

**Transmissible Spongiform Encephalopathy
(Creutzfeldt-Jakob Disease) Policy**

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Note: This policy has been assessed for any equality, diversity or human rights implications.			

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1 Introduction

1.1 What is a transmissible spongiform encephalopathy?

1.1.1 Transmissible spongiform encephalopathies (TSEs) are a group of diseases which affect both humans and animals. They are caused by unconventional infectious agents, free of DNA, which are probably proteins and are known as **prions**. Prions characteristically exhibit unusual and extreme resistance to conventional decontamination methods such as heat (e.g. autoclaving) or chemical disinfection. They are also extremely difficult to remove reliably from instruments during cleaning processes.

1.1.2 The human TSEs are all very rare. They fall into 3 groups as shown in table 1.1. These cause a variety of neurological symptoms including dementia and personality changes as well as neuromuscular symptoms such as unsteadiness, involuntary muscular jerking. Currently no effective treatment is available and the outcome is invariably fatal.

Table 1 Human TSEs

Idiopathic diseases	Sporadic Creutzfeldt-Jakob disease (CJD) Sporadic fatal insomnia
Familial diseases	Familial CJD Gerstmann-Sträussler-Scheinker disease (GSS) Fatal familial insomnia
Acquired diseases	Iatrogenic CJD Kuru Variant CJD (vCJD)

1.1.3 In 1996 a previously unrecognised form of TSE was described in humans, now known as variant CJD (vCJD). Patients are usually younger, and have different presenting features from sporadic CJD and a prolonged clinical course. Evidence suggests that this is due to infection with the same agent that causes Bovine Spongiform Encephalopathy (BSE) a cattle disease that was first seen in the UK in 1986. In recent years the number of cases of vCJD has shown a consistent downward trend, and very few cases, 5 or less, occur annually.

1.2 Infectivity

1.2.1 TSEs are not contagious diseases. Experimentally they may be transmitted by inoculation and in some cases orally, e.g. BSE. Transmission to humans has occurred from human and bovine sources, resulting in iatrogenic and variant CJD.

1.2.2 TSE agents are not uniformly distributed through the tissues of affected individuals and certain tissues pose a higher risk. In all TSEs, CNS tissues (including the retina) have the highest infectious risk, with cornea and dura mater having a lower infectious risk. In variant CJD tissues outside the CNS have also been shown to be potentially infectious, especially lymphoid organs and tissues containing lymphoid structures. Most body fluids and other tissues are of negligible risk, however blood donations from people with or incubating vCJD have been linked to transmission of vCJD. Categorization of infectivity of tissues in people with vCJD or other TSEs is in appendix A.

1.3 Iatrogenic Transmission

- 1.3.1 Iatrogenic transmission was first described in 1974 in a corneal graft recipient. Cases of iatrogenic CJD have also been associated with the administration of hormones prepared from human pituitary glands, *dura mater* grafts and following neurosurgical procedures with inadequately decontaminated instruments.
- 1.3.2 Variant CJD has been reported in recipients of blood transfusion from donations taken from individuals who later developed vCJD. There is no evidence of transmission of sporadic CJD from blood or its products.

1.4 Occupational Transmission

Occupational transmission of CJD or any other TSE has never been confirmed in either healthcare or any other occupational setting. If TSEs could be transmitted, this would most likely be due to exposure to high risk tissues by direct inoculation from a sharp injury or puncture wound.

2 Purpose of this policy

- 2.1 The purpose of this policy is to ensure that reasonable measures are in place to prevent patients, staff and others being put at risk of contracting transmissible spongiform encephalopathies, (including Creutzfeldt-Jakob disease and variant Creutzfeldt-Jakob disease) as a consequence of healthcare delivered by the Royal Devon and Exeter NHS Foundation Trust.

3 Scope of this Policy

- 3.1 This policy covers the infection control and prevention aspects of the management of TSE. It is not intended to be used for the clinical management and care of patients suffering from a TSE.
- 3.2 This policy is relevant to all practitioners who perform invasive surgical or endoscopic procedures on patients. It is also relevant to practitioners who have patients with a known or suspected TSE, or classified as at risk of vCJD for public health purposes.
- 3.3 Those involved with the decontamination and management of any medical device or surgical instrument must also be aware of this policy.

4 General Principles

- 4.1 There are essentially 3 main elements for protecting people from the risk of iatrogenic acquisition of TSE. These are effective decontamination practices, tracking of instruments and medical devices and identification of patients suffering from or considered to have a risk of TSE.
- 4.2 A high standard of decontamination practice must be maintained for all medical devices and surgical instruments used for invasive procedures. Special attention is needed to identify and manage instruments that are difficult to clean and where appropriate single use devices may be preferred. Relevant guidance including the Trust Decontamination Policy, Health Technical Memoranda , relevant National Standards and guidance from appropriate professional Bodies must be implemented.

- 4.3 It should be possible to track surgical instruments and medical devices including endoscopes to a validated decontamination procedure before and after each episode, and to the patients who have been exposed to the instruments and devices. Ideally individual instruments should be tracked, but sets of instruments may be tracked instead. Migration of instruments between sets, e.g. because of repair or maintenance should be minimized.
- 4.4 Patients who represent a risk as a source of a TSE must be identified. Once identified any medical devices or surgical instruments used on these patients can be appropriately managed to remove the risk of transferring infectious material to other people. Single use instruments should be used if possible, otherwise instruments with significant exposure to risk of contamination are quarantined for use on the same patient again if required, or destroyed by incineration. They may also be made available for research.
- 4.5 **No patient will have treatment compromised or denied because of their TSE risk status.**

5 Identifying patients with or at risk of TSE

5.1 Patients with a Known or Suspected TSE

- 5.1.1 For symptomatic cases there are internationally accepted diagnostic criteria for definite, probable and possible CJD or vCJD. The diagnosis of CJD / vCJD is beyond the scope of this policy. Patients suspected of having CJD or vCJD must be referred to a neurologist, or consultant with appropriate expertise for investigation. The National CJD Surveillance Unit (NCJDSU) must also be informed of all suspect cases. Information is available at <http://www.cjd.ed.ac.uk/referralsystem.htm>.
- 5.1.2 Specific laboratory investigations for the diagnosis of CJD must be discussed with microbiology and the NCJDSU before any specimens for special tests, for example cerebrospinal fluid, are taken. Contact details for the NCJDSU are:
- The National Creutzfeldt-Jakob Disease Surveillance Unit
Western General Hospital
Crewe Road
Edinburgh
EH4 2XU
Telephone Clinical Office: 0131 537 2128
 Pathology: 0131 537 1980
 Fax: 0131 343 1404
- 5.1.3 The document “Creutzfeldt-Jakob Disease: Guidance for Healthcare Workers” (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007012) states that any patient who has a clinical diagnosis of CJD or any other TSE should have a key worker. The key worker is a named professional who coordinates the patients’ case and is the patient’s advocate.
- 5.1.4 If an invasive procedure is required in a patient with a TSE it is the key workers responsibility to ensure that all clinicians are aware of the diagnosis, and that measures outlined in this policy should be followed.

5.2 Identifying Patients at risk of TSE

- 5.2.1 All patients undergoing any invasive surgery or endoscopy should be screened for TSE risk. There are a number of categories of patients who have been identified at risk of CJD and vCJD. These are tabulated in table 2. In many cases patients with a risk factor may have been identified following exposure through some form of medical intervention, and are likely to be aware of this.
- 5.2.2 For most surgical or endoscopic procedures, in which instruments and devices are only exposed to low or medium risk tissues (see Appendix A), it is sufficient screen patients for TSE risk by asking them the question:-

“Have you ever been notified that you are at increased risk of CJD or vCJD for public health purposes?”

- 5.2.3 Some surgical and endoscopic procedures will encounter high risk tissues. These tissues are largely found in the central nervous system, including the posterior part of the eye, and are listed in Appendix A. Effectively this only applies to neurosurgical and ophthalmic departments. In the RD&E this affects the West of England Eye Unit, particularly procedures involving the posterior part of the eye.
- 5.2.4 Patients having procedures which involve high risk tissues, who answer no to the screening question in paragraph 5.2.2 require a more detailed assessment. These people must be asked the questions outlined in table 3. In the RD&E this will be routine for patients requiring posterior ophthalmic procedures, but pragmatically will rarely involve any other patients.

5.3 Practical Aspects of Screening patients for TSE risk

- 5.3.1 Practitioners who are aware that their patient is in one of the risk categories identified in Table 2 should ensure that the patient’s notes contain this information. Whenever the patient is referred for an invasive surgical or endoscopic procedure the referral should include information on the TSE risk. The infection control team should also be informed to ensure that appropriate precautions including, if necessary, quarantining or destruction of contaminated instruments. Timely information in advance is essential in order to avoid delays or postponement of procedures and unnecessary distress for patients.
- 5.3.2 Prior to any surgical or endoscopic procedures patients must be asked must be asked about TSE risk factors. In the RD&E all patients should be asked (see 5.2.2):
- “Have you ever been notified that you are at increased risk of CJD or vCJD for public health purposes?”**
- This can most conveniently done, and recorded at the time of obtaining consent for the procedure.
- 5.3.3 If the answer to the screening question is “no”, then surgery or endoscopy can proceed as normal, unless the procedure involves high risk tissues in which cases all the questions as in table 3 must be asked.

Table 2 Categorization of groups of patients at risk of CJD

Patient groups	Categories of patient
Symptomatic patients	<ul style="list-style-type: none"> • Patients who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD • 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
Patients “at increased risk” from genetic forms of CJD	<ul style="list-style-type: none"> • Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD. • Individuals who have a blood relative known to have a genetic mutation indicative of genetic CJD; • Individuals who have or have had two or more blood relatives affected by CJD or other prion disease
Patients identified as “at increased risk” of CJD/vCJD through iatrogenic exposures	<ul style="list-style-type: none"> • Recipients of hormone derived from human pituitary glands, e.g. growth hormone, gonadotrophin. In the UK the use of human-derived gonadotrophin was discontinued in 1973, and use of cadaver-derived human growth hormone was banned in 1985. However, use of human-derived products may have continued in other countries after these dates. • Individuals who underwent intradural neurosurgical or spinal procedures before August 1992. These patients may have received a graft of human-derived dura mater and should be treated as being “at increased risk” unless evidence can be provided that human-derived dura mater was not used. Patients who received a graft of human-derived dura mater <u>before August 1992</u> are “at increased risk” of transmission of sporadic CJD. • Individuals who have had surgery using instruments that had been used on someone who went on to develop CJD/vCJD, or was “at increased risk” of CJD/vCJD; • Individuals who have received an organ or tissue from a donor infected with CJD/vCJD or “at increased risk” of CJD/vCJD; • Individuals who have been identified prior to high risk surgery as having received blood or blood components from 80 or more donors since January 1980; • Individuals who have received blood from someone who went on to develop vCJD; • Individuals who have given blood to someone who went on to develop vCJD; • Individuals who have received blood from someone who has also given blood to a patient who went on to develop vCJD; • Individuals who have been treated with certain implicated UK sourced plasma products between 1980 and 2001

Table 3 CJD risk questions for patients about to undergo elective or emergency procedures likely to involve contact with tissues of potentially high level infectivity (Appendix A)

Question to Patient	Notes to clinician
<p>1) Have you a history of CJD or other prion disease in your family? If yes, please specify</p>	<p>Patients should be considered to be at risk from genetic forms of CJD if they have or have had:</p> <ol style="list-style-type: none"> 1. Genetic testing, which has indicated that they are at significant risk of developing CJD or other prion disease; 2. A blood relative known to have a genetic mutation indicative of genetic CJD or other prion disease; 3. 2 or more blood relatives affected by CJD or other prion disease
<p>2) Have you ever received growth hormone or gonadotrophin treatment? If yes, please specify: i) whether the hormone was derived from human pituitary glands ii) the year of treatment iii) whether the treatment was received in the UK or in another country</p>	<p>Recipients of hormone derived from human pituitary glands, e.g. growth hormone or gonadotrophin, have been identified as at increased risk of sporadic CJD.</p> <p>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.</p> <p>In the UK, the use of human-derived gonadotrophin was discontinued in 1973 but may have continued in other countries after this time.</p>
<p>3) Have you ever had surgery on your brain or spinal cord?</p>	<p>(a) Patients who underwent intradural neurosurgical or spinal procedures before August 1992 may have received a graft of human-derived dura mater and should be treated as at increased risk, unless evidence can be provided that human-derived dura mater was not used. Patients who received a graft of human-derived dura mater before 1992 are at increased risk of transmission of sporadic CJD, but not vCJD.</p>
<p>4) Since 1980, have you had any transfusions of blood or blood components (red cells, plasma, cryo - precipitate or platelets)?* If yes, have you either: i) received more than 50 units of blood or blood components? or ii) received blood or blood components on more than 20 occasions? Where possible, please provide the names of all the hospitals where you received blood or blood components.</p>	<p>Patients who have received blood from more than 80 donors have been identified as at increased risk of vCJD.</p> <p>* This does not include:</p> <ul style="list-style-type: none"> - Autologous transfusion - Plasma products such as IVIG, albumin, coagulation factors and anti-D

- 5.3.4 If the answer to the screening question is “**yes**”, then the patient should be asked to explain further. The infection control team should be informed and appropriate infection control precautions should be taken. These are described in the relevant section of this policy.
- 5.3.5 If a patient is unable to respond then surgery or endoscopy should proceed using normal infection control procedures, unless there is likely to be contact with high risk tissues. If high risk contact is likely the patient should be managed as if there is a TSE risk. Instruments and devices should be quarantined, as described in the appropriate section of the policy, until the patients true risk status can be ascertained.
- 5.3.6 If a patient is to have a procedure on the posterior eye, or other high risk tissue, and answers no to the initial screening question, then the further 4 questions in table 3 should be asked. If the answers to any of these is yes, then further investigation into the nature of the risk is required. The infection control team must be informed and appropriate precautions must be taken to quarantine or if necessary dispose of surgical instruments, medical devices or endoscopes as described in the appropriate section of this policy.
- 5.3.7 If a patient answers yes to question 4 in table 3 regarding receiving more than 50 units of blood or blood components on more than 20 occasions the infection control team must be informed. A detailed risk assessment of the transfusions and/or blood components will be undertaken in cooperation with the transfusion services and haematology. The required documentation will be completed and forwarded to the HPA
- 5.3.8 TSE risk assessment is part of the normal consent process and training is required for all who undertake this function. In addition specific additional training is necessary for surgeons and other practitioners who routinely operate with high risk tissues. In the RD&E this is likely to be those who undertake ophthalmic procedures on the posterior eye.
- 5.3.9 An information leaflet is available for patients to explain what the TSE risk assessment is for and the implications for patients. This is included in appendix E
- 5.3.10 If a risk for TSE is identified in any patient, this should be documented in the patients notes and the patients GP and the local health protection unit of the HPA should be informed. The patient should also be informed by the most appropriate person who has adequate knowledge. This may be the patients GP, a member of the RD&E or Health Protection Unit Staff.

6 Care of patients with symptomatic TSE or at risk of TSE

6.1 General considerations

- 6.1.1 In most routine clinical contact, no additional precautions are needed for the care of patients in the risk groups defined in table 2. Available epidemiological evidence does not suggest that normal social or routine clinical contact with a CJD or vCJD patient presents a risk to healthcare workers, relatives and others in the community. Routine infection control practice should be observed and isolation is not required.
- 6.1.2 However, when certain invasive interventions are performed, there is the potential for exposure to the agents of TSEs. In these situations it is essential that control measures are in place to prevent the iatrogenic transmission of TSEs.

6.2 Communication

- 6.2.1 If any health care worker becomes aware of a patient falling into any of the risk categories listed in table 2, who was previously unknown, they should urgently inform a member of the ICT. No surgical or endoscopic invasive procedures may be undertaken until advice has been obtained and appropriate measures have been put in place. In emergencies when delay is not possible, all instruments and endoscopes should be quarantined until advice on processing or disposal is obtained.

6.3 Body fluids

- 6.3.1 There is no evidence of infectivity in saliva, body secretions or excreta. Any potential exposure to these body fluids should be handled in line with standard infection control precautions. Careful attention to standard infection control precautions *i.e.* avoidance of sharps injuries will minimise any risks from blood.
- 6.3.2 Experimental transmission of sporadic CJD has been achieved from CSF in primates by intracerebral inoculation - indicating that levels of infectivity are likely to be much lower than in the central nervous system (CNS). Never the less care should be taken when undertaking lumbar puncture.

6.4 Specimens for pathology - Invasive medical procedures and sample labeling

- 6.4.1 Because of the unusual resistance of the TSE agents, single-use disposable equipment should be used wherever practicable when obtaining specimens, and all other items of equipment contaminated whilst obtaining specimens should normally be destroyed by incineration. Discussion with infection control staff prior to any invasive procedure, for example obtaining a biopsy, is required, especially if expensive equipment which is not normally single use is involved.
- 6.4.2 Biopsy and lumbar puncture samples should only be taken by trained personnel who are aware of the hazards involved. The collection of blood specimens should involve the same precautions normally used for venepuncture. Particular care should be taken while obtaining and handling CSF and lymphoid tissue specimens. Standard practice should be to use disposable gloves and aprons. Eye protection should be worn for procedures where splashing may occur.
- 6.4.3 The agents of CJD and vCJD are classified as Hazard Group 3 pathogens by the Advisory Committee on Dangerous Pathogens (ACDP). For this reason, all specimens from known or at risk patients must be labeled with 'Danger of Infection' stickers. Specimens of cerebrospinal fluid, tissues and biopsies should be marked with a 'Biohazard' label. Normally the laboratory should be informed in advance that a sample is being sent. High risk material including any specimen from the eye, or likely to include olfactory epithelium or lymphoid tissue must only be submitted for examination after prior consultation with the appropriate laboratory.

6.5 Spillages

- 6.5.1 The infectious agent associated with TSEs is unusually resistant to inactivation techniques. Dilution is the most important element in cleaning up spillages on the hospital ward. Exposure to high-concentration (20,000 ppm available chlorine) sodium hypochlorite for one hour is known to be effective. But its use is unlikely to be practical in a ward situation, since it is highly corrosive to many surfaces, it can be used in exceptional circumstances to clean up spillages of high risk material, in which case advice should be sought from the infection control team.

- 6.5.2 Normally standard infection control precautions should be followed to clear up spillages on the ward, including spillages of blood and cerebrospinal fluid (CSF). Potentially infectious materials should be removed using absorbent material, and any waste (including cleaning tools such as mop-heads) disposed of as clinical waste for incineration. Disposable gloves and an apron should be worn when removing spillage.

6.6 Childbirth

- 6.6.1 In the event that a patient defined in table 2 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.
- 6.6.2 Childbirth should be managed using standard infection control procedures. The placenta and other associated material and fluids should be treated as if infected, and disposed of unless they are needed for investigation, in which case the precautions for dealing with infected tissue should be followed (see section 9). Currently disposal by incineration is recommended.
- 6.6.3 Instruments should be handled following the advice in the paragraphs below on surgical procedures.

6.7 Clinical Waste

Clinical waste generated while caring for patients with or at risk of a TSE is unlikely to contain high risk material. It should be disposed of as normal clinical waste in line with locally approved arrangements (See Waste Policy).

6.8 Bed linen & Crockery

No special precautions are needed. Linen and crockery can be handled in line with normal policies.

6.9 Room cleaning

There are no additional requirements above normal room cleaning or terminal disinfection.

7 Occupational exposure

7.1 Accidental

- 7.1.1 Although cases of CJD/vCJD have been reported in healthcare workers, there have been no confirmed cases linked to occupational exposure. However, it is prudent to take a precautionary approach. The highest potential risk in the context of occupational exposure is from exposure to high infectivity tissues through direct inoculation (e.g. as a result of “sharps” injuries, puncture wounds or contamination of broken skin), and exposure of the mucous membranes (e.g. conjunctiva) should also be avoided.
- 7.1.2 Compliance with standard infection control precautions is sufficient. Clinical or laboratory personnel who work with patients with *definite*, *probable* or *possible* CJD or vCJD, or with potentially infected tissues, should be informed about the nature of the risk and relevant safety procedures.

7.1.3 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 inoculation injury policy should be followed in case of additional risks from, for example, blood borne viruses. The accident should be reported an incident form completed.

7.2 List of workers exposed to TSE agents

7.2.1 Under certain circumstances COSHH (Control of Substances Hazardous to Health Regulations, 1999) requires employers to keep a list of employees who are exposed to Hazard Group 3 which includes TSE agents. The decision to keep a list depends on the local risk assessment. For TSE agents a list is only required where employees deliberately work with the agent.

7.2.2 The routine clinical care of patients with CJD or a related disorder is unlikely to pose a significant risk of exposure to CJD of any type. Such staff do not need to be included on such a list.

7.2.3 The Occupational Health Department should consider maintaining a list, and including details of exposure on the health record for the following staff:

- a those performing invasive clinical procedures on patients suspected to be suffering from CJD of any type, particularly where there is a risk of exposure to central nervous tissue, eye tissue or other tissues known to contain CJD infectivity
- b laboratory staff handling **tissue** specimens from patients with CJD of any type
- c staff undertaking post-mortem examinations of patients who have died of CJD of any type or where CJD of any type is suspected.
- d in cases of unintentional or accidental exposure, where risk assessment shows that there is a significant risk

7.2.4 The information that should be recorded includes the type of work done and, where known, any specific exposure, accident or incident. Because of the long latency period of TSE agents and their serious long-term sequelae, the list must be kept for 40 years after the last known exposure. The list is in addition to the health record (which is required for the purposes of health surveillance under COSHH or MHSWR) and must be made available to any doctor appointed to carry out health surveillance, e.g. the occupational health physician. It must also be available to any employee who is specifically responsible for health and safety.

8 Surgery and Invasive Procedures

8.1 General measures

8.1.1 Communication

All staff directly involved in invasive procedures on patients in the risk groups in table 2, or in the subsequent re-processing or disposal of potentially contaminated items, should be aware of the specific precautions required. These staff should also be made aware of any clinical intervention in sufficient time to allow the necessary preparations for the procedure; this should include notification to the HSDU when appropriate. This will also allow time to obtain the most suitable instruments and equipment, which may not be those used routinely. Single-use disposable items should always be used wherever possible.

8.1.2 Decontamination

Effective decontamination is the key to reducing the risk of transmission of TSEs via surgery. Decontamination should be carried out to the appropriate standard as set out in the Trust Decontamination Policy.

8.1.3 Instrument Tracking

All reusable surgical instruments and invasive devices (including endoscopes) must be subject to tracking procedures. Tracking provides a permanent record to indicate which instrument or device is used on which patient. Tracking also links each device to a validated decontamination cycle prior to use. The tracking system must be capable of the identification of instruments used on a particular patient, and also the patients on whom the same instruments had subsequently been used. In the case of surgical instruments, tracking may be a record of an individually marked instrument, or alternatively a set of instruments used and processed together. Sets of instruments should be managed to minimise migration of instruments between sets.

8.2 Specific precautions for symptomatic patients (definite, probable and possible) and asymptomatic patients potentially at risk of CJD

The measures to be taken when performing invasive surgery depend on how likely the patient is to be carrying the infectious agent (the risk status as set out in table 2), and how likely it is that infection could be transmitted by the procedure being carried out.

8.2.1 Precautionary measures for surgical procedures - Theatre management

For all symptomatic patients (*i.e.* those who fulfill the criteria for definite, probable or possible CJD or vCJD table 2), and for asymptomatic patients at risk from familial or iatrogenic TSE, the following precautions should be taken when high or medium risk tissues are encountered during the procedure, or as advised by the infection control team.

- a wherever appropriate and possible, the intervention should be performed in an operating theatre
- b where procedures are performed at the bedside, *e.g.* a lumbar puncture, care should be taken to ensure the environment may be readily cleaned should a spillage occur. The protective clothing described below (e) should be worn by healthcare personnel performing diagnostic procedures.

- c where possible, procedures should be performed at the end of the list, to allow normal cleaning of theatre surfaces before the next session
- d only the minimum number of healthcare personnel required should be involved
- e the following single-use protective clothing should be worn, and disposed of in line with local policies:
 - liquid repellent single use operating gown, over a plastic apron
 - gloves
 - mask and goggles, or full-face visor
- f use single-use disposable surgical instruments and equipment where possible.
- g destroy all single-use items by incineration
- h The principles for reducing the risks from percutaneous exposure to blood-borne viruses apply equally to CJD.

8.2.2 Handling of instruments that are not designated as single-use

8.2.2.1 Where single-use instruments are not available, the handling of re-usable instruments depends on a combination of the risk status of the patient, the tissue(s) involved in the procedure, and the type of CJD.

8.2.2.2 Tables 4 and 5 set out separately the actions to be taken for CJD and vCJD, whether instruments should be destroyed, quarantined or have no special precautions and reprocessed if not single use. These actions are also summarized in the algorithms in appendix B

8.2.3 Storage of instruments for research purposes

In some cases, instruments which are destined for disposal by incineration may be retained 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) to discuss whether it would be helpful to retain a particular instrument for research, and where and how it should be stored.

8.2.4 Complex Instruments and medical devices

8.2.4.1 Some expensive items of equipment, such as drills, may be prevented from being contaminated by using shields, guards or coverings, so that the entire items do not need to be destroyed. The drill bit, other parts in contact with high risk tissue(s), and the protective coverings would then need to be incinerated. However, in practice, it may be difficult to ensure effective protective covering, and advice should be sought from specialist staff including the CJD Incidents Panel and the manufacturer to determine practicality.

8.2.5 Quarantining of surgical instruments

8.2.5.1 Instruments that have been used on a *possible* CJD or vCJD patient must not be re-used, but may be quarantined rather than destroyed by securely storing in a rigid, sealed container after use, until the diagnosis is confirmed.

8.2.5.2 Detailed guidance on the procedure for quarantining instruments, including initial washing to remove gross soil, is set out in appendix C. If the case is confirmed as CJD or vCJD, or if after testing the diagnosis is inconclusive, the instruments should be disposed of by incineration or stored safely for use in research – see above. Only if a definitive alternative diagnosis is confirmed may the instruments be decontaminated following the usual routine procedures and returned to use.

8.2.6 Use of laser for tonsillectomy: smoke plumes

Some ENT surgeons may use laser techniques as an alternative to “conventional” surgery for tonsillectomy. There is no evidence of the transmission of TSEs by the respiratory route. Any risk to surgeons from smoke plumes is thought to be very low, but there are no data on vCJD.

8.3 Special considerations for Surgery on the Eye

- 8.3.1 At the RD&E the only department which would expect to routinely undertake procedures on tissues categorised as high risk (Appendix A) is the West of England Eye Unit. The tissues in the “posterior eye” are classed as high risk.
- 8.3.2 All patients who have procedures on the posterior eye and other high risk tissues must have the extended risk assessment, see table 3, and section 5.3. Staff must be trained in TSE risk assessment.
- 8.3.3 Precautions must be taken to ensure that migration between sets of instruments used on high risk tissues is at a minimum. Where possible individually identified instruments should be used, and consideration given to using single use instruments if practicable.
- 8.3.4 NICE guidance emphasises the need for a separate pool of instruments for high risk procedures on children born since 1st January 1997 and who have **not** previously undergone high risk procedures. These instruments should not be used for patients born before 1st January 1997 or those who underwent high risk procedures using reusable instruments before the implementation of this guidance.

Table 4 Handling of instruments that are not designated single use CJD other than vCJD

Tissue Infectivity	Status of patient			
	Definite/probable	Possible	At risk	
			Genetic	Iatrogenic
High: <ul style="list-style-type: none"> • Brain • Spinal cord • Posterior eye 	D	Q	D	D
Medium: <ul style="list-style-type: none"> • Anterior eye • Olfactory epithelium 	D	Q	D	D
Low/none detectable	NSP	NSP	NSP	NSP

Table 5 Handling of instruments that are not designated single use vCJD

Tissue Infectivity	Status of patient		
	Definite/probable	Possible	At risk
			Iatrogenic
High: <ul style="list-style-type: none"> • Brain • Spinal cord • Posterior eye 	D	Q	D
Medium: <ul style="list-style-type: none"> • Lymphoid tissue • Anterior eye • Olfactory epithelium 	D	Q	D
Low/none detectable	NSP	NSP	NSP

Key to Tables 4 and 5

D = destroy by incineration

Q = quarantine pending diagnosis (see [paragraphs 6.25](#) below and Annex C)

NSP = no special precautions

9 Flexible endoscopes

9.1 General Considerations

- 9.1.1 There is currently no evidence that vCJD has been transmitted from one patient to another via an endoscopic procedure. However because lymphoid tissue of the gastrointestinal tract sub-mucosa is considered a medium-infectivity tissue (Appendix A), investigation of patients defined in table 2 has implications for all patients requiring endoscopy.
- 9.1.2 Flexible endoscopes contaminated with prion containing material cannot be completely reliably decontaminated using current methods. Therefore the next few patients are considered potentially exposed to significant prion infectivity. The risks of transmission are not confined to the endoscope itself but also accessories such as biopsy forceps which have an equal or even greater risk as they are less easily cleaned. As a consequence, disposable accessory equipment is now advised wherever possible.

9.2 Communication

Should a patient in one of the risk groups in table 2 require endoscopy, the advice of the ICT must be sought in advance. Details of how to decontaminate endoscopes are held in the endoscopy decontamination suites in the Trust . For endoscopes other than gastrointestinal endoscopes, the ICT will discuss cases on an individual basis, based on the principles outlined in Tables 6 and 7 and the classification provided in appendix D.

9.3 Decontamination of endoscopes

- 9.3.1 The general procedures set out in the MDA Device Bulletin MDA DB2002(05), should be followed. In order to decrease the risk of transmission of TSEs through endoscopic procedures, additional precautions for the decontamination of flexible endoscopes used in all patients with definite, probable or possible TSE, and in those identified as at risk of developing TSE, are recommended and general precautions are reinforced in this annex:
- (a) Channel cleaning brushes and, if a biopsy has been taken, the valve on 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. 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 should 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.
- (b) As defined below, 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 (see Table 7.1 and 7.2). 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 principles behind the procedures recommended for quarantining of surgical instruments in Annex C of this Guidance 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).

- (c) 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. Contact the endoscope supplier for advice on appropriate alternatives.
- (d) When decontaminating the endoscope cleaning equipment, provided that the cleaning equipment is decontaminated as indicated below, there is no risk of transmission of TSE agents via this route. Following the decontamination of the endoscope, the automated endoscope reprocessor (AER) should be run through an empty cycle. Any solid waste or tissue remaining in the AER should be removed together with the outlet strainer and disposed of by incineration. Liquid waste should be disposed of safely by normal direct discharge from the AER. The usual self-disinfection cycle should be run as per recommended routine. Endoscopic accessories and cleaning aids such as brushes should be disposed of by incineration.

9.4 Precautionary measures for endoscopic procedures

- 9.4.1 Flexible endoscopes and their accessories are expensive pieces of equipment and the principles outlined below should minimise the need to quarantine them or destroy them after use on patients in table 3.1. See tables 7.1 and 7.2.
- 9.4.2 Gastrointestinal endoscopy on symptomatic or asymptomatic patients with, or at risk of, TSE **other than vCJD** will not involve high or medium risk tissues. Therefore no special precautions are necessary during or after the procedure, and the endoscopes should be cleaned and disinfected in the normal thorough way.
- 9.4.3 Prion protein has been detected in the olfactory epithelium of sporadic CJD patients. Endoscopic procedures involving the nasal cavity may come into contact with olfactory epithelium. If nasal endoscopy is performed on patients in table 2 the infection control team should be contacted for advice. Following consultation with the person carrying out the endoscopic procedure, the risk of contamination of the endoscope with olfactory epithelium can be assessed. If contamination cannot be excluded precautions appropriate for medium infectivity tissues must be taken, a single use endoscope or destruction of the endoscope following the procedure.
- 9.4.4 Neurological endoscopes should not normally be used on patients with possible CJD or in whom it is unclear if the patient may have CJD. If this is not possible then a single-use instrument should be used or the reusable endoscope should be quarantined pending a definitive diagnosis. If further clarification of the diagnosis is not possible, the endoscope should be destroyed.
- 9.4.5 As lymphoid follicles and germinal centres are widely distributed in the gastrointestinal tract and other mucosal surfaces, endoscopy on patients in table 2 may involve medium risk tissues, particularly if biopsy forceps are used. Patients with definite or probable **vCJD** should only undergo flexible endoscopy if this is deemed a clinical necessity. It may be possible to loan an instrument from the National CJD

Surveillance Unit – the Infection Control Team will advise. Instruments may also be returned to general service after refurbishment and channel replacement.

- 9.4.6 If a tissue biopsy or other invasive procedure (e.g. ERCP or diathermy) is performed on a patient with or at risk of vCJD the endoscope must be assumed to be potentially contaminated with lymphoid tissues. This applies to upper and lower gastrointestinal endoscopy, bronchoscopy and any other procedure where a flexible endoscope is used to obtain a tissue biopsy or another invasive procedure is performed (see Appendix D for detailed advice on specific procedures). Therefore endoscopic biopsies should only be performed if the results are deemed to be sufficiently important to warrant quarantine of the endoscope. Taking random biopsies in a patient with or at risk of vCJD is unacceptable clinical practice. However the fundamental principle that patient care must remain unaffected is paramount.
- 9.4.7 The BSG Decontamination Working Group and the TSE Working Party Endoscopy and vCJD sub-group have issued a joint statement which classifies the following procedures as “invasive” (i.e. expected to potentially contaminate instruments with lymphoid tissue and therefore requiring quarantine of the endoscope):
- a Endoscopy and biopsy
 - b Endoscopy and any use of diathermy (e.g. snare polypectomy, sphincterotomy)
 - c Endoscopy and dilatation (where the endoscope may come into contact with the sub-mucosa)
 - d Endoscopy and argon plasma coagulation
 - e Endoscopic ultrasound and biopsy
- 9.4.8 The BSG Decontamination Working Group and the TSE Working Party Endoscopy and vCJD sub-group have issued a joint statement which classifies the following procedures as “non-invasive” (i.e. no potential for contamination of the instruments with lymphoid tissue and therefore not requiring quarantine of the endoscope):
- a Endoscopy without biopsy (includes appropriate use of cytology)
 - b Endoscopy followed by bougie dilatation of stricture without repeat endoscopy
 - c Gastroscopy and insertion of a PEG feeding tube (provided performed with a “pull through” technique where the wire or thread is not withdrawn into the gastroscopy but withdrawn in full view)
 - d Endoscopic ultrasound without biopsy
 - e Endoscopy and injection of varices or ulcer (without diathermy)
- 9.4.9 Further details on the classification of flexible endoscopic procedures as invasive or non-invasive is provided in appendix D. If a patient with suspected vCJD is inadvertently endoscoped, the ICT must be called urgently, and the instrument quarantined. If a patient, who has been previously endoscoped, subsequently develops vCJD, the ICT must be called urgently and the instrument quarantined. The National CJD Incidents Panel may need to be contacted (see ‘Lookbacks’ for recently diagnosed CJD patients, Section 13.13 below). If endoscopy was performed without biopsy (and without contact with nasal tissues or central nervous system tissues) this can be regarded as a low risk procedure.
- 9.4.10 All endoscopes should have a unique identifier, and this must be recorded in the notes of the patient undergoing endoscopy with that instrument. This will enable a lookback exercise to be performed if necessary.
- 9.4.11 Disinfectants should be used which do not stabilise prions. Single use disposable, biopsy forceps should be used in all patients with definite, probable or possible CJD and in those identified as at risk of developing CJD. Biopsy channel brushes and the valve on the biopsy/ instrument channel port should be disposed of as clinical waste

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after each use. Where reusable accessories have to be used, these should be dedicated to the identified endoscope, and never interchanged between endoscopes. The endoscope's unique identifier will then enable a lookback exercise if necessary.

SUMMARY OF PRECAUTIONS ADVISED FOR THE USE OF ENDOSCOPES

Table 6 CJD other than vCJD

Tissue Infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/probable	Possible/diagnosis unclear ¹	At risk ² iatrogenic/familial
High: • Brain • Spinal cord	single use OR ³ destroy after use	single use OR ⁴ quarantine pending diagnosis	single use OR ³ destroy after use OR quarantine ⁴ for re-use exclusively on same patient
Medium: • Olfactory epithelium*	single use OR ³ destroy after use	single use OR ⁴ quarantine pending diagnosis	single use OR ⁵ destroy after use ³ OR quarantine ⁴ for re-use exclusively on same patient
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.

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 refer to the section on surgical instruments.

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 in Annex C of this Guidance 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.

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.

⁶ The decontamination procedures advised in 7.3, taken together with the MDA Device Bulletin MDA DB2002(05), should be followed.

Table 7vCJD

Tissue Infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/probable	Possible/diagnoses unclear ¹	At risk ² iatrogenic
High: • Brain • Spinal cord	single use OR ³ destroy after use	single use OR ⁴ quarantine pending diagnosis	single use OR ³ destroy after use OR ⁴ quarantine for re-use exclusively on same patient
Medium: ⁸ • Olfactory epithelium* • Lymphoid tissue**	single use OR ⁷ use dedicated endoscope OR ³ destroy after use	single use OR ⁴ quarantine pending diagnosis	single use OR ⁵ destroy after use OR ⁴ quarantine for re-use exclusively on same patient
Low/none detectable: ⁸ • 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 .

**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 sub-mucosa.

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, refer to the guidance for the use of all surgical instruments in section 6.

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 in Annex C of this Guidance 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 7.3 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.

⁶ The decontamination procedures advised in 7.3 of this guidance, taken together with the MDA Device Bulletin MDA DB2002(05), should be followed.

⁷ 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.

⁸ All endoscopes used for invasive procedures must be removed from use or quarantined. below clarifies which endoscopic procedures must be considered invasive.

10 Death of a patient

10.1 Ward Procedures

10.1.1 On the death of a patient defined in table 2 the removal of the body from the ward, community setting or hospice, to the mortuary, should be carried out using normal infection control measures.

10.1.2 It is recommended that the deceased patient is 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.

10.2 Mortuary

10.2.1 Post-mortem examinations are required in order to confirm a clinical diagnosis and the cause of death in patients with suspected CJD or vCJD. However, such

procedures have the potential to expose pathologists and mortuary staff to tissues containing high levels of infectivity.

- 10.2.2 If a post mortem is required for anyone who falls into the risk groups in table 3.1, arrangements should be made for the body to be removed to a regional neuropathology centre where specialist expertise exists. Liaison between local pathologists and the National CJD Surveillance Unit is preferable. Arrangements for refund of any removal costs for CJD autopsies can be made through the National CJD Surveillance Unit.
- 10.2.3 Following a request from relatives, decisions about whether tissues, blocks, slides etc of a patient defined in Table 3.1 can be returned, should be made on the basis of an assessment of the risks. If a risk assessment indicates that these items may be returned, this is best done *via* the funeral director. If return is not possible, families should have the reasons explained to them. Any retained items from such situations should only be returned to a funeral director, with information relating to the potential risks from the material (*e.g.* infection or chemical exposure), so they can consider all the risks before selecting the most appropriate option for immediate respectful disposal. Care must be taken to ensure confidentiality in all dealings between undertakers and a patient's relatives.
- 10.2.4 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 or kissing, need not be discouraged even if a post-mortem has taken place. Body bags may be rolled down temporarily to allow superficial contact; there is no need to deny the relatives this opportunity if a post-mortem has been performed.

10.3 Undertakers and embalmers

- 10.3.1 The undertakers should receive an infection control notification sheet appropriately completed, prior to handling the body of the deceased. Cosmetic work on bodies of patients from a risk group in table 3.1 may be undertaken observing the precautions routinely used when dealing with all human cadavers. However when the diagnosis of CJD or vCJD is known or suspected it is advisable to avoid embalming procedures.
- 10.3.2 No additional precautions are 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 Regulations and any additional requirements of the individual carrier, which should be discussed on a case-by-case basis.
- 10.3.3 There is no need to discourage burial of a patient with known or suspected CJD or vCJD, and no special arrangements for burial are required. Similarly, there is no need for any extra precautions to be taken for cremation.

11 Laboratories

11.1 General Considerations

- 11.1.1 All TSE agents, except scrapie, are all classified as Hazard Group (HG) 3, as listed in the Health and Safety commission's "Approved List of Biological Agents". In general the Control of Substances Hazardous to Health (COSHH) Regulations 2002 require that when working with an agent the laboratory containment level must match the hazard group of the agent.

11.1.2 No specific TSE diagnostic work is routinely performed at the RD&E. However most specimens examined from patients diagnosed with, or at risk of, a TSE are likely to carry a very low risk of infection for laboratory or other Trust staff. For this reason most specimens can be processed using standard operating procedures under normal containment for the specimen being examined - see section 10.3.

11.1.3 Each laboratory must have laboratory operating procedures for processing specimens from patients diagnosed with, or at risk of, a TSE as defined in table 3.1, and perform the normal risk assessment under COSHH regulations.

11.1.4 Any laboratory intending to work with known or suspected TSE infected material for specific TSE diagnostic or research reasons must set up appropriate containment facilities, perform the required risk assessments and obtain Trust approval for such work.

11.2 Specimens and Request forms

11.2.1 All specimens from patients who are diagnosed with, or at risk of, a TSE, must be labelled as "danger of infection", with details of diagnosis and examination required. The relevant laboratory must be contacted in advance for advice before submitting tissue specimens and CSF for examination.

11.3 Low risk specimens from patients diagnosed with, or at risk of, a TSE

11.3.1 Specimens such as blood, urine, faeces and CSF are considered to have a very low infectious risk. Manual processing of specimens should be carried out in a microbiological safety cabinet. Equipment used for the handling of infectious material should be disposable if possible or else cleaned thoroughly before being autoclaved.

11.3.2 These specimens can be analyzed in a fully enclosed automated system at containment level 2 providing any manual processing such as decanting is carried out within a microbiological safety cabinet. The low risk of infectivity together with the use of a fully enclosed system is considered sufficient to reduce any risk of exposure to the laboratory worker to a very low level. The assessment of these types of procedures should take into account whether:

- the system is fully enclosed and can contain spillage
- waste can be disposed of without risk
- there are suitable maintenance and emergency procedures in place.

11.3.4 Low risk specimens should be autoclaved prior to disposal by incineration

11.4 High and medium risk specimens from patients diagnosed with, or at risk of, a TSE

11.4.1 Brain, neural tissue (including olfactory epithelium and tissue from the eye) and for vCJD, lymphoid containing tissue, are considered high or medium risk.

11.4.2 Diagnostic analysis of all brain, eye and neural tissue preparations must be referred to specialist neuropathology laboratory or centre. Agreement for accepting the specimen and arrangements for transport must be made with the specialist laboratory prior to taking the specimen.

11.4.3 A risk assessment should be made prior to processing other specimens.

- Processing but can usually be at containment level 2 but must take place in a microbiological safety cabinet
- Care should be taken to avoid accidental inoculation or injury, e.g. when preparing samples for microscopy or culture
- disposable equipment should be used wherever practicable, e.g. cell counting chambers etc
- any items contaminated by the specimens should be either destroyed by incineration, autoclaved or disinfected to the required standard
- any residual contamination of automated equipment should be minimized
- any residual contamination of equipment should be dealt with before servicing
- delicate equipment such as microscopes should be cleaned and maintained to avoid accumulation of potentially contaminated debris

11.5 Specimen Transport

TSE specimens can be transported

11.4 Fixed specimens

11.4.1 It should be remembered that, although standard formalin is used for fixation for general histopathology purposes, formalin-fixed TSE tissue retains infectivity for long periods and should always be handled with the same precautions as fresh material. Similarly, tissue for electron microscopy fixed in glutaraldehyde retains its infectivity. Formalin-fixed TSE tissue can be decontaminated with formic acid treatment.

11.4.2 Once tissue blocks are fixed and formic acid-treated, sections can be cut on a standard microtome (preferably using a disposable knife) and processed as usual. Debris (wax shavings) from section cutting should be contained and disposed of by incineration.

12 Dentistry

12.1 The risks of transmission of infection from dental instruments are thought to be very low provided optimal standards of infection control and decontamination are maintained. New general advice on decontamination in dentistry has been issued in 2010

12.2 Dental instruments used on patients defined in table 2 can be handled in the same way as those used in any other low risk surgery, i.e. taking a precautionary approach, these instruments can be reprocessed according to best practice and returned to use. Optimal reprocessing standards must be observed.

12.3 Endodontic instruments, which may come into contact with branches of the trigeminal nerve, should be single patient use. Additionally, dentists are reminded that any instruments labelled by manufacturers as "single-use" should not be reused under any circumstances.

12.4 There is no reason why any of the categories of patients defined in 2, or their relatives, should be refused routine dental treatment. Such people can be treated in the same way as any member of the general public.

13 Lookback Exercises in the event of newly diagnosed cases of TSE

- 13.1 If a diagnosis of CJD or vCJD is suspected by clinical staff, the CJD Surveillance Unit in Edinburgh will be contacted for a clinical opinion. This will result in patients being classified as “possible”, “probable” or “confirmed” cases of CJD. Where patients are so classified, the doctor from the Surveillance Unit will require details of previous operations that the patient has undergone, and blood and organ donations that the patient may previously have made (a ‘lookback’).
- 13.2 In cases where operations and/or donations have occurred (with a time frame decided by the Surveillance Unit), the local Consultant in Communicable Diseases Control (CCDC) will be informed by the Surveillance Unit or clinician in charge of the case, so that procedures for detailed assessment of the operations/donations can be commenced. The CCDC will then decide if the formation of a local incident group is required.
- 13.3 The incident group will then assess whether the National CJD Incidents Panel need to be contacted. The Local Incident Group will be determined by the CCDC, but is likely to include the Infection Control Doctor, Infection Control Nurse, DIPC, Medical Director of the Trust (or representative), Chief Executive of the Trust (or representative), Director of Nursing (or representative), Occupational Health representative, Risk Management representative, Public Relations and Media Communications representative, Patient Liaison representative, senior managers from theatres and SSD, consultant in charge of the case, the Director of Public Health from the relevant PCT and a Regional representative (such as the Regional Epidemiologist). This Group, after consultation with the National CJD Incidents Panel, will determine the relevant investigations and management of the incident.

References and Information sources

- 1 The National Creutzfeldt-Jakob Disease Surveillance Unit (NCJDSU)
<http://www.cjd.ed.ac.uk/index.htm>
- 2 Creutzfeldt-Jakob disease guidance for health workers
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007012
- 3 Guidance from the ACDP TSE Working Group
<http://www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm>
- 4 NICE CJD guidance
<http://www.nice.org.uk/guidance/index.jsp?action=folder&o=35280>

Appendix A

Distribution of TSE Infectivity in Human Tissues and Body Fluids

Tissue	Presence of abnormal Prion Protein and level of infectivity			
	TSE other than vCJD		vCJD	
	PrP ^{TSE} detected	Assumed level of Infectivity	PrP ^{TSE} detected	Assumed level of infectivity
Brain	+ve	High P	+ve	High P
Spinal cord	+ve	High P	+ve	High P
Spinal ganglia	+ve	High	+ve	High P
<i>Dura mater</i>	-ve	High	-ve	High
Cranial nerves	+ve	High	+ve	High
Cranial ganglia	+ve	High	+ve	High P
Posterior eye	+ve	High P	+ve	High
Pituitary gland	+ve	High (?)	+ve	High (?)
Anterior eye and cornea	-ve	Medium	-ve	Medium
Olfactory epithelium	+ve	Medium	NT	Medium
Tonsil	-ve	Low	+ve	Medium P
Appendix	-ve	Low	+ve	Medium
Spleen	+ve	Low P *	+ve	Medium P
Thymus	-ve	Low	+ve	Medium
Other lymphoid tissues	-ve	Low P *	+ve	Medium P
Peripheral nerve	+ve	Low	+ve	Low
Skeletal muscle	+ve	Low	+ve	Low
Dental Pulp	-ve	Low	-ve	Low
Gingival Tissue	NT	Low	-ve	Low
Blood and bone marrow	NT	Low	-ve	Low
CSF	-ve **	Low P **	-ve**	Low
Placenta	-ve	Low	-ve	Low
Urine	-ve	Low	-ve	Low
Other tissues	-ve	Low P *	-ve	Low

Key: +ve = tested positive -ve = tested negative NT = not tested

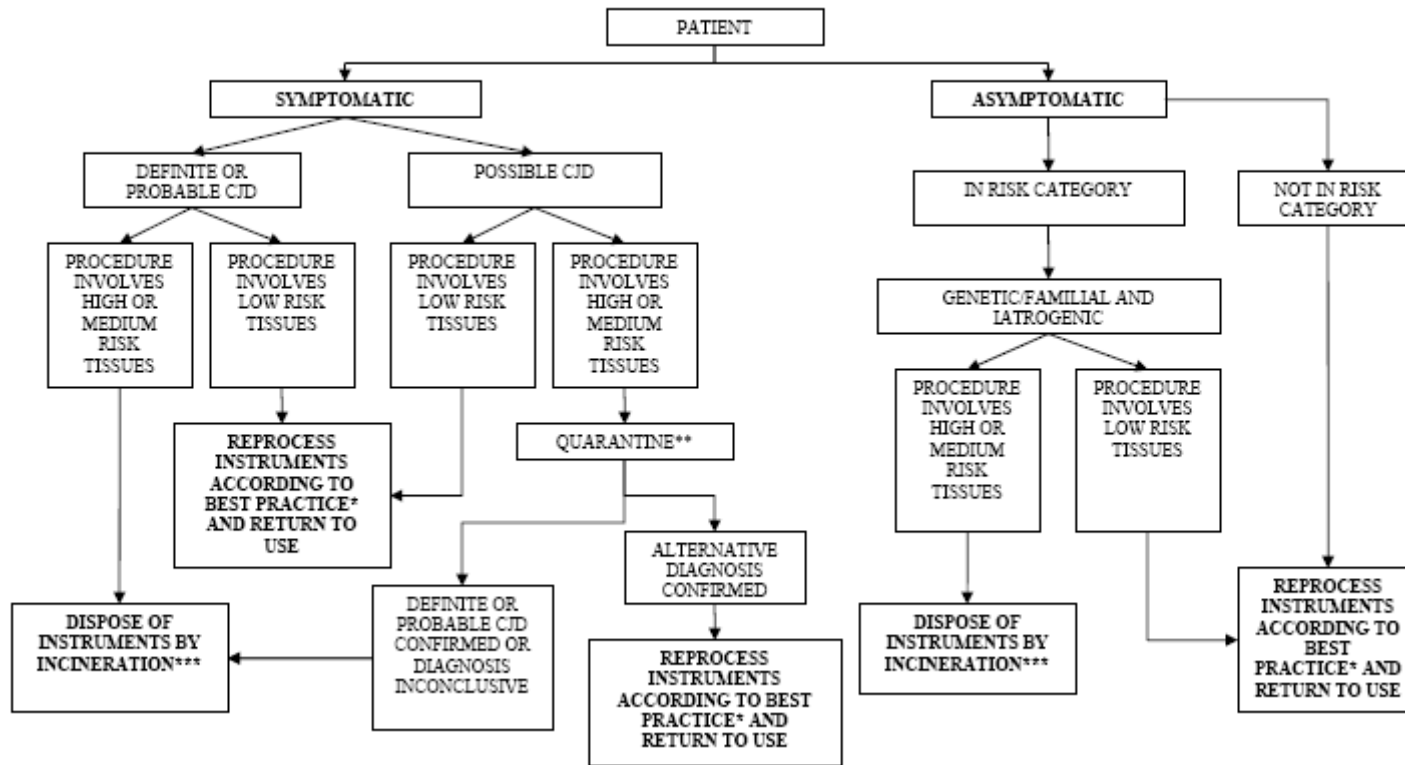
P = infectivity proven in experimental transmission studies

The table above summaries the current knowledge on the distribution of infectivity in human tissues and body fluids for TSEs other than vCJD, and for vCJD. This is derived from both experimental demonstration of infectivity, and infectivity inferred from the detection of infective forms of prion protein (PrP^{TSE}). Based on the best evidence available, infectivity is classed as High, Medium or Low. This provides a guide for the assessment of the relative risks of procedures involving any of these tissues.

Appendix B

Table B1

ALGORITHM CHART FOR PRECAUTIONS FOR SURGICAL PROCEDURES ON KNOWN, SUSPECT OR AT RISK PATIENTS: CJD OTHER THAN VARIANT CJD



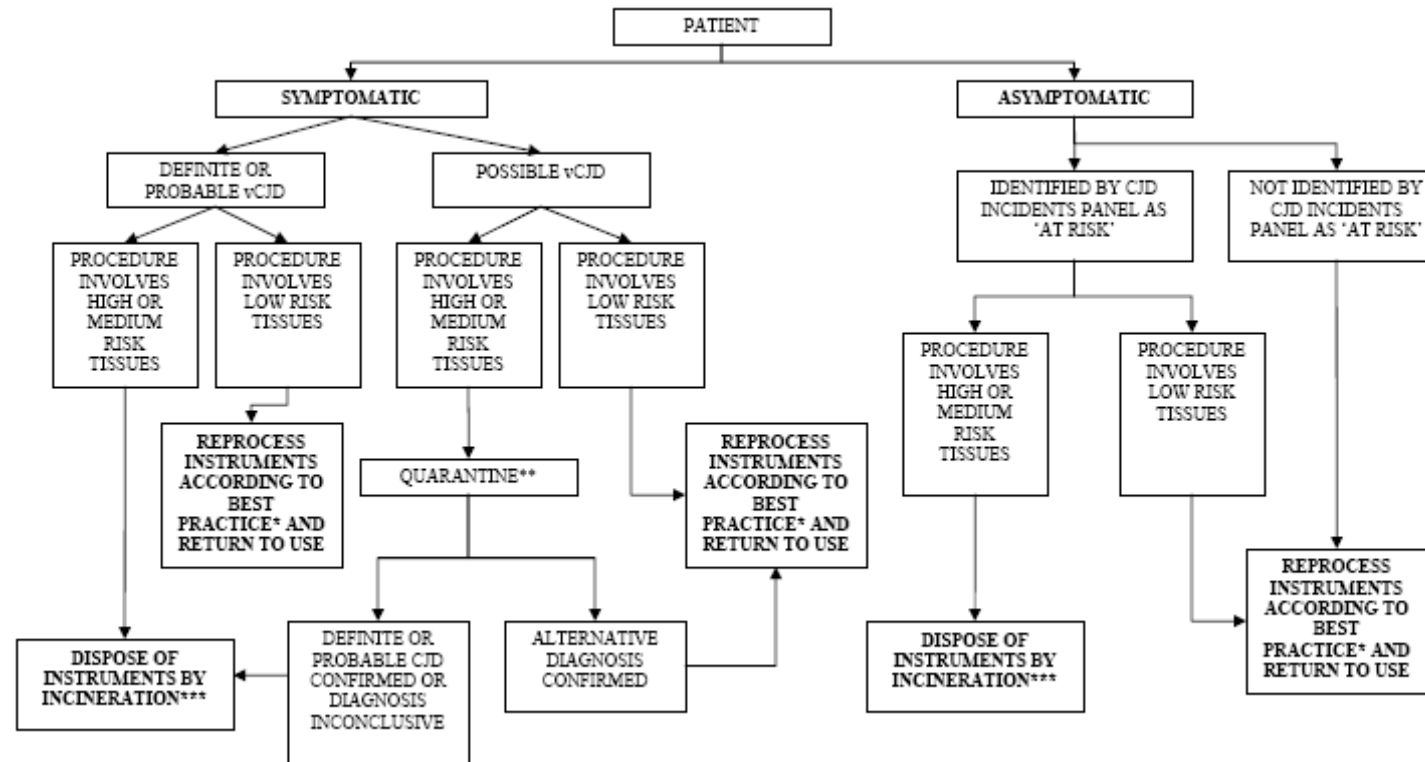
*Refer to Trust Decontamination Policy

**Refer to Annex C on Quarantining of Surgical Instruments

***Instruments which are destined for disposal by incineration may be retained for use in research. Contact Dr. James Walker, Surgical Instrument Store, Health Protection Agency, Porton Down on 01980 612643 (answer phone on out-of-hours)

Appendix B Table B2

ALGORITHM CHART FOR PRECAUTIONS FOR SURGICAL PROCEDURES ON KNOWN, SUSPECT OR AT RISK PATIENTS: VARIANT CJD



*Refer to Trust Decontamination Policy

**Refer to Annex C on Quarantining of Surgical Instruments

***Instruments which are destined for disposal by incineration may be retained for use in research. Contact Dr. James Walker, Surgical Instrument Store, Health Protection Agency, Porton Down on 01980 612643 (answer phone on out-of-hours)

Appendix C

Quarantining of Surgical Instruments and Endoscopes

- D.1 Instruments that have been used in procedures involving tissues designated as high or medium infectivity, on a *possible* CJD or vCJD patient, can be quarantined pending a confirmed diagnosis. This appendix provides guidance on the procedures which should be followed when quarantining surgical **instruments** or **endoscopes**.
- D.2 After completion of a surgical procedure on a *possible* CJD or vCJD patient, single-use instruments should be separated and disposed of by incineration. Re-usable instruments should be washed to remove gross soil, using enzymatic detergent as standard. Care should be taken to avoid splashing and generating aerosols, by holding instruments below the surface of the water in a sink into which water is running and draining out continuously. Instruments should not be held directly under a flowing tap, as this is likely to generate splashes. Operatives should wear protective gloves and either a visor or goggles, and care must be taken to avoid penetrating injuries.
- D.3 After washing, instruments should be placed on a disposable instrument tray and allowed to air-dry. They should then be placed in an impervious rigid plastic container with a close-fitting lid. The lid should be sealed with heavy duty tape (e.g. autoclave tape) and labelled with the patient's identification details (*i.e.* name, date of birth and hospital number). The label should also state the surgical procedure in which the instruments were used and the name of the responsible person (e.g. the theatre superintendent). The instrument tray should be disposed of by incineration.
- D.4 The sealed box can be stored indefinitely until the outcome of any further investigations are known. Currently this will be in the designated area in the Microbiology Department Store at the RD&E, under the responsibility of the Infection Control Doctor. If the patient is confirmed as suffering from CJD or vCJD, the box and its contents should be incinerated without any further examination.
- D.5 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 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 then be run empty for a cycle.
- D.6 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.
- D.7 Records must be kept of all decisions, and the Sterile Service Department (SSD) must be informed about the decision before the instruments are sent for routine reprocessing.

Appendix D Common flexible endoscopic procedures classified as invasive or non-invasive Table D1

	Procedure	Contamination of biopsy channel	Mechanism	Invasive (+) or Non-Invasive (-)	Notes/ Exceptions
1	ARTHROSCOPY, BRONCHOSCOPY AND CYSTOSCOPY				
1a	All arthroscopy procedures	This procedure will not involve contact of the endoscope with infectious tissue.	None	-	
1b	Diagnostic cystoscopy or bronchoscopy	Providing no biopsy is taken it is very unlikely that the endoscope will become contaminated.	None. Tissue contamination would not result from a straightforward diagnostic procedure.	-	
1c	Cystoscopy with biopsy to obtain fixed lymphoid tissue	When a biopsy is taken of lymphoid tissue, there is a risk that the suction/ biopsy channel could become contaminated with potentially infectious tissue.	Lymphoid tissue could come into contact with the lining of the biopsy channel. Tissue may be deposited in the biopsy channel.	+	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.
1d	Bronchoscopy with biopsy to obtain fixed lymphoid tissue	When a biopsy is taken of lymphoid tissue, there is a risk that the suction/ biopsy channel could become contaminated with potentially infectious tissue.	Lymphoid tissue could come into contact with the lining of the biopsy channel. Tissue may be deposited in the biopsy channel.	+	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.
1e	Transbronchial biopsy	There is a risk that the biopsy channel may become contaminated with lymphoid tissue during transbronchial biopsy.	Lymphoid tissue could come into contact with the lining of the biopsy channel. Tissue may be deposited in the biopsy channel.	+	

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Appendix D Common flexible endoscopic procedures classified as invasive or non-invasive Table D2

	Procedure	Contamination of biopsy channel	Mechanism	+/ –	Notes/ Exceptions
2	Endoscopic Ultrasound (EUS)				
2a	Diagnostic EUS	Providing no biopsy is taken it is very unlikely that the endoscope will become contaminated.	None. Tissue contamination would not result from a straightforward diagnostic ultrasound procedure.	–	
2b	EUS with biopsy	Biopsy utilises a needle that may result in contamination of the suction/biopsy channel with lymphoid tissue.	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.	+	
3	UPPER GI ENDOSCOPY				
3a	Diagnostic gastroscopy	Providing no biopsy is taken it is very unlikely that the endoscope will become contaminated.	None. Tissue contamination would not result from a straightforward diagnostic endoscopy.	–	
3b	Gastroscopy with biopsy	Even with efficient disposable biopsy forceps contamination of the suction/biopsy channel with submucosal lymphoid tissue is likely.	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.	+	Cytology should be used as an alternative technique for assessing gastric ulcers if malignancy is suspected.
3c	Gastroscopy with brush cytology	The instrument is sheathed and therefore there is low risk of the biopsy channel becoming contaminated with lymphoid tissue	No contact of lymphoid tissue with the biopsy channel.	–	

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Appendix D Common flexible endoscopic procedures classified as invasive or non-invasive Table D3

	Procedure	Contamination of biopsy channel	Mechanism	+ / -	Notes/ Exceptions
3d	Gastroscopy and balloon dilatation of stricture (oesophagus or pylorus)	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.	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.	-	This technique should be considered non-invasive <u>ONLY</u> 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.
3e	Gastroscopy and bougie dilatation of oesophagus	Bougie dilatation over a guide wire involves disruption of submucosal tissue only when the endoscope has been withdrawn.	No contamination of the biopsy channel with lymphoid tissue.	-	
3f	Gastroscopy and polypectomy	Polypectomy snares 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.	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.	+	
3g	Gastroscopy and endoscopic mucosal resection	The risks are the same as for polypectomy but the disruption of submucosal lymphoid tissue will be greater. A diathermy current is used and tissue will adhere to the snare.	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.	+	
3h	Gastroscopy and argon plasma coagulation	In theory the technique involves no contact with the mucosa and no risk. However contact frequently occurs and tissue adheres to the catheter.	Tissue is likely to enter the suction/biopsy channel. Uncertain risk associated with vaporisation of tissue and smoke.	+	

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Appendix D Common flexible endoscopic procedures classified as invasive or non-invasive Table D4

	Procedure	Contamination of biopsy channel	Mechanism	+/ –	Notes/ Exceptions
3i	Gastroscopy and use of heater probe	May be used to arrest bleeding but tissue may adhere to the probe and contaminate the biopsy channel.	Lymphoid tissue contamination of the biopsy channel is possible.	+	
3j	Gastroscopy and injection of ulcer	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 submucosal tissue.	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 channel.	–	
3k	Gastroscopy and injection of varices	This may be a necessary procedure and haemostasis may be achieved through a variety of methods. Injection of a sclerosing agent would not disrupt submucosal lymphoid tissue but there is contact between the needle and submucosal tissue.	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 channel.	–	
3l	Gastroscopy and banding of varices	Bands are applied to prominent veins in the oesophagus. Submucosal lymphoid tissue should not be disrupted and in theory the risk should be low.	Contamination of the suction /biopsy channel should be minimal as the procedure is atraumatic.	–	
3m	Gastroscopy and mucosal clipping	No disruption of lymphoid tissue.	No contamination of the biopsy channel with lymphoid tissue.	–	

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Appendix D Common flexible endoscopic procedures classified as invasive or non-invasive Table D5

	Procedure	Contamination of biopsy channel	Mechanism	+/ –	Notes/ Exceptions
3n	Gastroscopy and insertion of a PEG (Percutaneous Endoscopic Gastrostomy) feeding tube	Patients with vCJD may require a PEG feeding tube. Contamination of the biopsy channel is possible with some techniques.	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 this 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).	– if modified technique is used	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 or thread is NOT withdrawn into the endoscope). If the wire or thread is withdrawn into the endoscope, the procedure must be considered invasive.
3o	Gastroscopy and stenting	No contact between suction biopsy channel and lymphoid tissue.	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.	–	
3p	Gastroscopy and drainage of pancreatic pseudocysts	This is an invasive procedure that is potentially liable to contaminate the biopsy channel.	Contact between suction/ biopsy channel with gastric submucosal lymphoid tissue is possible.	+	

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Appendix D Common flexible endoscopic procedures classified as invasive or non-invasive Table D6

	Procedure	Contamination of biopsy channel	Mechanism	+/-	Notes/ Exceptions
4	Endoscopic Retrograde Cholangiopancreato-graphy (ERCP)				
4a	ERCP without sphincterotomy	It is unlikely that the endoscope will become contaminated.	No contamination of the biopsy channel with lymphoid tissue.	-	
4b	ERCP with sphincteroplasty	There is a significant risk that the biopsy channel will become contaminated with lymphoid tissue.	It is necessary to withdraw the balloon through the biopsy channel of the endoscope so contamination with lymphoid tissue is possible.	+	
4c	ERCP with sphincterotomy	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.	Adherent tissue may be deposited in the suction/biopsy channel.	+	
5	ENTEROSCOPY				
5a	Enteroscopy without biopsy	Tissue contamination of the suction/biopsy channel is very unlikely.	No contamination would result from a straightforward diagnostic enteroscopy.	-	
5b	Enteroscopy with biopsies	It is likely that the suction/biopsy channel will become contaminated with lymphoid tissue.	The small bowel submucosal tissue contains infectious prions, which may be deposited in the biopsy/suction channel.	+	
6	COLONOSCOPY				
6a	Colonoscopy without biopsy	A diagnostic colonoscopy is unlikely to contaminate the suction/biopsy channel with submucosal lymphoid tissue.	No contamination would result from a straightforward diagnostic colonoscopy.	-	

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Appendix D Common flexible endoscopic procedures classified as invasive or non-invasive Table D7

	Procedure	Contamination of biopsy channel	Mechanism	+/ –	Notes/ Exceptions
6b	Colonoscopy and biopsy	Small bowel (ileum) submucosal tissue contains large amounts of prion protein. Colonic submucosal also contains prions.	Contamination of the suction/biopsy channel very likely.	+	
6c	Colonoscopy and balloon dilatation procedure	Balloon dilatation of an inflammatory stricture would disrupt lymphoid tissue and contaminate the balloon.	Withdrawing the balloon through the suction/biopsy channel would contaminate the colonoscope.	–	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.
6d	Colonoscopy and polypectomy	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.	If the snare is always retracted into the sheath before withdrawal into the suction/biopsy channel the risk will be less.	+	
6e	Colonoscopy and endoscopic mucosal resection	As with biopsy, lymphoid tissue may contaminate the biopsy channel.	Tissue adheres to the snare which would have to be withdrawn through the colonoscope on most occasions.	+	
6f	Colonoscopy and argon plasma coagulation	Adherent tissue is likely to contaminate the suction/biopsy channel.	Contact with lymphoid tissue frequently occurs and tissue adheres to the catheter. In addition vaporisation of tissue may constitute a risk.	+	

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Appendix D Common flexible endoscopic procedures classified as invasive or non-invasive Table D8

	Procedure	Contamination of biopsy channel	Mechanism	+/ –	Notes/ Exceptions
6g	Colonoscopy and stenting	No contact between suction biopsy channel and lymphoid tissue.	Insertion of colonic 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.	–	
7	FLEXIBLE SIGMOIDOSCOPY				
7a	Flexible sigmoidoscopy	This diagnostic procedure is unlikely to result in contamination of the suction/ biopsy channel.	No contamination of the channel with lymphoid tissue would occur.	–	For 'invasive' procedures the risks are identical to those procedures associated with colonoscopy (see above)