td>
<td>Bands are applied to prominent veins in the oesophagus. Submucosal lymphoid tissue should not be disrupted and in theory the risk should be low.</td>
<td>Contamination of the suction/biopsy channel should be minimal as the procedure is atraumatic.</td>
<td>—</td>
</tr>
<tr>
<td>3m</td>
<td>Gastroscopy and mucosal clipping</td>
<td>No disruption of lymphoid tissue</td>
<td>No contamination of the biopsy channel with lymphoid tissue.</td>
<td>—</td>
</tr>
<tr>
<td>3n</td>
<td>Gastroscopy and insertion of a PEG (Percutaneous Endoscopic Gastrostomy) feeding tube</td>
<td>Patients with vCJD may require a PEG feeding tube. Contamination of the biopsy channel is possible with some techniques.</td>
<td>The most common ‘pull-through’ method does involve a needle penetrating the stomach via the abdominal wall. In theory a small amount of submucosal lymphoid tissue might adhere to the needle and transfer to the wire or thread, which is pulled up the suction/biopsy channel. However, the wire or thread can be withdrawn without entering the channel if the technique is modified so that the endoscope and wire or thread are withdrawn with the grasping device in full view (i.e. not withdrawing the wire or thread into the endoscope)</td>
<td>— Non-endoscopic (radiological) gastrostomy is recommended if possible. However, if this is not an option, the modified PEG technique must be used. This means that the endoscope and wire or thread are withdrawn with the grasping device in full view (i.e. the wire is NOT withdrawn into the endoscope) if the wire or thread is withdrawn into the endoscope the procedure MUST be considered as invasive.</td>
</tr>
<tr>
<td>Procedure</td>
<td>Contamination of biopsy channel</td>
<td>Mechanism</td>
<td>Invasive (+) or Non-Invasive (-)</td>
<td>Notes/Exceptions</td>
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<tr>
<td>3o Gastroscopy and stenting</td>
<td>No contact between suction biopsy channel and lymphoid tissue.</td>
<td>Insertion of oesophageal stents does not disrupt lymphoid tissue during placement as the endoscope has been withdrawn and even with rescoping the biopsy channel is unlikely to become contaminated.</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>3p Gastroscopy and drainage of pancreatic pseudocysts</td>
<td>This is an invasive procedure that is potentially liable to contaminate the biopsy channel</td>
<td>Contact between suction/biopsy channel with gastric submucosal lymphoid tissue is possible</td>
<td>+</td>
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</tr>
<tr>
<td>4 ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY (ERCP)</td>
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<tr>
<td>4a ERCP without sphincterotomy</td>
<td>It is unlikely that the endoscope will become contaminated</td>
<td>No contamination of the biopsy channel with lymphoid tissue.</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>4b ERCP with sphincteroplasty</td>
<td>There is a significant risk that the biopsy channel will become contaminated with lymphoid tissue</td>
<td>It is necessary to withdraw the balloon through the biopsy channel of the endoscope so contamination with lymphoid tissue is possible.</td>
<td>+</td>
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</tr>
<tr>
<td>4c ERCP with sphincterotomy</td>
<td>The diathermy papillotomy knife used in this procedure frequently has adherent tissue and it is likely that the biopsy channel could become contaminated with lymphoid tissue</td>
<td>Adherent tissue may be deposited in the suction/biopsy channel.</td>
<td>+</td>
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<tr>
<td>5 ENTEROSCOPY</td>
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<tr>
<td>5a Enteroscopy without biopsy</td>
<td>Tissue contamination of the suction/biopsy channel is very unlikely</td>
<td>No contamination would result from a straightforward diagnostic enteroscopy</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>5b Enteroscopy with biopsies</td>
<td>It is likely that the suction/biopsy channel will become contaminated with lymphoid tissue</td>
<td>The small bowel submucosal tissue contains infectious prions, which may be deposited in the biopsy/suction channel</td>
<td>+</td>
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<tr>
<td>Procedure</td>
<td>Contamination of biopsy channel</td>
<td>Mechanism</td>
<td>Invasive (+) or Non-Invasive (-)</td>
<td>Notes/Exceptions</td>
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<tr>
<td>6 COLONOSCOPY</td>
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<tr>
<td>6a Colonoscopy without biopsy</td>
<td>A diagnostic colonoscopy is unlikely to contaminate the suction/biopsy channel with submucosal lymphatic tissue</td>
<td>No contamination would result from a straightforward diagnostic colonoscopy</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>6b Colonoscopy with biopsy</td>
<td>Small bowel (ileum) submucosal tissue contains large amounts of prion protein. Colonic submucosal also contains prions</td>
<td>Contamination of the suction/biopsy channel very likely</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>6c Colonoscopy and balloon dilatation procedure</td>
<td>Balloon dilatation of an inflammatory stricture would disrupt lymphoid tissue and contaminate the balloon</td>
<td>Withdrawing the balloon through the suction/biopsy channel would contaminate the colonoscope.</td>
<td>- If modified technique used. This technique should be considered non-invasive ONLY if the colonoscope and balloon are withdrawn from the patient as one (i.e. without retracting the balloon into the suction/biopsy channel) and the balloon is cut-off and destroyed by incineration</td>
<td></td>
</tr>
<tr>
<td>6d Colonoscopy and Polypectomy</td>
<td>Coagulation of tissue which then adheres to the snare. Sometimes small polyps retrieved using the suction channel and a biopsy 'trap' This would increase the risk of contamination with lymphoid tissue</td>
<td>If the snare is always retracted into the sheath before withdrawal into the suction/biopsy channel the risk will be less</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>6e Colonoscopy and endoscopic mucosal resection</td>
<td>As with biopsy, lymphoid tissue may contaminate the biopsy channel</td>
<td>Tissue adheres to the snare which would have to be withdrawn through the colonoscope on most occasions</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>6f Colonoscopy and argon plasma coagulation</td>
<td>Adherent tissue is likely to contaminate the suction/biopsy channel</td>
<td>Contact with lymphoid tissue frequently occurs and tissue adheres to the suction catheter. In addition vaporisation of tissue may constitute a risk</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>Invasive (+) or Non-Invasive (-)</td>
<td>Mechanism</td>
<td>Notes/Exceptions</td>
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</tr>
<tr>
<td>6g Colonoscopy and stenting. No contact between suction biopsy channel and lymphoid tissue.</td>
<td>-</td>
<td>Insertion of colonic stents does not disrupt lymphoid tissue. Channel is unlikely to become contaminated even with rescoping.</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>7a Flexible Sigmoidoscopy</td>
<td>-</td>
<td>This diagnostic procedure is unlikely to result in contamination (no suction biopsy channel).</td>
<td>For invasive procedures the risks are identical to those associated with colonoscopy (see above).</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 3 Diagnostic Criteria

Symptomatic patients are those who fulfil internationally accepted diagnostic criteria, set out below, for definite, probable and possible CJD or vCJD.

Classification criteria

Sporadic CJD

1. Neuropathological/immunocytochemical confirmation is required for a diagnosis of definite sporadic CJD.

2. Probable sporadic CJD patients will have rapidly progressive dementia, and at least two of the following four symptoms:
   (a) myoclonus
   (b) visual or cerebellar problems
   (c) pyramidal or extrapyramidal features
   (d) akinetic mutism

   plus typical electroencephalogram (EEG) with generalised triphasic periodic complexes at approximately 1 per second,

   or clinical criteria for possible sporadic CJD (see below) and a positive assay for 14-3-3 protein in the cerebrospinal (CSF).

3. Possible sporadic CJD patients will have rapidly progressive dementia, two of the symptoms listed in point 2 (a)-(d) above and a duration of less than 2 years.

Iatrogenic CJD

4. Iatrogenic CJD patients display progressive cerebellar syndrome in a pituitary hormone recipient or sporadic CJD with a recognised exposure risk (e.g. dura mater transplant). A definite diagnosis of iatrogenic CJD still requires a neuropathological examination.

Familial CJD

5. Patients with familial CJD will have definite or probable CJD (see 1 and 2 above), plus definite or probable CJD in a first degree relative (i.e. a parent, child or sibling)

   or a neuropsychiatric disorder plus a disease-specific mutation in the prion protein gene.

Variant CJD (vCJD)

6. Definite vCJD patients will have a progressive neuropsychiatric disorder and neuropathological confirmation of the disease, showing spongiform change
and extensive PrP$\text{C}$ deposition with florid plaques throughout the cerebrum and cellebellum.

7. **Probable** vCJD patients can be classified under two sets of criteria:

   (I) They will have progressive neuropsychiatric disorder of a duration greater than 6 months where routine investigations do not suggest an alternative diagnosis. They will also have at least four of the following five symptoms:

   (a) early psychiatric symptoms (depression, anxiety, apathy withdrawal, delusions)
   (b) persistent painful sensory symptoms (including both frank pain and/or unpleasant dysaesthesia)
   (c) ataxia
   (d) myoclonus or chorea or dystonia
   (e) dementia

   An EEG will not show the typical appearances of sporadic CJD, or no EEG has been done and there is a symmetrical high signal in the posterior thalamus on a MRI brain scan.

   These patients would have had no history of potential **iatrogenic** exposure.

   (II) Alternatively, a **probable** vCJD patient will have had a progressive neuropsychiatric disorder for a period of longer than six months, where routine investigations do not support an alternative diagnosis, and where there is no history of potential of iatrogenic exposure, plus a positive tonsil biopsy which is positive for PrP-res.

8. **Possible** vCJD patients will have progressive neuropsychiatric disorder of a duration greater than 6 months where routine investigations do not suggest an alternative diagnosis, and no history of potential iatrogenic exposure. They will also have at least four out of five of the symptoms listed (see 7(I) (a)-(e) above) and an EEG does not show the typical appearance of sporadic CJD or no EEG has been performed.

**Patients who do not fulfil the criteria for possible CJD**

9. The National CJD Surveillance Unit have designated three additional categories for patients who are referred to the Unit but who do not meet the criteria for **possible** CJD. These can be summarised as:

   (I) **Diagnosis unclear** – the diagnostic criteria for definite, probable or possible CJD are not met, nor is there a reasonable alternative diagnosis. CJD, therefore, remains a possibility;

   (II) **CJD thought unlikely** – information indicates that a clinical diagnosis of CJD is very unlikely because atypical disease features, an/or an atypical course, and/or atypical clinical investigation results, and/or a reasonable alternative diagnosis is made but is not confirmed. This
category includes cases which recover clinically without a firm alternative diagnosis;

(III) **Definitely not CJD** – information indicates that CJD is not the diagnosis and there is an alternative definite diagnosis proven on the basis of clinical examination, clinical investigations or pathology.

**Assessment to be carried out before surgery and endoscopy to identify patients with, or at risk of CJD**

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**Appendix 4**

**Categorisation of patients by CJD risk and infection control guidance;**

1. **Symptomatic**
   - Patients who fill the diagnostic criteria of *definite, probable or possible* CJD and other human TSE (including sporadic CJD, sporadic fatal insomnia, variant CJD, iatrogenic CJD and familial disorders such as familial CJD, Gerstmann-Straussler-Scheinker Disease and fatal familial insomnia)
   - Patients with neurological disease of unknown aetiology where the diagnosis of CJD is being actively considered.

2. **Asymptomatic patients**
   - Those with no clinical symptoms, but who are identified as potentially at risk of CJD because of either their family history, or iatrogenic exposures.

**The need to ask CJD risk questions as part of pre-surgery assessment**
It is essential that clinicians ask CJD risk questions to all patients about to undergo a surgical or endoscopic procedure that may involve contact with tissues with high or medium level infectivity, such as brain, spinal cord, eye, olfactory epithelium, spleen, tonsil, gastrointestinal lymphoid tissue and other fixed lymphoid tissue, as part of the pre-surgery assessment. Please refer to Trust TSE protocol 2008

**Recommended CJD risk questions**

Patients with or at risk of CJD must be identified before surgery and therefore to allow the appropriate infection controls to be followed. To facilitate this it is recommended that patients are asked the questions in the following table prior to elective or emergency surgical procedures likely to involve contact with tissues of potentially high or medium level infectivity.

**CJD Risk Questions for patients about to undergo elective or emergency surgical procedures likely to involve contact with tissues of potentially high or medium level infectivity. Please see Trust TSE protocol for advice on surgical procedures and CJD tissue infectivity.**

<table>
<thead>
<tr>
<th>Question to Patient</th>
<th>Notes to clinician</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Have you any history of CJD or other prion disease in your family? If yes, please specify.</td>
<td>Patient should be considered to be at risk from familial forms of CJD linked to genetic mutations if they have or have had: i) Genetic testing, which has indicated that they are at significant risk of developing CJD or other prion disease; ii) A blood relative known to have a genetic mutation indicative of familial CJD; iii) 2 or more blood relatives affected by CJD or other prion disease.</td>
</tr>
<tr>
<td>2  Have you ever received growth hormone or gonadotrophin treatment? If yes, please specify whether the hormone was derived from human pituitary glands?</td>
<td>Recipients of hormone derived from human pituitary glands, e.g. growth hormone or gonadotrophin, have been identified as potentially at risk of CJD. In the UK, the use of human-derived growth hormone was discontinued in 1985 but human-derived products may have continued to be used in other countries.</td>
</tr>
<tr>
<td>3  Have you had surgery on your brain or spinal cord before August 1992?</td>
<td>People who underwent neurosurgical procedures or operations for a tumour or cyst of the spine before August 1992 may have received a graft of <em>dura mater</em>, and should be treated as at risk, unless evidence can be provided that <em>dura mater</em> was not used.</td>
</tr>
</tbody>
</table>
4  Have you ever been contacted as potentially at-risk of CJD for public health purposes? If yes, please specify.

The CJD Incidents Panel has identified a number of individuals who are potentially at risk of CJD or vCJD for public health purposes.

The need for comprehensive pre-surgery assessment

The following actions should also be carried out before any surgical procedure involving tissues with high or medium level infectivity. The clinician undertaking the pre-surgery assessment must:

- Check the patient’s medical notes and/or referral letter for any mention of CJD status.
- Consider whether there is a risk that the patient may be showing the early signs of CJD, i.e. consider whether the patient may have an undiagnosed neurological disease involving cognitive impairment or ataxia.

These actions, in conjunction with the CJD risk questions, will minimise the chance of a CJD incident occurring and therefore greatly reduce the risk of transmission of CJD to subsequent patients.

Emergency Surgery

In the event that a patient about to undergo emergency surgery is physically unable to answer questions, the next of kin should be asked the CJD risk questions before surgery takes place. If this is also not a viable option, the questions must be answered as soon as possible after the operation by either the patient or next of kin.

Patients at risk of CJD for public health purposes

A number of patients have been identified as potentially at risk for public health purposes on the recommendations of the CJD Incidents Panel. This group of patients includes individuals identified to be 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;
- CJD/vCJD due to receipt of tissues/ organs;
- vCJD due to receipt of blood components or plasma derivatives;
- 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.

When someone is notified that they are at risk of CJD, they are asked to take certain precautions to reduce the risk of spreading the infection to others. These include:
- Not donating blood, tissue or organs;
- Informing medical carers if they need to undergo an invasive medical procedure;
- Informing their next of kin, in case they need emergency surgery in the future.

The individual’s GP is asked to record the patient’s CJD at-risk status in their primary records. The GP should also include this information in any referral letter should the patient require invasive medical procedures.

Further information on the work of the CJD Incidents Panel is available on the HPA website, http://www.hpa.org.uk/infections/topics_az/cjd/menu.htm
Appendix 5

Known CJD case sign

**CLINICAL WASTE WARNING**

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Site</th>
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<tr>
<td>Date</td>
<td>Signature</td>
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</table>


Possible CJD case sign

**POSSIBLE CJD CASE WARNING**

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Site</th>
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</thead>
<tbody>
<tr>
<td>Theatre</td>
<td>Date</td>
</tr>
<tr>
<td>Signature</td>
<td>Test result / date</td>
</tr>
</tbody>
</table>
Appendix 6

CJD Log Book

ONLY APPROPRIATELY TRAINED STAFF ARE TO CARRY OUT THIS CASE/PROCEDURE.

Please ensure all information is recorded prior to carrying out the case/procedure.

<table>
<thead>
<tr>
<th>DATE</th>
<th>STAFF INVOLVED</th>
<th>LOCATION</th>
<th>TRAYS / EQUIPMENT INVOLVED</th>
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<tbody>
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Appendix 7

Theatre SOP / CJD 001

1. Title: CJD Protocol and Procedure
2. Purpose: To ensure that all staff involved with the care of patients who have been identified as at risk, suspected of having or confirmed of having CJD or vCJD are fully conversant with all infection control requirements for the control of instrumentation used, or waste generated from a surgical procedure and the records that are necessary to be completed in the event of such a case.
3. Scope: All staff working in Operating Theatres and or DTC and or Endoscopy suite.
4. Responsibility: Theatre Manager / Matron.
5. Related Documents: HSC1999 / 178
   HSC1999 / 179
   SAFE WORKING AND PREVENTION OF INFECTION – SEAC
   MDA DB 2000 (04)
   MDA 2000 (018)
   HSC 2000 / 032
   HTM 2010
   CONTROL OF INFECTION SEAC DOC.
   THE HEALTH ACT 2006
   NICE Documentation Feb 2007
6. Procedure
   6.1 Theatres carrying out such procedures will have source isolation notices attached to the entrance to the theatre concerned.
   6.2 Access will be only to those who are involved with the procedure. Once in place staff will be dedicated to that theatre and will not leave until the procedure is completed.
   6.3 The theatre will be emptied of all unnecessary equipment so that minimal stock and minimal equipment is exposed.
   6.4 An outside runner will be made available and will remain on hand for that theatre at all times. In the event that they have to move from that location, a replacement will be found.
   6.5 3 Biohazard bins for Limbs will be prepared and labeled in advance with biohazard labels and an additional made available in the anaesthetic room.
   6.6 Staff identified to work in the designated theatre will ensure that they have a clean scrub suit available in the anaesthetic room. This is their responsibility.
   6.7 Designated staff will wear visitors shoes that will be disposed of after the case along with their scrub suits.
   6.8 All shoes and scrub suits will be disposed of after the case.
and placed into the limb bins located in the anaesthetic room.

6.9 All designated staff will wear PPE (Personal Protective Equipment at all times this includes:
Visor, Aprons, and gloves.

6.10 Walker smoke extraction system will be made available in the theatre concerned in advance of surgery commencing

7 Anaesthetic room
7.1 Wherever possible single use devices will be used. All devices that have been used single use and re usable will be disposed of into the limb bin container, this includes:
Laryngoscopes. Forceps etc.

8 Theatres
8.1 Once the case has commenced, no one will be allowed to enter or leave until the case is complete.
8.2 The lead nurse will record the names of all staff involved with the case for Occupational Health records.
An accurate record of staff involved will be maintained on the theatre sapphire system
8.3 An inventory of instruments used will be maintained and updated throughout the case.
8.4 Whenever possible single use drapes will be used. Any re usable linen will be disposed of as clinical waste at the end of the case.

9 Scrub Team
9.1 2 sets of mature scrub nurses will be used. One scrub nurse will be directly involved with the surgical team and will work in the usual manner as part of that team. This nurse will take only the minimal amount of instruments that are necessary for the procedure. The second scrub nurse will manage additional instrument sets in such a way that they are not exposed to contamination. This will be considered a Bank of instruments that may be called upon. Once passed over they must stay with the instruments in use and not be passed back to the bank or clean nurse.
9.2 At the completion of the case all contaminated / used or unused instruments will be sprayed with Pre Klenze Gel and wrapped in the original outer wrapping of the tray. No washing of any items is allowed.
9.3 The wrapped tray must then be placed into prepared double bags, which are clearly labelled as biohazard and sealed. These are then placed into the Limb Bin and sealed securely and labelled correctly BIOHAZARD. An additional label is required to identify the patient, the lead nurse and the set identity. This limb bin is then placed in quarantine in the TSSU quiet room
9.4 The remaining clean Bank of instruments will be wrapped in the original outer wrapping and returned to Sterile Services Department marked as used bank. These will be sorted and checked. Any items missing will be listed and agreed with the

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lead theatre nurse.

9.5 Sterile Services will be informed so that immediate collection can be arranged.

9.6 All theatre linen will be disposed of into the limb bin along with all other clinical waste. Care must be taken not to contaminate the outside of the limb bin which must be sealed and labelled BIOHAZARD.

9.7 As each member of staff leave the theatre, they will exit via the anaesthetic room where they will remove their scrub suits and place them in the limb bin provided. Take care not to contaminate the outside of the limb bin. Staff can then change into the clean scrub suits that were placed there at the beginning of the case. The lead nurse will ensure privacy when staff are changing.

9.9 As each member of staff leave the theatre they must wash and dry their hand thoroughly before leaving the anaesthetic area.

9.10 The anaesthetist will have continued responsibility for the recovery of the patient and will need assistance when changing to leave theatres. The anaesthetic nurse will ensure that the anaesthetist is able to comply with this operational procedure.

10 Theatre cleaning

10.1 If the floor is contaminated with blood or body fluids, the excess is mopped up using paper towels and disposed of into the limb bin.

10.2 The area should be covered with a solution of chlorine 1:1000 and allowed to stand for 5 minutes. This is then mopped up and the floor mop disposed of into the limb bin.

10.3 At the end of the procedure the limb bins should be placed in the euro carts to await removal and incineration.

10.4 All furniture will be cleaned in the normal manner with hot soapy water and dried. Any blood or contamination should be treated using a solution of chlorine 1:1000.

10.5 Theatre floors are then cleaned and scrubbed in the usual manner for a source isolation theatre.
Appendix 8

Theatre Spillage SOP / CJD 002

1. Title: Spillage of Bodily Fluid Procedure

2. Purpose: To ensure that all staff are made aware of the procedure to follow in the event of a spillage of body fluids and the additional measure that are necessary for those patients who are categorised as at risk, suspect or know to have CJD or vCJD.

3. Scope: All bodily fluids in the theatre areas and materials contaminated with these substances but excluding urine.

4. Responsibility: Theatre Manager
   Theatre Sister

5. Related Documents: Staff training Documents
   Spillage procedure
   Health and Safety document
   COSHH
   Standard (universal) precautions

6. Procedure:
   Documents will be held in the Theatre Managers Office and in areas where staff may have access. All theatres will experience spillage of bodily fluids and these precautions apply to everyone working in those areas.
   
   6.1 COSHH register will be maintained and staff trained in handling and dealing with spills of body fluids
   
   6.2 Amendments or additions to any of the documents held must be authorised by the manager. No chemical will be introduced and used for cleaning body fluid spills other than those advocated in this procedure, without the managers express permission so that appropriate training can be provided prior to the chemical being introduced.
   
   6.4 The Manager will check the amendment with the health and Safety Warden and Infection Control Officer as appropriate.
   
   6.4 On approval the Theatre Manager will sign the COSHH register to indicate that the product has been checked and all staff made aware and signed off on the training form.
   
   6.5 Blood spills from a patient diagnosed as at risk, suspected or known to have CJD. These cases will normally be carried out at the end of an operating session:
   
   - Evacuate area involved of all unnecessary equipment.
   - Restrict entry into area to essential personnel only
   - Wear PPE designated for this purpose (see 6.6 )
   - Ensure that double clinical waste bags and or Limb Bins are prepared in advance. (In theatres this will be known)
   - Ensure that Limb Bins and Double Bags are available in the anaesthetic room for disposal of used scrubs, foot w
wear and other PPE

- Ensure that you have prepared your own fresh scrub suit and made it available in the anaesthetic room
- Ensure that a runner is available outside theatres
- Ensure that cleaning chemicals are available in advance of the procedure being undertaken. Cleaning materials Antichlor Tablets and a solution of 1:10,000 actichlor made available for end of case so that staff do not have to leave the area
  Staff must not leave once they have entered the theatre until the case is over and then only by removing all protective uniform and shoes. These must be disposed of in the Limb Bins provided taking care not to contaminate the outside of the bins.

6.6  **Personal Protective Equipment:**
- All staff must wear Personal Protective Equipment
- Apron or protective gown
- Gloves
- Goggles Visor
- Filter Mask
- Hat
- Shoes

6.7  **Cleaning Theatres after case.**
- Evacuate the area.
- Ensure spillage is adequately soaked with 1:10,000 solution of actichlor.
- Allow to stand for 5 minutes
- Mop up spillage with disposable paper towels and dispose of in the double bags for clinical waste
- Ensure area is visible free from blood
- Floors scrubbed and cleaned usual way for a source isolation case.
- Contact domestic team as soon as possible to have this work done. It must not be allowed to stand for long periods before cleaning.
- Theatre must be isolated to ensure no one enters the area other than those actively involved with the cleaning.
- The cleaner should wear visitors’ shoes that can be disposed of after cleaning.

6.8  **Register of trained staff:**
The theatre manager holds a register of staff that has attended training in spillage management. Refer to this if in doubt or in order to obtain information from a competent person about any spillage that you are not sure about.