

Guidelines for the control of transmissible spongiform encephalopathies in hospital patients

**Newcastle upon Tyne Hospitals NHS Trust
Infection Control Committee**

**Guidelines for the Control of Transmissible Spongiform
Encephalopathies
(TSEs) in hospital patients**

January 2005

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A. Introduction

These guidelines are intended to provide information and advice about the clinical care of patients known or suspected to have a transmissible spongiform encephalopathy, including advice about laboratory work, procedures after death, cleaning and decontamination of instruments, and waste disposal. They are based on national guidance from the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee¹⁻⁴.

A.1. Background

Transmissible spongiform encephalopathies (TSEs), sometimes known as prion diseases, are rare, fatal degenerative brain diseases which occur in humans and certain other animal species. The human TSEs are:

- Creutzfeldt-Jacob Disease (CJD), including classical (sporadic); familial; iatrogenic and variant (vCJD)
- Gerstmann Straussler Scheinker syndrome (GSS)
- Fatal familial insomnia (FFI)
- Kuru

The infectious agents of these conditions are highly resistant to standard methods for disinfection and sterilisation, and these conditions therefore require a special approach to be adopted in care of patients, and particularly the disposal of clinical waste and the handling of surgical instruments and other medical devices.

A.2. Patient risk groups

A.2.1 Classification of patients by diagnostic criteria

Patients are classified on established, published criteria and fall into three groups.

A.2.1.1 Definite cases are those patients who have been shown by currently available neuropathological and immunocytochemical investigations to have a TSE.

A.2.1.2 Probable cases

- (i) CJD (sporadic) patients will have a rapidly progressive dementia, at least two of four specific symptoms, plus either a typical electroencephalogram (EEG) or positive TSE associated marker (14-3-3) in the cerebrospinal fluid (CSF).
- (ii) vCJD
Patients will have a neuropsychiatric disorder of greater than 6 months (with no alternative diagnosis) at least four of five specific symptoms, and a symmetrical high signal (pulvinar sign) in the posterior thalamus on MRI brain scan.

Alternatively patients will have a neuropsychiatric disorder of duration of greater than 6 months (with no alternative diagnosis) plus a tonsil biopsy positive for PrP-res. There will be no history of iatrogenic exposure.

A.2.1.3 Possible cases

- (i) CJD
Patients will have a rapidly progressive dementia, two of four specific symptoms and a duration of less than two years.
- (ii) vCJD
Patients will have a progressive neuropsychiatric disorder of duration of greater than 6 months (with no alternative diagnosis) and at least four of five specific symptoms. An EEG does not show the typical appearance of sporadic CJD (or no EEG has been performed). There will be no history of potential iatrogenic exposure.
Note: Patients who do not meet the criteria for possible CJD can be categorised as either: diagnosis unclear, CJD thought unlikely or definitely not CJD.

A.2.2 Further classification of CJD patients

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 still requires confirmation by neuropathological examination.

Familial CJD

Patients will have a definitive or probable CJD 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.

A.2.3 Categorisation of patients by risk

A.2.3.1 Symptomatic patients

- (i) Patients who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD
- (ii) Patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD or vCJD but where the diagnosis of CJD is being actively considered.

A.2.3.2 At risk asymptomatic patients

- (i) Patients at risk from familial forms of CJD linked to genetic mutations
- (ii) Patients at risk from iatrogenic exposure
 - (a) recipients of hormone derived from human pituitary glands
 - (b) individuals who have received a graft of *dura mater*
 - (c) individuals exposed 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

A question which inevitably arises is when the precautions laid down in this document should be applied to a suspected case – in other words, how strong does

A.3. Infective material (see table 1)

It is believed that the most infective material is that obtained from the central nervous system and eye. This includes:

- brain or spinal cord tissue
- intraocular tissue or fluid

Other tissue is thought to be less infective, although in vCJD lymphoid tissue has also been shown to contain infective material.

There is no evidence of infectivity in saliva, body secretions, or excreta. The risks of blood exposure are uncertain, but standard infection control procedures should minimise any such risk.

A.4. Reporting of cases

All cases where TSE of any type is suspected should be reported to the National CJD Surveillance Unit in Edinburgh so that any necessary action can be taken². The infection control team will do this if requested.

A.5. Health surveillance of health care workers

There are no confirmed reports of occupationally-acquired CJD or related disorders in health care workers. However, employers are required to maintain a list of those health care workers where:

- there is a deliberate intention to work with the agents of TSE
- there may have been accidental exposure to a TSE agent (e.g. a sharps injury)
- staff (e.g. medical and nursing) who undertake certain procedures on patients who may have a TSE

This list must be kept for 40 years. The occupational health department should set up and maintain such a list following the guidance in HSC 1999/178³.

For the management of sharps and other exposure incidents, see also section B.8.

B. Guidance for ward staff

Note: the methods outlined below are applicable to definite, probable and possible patients or at risk patients, unless otherwise stated.

B.1. Isolation

For practical and confidential reasons, and to ensure correct waste/used linen disposal routes, patients are nursed in side rooms. There is no evidence of a risk to staff, relatives or the community from normal social or routine clinical contact with TSE patients.

B.2. Drug administration

Drug administration by injection should involve standard precautions (i.e. avoidance of sharps injuries and other forms of parenteral exposure, and the safe disposal of sharps and contaminated waste by incineration) and should be carried out by trained staff who are aware of the hazards involved.

B.3. Bed linen

Used or fouled bed linen (contaminated with body fluids or excreta) should be removed from the bed and washed and dried in accordance with standard practice. No further handling or processing requirements are necessary. If sheets or other bed linen are contaminated with high-risk material (see section A.3.) they should be disposed of by incineration.

B.4. Clinical waste

Material or objects that are contaminated with blood, blood stained secretions or other potentially infectious fluids (e.g CSF), should be disposed of as special clinical waste. It should be bagged or placed in a sharps bin (as appropriate) and sent for incineration in accordance with the Trust waste policy.

B.5. Spillages of potentially infected material

The method for dealing with a spillage of potentially infected material is given in section D.6. Any waste must be disposed of as clinical waste. Disposable gloves and an apron should be worn when removing such spillages, and also disposed of by incineration.

B.6. Childbirth

In the event that a symptomatic or at risk patient (see section A.2.3) is found to be pregnant, childbirth should be managed using standard infection control procedures. The placenta, other associated material and fluids should be treated as special waste, unless they are needed for investigations, in which case the precautions for dealing with potentially infected specimens should be followed (see section B.7). Instruments should be handled following the advice in section C.3.

B.7. Collection of laboratory samples

The collection of blood samples should involve standard precautions (i.e. avoidance of sharps injuries and other forms of parenteral exposure), and the safe disposal of sharps and contaminated waste by incineration. The procedure should be carried out by competent staff who are aware of the hazards involved.

Biopsy and lumbar puncture samples should only be taken by competent staff who are aware of the hazards involved. Disposable gloves and eye protection should be worn (see section C.3.1). **All** lumbar punctures on any patient (regardless of a possible diagnosis of a TSE) must always be carried out with single-use lumbar puncture kits.

Single-use equipment should be used wherever practicable and all inexpensive items contaminated by such specimens should be destroyed by incineration.

Samples should be marked with a 'Biohazard' label, and the laboratory should be contacted before sending the specimen. Particular care must be given to maintaining patient confidentiality.

B.8. Sharps injuries and contamination of wounds or mucous membranes

Any accident involving sharps, or contamination of abrasions with blood or body fluid, 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 according to the type of injury. Splashes into the eye or mouth should be dealt with by thorough irrigation. The accident must be reported to the line manager and to the Occupational Health Department. A Trust accident/incident record form must be completed within 24 hours – see *the Trust Operational Policy and Procedure for Accident and Incident Reporting* for further details.

B.9. Procedure after death

The infection control team must be informed of the death of a definite, probable, possible or at risk patient. 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 is placed in a cadaver bag prior to transportation to the mortuary, in line with normal procedures for bodies where there is known infection risk. (See also Trust Policy for the use of Cadaver Bags.)

Relatives of the deceased may wish to view or have some final contact with the body. Such viewing, and possible superficial contact, such as touching the face, need not be discouraged.

B.10. Organ transplants

To minimise the risk of transmission of a TSE, organ donations should be rejected from:

- recipients of pituitary-derived hormones such as human growth hormone or gonadotrophins
- people known or assumed to have received dura mater implants, including:
 - people who had brain surgery before August 1992
 - people who had surgery for a tumour or cyst of the spine before August 1992
- patients diagnosed or suspected of suffering from any form of a TSE
- patients with a family history of CJD
- patients with degenerative neurological conditions of unknown cause
- recipients of corneal transplants

C. Invasive clinical procedures

C.1. Rationale

Invasive clinical procedures performed on patients who are categorised as definite, probable, possible, or at risk of a TSE pose a particular problem. This arises from the extreme difficulty in decontaminating or sterilising an instrument which has potentially been contaminated with a TSE

agent, due to their inherent resistance to commonly used disinfectants and methods of sterilisation. This means that there is a possibility of transmission of a TSE to other patients, even after apparently effective methods of decontamination or sterilisation have been used. For this reason, it may be necessary to destroy instruments after use on such a patient, or at least to remove the instrument from further use until the diagnosis is either confirmed or an alternative diagnosis is established.

Such problems may also occur when procedures are carried out on a patient with an unexplained neurological illness and the diagnosis of a TSE has not been considered. When the diagnosis is subsequently made, this may require the tracking down and destruction of equipment which may have been used on other patients. Follow-up of such patients may also be required. These problems can be avoided if the diagnosis of the TSE is considered in a patient with an unexplained neurological condition before carrying out procedures on the patient. If in doubt, consult a neurologist.

C.2. General points

- All lumbar punctures on any patient (regardless of a possible diagnosis of a TSE) must always be carried out with single-use lumbar puncture kits
- The infection control team must be informed before invasive clinical procedures are undertaken on any definite, probable, possible or at risk patient
- Procedures on such patients, and the practicalities of instruments handling, storage, cleaning and decontamination, or disposal, should be planned carefully in advance. For non-invasive procedures, e.g. EEG, certain imaging or X-ray procedures, no specific precautions are required. In all cases to minimise the loss of instrument, single-use disposable instrument should be used whenever possible. All staff directly involved in procedures on patients in the risk groups, or in the subsequent re-processing or disposal of potentially contaminated items, should be aware of the specific precautions, and adequately trained. Sufficient notice should be allowed for the necessary preparations, which should include informing TSSU.

C.3. Precautions during invasive clinical procedures on definite, probable, possible, or at risk patients

Think before carrying out such a procedure. Does it really need to be performed? Remember that in doing so instruments may have to be destroyed, or set aside for a significant/prolonged period of time until a diagnosis is made.

The precautions below must be taken for all invasive clinical procedures. Guidance on the use and management of surgical instruments or other equipment is also given below.

C.3.1. Definite or probable patients

- The infection control team must be informed before any invasive clinical procedures are undertaken.
- Wherever appropriate and possible, the intervention should be performed in an operating theatre, and the procedure should be performed at the end of the list to allow normal

cleaning of the theatre before the next session. If a procedure is performed on a ward it should take place in the treatment room.

- Where procedures are performed at the bedside, e.g. a lumbar puncture, care should be taken to ensure that the environment can be readily cleaned should a spillage occur (see section D.6.). The protective clothing described below should be worn by the staff carrying out the procedures.
- Involve only the minimum number of staff required.
- Wear the following protective clothing:
 - Liquid repellent operation gown, over a plastic apron
 - Gloves
 - Mask
 - Visor or goggles
 - This protective clothing should be treated as single-use and disposed of by incineration after use.

Instruments (single-use or otherwise) and other medical devices that are contaminated with tissue of high or medium infectivity (see table 1) must be destroyed by incineration. The Infection Control team will advise where there is doubt as to whether contamination of instruments or medical devices has occurred.

Some expensive items such as drills, may be prevented from being contaminated by using shields, guards or covering, so that the entire item need not to be destroyed. The drill bit, or other parts in contact with high risk tissue and the protective covering, would then need to be incinerated. In practice it may be difficult to ensure protective covering and advice should be sought from the infection control team.

C.3.2 Possible patients

Instruments that are, or may be, contaminated with tissue of high or medium infectivity (see table 1) will be quarantined (see section C.4.1) until the diagnosis is confirmed or an alternative diagnosis made. Instruments and other medical devices that have been in contact with tissue of low infectivity (see table 1) can be cleaned and decontaminated (see section D) and reused.

C.3.3 At risk asymptomatic patients

In general it is not possible to identify specific risk groups for the iatrogenic transmission of vCJD. However the CJD Incidents Panel may identify individual patients who have been potentially exposed to vCJD (e.g. via surgical instruments used on a patient who went on to develop vCJD, or blood products derived from a donor who went on to develop vCJD). In these circumstances the individuals will have been informed of the risk by the Panel and advised to inform clinicians in the event of them needing surgery.

- The infection control team **must** be informed before clinical procedures are undertaken.

- Instruments and other medical devices that are, or may be, contaminated with tissues of high or medium infectivity (see table 1) that have been used on at risk asymptomatic patients **must be destroyed by incineration**.
- All single-use items must be destroyed by incineration.
- Instruments and other medical devices in contact with tissues of low infectivity (see table 1) can be cleaned and decontaminated (see section D) and reused.

The protective clothing described in C.3.1 should be worn by staff carrying out the procedures although the protective clothing may be reprocessed if not designated single-use. If protective clothing is contaminated then it should not be reprocessed but should be destroyed as clinical waste by incineration.

C.4 Quarantining of surgical instruments

Note: All surgical instruments that are used in brain biopsy operations not for focal lesions from any patient (even where a TSE is not suspected) must be quarantined. They will remain quarantined until a definitive diagnosis has been established.

Instruments that have been used on a possible CJD or vCJD (high and medium infectivity tissue) must **not** be re-used, but will be quarantined by securely storing in a rigid, sealed container after use, with patient unique markers/information, until the diagnosis is confirmed.

C.4.1 Quarantine procedures

- TSSU staff are responsible for ensuring the instruments are stored in a safe and secure place. The final decision on whether to release the instruments for re-use or to destroy them is made by the Infection Control team
- The instruments should first be cleaned in TSSU in an ultrasonic washer/disinfector to remove visible organic material. The instruments are then checked to see they are clean. If not they are reprocessed in the ultrasonic washer/disinfector, manually cleaned (the operator wearing gloves, visor or goggles) and then reprocessed in the TSSU washer/disinfector. Instruments are only stored in quarantine if they are seen to be clean.
- The instruments should then be placed in a disposable instrument tray and allowed to dry.
- They should then be placed in an impervious rigid container with a close fitting lid. The lid should be sealed with heavy-duty tape, and labelled with the:
 - patient identification details (i.e. name, date of birth and hospital number)
 - the surgical procedure in which the instruments were used
 - the name of the person responsible for them
- The sealed box may then be stored indefinitely in a suitable designated area until the outcome of any further investigation is known.
- The instrument tray should be disposed of by incineration.

If the case is confirmed as CJD or vCJD or if after testing the diagnosis is inconclusive, the container and its contents must be sent for incineration. Only if a definitive diagnosis other than CJD or vCJD is confirmed may the instruments be decontaminated following the usual routine procedures and returned to use.

Records must be kept of all decisions made regarding the disposition of the instrument.

C.4.2 CJD Incidents Panel

On occasions it may be unclear as to whether a patient has been exposed to a TSE and decisions need to be made about whether instruments used on the patient need to be quarantined. In such cases expert advice can be sought from the panel. Contact: Dr Philippa Edwards, tel. 0207 972 5324, email, philippa.edwards@dh.gsi.gov.uk

C.5. Endoscopic Instrumentation

There is a considerable cost attached to the incineration of endoscopic instruments which have been used on a patient with a TSE. Best practice, national guidance, dictates that all endoscopic instruments must be trackable to patients records currently. If this is not done considerable problems may arise.

For this reason, all endoscopic instruments must possess a unique identifier and whenever endoscopy is performed on a patient, the instrument used **must** be recorded in the patient's notes and in the department's log book.. The endoscopy unit must develop policies which allow any instrument used on a patient to be identified and an audit trail followed. It is **imperative** that these policies are followed. This is particularly so when an instrument leaves the endoscopy suite to be used on a ward or other area, since it is all too easy for this procedure to be omitted.

Prion protein (Pr Pres) has been detected in the olfactory epithelium, but not the respiratory epithelium of sporadic CJD patients. The olfactory epithelium is normally located deep within the nasal turbinates but its distribution varies between individuals.

The advice of the consultant carrying out a procedure in the nasal cavity (CJD and vCJD patients) should be sought to determine whether a risk of contamination of the endoscopic instrument with olfactory epithelium can be excluded with confidence. If such contamination cannot be excluded, take precautions for medium infectivity tissue.

C.5.1 Decontamination of endoscopic instruments

The general procedures set out in the MDA Device Bulletin MDADB 2002 (05)⁶ should be followed. In order to decrease the risk of transmission of TSEs through endoscopic procedures additional precautions for the decontamination of flexible endoscopes are required (see below).

C.5.1.1 Accessories

Channel cleaning brushes and the valve on the biopsy/instrument channel port used with flexible endoscopes should be disposed of as clinical waste after each use. This guidance endorses the advice of the MDA Bulletin that other accessories should be single-use wherever possible, but where this is not possible, 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.

C.5.1.2 Disinfectants

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 (see A.2.1.3) or the patient is at risk of developing CJD. Contact the endoscope supplier for advice on appropriate alternatives.

C.5.1.3 Summary of precautions advised for the use of endoscopes

See tables 2 and 3.

D. Cleaning, decontamination, and waste disposal

D.1. Background

Important: the recommendations given in this section for the decontamination of surgical instruments and other medical devices refers only to instruments that have been used on possible or at risk patients where there has **not** been involvement of the brain, spinal cord or eye. All instruments used on definite or probable patients, and those used on at risk patients where there has been exposure to brain, spinal cord or eye **must** be disposed of by incineration. For patients where the diagnosis has been suggested but not yet proven, quarantine procedures will be used to hold the instruments pending confirmation of the diagnosis (see section C.4.1).

The agents of TSE are highly resistant to standard physical and chemical methods of inactivation and decontamination. Since the standard methods of decontamination cannot ensure complete inactivation of the agent, the emphasis must be on removal of the agents by thorough cleaning. This should be followed by an appropriate treatment either by autoclaving or chemical decontamination as described below.

Table 4 gives a summary of the basic precautions for decontamination. Table 5 gives a summary of recommended processes and agents, and Table 6 shows those which are known to be ineffective. These tables may be found at the end of this document.

D.2. Cleaning contaminated instruments

Manual handling of contaminated instruments should be kept to a minimum and automated decontamination process, as described below, should be used wherever possible. The cleaning of contaminated items to remove all body fluids and tissue in which a transmissible agent may be present is critical in ensuring the effectiveness of the decontamination regime. All items must be cleaned at least twice or until considered clean before treatment by autoclaving or liquid chemicals. The first clean should be carried out in an ultrasonic cleaner; the second in an automated thermal washer/disinfector. Neutral or enzymatic detergent suitable for use with this processing equipment should be used.

Contaminated instruments must be processed through a covered ultrasonic bath and automated washer/disinfector in which no other instruments are being cleaned. Items should be cleaned as soon as possible after use to minimise drying of blood and body fluids onto the item, which may then be more difficult to remove. Items should not be soaked in disinfectants prior to cleaning.

Staff carrying out the cleaning and subsequent processing of instruments and equipment must follow standard basic precautions for avoiding exposure to infectious material (e.g. use protective clothing, cover abrasions with waterproof dressings, avoid use of sharps).

Instruments which are difficult to clean (perhaps due to poor conditions) may render the decontamination procedure less effective. Such instruments should be identified, and where practicable replaced as part of a planned programme, and the risk identified to the appropriate Trust managers.

D.3. Decontaminating the cleaning equipment

Following processing of instruments, the ultrasonic bath and automated washer/disinfector should be run through an empty cycle. Any solid waste/tissue should be disposed of by incineration. Liquid waste should be disposed of safely, either by normal direct discharge of waste from automated washers or by collection and inactivation of waste from equipment such as ultrasonic baths. Any cleaning aids such as brushes, if used, must be disposed of by incineration.

D.4. Decontamination of EEG electrodes

The main risk to both patients and staff from EEG electrodes, though small, is from blood-borne viruses such as Hepatitis B, C and HIV. This is due to the fact that a small amount of blood may be drawn when abrading the scalp during application of the electrode. However patients definite, probable, possible or at risk of having CJD/vCJD also undergo EEG examinations, therefore specific precautions for these patients are also detailed below.

1. Universal Precautions must always be practised when performing any EEG examination.
2. All EEG electrodes must be disinfected through the washer disinfector in the Sterile Services Department **after each patient use**.
3. Any EEG electrodes used on patients definite, probable, possible or at risk of having CJD/vCJD which have had **NO possible or definite contamination with CSF or blood** can be sent to the Sterile Services Department for processing as above.
4. All the above electrodes should be placed in a plastic bag supplied by the Sterile Services Department which will then be collected by them in a rigid box.
5. Any EEG electrodes used on patients definite, probable, possible or at risk of having CJD/vCJD which have **HAD possible or definite contamination with CSF or blood** must firstly be sent for processing in the Sterile Services Department (with prior notification to the Sterile Services Department). They should be placed separately in the plastic bag as above, labelled clearly with the patient details on whom they have been used, and collected in a high risk box by

the Sterile Services Department. On return to the department the electrodes must then be **quarantined** for use on that patient **ONLY** until a definitive diagnosis has been made or until no longer required.

6. When the electrodes in section 5 are no longer required and an alternative diagnosis has not been found they must be sent for incineration as infected waste. They should be disposed of in a sealed disposable sharps bin with a red ratchet tie attached and labelled with the date, department and hospital of origin.

D.5. Decontaminating instruments used on possible or at risk patients

D.5.1. Autoclaving

After cleaning, the items should be processed in a porous load (high vacuum) steam sterilizer using one of the following cycles.

- A single cycle of 134-137°C for a minimum holding time of 18 minutes; or
- 6 successive cycles of 134-137°C for a minimum holding time of 3 minutes for each cycle.

Note: other cycles are not recommended. Downward or upward displacement autoclaves must not be used.

D.5.2. Treatment with liquid chemicals

If the instrument is unable to tolerate the moist heat porous load cycles specified above, then liquid chemical treatment may be considered.

Chemical agents and contact times that have been found to be most effective include:

- 20,000ppm available chlorine of sodium hypochlorite for 1 hour
- 2M sodium hydroxide for 1 hour

Important: As 20,000ppm available chlorine of sodium hypochlorite can be irritant, charcoal-filter masks should be worn.

These chemical agents at the concentrations and contact times specified may have a detrimental effect on clinical instruments and equipment, and should only be used after seeking advice from the manufacturer of the instrument to ensure the item will withstand these corrosive processes. 10,000ppm hypochlorite must not be used as it is ineffective against the agents of TSE at this concentration. Sodium dichloroisocyanurate (e.g. 'Presept' tablets) has also been shown to be ineffective and must not be used.

D.6. Surface decontamination and the management of spillages

The infectious agents associated with TSE are unusually resistant to inactivity by chemicals and certain processes (see Table 4). Dilution is the most important element in cleaning up spillages on a hospital ward. Spills of blood stained excreta (such as urine or faeces) should have a higher level of decontamination (see below).

Standard methods (see Trust decontamination policy) should be followed to clear up spillages on the ward, including spillages of blood and CSF, where gloves and an apron should be worn. The

spillages should be covered with paper towels to absorb fluid, disposed of as infected waste, then the affected area should be disinfected with 10,000ppm hypochlorite solution for 30 minutes. Note: wet puddles should be avoided. If necessary the disinfected area should be cordoned off during this period (and until dry) in order to avoid people slipping on a damp area.

All waste, including the used protective clothing, must be placed in clinical waste bags and disposed of by incineration. The area should then be cleaned with detergent and warm water and left to dry.

High concentration (20,000ppm) hypochlorite is unlikely to be practical in a ward situation, since it is highly corrosive to many surfaces. However it can be used in exceptional circumstances to clear up spillages of high risk material (e.g. brain tissue. See Table 1). In such instances the area must be well ventilated and barred to patient access.

For all other spillages (e.g. urine, faeces), the use of disinfectants is unnecessary. The spillage should be absorbed with paper towels and disposed of as clinical waste by incineration. The area should then be cleaned with detergent and warm water and left to dry.

There is no need for terminal cleaning **over and above the routine standard** after patients have left a ward other than the decontamination of any spillage

E. Laboratories and post-mortem rooms

E.1. Laboratory work

The agents of TSE are classed as hazard group 3 pathogens, and all clinical specimens from definite, probable, possible or at risk patients should be handled at containment level 3. However, the option of derogation does apply and, based on local risk assessment, certain containment level 3 precautions can be dispensed with. All Trust laboratories must ensure that appropriate risk assessments have been made and that procedures are in place for the safe handling of specimens from TSE patients. Such procedures must be applied to all specimens from definite, probable, possible, or risk patients, and must include procedures for the inactivation and safe disposal of clinical specimens.

More detailed information can be found in Annex A of this document. Laboratories may use this when drawing up their own local policies and procedures for handling specimens from these patients.

E.2. Post mortems

Cellular pathology departments must ensure that appropriate procedures are in place for the safe performance of post mortem examinations. It is recommended that post mortems are only carried out in one post mortem room to reduce the risk of potential infection; the post mortem room at Newcastle General Hospital is recommended because the neuropathology department is on that site.

More detailed information can be found in Annex B of this document. Post-mortem rooms may use this when drawing up their own local policies and procedures for carrying out post-mortem examinations on these patients.

F. Annex A: Routine laboratory work on specimens from definite, probable, possible, or at risk patients

F.1. General points

A range of laboratory tests may be required for the clinical management of definite, probable, possible or at risk patients, for example, routine biochemical, haematological or microbiological analyses. Because the agents of TSE are classified in Hazard Group 3, all clinical specimens from definite, probable, possible or at risk patients should be handled at Containment Level 3. However, the option of derogation does apply and, based on local risk assessment, certain Containment Level 3 precautions can be dispensed with¹.

F.2. Samples from known or suspect patients

When handling all specimens from definite, probable, possible patients, or CNS/eye specimens from at risk patients, particular care should be taken to avoid accidental inoculation or injury, for example, when preparing samples for microscopy or culture. Whenever practicable disposable equipment should be used (e.g. cell counting chambers) and items contaminated by the specimens must be destroyed by incineration, or else autoclaved or disinfected to the required standard (see section D). Special arrangements may be needed to minimise any residual contamination of equipment. Where manual analysis using disposable equipment is not feasible, and automated equipment is to be used, the potential for residual contamination must be considered and be dealt with appropriately before equipment is serviced. Where stringent decontamination procedures are inappropriate, as in the case of microscopes, the equipment should be cleaned and regularly maintained to avoid accumulation of potentially contaminated debris.

F.3. Samples from at risk patients

It is thought that samples from the CNS or eye present a greater risk of exposure to the agents of TSE than other samples. For routine clinical analysis not involving deliberate intention to work with the agents of TSE, samples from at risk patients that are not from the CNS, and are not known to be contaminated with material from the CNS, can generally be handled in the same way as other clinical samples, providing that the risks have been assessed as required by the COSHH Regulations. In general, blood, urine, faecal specimens and swabs can be collected, processed, and handled as for any other patient.

F.4. Neuropathology specimens

The general precautions above for handling specimens apply for similar work with brain and neural biopsy specimens from definite, probable, possible or at risk patients. However, as infectivity may be concentrated in such samples, they present a greater risk of exposure, and additional precautionary measures are appropriate. It may be more appropriate for such specimens to be handled in a specialist neuropathology laboratory or centre. Where there are facilities locally, limited histological processing can be undertaken with care by staff taking suitable precautions and wearing the appropriate protective clothing. For the specialist laboratory handling large number of samples, additional precautions may be necessary because of the possibility of increased residual contamination.

All preparations of brain and neural tissue from definite, probable, possible or at risk patients for diagnosis and confirmation must be treated as potentially infectious, and handled in the laboratory at containment level 3 (subject to derogation). The use of disposable non-permeable material is a convenient way of preventing contamination of the work surface. This covering and all washings, other waste material and protective clothing should be disposed of by incineration.

For optimal fixation of whole brain for general histopathology purposes, standard formalin should be used. However, formalin-fixed TSE tissue retains infectivity for long periods, if not indefinitely, and should be handled with the same precautions as fresh material. Similarly, tissue for electron microscopy fixed in glutaraldehyde retains its infectivity. This is of equal importance when handling archive material stored in fixative, blocks or as mounted slides. Formalin-fixed TSE tissue can be decontaminated largely, if not completely, by formic acid treatment. However, because the full efficacy of this treatment is still uncertain, histological preparations of known TSE brain and neural tissue should be regarded as potentially infective, and special care taken to avoid breaking the microscope slides or similar accidents during when penetrating injuries could occur. Once tissue blocks are fixed and acid-treated, sections can be cut on a standard microtome (using a disposable knife) and processed as usual. Debris (wax shavings) from section cutting should be contained and disposed of by incineration.

G. Annex B: Post mortem examination

G.1. Procedure after death

The Infection Control Team must be informed of the death of a symptomatic or at risk patient (see section A.2.3). The removal of the body from the ward, community setting or hospice, to the mortuary, should be carried out using normal infection control measures. It is recommended that the deceased patient is placed in a cadaver bag prior to transportation to the mortuary; in line with normal procedures for bodies where there is a known infection risk. An infection control notification sheet should be completed and given to the undertakers concerned with the deceased. (See Trust Policy for the use of Cadaver Bags).

G.2. Post mortem

Currently post mortem examinations are essential in order to confirm the clinical diagnosis and the cause of death as a TSE. However, such procedures have the potential to expose pathologists and mortuary staff to infectious material. Advice should be obtained from the infection control team before post-mortem examination of any definite, probable, possible or at risk patients. Further advice is given in the Health Services Advisory Committee publication "Safe working and the prevention of infection in the mortuary and post mortem room". Specific information on neuropathological autopsy in TSE cases has been published¹.

Only fully competent staff should undertake any necessary post mortem examination on symptomatic or at risk patients (see section A.2.3). Ideally three people should be present during the examination: The pathologist assisted by one technician, and a further circulator to open or label specimens containers. Observers should be prohibited or kept to a minimum. Post mortem technicians, and others attending out of necessity, should be fully trained in or informed of procedures for such post mortems and made aware of the relevant history of the patient.

Restricted post mortem examinations on TSE cases can be undertaken in any mortuary. If only an examination of the brain is to be undertaken, the scalp is reflected in the normal way with absorbent wadding underneath the head to soak up CSF and other material when the cranium is opened. The head and neck of the cadaver should then be enclosed in a large polythene bag. The bag serves to contain bone dust while opening the cranium with either an electrical oscillating saw or hand saw. The bag and skull cap can be detached together before sampling the CSF and removing the brain and pituitary. If a hand saw is to be used and the polythene bag restricts manoeuvrability (and may increase the inoculation risk) all bone material should be removed and tissue decontaminated with hypochlorite (see section D.4.2).

If a full-scale post mortem examination of a case of TSE is indicated, including removal of the viscera and spinal cord, it is recommended that the body is removed for special handling in a high risk autopsy suite. Arrangements for refund of any removal costs for bodies for TSE autopsies are made through the TSE Surveillance Unit ². To minimise contamination of the working environment, post mortem examinations should be carried out with the body in an open bag with absorbent wadding. On completion of the autopsy, the body should be sewn up leaving the wadding in situ in the cadaver bag. This has the advantage of absorbing fluids. Any excess wadding should be incinerated. Care should be taken in sewing up the body that 'burning' through gloves does not occur by pulling too hard on the twine. The cadaver bag is then sealed. In some circumstances, it may be necessary to remove the body from the bag for autopsy; in these cases the body should be placed into another bag after autopsy, using absorbent wadding as previously, and the original bag should be disposed of by incineration.

Disposable protective clothing should be worn including theatre suit, gown, plastic apron, hat and double gloves, and a face visor, which completely encloses the operator's head to protect the eyes, nose and mouth. Consideration should be given to the use of hand protection, such as armoured or cut-resistant gloves.

Disposable instruments should be used wherever possible, and incinerated after use. If this is not feasible, a set of dedicated instruments for definite, probable, possible or at risk cases is recommended, in order to minimise the frequency of their use and the risk of transmitting infection. Manual or electric saws may be used, although the former do not create aerosols and are easier to decontaminate after use. Instruments and mortuary working surfaces should be decontaminated following the guidance in section D.

G.3 Undertakers and Embalmers

The undertakers should receive an infection control notification sheet. Concern about possible unknown TSE cases does not warrant a level of precaution for undertakers handling intact bodies other than those used generally for all work of this nature. In cases of traumatic injury, it is sensible general practice to minimise contact, particularly in circumstances under which penetrating injuries could arise. Cosmetic work on bodies of patients from an at risk group may be undertaken, taking the precautions routinely used when dealing with human cadavers.

Where the diagnosis of TSE is definite, probable or possible it is advisable to avoid embalming procedures.

G.4 Funerals and Cremations

Relatives of the deceased may wish to view or have some final contact with the body. Such viewing, and possible superficial contact, such as touching the face, need not be discouraged.

There have been some concerns expressed about whether burial or cremation presents any risk of environmental contamination. Although it is difficult to quantify the risk of environmental contamination associated with burial, due to the range of unknown factors it is accepted that the risk is likely to be vanishingly small, and there is no need to discourage burial. Similarly, the risk of residual infectivity after cremation is likely to be negligible. There is no need for extra precautions to be taken for either burial or cremation.

There are no additional precautions needed for transporting the body within the UK. If there is a need to transport the body internationally, it will be necessary to comply with the IATA Restricted Articles Regulations⁷, and any additional requirements of the individual carrier, which should be discussed on a case-by case basis.

H. Annex C: Protocol for management of instruments and tissues from brain biopsy procedures on patients with progressive neurological disorders⁸

H.1. Clinical assessment and biopsy procedure

- Protocol applies to all patients who have unexplained progressive dementia/or ataxia or neuropsychiatric syndromes) in whom brain biopsy is considered appropriate in order to establish or exclude a diagnosis.
- Neuro-radiology usually shows no evidence of a space-occupying lesion.
- Patient does not fulfil WHO criteria for probable or possible CJD. Indeed CJD may not have been considered on clinical grounds.
- Brain biopsy (preferably open block biopsy) is performed for diagnosis.

H.1.2. Handling the neurosurgical instruments

- Single use instruments must be used if possible.
- Any instruments that may have come into contact with brain or meninges of patients must be transported as soon as possible to TSSU for washing and quarantined immediately (see C.4.1).

H.1.3 Neuropathological diagnosis and fate of neurological instruments

- If a definite diagnosis of a disorder other than CJD or vCJD is made (and there is no other evidence to suggest CJD or vCJD) – instruments can be reprocessed and reused (see D2, D3, D5).
- If a definite diagnosis of CJD or vCJD is made – instruments are destroyed.
- If the local neuropathologist cannot exclude CJD or VCJD, the case should be referred to the NCJDSU for further investigation.

H.1.4 If the patient dies without a diagnosis consent should be sought for post mortem examination. If consent is refused or the diagnosis is still uncertain after post mortem examination, then any quarantined instruments should be destroyed.

I. Table 1

DISTRIBUTION OF TSE INFECTIVITY IN HUMAN TISSUE AND BODY FLUIDS

The table below presents current information on the distribution of infectivity in tissue and body fluids in CJD and vCJD, based on data from experimental studies, where available, and on information from other studies of natural TSE disease in humans and animals.

Tissue	CJD Assumed level of Infectivity	VCJD Assumed level of Infectivity
Brain	High	High
Spinal cord	High	High
Spinal ganglia	High	High
Dura mater	High	High
Cranial nerves	High	High
Cranial ganglia	High	High
Posterior eye	High	High
Anterior eye and cornea	Medium	Medium
Olfactory epithelium	Medium	Medium
Tonsil	Low	Medium
Appendix	Low	Medium
Spleen and thymus	Low	Medium
Other lymphoid tissue	Low	Medium
Peripheral nerve	Low	Low
Dental pulp	Low	Low
Gingival tissue	Low	Low
Blood and bone marrow	Low	Low
CSF	Low	Low
Placenta	Low	Low
Urine	Low	Low
Other tissue	Low	Low

J. Tables of cleaning and decontamination methods

Table 2 Summary of precautions advised for the use of endoscopes in patients with CJD (other than vCJD)

Tissue Infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/probable	Possible/diagnosis	At risk ²

		unclear¹	iatrogenic/familial
High • Brain • Spinal cord	single use OR destroy ³ after use	single use OR quarantine ⁴ pending diagnosis	single use ⁵ OR quarantine ⁴ pending exclusion of CJD
Medium • Olfactory epithelium*	single use OR destroy ³ after use	single use OR quarantine ⁴ pending diagnosis	single use ⁵ OR quarantine ⁴ pending exclusion of CJD
Low/none detectable • All other tissues	no special precautions ⁶	no special precautions ⁶	no special precautions ⁶

* 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.

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 (see A.2.1.3).

² This advice refers to the use of flexible endoscopes and endoscopes with lumens in patients at risk of developing CJD. For guidance on the use of rigid endoscopes without lumens that can be autoclaved, refer to the guidance for the use of all surgical instruments in at risk patients in (C.3.3)

³ Instruments that are destined for disposal by incineration may be collected for use in research. Anyone considering such a course of action should contact the Surgical Instruments Store, Health Protection Agency, Porton Down. Telephone 01980 612100.

⁴ Quarantined endoscopes may be re-used exclusively on the same individual patient if required.

⁵ For some procedures, the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. In practice, however, it may be difficult to ensure effective protection and advice should be sought from surgical staff carrying out the procedure and the manufacturer of the endoscope to determine practicality.

⁶ The decontamination procedures advised in C.5.1.1 and C.5.1.2, taken together with the MDA Device Bulletin MDA DB2002 (05)⁶ should be followed.

Table 3 Summary of the precautions advised for the use of endoscopes in patients with vCJD

Tissue Infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/probable	Possible/diagnosis unclear ¹	At risk ² iatrogenic
High • Brain • Spinal cord	single use OR destroy ³ after use	single use OR quarantine ⁴ pending	single use OR quarantine ⁴ pending

		diagnosis	exclusion of CJD
Medium	single use OR	single use OR	single use ⁵ OR
<ul style="list-style-type: none"> Olfactory epithelium* Lymphoid tissue 	use dedicated endoscope ⁷ OR	quarantine ⁴ pending diagnosis	quarantine ⁴ pending exclusion of CJD
Low/none detectable ⁸	destroy ³ after use	no special precautions ⁶	no special precautions ⁶
<ul style="list-style-type: none"> All other tissues 			

* See footnote to Table 2

Lymphoid tissue refers to the spleen, thymus, tonsils and adenoids, lymph nodes, the appendix and other lymphoid tissue associated with the gastro-intestinal tract sub-mucosa.
^{1,2,3,4,5} and ⁶ See footnotes to table 2.

⁷The NCJSU 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 patient at risk of CJD.

⁸All endoscopes used for biopsy or other invasive procedures (e.g. ERCP, diathermy) must be quarantined after use.

Table 4: Basic precautions for disinfection and decontamination		
<ul style="list-style-type: none"> Clean instruments thoroughly at least twice to remove body fluids prior to disinfection. Use automated decontamination processes where possible, and avoid mixing routine instruments with those used in TSE-related work in the same cycle. Recycle durable items for re-use only after appropriate decontamination – use only stringent autoclaving procedures or recommended chemical disinfection methods. Where possible, cover surfaces with disposable material, which can then be removed and incinerated; otherwise clean the decontaminated surfaces thoroughly – use only recommended decontamination procedures. Use absorbent material to soak up spillages, which can then be contained and incinerated. Use secure leak-proof containers, e.g. double-bagged, for the safe handling of clinical waste. Avoid external contamination of the waste container. Wear protective clothing at all times. 		
20,000ppm available chlorine or sodium hypochlorite for 1 hour	None	Forous load steam steriliser 134-137°C for a single cycle of 18 minutes or 6 successive cycles of 3 minutes each*
2M sodium hydroxide for 1 hour*		

For histological samples only, 96% formic acid for 1 hour		
* but known not to be completely effective		

Table 6: Chemicals & processes INEFFECTIVE for use against TSE agents		
Chemical disinfectants	Gaseous disinfectants	Physical processes
Alcohols Ammonia B-propiolactone Chlorine dioxide Formalin Glutaraldehyde Hydrochloric acid Hydrogen peroxide Iodophors (e.g. Betadine) Peracetic acid Phenolics Sodium dichloroisocyanurate (e.g. 'Presept')* 10,000ppm sodium hypochlorite	Ethylene oxide Formaldehyde	Dry heat Ionising, UV or microwave radiation Moist heat at 121°C for 15 minutes
* the rate of release of chlorine from this product is insufficient to ensure complete inactivation of the agent		

K. References

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Control of Infection Committee January 2005
Review date: January 2008
Reviewer: Dr. C. Taylor