CREUTZFELDT–JAKOB DISEASE (CJD) AND VARIANT CJD (vCJD) – MINIMISING THE RISK OF TRANSMISSION

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

These guidelines are to assist in the identification and management of all aspects involving CJD and vCJD.

This Guideline is for use by all staff groups

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This is the most current document and is to be used until a revised version is available	

Key amendments to this guideline:

Date	Amendment	By:
July 2010	**3A** Addition to **Tables J1** and **J6** regarding risk from multiple blood transfusions **5B** Updated precautions for surgery on at risk patients **5C** Clarification of management of instruments **5D** Specification of mortuaries as designated storage place for quarantined instruments. Inclusion of: **Appendix A** – Management of patients undergoing procedures which may involve contact with high risk tissues **Appendix B** – Information for patients undergoing surgery or neuro-endoscopy on high risk tissues **Appendix C** – Algorithm pre-surgical assessment roles **Appendix D** – Highly transfused vCJD risk assessment form **Appendix E** – Pre-surgical assessment – letter to other blood laboratories	Dr C Catchpole
October 2010	**5D** Quarantining of surgical instruments amended to include mortuary storage	Stephen Steward HSDU Manager
09/10/11	Extension of expiry date by 12 months	H Gentry
June 2013	Removal of blood transfusion history from surgery/endoscopy risk assessment (Tables J1 and J6) and associated appendices Update to Endoscopy guidance Definition of threshold for increased risk of vCJD because of transfusion history raised (from 80) to 300	Dr C Catchpole
August 2015	Document extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
Dec 2016	Further extension as per TMC paper approved on 22ND July 2015	TMC
Nov 2017	Document extended whilst under review	TLG
Dec 2017	Sentence added in at the request of the Coroner	
March 2018	Document extended for 3 months as approved by TLG	TLG
June 2018	Document extended for 3 months as approved by TLG	TLG
October 2018	Document extended until end of November	Heather Gentry
April 2019	Document extended for 6 months whilst review process takes place	TIPCC

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1. Key Points

- Follow Universal Infection Control precautions. Always wear gloves when handling body fluids and eye protection if splashing of body fluids is likely.
- Use disposable lumbar puncture sets.
- Instruments and equipment used in the care of patients with confirmed CJD of any type should not be re-used and should be disposed of by incineration.
- Instruments used on patients suspected of having CJD of any type should be quarantined pending confirmation of diagnosis.
- See later endoscopy sections for specific guidance on endoscopic procedures.
- Flexible endoscopes must have a unique identifier recorded on every patient usage.
- Instruments and equipment used in procedures involving brain, spinal cord or eyes, carried out on a patient without CJD but in a risk category, should be destroyed by incineration.

2. General Information

2.1 What is CJD?

Creutzfeldt-Jakob Disease (CJD) in its classical form was first described in the 1920s. It is one of a group of diseases called transmissible spongiform encephalopathies (TSEs) which can occur in people or animals. The diseases are characterised by degeneration of the nervous system and are invariably fatal.

CJD in its classical form is the commonest of the human TSEs but it is still rare with an annual incidence across the world of 0.5 to 1.0 cases per million population. In the UK about 60 cases are reported per year. The average age of onset of classical CJD is between 55 and 75 years. Classical CJD has no known cause in the majority of cases. However, about 10% of cases are inherited and are caused by gene mutations. About 1% in the past have been transmitted as a result of medical treatments such as human pituitary derived growth hormone injections, corneal transplants and brain surgery involving contaminated instruments.

2.2 What is Variant CJD?

Early in 1996, the National CJD Surveillance Unit identified a form of CJD that differed from previously recognised types of the disease. The patients affected were usually younger, their symptoms were different and the appearance of their brain tissue after death was not the same as in the classical form of CJD. The disease was initially labeled new variant CJD (nvCJD), and is now known as variant CJD (vCJD).

The number of definite and probable vCJD cases (reported since 1990) in the UK at the beginning of June 2008 was 166, only 3 of which were still alive. Analysis of the incidence data indicates that the vCJD epidemic reached a peak in mid-2000 and has since declined. However, it is important to note that although a peak has passed, it is possible that there will be future peaks, possibly in other genetic groups. There is also the possibility of ongoing person-to-person spread.

The precise nature of the agent which causes vCJD is not known, but the most likely theory implicates an abnormal form of a protein which is called a ‘prion’. Normal prion proteins are distributed throughout nature and are found in the tissues of healthy people and animals. It is believed that prions can cause disease when they become altered in shape, by folding in an abnormal way. The abnormally shaped prion protein then influences the normal protein to alter its shape. This leads to

destruction of nervous tissue, particularly in the brain, giving it a spongy appearance under the microscope.

The Government's Spongiform Encephalopathy Advisory Committee (SEAC) concluded that the most likely explanation for the emergence of vCJD was that it had been transmitted to people through exposure to Bovine Spongiform Encephalopathy (BSE).

2.3 What are the Symptoms?

a) Classical Sporadic Creutzfeldt-Jakob Disease

- Average age of onset – 60 years (range 16-83)
- Rapidly fatal. Average survival 8 months (range 1-30), under 5% survive 2 years.
- Initial non-specific decline in attention, sleeping and eating patterns, memory and fatigue
- Quickly develops into a rapidly progressive dementia
- May be accompanied by aphasia, cortical visual failure, myoclonus, cerebellar ataxia, extrapyramidal features, prominent startle responses and late seizures (8%)
- Unusual early features include vertigo and paraesthesia
- Typical EEG appearance

b) Variant Creutzfeldt-Jakob Disease

Distinguishing features from classical sporadic CJD are:

- Slower clinical deterioration with typical survival 12 – 23 months
- Younger age of onset
- Insidious onset of personality and behavioural change
- Ataxia is more prominent

All patients with suspected CJD should be referred for full neurological assessment.

2.4 Can Person-to-Person Spread Occur?

Available epidemiological evidence suggests that normal social or routine clinical contact with a patient suffering from any type of CJD, including vCJD, does not present a risk to healthcare workers, relatives and the community.

The possibility that vCJD might be spread from person-to-person in healthcare situations arises for a number of reasons

- Classical CJD has been transmitted from person-to-person by medical procedures
- Abnormal prion protein has been demonstrated in the lymphatic tissue (including tonsils) of patients with established vCJD
- Abnormal prion protein has been demonstrated in the appendix of a patient who subsequently developed vCJD
- Abnormal prion protein may not be inactivated by normal sterilization procedures

3. Risk Assessment

3.1 patient risk groups

When considering measures to prevent transmission to patients or staff in the healthcare setting, it is useful to make a distinction between those patients who are ***known or suspected*** to have CJD or a related disorder, i.e. those with clinical symptoms, and those who have been **identified as at increased risk** of CJD or vCJD i.e. asymptomatic, but having a clinical or family history which places them in one of the risk groups**.**

Table 4a

Categorisation of patients by risk patient groups	
Symptomatic patients	• Patients who fulfil the diagnostic criteria for definite, probable or possible CJD or • 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	• Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD. • Individuals who have a blood relative known to have a genetic mutation indicative of genetic CJD; • Individuals who have or have had two or more blood relatives affected by CJD or other prion disease
Patients identified as "at increased risk" of vCJD through receipt of blood from a donor who later developed vCJD	• Individuals who have received labile blood components (whole blood, red cells, white cells or platelets) from a donor who later went on to develop vCJD.
Patients identified as "at increased risk" of CJD/vCJD through iatrogenic exposures	• Recipients of hormone derived from human pituitary glands, *e.g*. growth hormone, gonadotrophin, are "at increased risk" of transmission of sporadic CJD. In the UK the use of human-derived gonadotrophin was discontinued in 1973, and 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 brain or intradural spinal surgery before August 1992 who received (or might have received) a graft of human-derived dura mater are "at increased risk" of transmission of sporadic CJD (unless evidence can be provided that human-derived

	dura mater was not used). • 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 as having received blood or blood components from **300** or more donors since January 1990; • Individuals who have given blood to someone who went on to develop vCJD; • Individuals who have received blood from someone who has also given blood to a patient who went on to develop vCJD; • Individuals who have been treated with certain implicated UK sourced plasma products between 1990 and 2001

NB Recipients of ocular transplants, including corneal transplants, are not considered to be "at increased risk" of CJD/vCJD.

Latest guidance recommends that all patients about to undergo surgery or neuro-endoscopy should be asked if they have ever been notified as at risk of CJD or vCJD for public health purposes. In addition those patients about to undergo surgery or endoscopy which may involve contact with tissues of potentially high TSE infectivity should be assessed for risk through a set of detailed questions relating to possible exposure to CJD/vCJD.

All patients undergoing **any** surgical and endoscopy procedure should be asked:

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

Actions to be taken based on the response are:

Patient's response	Action
No	Surgery or endoscopy can proceed using the normal infection control procedures unless the procedure is likely to lead to contact with high risk tissue.
Yes	Please ask the patient to explain further the reason they were notified. See Table **J1** for further questions Special infection control precautions should be taken for all surgery or endoscopy involving contact with medium or high infectivity tissues) and the local infection control team should be consulted for advice. This Guidance provides advice on the precautions to be taken during the treatment of patients with or at increased risk of CJD or

	vCJD, and **Appendix B provides information on endoscopic procedures**. The patient's response should be recorded in their medical notes for future reference.
Unable to respond	Surgery and endoscopy can proceed using the normal infection control procedures **unless** the procedure is likely to lead to contact with high risk tissue. If this is the case, refer to precautions to be taken for high risk procedures

The patient's response should be recorded in their medical notes for future reference

The following questions should be asked of patients about to undergo elective or emergency surgical or endoscopic procedures likely to involve contact with tissues of potentially high infectivity (see below):

Table J1
Questions to be asked of patients about to undergo elective or emergency surgical or endoscopic procedures likely to involve contact with tissues of potentially high infectivity.

	Question to patient	**Notes to clinician**
1	Have you a history of CJD or other prion disease in your family? If yes please specify.	Patient should be considered to be at risk from genetic forms of CJD if they have or have had: • Genetic testing, which had indicated that they are at significant risk of developing CJD or other related prion disease • A blood relative known to have a genetic mutation indicative of genetic CJD or other prion disease • 2 or more blood relatives affected by CJD or other prion disease
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	Recipients of hormone derived from human pituitary glands e.g. growth hormone or gonadotrophin, have been identified as at risk of CJD In the UK, the use of human-derived growth hormone was **discontinued in 1985** but human-derived products may have continued to be used in other countries. In the UK, the use of human-derived gonadotrophin was **discontinued in 1973** but may have continued in other countries after this time.
3	Have you had surgery on your brain or spinal cord?	(a) Individuals who underwent intradural brain or intradural spinal surgery before August 1992 who received (or might have received) a graft of human-

		derived dura mater are "at increased risk" of transmission of sporadic CJD (unless evidence can be provided that human-derived dura mater was not used). (b) NICE guidance emphasises the need for a separate pool of new neuroendoscopes and reusable surgical instruments for high risk procedures on children born since 1st January 1997 and **who have not previously undergone high risk procedures**. These instruments and neuroendoscopes 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.

The actions to be taken following the response to the above questions are:

Table J6
Actions to be taken following response to questions in **Table J1**

Patient's response	**Action**
No to **all** questions	Surgery or neuro-endoscopy can proceed using normal infection control procedures.
Yes to **any** of the questions 1, 2 or 3 in Table J1	Further investigation into the nature of the patient's CJD risk should be undertaken, and the patient's CJD risk assessed. This assessment of CJD risk should be recorded in the patient's medical notes for future reference. If the patient is found to be at increased risk of CJD or vCJD following investigation, or the risk status is unknown at the time of the procedure, special infection control precautions should be taken for the patient's procedure including quarantining of instruments, and the local infection control team should be consulted for advice. Part 4 of this guidance provides advice for the precautions to be taken during the treatment of patients with or at increased risk of CJD or vCJD, and Annex F provides information on neuro-endoscopic procedures. If the patient is found to be at increased risk of CJD or vCJD they should also be referred to their GP, who will need to inform them of their increased risk of CJD or vCJD and provide them with further information and advice. This is available from Public Health England: http://www.hpa.org.uk/cjd Patients who are at increased risk of genetic forms of CJD should be offered the opportunity of referral to the National Prion Clinic, based at the National Hospital for Neurology and Neurosurgery, Queen Square, London: http://www.nationalprionclinic.org/ Patients who are at increased risk of sporadic CJD due to receipt of human-derived growth hormone or gonadotrophin should be offered the opportunity of referral to the UCL Institute of Child Health, London. Contact: L.Davidson@ich.ucl.ac.uk, 020 7404 0536
Unable to respond	See below

The patient's response should be recorded in their medical notes for future reference. In the event that a patient about to have emergency surgery or neuro-endoscopy is physically or otherwise unable to answer any questions, a family member, or someone close to the patient (in the case of a child, a person with parental responsibility), should be asked the CJD risk questions as set out in **Table J1** prior to the surgery or neuro-endoscopy.

If the family member or someone close to the patient, is not able to provide a definitive answer to the CJD risk questions, the surgery or neuro-endoscopy should proceed but all instruments should be quarantined following the procedure (see guidance for details on quarantining). The patient's GP should be contacted after the surgery or neuro-endoscopy, and enquiries made as to whether the patient is at increased risk of CJD/vCJD according to the questions as set out in **Table J1**.

The actions to be taken following the GP's response to the questions in **Table J1** are:

GP's response	Action
No to all questions	The instruments can be returned to routine use after undergoing normal decontamination processes.
Yes to **any** of questions 1, 2 or 3	Further investigation into the nature of the patient's CJD risk should be undertaken, and the patient's CJD risk confirmed or rejected. Confirmation or rejection of CJD risk should be recorded in the patient's medical notes for future reference. If the patient is found to be at increased risk of CJD or vCJD following investigation then the quarantined instruments should be destroyed. Alternatively, instruments destined for disposal may instead be retained for research – refer to Annex E for details. The patient's GP should inform the patient that they are at increased risk of CJD or vCJD and provide them with further information and advice. This is available from Public Health England: http://www.hpa.org.uk/cjd: Patients who are at increased risk of genetic forms of CJD may benefit from discussions with the National Prion Clinic, based at the National Hospital for Neurology and Neurosurgery, Queen Square, London: http://www.nationalprionclinic.org/ Patients who are at increased risk of sporadic CJD due to receipt of human derived growth hormone or gonadotrophin may benefit from discussions with the UCL Institute of Child Health, London. Contact: L.Davidson@ich.ucl.ac.uk, 020 7404 0536.
Uncertain about **any** of questions **1, 2, or 3**	The instruments should be kept in quarantine. The local infection control team should carry out a risk assessment, and they may wish to involve the local Control of Communicable Disease Consultant in this process. The outcome of the risk assessment should determine whether or not to return the instruments to routine use.

Additional actions to be taken during pre-surgery assessment for CJD risk

In addition to asking the patient CJD/vCJD risk questions, the following actions should also be carried out before **any** surgical or endoscopic procedure involving contact with high risk tissue.

The clinician undertaking the pre-surgery assessment should:

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

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

3.2 Infectivity of Tissues and Body Fluids for CJD

3.2.1Transmission of infection issues

Iatrogenic transmission
There is no evidence to suggest that CJD/vCJD are spread from person-to-person by close contact, though it is known that transmission of CJD/vCJD can occur in specific situations associated with medical interventions – iatrogenic infections. Due to the possibility of iatrogenic transmission of CJD/vCJD, precautions need to be taken for certain procedures in healthcare, to prevent transmission.

CJD
Worldwide, cases of iatrogenic CJD have been associated with the administration of hormones prepared from human pituitary glands and *dura mater* preparations, and one definite case has been reported associated with a corneal graft (it is possible that the corneal tissue was contaminated by posterior segment tissue during processing). Iatrogenic transmission has also been identified following neurosurgical procedures with inadequately decontaminated instruments or EEG needles.

vCJD
There have been no known transmissions of vCJD via surgery or use of tissues or organs. Since 2003, four cases (three clinical and one asymptomatic) of presumed person-to-person transmission of vCJD infection via blood transfusion of non-leucodepleted red blood cells have been reported in the UK. In addition, in 2009, a case of probable asymptomatic vCJD infection via plasma products was reported in a haemophiliac.

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

Blood components, plasma products or tissues obtained from any individual who later develops vCJD are withdrawn/recalled to prevent their use;

Plasma for the manufacture of plasma products, such as clotting factors, has been obtained from non-UK sources since 1998;

Synthetic (recombinant) clotting factor for treatment of haemophilia has been provided to the under-16s since 1998, and for all patients in whom it is suitable since 2005;

Since 1999 white blood cells (which may carry a significant risk of transmitting vCJD) have been reduced in all blood used for transfusion, a process known as leucodepletion;

Since 2002, fresh frozen plasma for treating babies and young children born on or after 1 January 1996 has been obtained from the USA. In 2005 its use was extended to all children up to the age of 16;

Since 2004, individuals who have received a transfusion of blood components since January 1980, or are unsure if they have had a blood transfusion, are excluded from donating blood or platelets;

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

3.2.2 Patient categorisation

When considering measures to prevent transmission to patients or staff in the healthcare setting, it is useful to make a distinction between:

symptomatic patients, i.e. those who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD (see Annex B for full diagnostic criteria), and;

Patients "at increased risk" i.e. those with no clinical symptoms, but who are "at increased risk" of developing CJD or vCJD, because of their family or medical history. For this group of patients, the infection control advice differs in some circumstances for:

- Patients at increased risk of genetic CJD
- Patients at increased risk because they have received blood from an individual who later developed variant CJD
- Other patients at increased risk of iatrogenic CJD

Table 4a details the classification of the risk status of symptomatic patients and patients "at increased risk".

Patients "at increased risk" of CJD or vCJD

A number of patients have been identified as "at increased risk" of CJD or vCJD on the recommendation of the CJD Incidents Panel due to a medical or family history which places them "at increased risk" of developing CJD or vCJD. These patient groups are outlined in Table 4a.

In most routine clinical contact, no additional precautions are needed for the care of patients in the "increased risk" patient groups. 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 iatrogenic CJD/vCJD transmission.

All people who are "at increased risk" of CJD/vCJD are asked to help prevent any further possible transmission to other patients by following this advice:

- Don't donate blood. No-one who is "at increased risk" of CJD/vCJD, or who has received blood donated in the United Kingdom since 1980, should donate blood;
- Don't donate organs or tissues, including bone marrow, sperm, eggs or breast milk;
- If you are going to have any medical, dental or surgical procedures, tell whoever is treating you beforehand so they can make special arrangements

for the instruments used to treat you if you need certain types of surgery or investigation;

- You are advised to tell your family about your increased risk. Your family can tell the people who are treating you about your increased risk of CJD/vCJD if you need medical or surgical procedures in the future and you are unable to tell them yourself.
- GPs are asked to record their patient's CJD/vCJD risk status in their primary care records. The GP should also include this information in any referral letter should the patient require surgical, medical or dental procedures.
- The following table gives the current information on infectivity of tissues and body fluids for vCJD and CJD other than vCJD

Tissue	**Level of infectivity**	
	CJD other than vCJD	vCJD
Brain, spinal cord, dura mater, cranial nerves, cranial ganglia, posterior eye, pituitary gland	high	high
Spinal ganglia, anterior eye and cornea, olfactory epithelium,	medium	medium
Tonsil, appendix, spleen, thymus, other lymphoid tissues	low	medium
Peripheral nerve, skeletal muscle, dental pulp, gingival tissue, blood and bone marrow, CSF, placenta, urine, other tissues	low	low

Table: Infectivity of tissues and body fluids for CJD and vCJD

The tissues that present the highest risk of exposure to the agents of CJD are the **brain, spinal cord and eyes**. Therefore, special precautions need to be taken for interventions involving these tissues for *known, suspect or at risk patients* (see also below).

4. Hospital care of CJD/vCJD patients

There is no evidence that normal social or routine clinical contact of a CJD/vCJD patient presents a risk to healthcare workers, relatives and others. Isolation of patients with CJD/vCJD is not necessary, and they can be nursed in an open ward using standard infection control precautions in line with those used for all other patients.

4.1 Sample taking and other invasive medical procedures

When taking samples or performing other invasive procedures, the possible infectivity of the tissue(s) involved must be considered, and if necessary suitable precautions taken. Information on tissue infectivities for CJD/vCJD is included in table above (3.22). **It is important to ensure that only trained staff, who are aware of the hazards, carry out invasive procedures that may lead to contact with medium or high risk tissue.**

Body secretions, body fluids (including saliva, blood and cerebrospinal fluid (CSF) and excreta) are all low risk for CJD/vCJD. It is therefore likely that the majority of samples taken or procedures performed will be low risk. Contact with small volumes of blood (including inoculation injury) is considered low risk, though it is known that

transfusion of large volumes of blood and blood components may lead to vCJD transmission.

Blood and body fluid samples from patients with, or "at increased risk" of, CJD/vCJD, should be treated as potentially infectious for blood-borne viruses and handled with standard infection control precautions as for any other patient, i.e.;

- use of disposable gloves and eye protection where splashing may occur;
- avoidance of sharps injuries and other forms of parenteral exposure;
- safe disposal of sharps and contaminated waste in line with locally approved arrangements; and
- single-use disposable equipment should be used wherever practicable.

When taking biopsy specimens of medium or high risk tissue, for example tonsil biopsy in a patient with suspected vCJD, or intestinal biopsy in a patient "at increased risk" of vCJD, every effort should be taken to minimise the risk of infecting the operator or contaminating the environment.

Samples from patients with, or "at increased risk" of, CJD/vCJD should be marked with a 'Biohazard' label, and it is advisable to inform the laboratory in advance that a sample is being sent.

4.2 Spillages

When a spillage of any fluid (including blood and CSF) from a patient with, or "at increased risk" of, CJD/vCJD occurs in a healthcare setting, the main defence is efficient removal of the contaminating material and thorough cleaning of the surface.

Standard infection control precautions should be followed for any spillages, which should be cleared up as quickly as possible, keeping contamination to a minimum. Disposable gloves and an apron should be worn when removing such spillages.

For spillages of large volumes of liquid, absorbent material should be used to absorb the spillage, for which a number of proprietary absorbent granules are available.

Standard disinfection for spillages (eg. 10,000ppm chlorine-releasing agent) should be used to decontaminate the surface after the spillage has been removed. A full risk assessment may be required. It should be noted that none of the methods currently suggested by WHO for prion inactivation are likely to be fully effective.

Any waste (including cleaning tools such as mop heads and PPE worn) should be disposed of as clinical waste **(see Table 4b).**

4.3 Clinical waste

General guidance on the safe management of clinical waste is given in the Department of Health's guidance document 'Health Technical Memorandum 07-01: Safe Management of Healthcare Waste', available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063274.

According to this guidance, "Waste known or suspected to be contaminated with transmissible spongiform encephalopathy (TSE) agents, including CJD, must be disposed of by high temperature incineration in suitable authorised facilities." Additional guidance on the management of TSE-infected waste is given in the

Department of Health's 'Transmissible spongiform encephalopathy: Safe working and the prevention of infection.'

The ACDP TSE Risk Management Sub Group have considered the disposal of clinical waste, and have agreed that tissues, and contaminated materials such as dressings and sharps, from patients with, or "at increased risk" of, CJD/vCJD, should be disposed of as in the following table

Table 4b: Disposal of clinical waste from patients with, or "at increased risk" of, CJD or vCJD

Diagnosis of CJD	High or medium risk tissue*	Low risk tissue and body fluids**
Definite	Incinerate	Normal clinical waste disposal
Probable	Incinerate	Normal clinical waste disposal
"At increased risk"	Incinerate	Normal clinical waste disposal

Disposal of Clinical Waste from patients with, or 'at increased risk' of, CJD or vCJD.

4.4 Childbirth

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

Childbirth should be managed using standard infection control procedures. The placenta and other associated material and fluids are designated as low risk tissues, and should be disposed of as clinical waste, unless they are needed for investigation, in which case the precautions outlined above (4.1) should be followed. Instruments should be handled following the advice below (4.7).

4.5 Bed linen

Used or fouled bed linen (contaminated with body fluids or excreta), should be washed and dried in accordance with current standard practice. No further handling or processing is necessary.

4.6 Occupational exposure

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, for example as a result of sharps injuries, puncture wounds or contamination of broken skin, and exposure of the mucous membranes.

Healthcare personnel who work with patients with definite, probable or possible CJD/vCJD, or with potentially infected tissues, should be appropriately informed about the nature of the risk and relevant safety procedures.

Compliance with standard infection control precautions, in line with those set out in Blood-borne Viruses" recommended by the Expert Advisory Group on AIDS and the Advisory Group on Hepatitis will help to minimise risks from occupational exposure.

For any accident involving sharps or contamination of abrasions with blood or body fluids, wounds should be gently encouraged to bleed, gently washed (avoid scrubbing) with warm soapy water, rinsed, dried and covered with a waterproof dressing, or further treatment given appropriate to the type of injury. Splashes into the eyes or mouth should be dealt with by thorough irrigation. The accident should be reported as defined in local practice, and an incident reported via Datix.

4.7 Surgical procedures and instrument management

For all patients with, or "at increased risk" of, CJD or vCJD, the following precautions should be taken for surgical procedures:

- Wherever appropriate and possible, the intervention should be performed in an operating theatre;
- Where possible, procedures should be performed at the end of the list, to allow normal cleaning of theatre surfaces before the next session;
    - Only the minimum number of healthcare personnel required should be involved; Protective clothing should be worn, i.e. liquid repellent operating gown, over a plastic apron, gloves, mask and goggles, or full-face visor; for symptomatic patients, this protective clothing should be single use and disposed of in line with local policies; for patients "at increased risk" of CJD/vCJD, this protective clothing need not be single use and may be reprocessed;
- Single-use disposable surgical instruments and equipment should be used where possible, and subsequently destroyed by incineration or sent to the instrument store;
- Effective tracking of re-usable instruments should be in place, so that instruments can be related to use on a particular patient.

Single use instruments

Single-use instruments are utilised variably across surgical specialities and NHS Trusts. The following should be taken into account when using single-use instruments:

- The quality and performance of single-use instruments should be equivalent to those of reusable instruments with appropriate procurement, quality control and audit mechanisms in place;
- Procurement should be quality based not cost based, with the minimum safe functional requirements of each instrument purchased being understood by the purchaser;
- For reusable instruments there is an internal quality control, with instruments noted as faulty being either repaired or returned to the system

manufacturer. A similar process needs to be put in place for any single-use instrument that is purchased;

- A CE mark is not necessarily a mark of quality of instruments, and quality control of sub-contractors is often difficult when the number of instruments increases.

Handling of instruments that are not designated as single-use
Where single-use instruments are not available, the handling of reusable instruments depends on:

- how likely the patient is to be carrying the infectious agent (the patient's risk status);
- whether the patient has, or is "at increased risk" of, CJD/vCJD; and
- how likely it is that infection could be transmitted by the procedure being carried out i.e. whether there is contact with tissues of high or medium infectivity.

Tables 4c and 4d separately set out the actions to be taken for instruments used on patients with, or "at increased risk" of, CJD/vCJD. The differences in instrument management are due to differences in tissue infectivities between CJD/vCJD. These actions are also summarised in the algorithm at the end of this document.

Table 4c: Handling of instruments – patients with, or "at increased risk" of, CJD (other than vCJD)

Tissue Infectivity		**Status of patient**	
	Definite or probable	**Possible**	**At increased risk**
High*	Single use	Single use	Single use
Brain	or	or	or
Spinal cord	Destroy	Quarantine for re-use exclusively on the same patient pending diagnosis	Destroy
Cranial nerves, specifically the entire optic nerve and the intracranial components of the other cranial nerves Cranial ganglia	or		or
Posterior eye, specifically the posterior hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve	Quarantine for re-use exclusively on the same patient		Quarantine for re-use exclusively on the same patient
Pituitary gland			

Medium Spinal ganglia Olfactory epithelium	Single use or Destroy or Quarantine for re-use exclusively on the same patient	Single use or Quarantine for re-use exclusively on the same patient pending diagnosis	Single use or Destroy or Quarantine for re-use exclusively on the same patient
Low	No special precautions	No special precautions	No special precautions

Table 4d: Handling of instruments – patients with, or "at increased risk" of vCJD

Tissue Infectivity		**Status of patient**	
	Definite or probable	**Possible**	**At increased risk**
High*	Single use	Single use	Single use
Brain	or	or	or
Spinal cord	Destroy	Quarantine for re-use exclusively on the same patient pending diagnosis	Destroy
Cranial nerves, specifically the entire optic nerve and the intracranial components of the other cranial nerves	or		or
Cranial ganglia	Quarantine for re-use exclusively on the same patient		Quarantine for re-use exclusively on the same patient
Posterior eye, specifically the posterior hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve			
Pituitary gland			
Medium	Single use	Single use	Single use
Spinal ganglia	or	or	or
Olfactory epithelium	Destroy	Quarantine for re-use exclusively on the same patient pending diagnosis	Destroy
Tonsil	or		or
Appendix	Quarantine for re-use exclusively on the same patient		Quarantine for re-use exclusively on the same patient
Spleen			
Thymus			

Adrenal gland Lymph nodes and gut-associated lymphoid tissues			
Low	No special precautions	No special precautions	No special precautions

*Although dura mater is designated low infectivity tissue, procedures conducted on intradural tissues (i.e. brain , spinal cord and intracranial sections of cranial nerves) or procedures in which human dura mater has been implanted in a patient prior to 1992, are high risk and instruments should be handled as such.

4.8 Quarantining of surgical instruments

This guidance allows for the quarantining of instruments that have been used for procedures involving tissues designated as high or medium infectivity, on patients either;

• with, or at increased risk of, CJD/vCJD, for reuse exclusively on the same patient; or

• with a possible CJD/vCJD diagnosis, pending a confirmed diagnosis.

Although it is not expected that this facility will need to be used widely, this section provides guidance on the procedures which should be followed when quarantining surgical instruments may be considered.

During a surgical procedure as defined in paragraph above, instruments should be separated according to the principles set out in the NICE interventional procedures guidance 196. Instruments that come into contact with tissues designated as high or medium infectivity should be kept separate from those that only come into contact with tissues designated as low infectivity.

After completion of a surgical procedure as defined in paragraph above, single-use instruments should be separated and disposed of by incineration with normal clinical waste. Re-usable instruments that have only come into contact with tissues designated as low infectivity may be decontaminated and returned to routine use.

Re-usable instruments that have come into contact with tissues designated as high or medium infectivity and that are intended to be quarantined should be washed to remove gross soil. 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, for example in a sink in the theatre sluice room. 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. The sink does not require high level decontamination afterwards – the dilution effect from the running water will be sufficient to remove contamination.

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 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 Team or Unit Manager). The disposable instrument tray should be disposed of by incineration with normal clinical waste. The sealed box can be stored indefinitely in a suitable designated place until the outcome of any further investigations is known (see above), or the instruments are required for another surgery on the same patient (see above).

For patients with a possible CJD/vCJD diagnosis, if the patient is confirmed as suffering from CJD or vCJD, the box and its contents should be incinerated, or retained for use in research, without any further examination. If an alternative diagnosis is confirmed, the instruments may be removed from the box by the responsible person (or a named deputy) and reprocessed according to best practice and returned to use. Additional decontamination procedures are not required.

Rarely, it may be necessary to consider the re-use of a quarantined set of surgical instruments on the same patient. One such scenario would be the need to repeat a liver transplant on a patient who is at increased risk of vCJD. In these circumstances, the instrument set should be reprocessed through the Sterile Services Department in the usual manner. No special precautions are necessary because of the high dilution factor involved in the washer/disinfection process. It is important to ensure that the set is tracked through the whole decontamination cycle as previously directed.

Under no circumstances should quarantined instrument sets be reprocessed for use on other patients unless the diagnosis of CJD or vCJD has been positively excluded. The possibility of residual abnormal prion on the instruments is of far greater concern than the possibility of contamination of instruments in other sets processed in the washer/disinfector either concurrently or subsequently.

Records must be kept of all decisions, and the Sterile Service Department must be informed about the decision before the instruments are sent for routine reprocessing.

4.9 Decontamination of instruments

Effective decontamination is key to reducing the risk of transmission of CJD/vCJD through surgery. Section 4.7 contains advice on the general principles of decontamination for TSE agents.

It is important that the efficacy, safety, and compatibility with other decontamination processes, of products and technologies claiming to remove or inactivate prion protein from contaminated medical devices in laboratory and clinical practice, is established. Until this occurs, clinicians and laboratory managers should ensure that current guidelines are followed.

Incineration of instruments

The instruments should already be in a combustible sealed container. This should then be disposed of via the clinical waste stream, ensuring that this results in incineration.

Complex instruments

Some expensive items of equipment, such as drills and operating microscopes, may be prevented from being contaminated by using shields, guards or coverings, so that the entire items does not need to be destroyed. In this case, the drill bit, other parts in contact with high or medium risk tissues, 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 neurosurgical staff and the manufacturer to determine practicality.

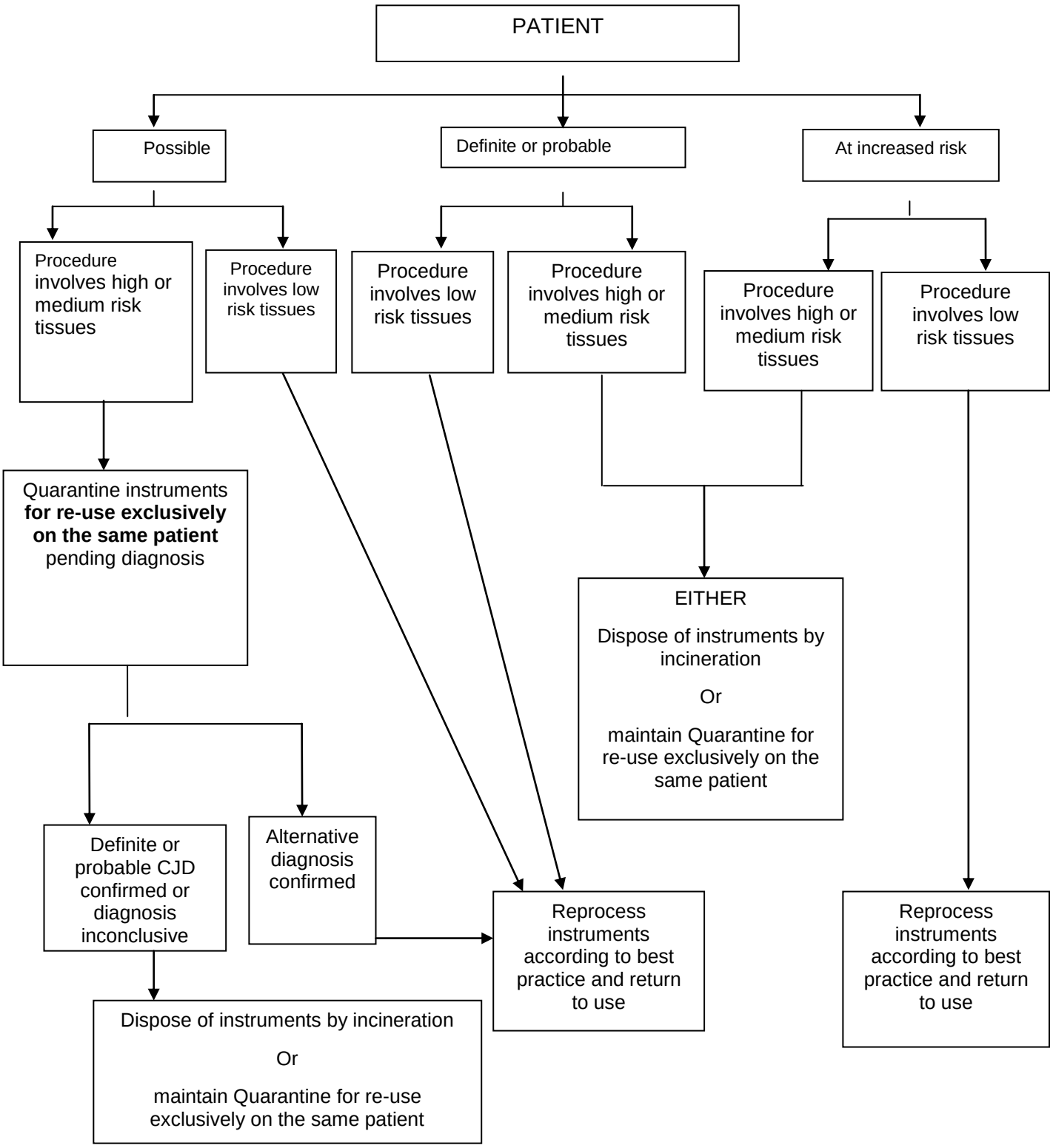
4.10 Use of laser for tonsillectomy – smoke plumes

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. General guidance on the safe use of lasers is available from MHRA - Device Bulletin 2008(03) 'Guidance on the safe use of lasers, IPL systems and LEDs' – available here.

4.11 Anaesthesia and intensive care

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) in 2008 published an update to their guidance "Infection Control in Anaesthesia." This guidance includes a section on prion diseases and can be found here.

Algorithm chart for precautions for reusable instruments for surgical procedures on patients with, or "at increased risk" of, CJD, vCJD and other human prion diseases



5. Special Precautions In Ophthalmology

The tissue that present the highest risk of exposure to CJD are brain, spinal cord and eyes. Therefore special precautions need to be taken for interventions involving eyes for known, suspect or at risk patients.

A risk assessment should be carried out as part of the clerking procedure

(see above and **Tables J1** and **J6**), and full theatre precautions taken with at risk patients undergoing surgery.

Further guidance has been issued by the National Institute for Health and Clinical Excellence (2006) regarding precautions for all high-risk surgical procedures (intradural operations on the brain and operations on the retina or optic nerve – 'high-risk tissues') – see **Appendix C**.

- Instruments that come into contact with high-risk tissues must not move from one set to another. Practice should be audited and systems should be put in place to allow surgical instruments to be tracked, as required by Health Service Circular 2000/032: 'Decontamination of medical devices' and described in the NHS Decontamination Strategy.

- Supplementary instruments that come into contact with high-risk tissues should either be single use or should remain with the set to which they have been introduced. Hospitals should ensure without delay that an adequate supply of instruments is available to meet both regular and unexpected needs.

Recent Department of Health advice recommends that wherever practicable, components of devices that touch the surface of the eye, eg tonometer heads, should be restricted to single use. This should be implemented immediately for known, suspect or at risk patients and a gradual move made over to disposables for all patients.

6. Special Precautions In Endoscopy

The general procedures set out in the ***Choice Framework for local Policy and Procedures 01-06 – Decontamination of flexible endoscopes: Policy and Management (CFPP 01-06)***[i] or equivalent national guidance and the updated ***BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy***[ii] (2008, to be updated 2013) 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 CJD/vCJD, and in those identified as "at increased risk" of developing CJD/vCJD, are recommended:

(a) Channel cleaning brushes and, if biopsy forceps or other accessories have been passed, the rubber valve on the endoscope biopsy/instrument channel port should be disposed of as clinical waste after each use. Single use (i.e. disposable) biopsy forceps should be used routinely in all patients. This guidance endorses the advice of the BSG guidelines that endoscope accessories should be single use wherever possible. It is essential to have systems in place that enable endoscopes, together with all their detachable components and any re-used accessories, to be traced to the patients on whom they have been used.

(b) As defined below, endoscopes used for certain procedures in the CNS and nasal cavity in individuals with possible sporadic CJD, or in whom the diagnosis is unclear[iii], should be removed from use or quarantined pending diagnosis or exclusion of CJD (see Table F1 for clarity of this issue). The principles and 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.

(c) Endoscopes other than those used in the CNS and nasal cavity, which have been used for invasive procedures in most[iv] individuals designated as "at increased risk" of vCJD, can be decontaminated to the standards set out in *CFPP 01-06* or equivalent national guidance and the *BSG guidelines* and returned to use (see Table F2a). The endoscope should be put through all the normal stages of cleaning, and be disinfected separately from other equipment within an automated Endoscope Washer Disinfector (EWD).

(d) Aldehyde disinfectants with fixative qualities (such as glutaraldehyde and OPA) tend to stabilise rather than inactivate prions, and are no longer recommended for use in the UK. Non-fixative disinfectants are used instead.

(e) When decontaminating the endoscope cleaning equipment, the EWD should be put through an "empty" self-disinfection cycle as per recommended routine. Provided that the cleaning equipment is decontaminated as indicated, there is no known risk of transmission of TSE agents via this route.

(f) Following use in patients at risk of vCJD endoscopic accessories (including normally reusable devices such as heater probes) and cleaning aids such as brushes should be disposed of by incineration.

PrP_{res} has been detected in the olfactory epithelium, but not the respiratory epithelium, of sporadic CJD patients. The olfactory epithelium is normally located along the roof of the nasal cavity but its distribution varies between individuals. On the lateral wall it may extend inferiorly onto the superior turbinate and the anterior insertion of the middle turbinate; on the medial wall it may extend onto the uppermost part of the septum. 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, precautions should be taken appropriate for medium infectivity tissues.

Definitions

- **Sporadic and other non-variant CJD**
  This includes sporadic CJD, iatrogenic CJD other than variant CJD and genetic prion diseases.

- **Symptomatic sCJD patients (definite, probable)**
  Neurological endoscopes would not normally be used on patients whose diagnosis is definite or probable sCJD. However, should such use be necessary, the endoscope should be single use if possible. If this is not feasible or appropriate, the endoscope should be removed from use or destroyed.
  Endoscopes that come into contact with the nasal cavity may, on occasion, be used in patients with definite or probable sCJD. If there is a risk that the endoscope could become contaminated with olfactory epithelium, a single use endoscope should be used if possible. If this is inappropriate, the endoscope should be removed from use or destroyed (as above).

  For all other types of endoscopy, decontaminate according to *CFPP 01-06* or equivalent national guidance and the *BSG guidelines*, with the additional precautions for flexible endoscopes as set out in paragraph above.

- **Symptomatic patients (possible sporadic, or diagnosis unclear but variant CJD is not being considered)**
  Neurological endoscopes would not normally be used on patients whose diagnosis is possible CJD or for whom the diagnosis of CJD is unclear. However, should use be necessary, a single use endoscope should be used if possible. If this is not appropriate, the re-usable endoscope should be quarantined pending a more definitive diagnosis. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be removed from use.
  Endoscopes that are used in the nasal cavity may, on occasion, be used in patients with CJD. If there is a risk that the endoscope could become contaminated with olfactory epithelium (see above), a single use endoscope should be used where possible. If this is not appropriate, the endoscope should be decontaminated singly as above, then quarantined pending a more definitive diagnosis. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be removed from use.

  For all other types of endoscopy, decontaminate according to *CFPP 01-06* or equivalent national guidance and the *BSG guidelines*, with the additional precautions for flexible endoscopes as set out in above.

- **Asymptomatic patients at increased risk of CJD (other than variant CJD)**
  No special precautions are required for the use, in patients at increased risk of CJD, of rigid endoscopes without lumens that can be autoclaved. The general guidance in for all surgical instruments can be followed.

  For other types of endoscope that are used for central nervous tissue investigations, single-use instruments should be used if possible. Where this is not possible without compromising clinical standards, the endoscope should be removed from use. Alternatively the endoscope can be decontaminated singly, as above then quarantined after use to be re-used exclusively on the same individual patient if required.

  If there is a risk that an endoscope used in the nasal cavity could become contaminated with olfactory epithelium (see above), a single use endoscope should be used where possible. If this is not appropriate, the endoscope should be removed from use. Alternatively the endoscope can be quarantined after use to be re-used exclusively on the same individual patient if required. 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 the practicality of this option.

  For all other types of endoscopy, decontaminate according to *CFPP 01-06* or equivalent national guidance and the *BSG guidelines.*

Variant CJD & CJD type uncertain

Symptomatic vCJD patients (definite, probable)

Neurological endoscopes would not normally be used on patients whose diagnosis is definite or probable vCJD. However, should such use be necessary, the endoscope should be single

use if possible. If this is not feasible or appropriate, the endoscope should be removed from use.

Endoscopes that come into contact with the nasal cavity may, on occasion, be used in patients with definite or probable vCJD. If there is a risk that the endoscope could become contaminated with olfactory epithelium (see above), a single use endoscope should be used if possible. If this is inappropriate, the endoscope should be removed from use.

For all other types of endoscopy, providing decontamination of the endoscope is to approved standards, the use of the instrument for inspection in the absence of an invasive procedure, as defined in Table F2b, is deemed to be of low risk. If biopsy or another invasive procedure is carried out, the possibility of contamination of the instrument channel with lymphoid tissue means the endoscope should be decontaminated singly as above, then quarantined pending assessment of likely contact with potentially infected tissue.

Symptoms consistent with vCJD (possible or unclear diagnosis[v])
Neurological endoscopes would not normally be used on patients whose diagnosis is possible vCJD or for whom the diagnosis of vCJD is unclear. However, should such use be necessary, a single use endoscope should be used if possible or the endoscope should be decontaminated singly as above then quarantined pending a more definitive diagnosis. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be removed from use.

Endoscopes that are used in the nasal cavity may, on occasion, be used in vCJD patients, and there is a risk that the endoscope could be contaminated with infectivity from the olfactory epithelium. Single use instruments should be used where possible. If this is not feasible or appropriate, the endoscope should be decontaminated singly as at F1(c-f), then quarantined pending confirmation of the diagnosis. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be removed from use.

For all other types of endoscopy, providing decontamination of the endoscope is to approved standards, the use of the instrument for inspection in the absence of invasive procedures as defined in Table (Appendix B), is deemed to be a low risk procedure. If an invasive procedure is carried out, the possibility of contamination of the instrument channel with lymphoid tissue means the endoscope should be decontaminated singly as above, then quarantined pending assessment of likely contact with potentially infected tissue. If this is considered possible and an alternative diagnosis is not obtained, the endoscope should be removed from use.

Asymptomatic patients "at increased risk" through receipt of labile blood components (whole blood, red cells, white cells or platelets) from a donor who later developed vCJD)
No special precautions are required for the use, of rigid endoscopes without lumens that can be autoclaved. The guidance in Part 4 for all surgical instruments can be followed.

Endoscopes that are used for central nervous tissue investigations may, on occasion, be used on patients at increased risk of developing vCJD and there is a risk that the endoscope could be contaminated with infectivity from the nerve tissue. Single use instruments should be employed if possible. Where this is not possible, the endoscope should be removed from use. Alternatively the endoscope can be decontaminated singly as above, then quarantined after use to be re-used exclusively on the same individual patient if required.

If there is a risk that an endoscope used in the nasal cavity could become contaminated with olfactory epithelium (see paragraph F2 of this Annex), a single use endoscope should be

employed where possible. If this is not feasible or appropriate, the endoscope should be removed from use. Alternatively the endoscope can be decontaminated singly as at F1(c-f)), then quarantined after use to be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be removed from use.

For all other types of endoscopy, providing decontamination of the endoscope is to approved standards, the use of the instrument for inspection in the absence of an invasive procedure, as defined in Table (Appendix B), is deemed to be a low risk procedure. If an invasive procedure is carried out, the possibility of contamination of the instrument channel with lymphoid tissue means the endoscope should be decontaminated singly as above, then quarantined pending assessment of likely contact with potentially infected tissue. If this is considered possible the endoscope should be removed from use. For some procedures, it may be possible to shield the working channel of the endoscope from contamination by a disposable sheath. Once the procedure is completed, the tip of the accessory (e.g. biopsy forceps) is withdrawn into the sheath, before the tip of the sheath is cut off and, like the remainder of the sheath, is later destroyed by incineration.

All other asymptomatic patients at increased risk of vCJD

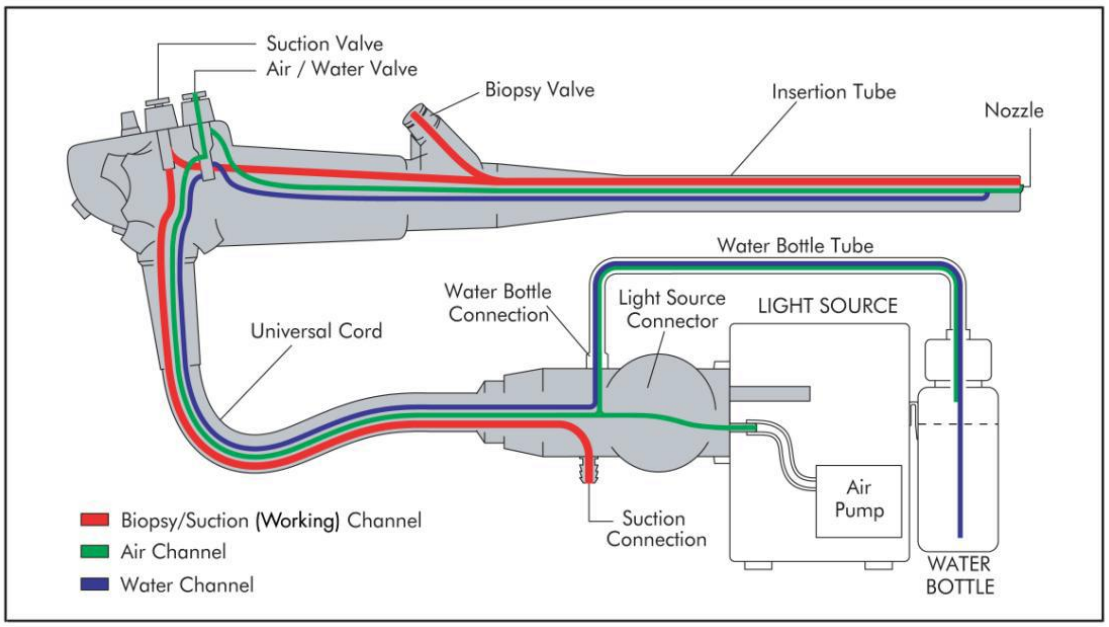
No special precautions are required for the use, in all other patients at increased risk of vCJD, of rigid endoscopes without lumens that can be autoclaved. The general guidance for all surgical instruments can be followed.

Endoscopes that are used for central nervous tissue investigations may, on occasion, be used on patients at increased risk of developing vCJD and there is a risk that the endoscope could be contaminated with infectivity from the nerve tissue. Single use instruments should be employed if possible. Where this is not possible, the endoscope should be removed from use. Alternatively the endoscope can be decontaminated singly as above, and quarantined thereafter to be re-used exclusively on the same individual patient if required.

If there is a risk that an endoscope used in the nasal cavity could become contaminated with olfactory epithelium, (a single use endoscope should be employed where possible. If this is not feasible or appropriate, the endoscope should be removed from use. Alternatively the endoscope can be decontaminated singly as above), then quarantined after use to be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be removed from use.

For all other types of endoscopy, decontaminate according to *CFPP 01-06* or equivalent national guidance and the *BSG guidelines*, with the additional precautions for flexible endoscopes as set out in paragraph F1 above.

Definition of the working channel of an endoscope



SUMMARY OF PRECAUTIONS ADVISED FOR THE USE OF ENDOSCOPES

Table F1. CJD other than vCJD Tissue

Infectivity	**Status of patient**		
	Symptomatic		**Asymptomatic**
	Definite/ probable	**Possible / diagnosis unclear[1]**	**At risk[2] inherited/ iatrogenic**
High: • Brain • Spinal cord	single use OR destroy after use	single use OR quarantine pending diagnosis	single use OR destroy after use OR quarantine[3] for re-use exclusively on same patient
Medium: • Olfactory epithelium*	single use OR destroy after use	single use OR quarantine pending diagnosis	single use4 OR destroy after use OR quarantine[3] for re-use exclusively on same patient
Low/none detectable: • All other tissues	no special precautions5	no special precautions5	no special precautions

Notes

* 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 guidance for the use of all surgical instruments in at risk patients in this guidance.

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

4 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.

5 The decontamination procedures advised in paragraph 6 of this guidance, taken together with the ***CFPP 01-06*** or equivalent national guidance and ***BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy*** (2008, to be updated 2013), should be followed.

Table F2a. vCJD and CJD type uncertain

Tissue Infectivity	**Status of patient**			
	Symptomatic		**Asymptomatic**	
	Definite /probable	**Possible vCJD, possible sCJD or diagnosis unclear1**	**At risk (blood*** recipient from a donor who later developed vCJD)**	**At risk2 Other iatrogenic**
High: • Brain • Spinal cord	single use OR destroy after use	single use OR quarantine pending diagnosis	single use OR destroy after use OR quarantine4 for re-use exclusively on same patient	single use OR destroy after use OR quarantine4 for re-use exclusively on same patient
Medium: • Olfactory epithelium* • Lymphoid tissue**	single use5 OR use dedicated endoscope6 OR remove from use	single use5 OR quarantine pending diagnosis	single use OR destroy after use OR quarantine3,4 for re-use exclusively on same patient	no special precautions
Low/none detectable: • All other tissues	no special precautions7	no special precautions7	no special precautions7	no special precautions7

Notes

*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 guidance, lymphoid tissue refers to the spleen, thymus, tonsils and adenoids, lymph nodes, the appendix and the gastro-intestinal tract sub-mucosa.

***A small number of individuals are known to have received labile blood components (whole blood, red cells, white cells or platelets) from a donor who later developed vCJD

1 This includes patients with neurological disease of unknown aetiology who do not fit the criteria for possible vCJD but where a diagnosis of vCJD is being actively considered (see also Annex B of this guidance).

2 This advice refers to the use of flexible endoscopes in patients at risk of developing vCJD. For guidance on the use of rigid endoscopes that can be autoclaved, refer to the guidance for the use of all surgical instruments in at risk patients.

3 Flexible gastrointestinal endoscopes may be suitable for refurbishment by their manufacturers/distributors to allow their return to later use. This refurbishment process may be considered as an alternative to quarantining the instrument if a flexible gastrointestinal endoscope has been used in the performance of an invasive procedure in patients at risk of vCJD because they received blood from a donor who later developed vCJD. Refurbishment is not available for endoscopes that have been used for invasive endoscopy in patients with definite or probable vCJD. The decision to undertake refurbishment will be made on a case by case basis by the manufacturer/distributor, taking into account the age and condition of the endoscope, the reprocessing methods and methods of storage following last use.

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

5 For some procedures, the working channel of 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 NCJDRSU holds a few flexible endoscopes dedicated for use on probable vCJD 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 vCJD, patients for whom the diagnosis of vCJD is unclear or patients at risk of vCJD.

7 The decontamination procedures advised in paragraph 6 of this guidance, taken together with the ***CFPP 01-06*** or equivalent national guidance and ***BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy*** (2008, to be updated 2013), should be followed..

7. Notification Of New Cases Of Cjd To The Cjd Surveillance Unit In Edinburgh

Any patient suspected on clinical grounds of having CJD (either vCJD or any other type of CJD) should be referred to the CJD Surveillance Unit in Edinburgh. Not only is this required for epidemiological and surveillance purposes, but it is necessary as a control measure to guard against the theoretical risk of transmission of vCJD. Failure to notify promptly would prevent early action to trace and withdraw any blood donations which the sufferer of vCJD may have made. Similarly, such failure to notify could also prevent the institution of other control measures.

Contact details for the CJD Surveillance Unit are:-

Professor R G Will
Director
National CJD Surveillance Unit
Western General Hospital
Crewe Road
Edinburgh
EH4 2XU Tel: 0131 537 2128 Fax: 0131 343 1404

8. Management Of A Possible Exposure To Cjd Through Medical Procedures

Occasionally, patients who are diagnosed or suspected of having CJD are found to have undergone a medical or surgical procedure at some time in the past.

Current procedures for decontaminating surgical instruments between uses cannot be guaranteed to eliminate the abnormal prion proteins that are thought to be responsible for the transmission of CJD, although there is a great deal of scientific uncertainty about the infectivity of different tissues (including blood products) in people incubating CJD.

Advice should be sought at the earliest opportunity when an incident is identified. Within a Hospital Trust, this should be done with full involvement of the Infection Control Team, and local Consultant in Communicable Disease Control.

9. National Organisations Able To Give Advice

The following resources are available to health professionals dealing with cases of CJD:-

- Public Health England: http://www.hpa.org.uk/cjd
- Patients who are at increased risk of sporadic CJD due to receipt of human-derived growth hormone or gonadotrophin should be offered the opportunity of referral to the UCL Institute of Child Health, London. Contact: L.Davidson@ich.ucl.ac.uk, 020 7404 0536
- The National CJD Surveillance Unit in Edinburgh can provide advice on all clinical and neuropathological aspects of CJD. It can be contacted at:

  Professor R G Will – Director
  National CJD Surveillance Unit
  Western General Hospital
  Crewe Road
  Edinburgh
  EH4 2XUT Tel: 0131 537 2128 Fax: 0131 343 1404

- The National Prion Clinic at Queen Square, London specialises in the care of patients suffering from CJD. It can be contacted at:

  National Prion Clinic
  The National Hospital for Neurology and Neurosurgery
  Queen Square
  London
  WC1N 3BG Tel: 0207 692 2397

  http://www.nationalprionclinic.org/

- The CJD Support Network is a voluntary organisation set up to provide help and support for patients of all types of CJD and their families. The Network has undertaken a case co-ordination initiative aimed at facilitating the co-ordination of care for patients affected by all types of CJD, and gives advice on all case co-ordination enabling cost effective care and ensuring appropriate responses to carers' needs. It can be contacted at:

  Gillian Turner – National CJD Co-ordinator
  CJD Support Network
  Birchwood
  Heath Top
  Ashley Heath
  Market Drayton
  Shropshire TF9 4QL Tel: 01630 673 993

  http://www.cjdsupport.net/

- The Human BSE Foundation is a voluntary organisation run by families of vCJD patients aimed at helping relatives, friends and carers of vCJD patients by providing support, information and practical advice. It can be contacted at:

  The Human BSE Foundation
  99 Warkworth Drive
  Deneside View
  Chester-le-Street
  Co Durham
  DH2 3TW Tel: 0191 389 4175 (Helpline)

MONITORING TOOL
There are presently no plans to monitor compliance with the guideline

STANDARDS	%	CLINICAL EXCEPTIONS
The advice within the protocol must be complied with.	100%	None

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10. References

- Transmissable Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection. January 1999. HMSO. (ISBN 011-322166).
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- Creutzfeldt-Jakob Disease: Implications for Gastroenterology.
- Bramble M G, Ironside J W. Gut 2002; **50**: 888-890.
- Assessing the implications for blood donors if recipients are infected with vCJD. Department of Health. July 2005
- Endoscopy and individuals at risk of vCJD for public health purposes. A consensus statement from the British Society of Gastroenterology Decontamination Working Group and the ACDP TSE Working Group on Endoscopy and vCJD sub-group. November 2005
- Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures. National Institute for Health and Clinical Excellence. November 2006
- Updated sections from: Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection, Guidance from the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee Annexes A1, E,J.; Department of Health March 2007 – May 2008
- Assessment to be carried out before surgery and/or endoscopy to identify patients with or at increased risk of CJD, vCJD. Annex J (Updated May 2013).
- Quarantining of surgical instruments Annex E (updated January 2011)
- Endoscopy – Annex F (updated January 2013)
- Quarantining of surgical instruments - Annex E (updated January 2011)
- Part 4 infection control of CJD,vCJD and other human prion diseases in healthcare and community settings (updated January 2013)
- Alert to urological surgeons regarding the equipment used for patients at risk of vCJD requiring transrectal prostatic biopsy

updated versions (PDF) are available at:

https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

11. Contribution List

Key individuals involved in developing the document

Name	Designation
Dr Chris Catchpole	Consultant Microbiologist
Dr Jane Stockley	Consultant Microbiologist

Circulated to the following individuals for comments

Name	Designation
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Stephen Steward	Trust Lead TSSU Manager
Dr Claire Constantine	Consultant Microbiologist, ICD WRH
Dr Anne Dyas	Consultant Microbiologist, Associate DIPC

Circulated to the following CDs / Heads of department for comments from their directorates / departments

Name	Directorate / Department
Mr Graham James	Clinical Director Head and Neck
Mr Neal Barnard	Clinical Director Oral/Maxillo-facial
Mr Jonathon Eaton	Clinical Director Theatres
Mr Stephen Perry	Clinical Director Ophthalmology
Mr Terry Chen	Clinical Director Urology
Mr Eric Grocott	Clinical Director Vascular
Dr Salim Shafeek	Clinical Director Oncology/Haematology
Dr Nicholas Pemberton	Consultant Haematologist
Dr Simon Hellier	Clinical Director Respiratory/Gastroenterology
Mr Richard Tudor	Clinical Director General Surgery AH
Mr Steven Thrush	Clinical Director General Surgery WRH
Mr Alexander Reading	Clinical Director T+O
Mr John Watts	Clinical Director O+G
Mr Lance Hollis	Clinical Director ENT

Circulated to the chair of the following committees / groups for comments

Name	Committee / Group
Mr John Rostill	Trust Infection Prevention & Control Committee

June 2013 update circulated to the following for comment:

Name	Committee/ Group
Dr A Dyas	Consultant Microbiologist, ICD Alex
Dr C Constantine	Consultant Microbiologist ICD WRH
Ms H Gentry	Lead IPC Nurse
Mr S Steward	Trust Lead TSSU Manager
Mr S Lake	Clinical Director
Mr G James	Clinical Director
Mr N Hickey	Clinical Director
Dr S Larkin	SpR Microbiology
Membership	TIPCC

Information for patients undergoing surgery or neuro-endoscopy on high risk tissues

Part of your routine assessment before surgery includes some questions to find out whether you could have an increased risk of Creutzfeldt-Jakob disease (CJD). We will ask you:

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

Have you any history of CJD or other prion disease in your family?

Have you ever received growth hormone or gonadotrophin treatment?

Have you had surgery on your brain or spinal cord at any time in the past?

Since 1980, have you had any transfusions of blood or blood components (red cells, plasma or platelets)?

What is CJD?

Creutzfeldt-Jakob disease (CJD) is a rare brain disorder that affects about 1 in a million people each year. CJD is thought to be caused by the build up in the brain of an abnormal form of a protein called a 'prion'. Unfortunately CJD is fatal, and as yet there is no known cure. There are different types of CJD, including variant CJD (vCJD). vCJD is caused by eating meat from cows infected with BSE.

How can CJD spread from person to person?

A person who is infected with CJD may have abnormal prion protein in their body for years before becoming ill. If that person has an operation, or donates blood, tissues or organs, during that time, the abnormal prion protein that causes CJD could spread to other patients.

Why are we asking you about CJD before your operation?

The abnormal prion protein that causes CJD is very hard to remove or destroy. If surgical instruments are used on a patient who is infected with CJD they may still have prion protein on them, even after they have been properly washed and disinfected. They could then spread CJD to other patients. This is particularly important for operations on the brain, spinal cord and the back of the eye as these parts of the body contain the largest amount of abnormal prion protein.

What have these questions got to do with CJD?

CJD has been spread in several ways and different groups of people may have an increased risk of CJD.

We ask whether there is anyone in your family who has had CJD because some types of CJD can be inherited. These types of CJD are caused by faulty genes and may be passed from parent to child.

We ask whether you have had surgery on the brain or spinal cord because some of these operations used to use grafts of 'dura mater' (the tough lining round the brain

and spinal cord). Some of these grafts have been linked to CJD infection - these grafts are no longer used.

We ask whether you have been treated with growth hormone or gonadotrophin infertility treatment because these used to be prepared from pituitary glands. Some of these hormone treatments have been linked to CJD infection - these hormones are no longer used.

We ask whether you have had a large number of blood transfusions as this could be related to an increased risk of variant CJD (vCJD). vCJD is the type of CJD which is caused by eating meat from cows infected with BSE. vCJD can be spread through blood transfusions.

We don't know how many blood donors are infected with vCJD, even though they appear to be healthy, or how easily vCJD might spread through blood transfusions.

This means that the risk of vCJD to someone who has received blood is very uncertain. It is only worth considering if patients have received extremely large amounts of blood. Even then the risk is still very uncertain.

What happens if I answer 'Yes' to any of these questions?

If you answer 'Yes' to any of these questions, medical staff will now examine your medical records in more detail to determine whether or not you may have an increased risk of CJD.

What will happen then?

If you do have an increased risk of CJD special precautions will be taken with the surgical instruments used in your operation. Your GP will be informed and will ask you to come and discuss what this means in more detail.

Please remember that the overall risk of CJD spreading by these routes is generally **very low.** These questions are an extra measure to prevent CJD spreading through surgery. **This should not affect the medical care you receive now or in the future.**

What if I don't have a GP?

The health protection unit for your area will make sure that another doctor discusses this with you.

Can I have a blood test to see if I am infected with CJD?

Unfortunately there is no blood test available yet which could show if you have CJD.

Where can I find out more?

The following organisations offer further information and support.

- Health Protection Agency website: www.hpa.org.uk/cjd
- CJD Support Network website: www.cjdsupport.net
- National CJD Surveillance Unit website: www.cjd.ed.ac.uk
- National Prion Clinic website: www.nationalprionclinic.org/

APPENDIX B

Common flexible endoscopic procedures classified as invasive or non-invasive (the term 'working channel applies to the endoscope el that is used for both the passage of accessories and the suction removal of liquids and gases).

Procedure		Contamination of working channel	Mechanism	Invasive (+) or Non-Invasive (-)	Notes/ Exceptions
1.	**Arthroscopy, Bronchoscopy And Cystoscopy**				
1a	All arthroscopy procedures	These procedures 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 working channel could become contaminated with potentially infectious tissue.	Lymphoid tissue could come into contact with the lining of the working channel. Tissue may be deposited in the working 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 working channel could become contaminated with potentially infectious tissue.	Lymphoid tissue could come into contact with the lining of the working channel. Tissue may be deposited in the working 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 working channel may become contaminated with lymphoid tissue during transbronchial biopsy.	Lymphoid tissue could come into contact with the lining of the working channel. Tissue may be deposited in the working channel.	**+**	

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 working channel with lymphoid tissue.	The needle is sheathed and therefore not in contact with working channel	_	

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 single use forceps contamination of the working channel with submucosal lymphoid tissue is likely.	Contaminated tissue may come into contact with the lining of the endoscope working channel. Tissue may be deposited on the internal surface of the working channel. Decontamination not proven to remove the infective agent.	**+** (but see exception, right)	Cytology is of negligible risk provided a sheathed technique is used. Alternatively cytology (using a sheathed cytology device) could be taken at the first gastroscopy if malignancy is strongly suspected. Some larger channel endoscopes allow the passage of a sheath through which biopsy may be done while protecting the endoscope working channel from tissue contamination. Following biopsy, the tip of the biopsy forceps is fully retracted into the sheath, the tip of which is kept protruding from the endoscope tip throughout. The practice of taking a single biopsy and removing the endoscope with the forceps protruding, then severing it with wire cutters, is to be discouraged.
3c	Gastroscopy with brush cytology	The cytology brush is sheathed and therefore there is low risk of the working channel becoming contaminated with lymphoid tissue. Cytology is of negligible risk provided a sheathed technique is used.	No contact of lymphoid tissue with the working channel.	_	
3d	Gastroscopy and balloon dilatation of stricture (oesophagus or pylorus)	Balloon dilatation may disrupt submucosal lymphoid tissue, which could be transferred to the working 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 working channel) would minimise the risk.	_	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 working 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 working 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 working channel.	Polyp tissue fragments are readily sucked into the working channel during and after polypectomy.	**+** (but see exception, right)	Some endoscopists advocate the use of slow continuous irrigation of the working channel with water during polypectomy in order to minimise the risk of polyp fragments coming into contact with the internal surface of the endoscope working channel. Experience is, however, limited, and if polyp fragments become aspirated into the working channel (as is normally the case) the procedure is immediately deemed invasive.
3g	Gastroscopy and endoscopic mucosal resection (EMR)	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.	Polyp tissue fragments are readily sucked into the working channel during and after EMR.	**+** (but see exception, right)	Some endoscopists advocate the use of slow continuous irrigation of the working channel with water during polypectomy in order to minimise the risk of polyp fragments coming into contact with the internal surface of the endoscope working channel. Experience is, however, limited, and if polyp fragments become aspirated into the working channel (as is normally the case) the procedure is immediately deemed invasive.
3h	Gastroscopy or enteroscopy and argon plasma coagulation	In theory the technique involves no contact with the mucosa. However contact frequently occurs and tissue adheres to the catheter.	Tissue is likely to enter the working channel.	**+**	
3i	Gastroscopy and use of heater probe	Can be used to arrest bleeding but tissue may adhere to the probe and contaminate the working channel.	Lymphoid tissue contamination of the working channel is possible.	**+**	Heater probe should be discarded after use and disposed of by incineration.
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	Good technique would minimise risk. The needle is sheathed and therefore not in contact with the working channel. Poor technique might result in the unsheathed needle coming into contact with the channel, rendering	_	

		tissue.	the procedure invasive.		
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 minimises the risk. The needle is sheathed and therefore not in contact with the working channel. Poor technique might result in the unsheathed needle coming into contact with the channel, rendering the procedure invasive.	_	
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.	Tissue does not come into contact with the working channel during banding.	_	
3m	Gastroscopy and mucosal clipping	No disruption of lymphoid tissue.	No contamination of the biopsy channel with lymphoid tissue.	_	
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 via the working 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 working 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 working 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 working channel with gastric submucosal lymphoid tissue is possible.	**+**	

4. Endoscopic Retrograde Cholangiopancreato-Graphy (Ercp)					
4a	ERCP without sphincterotomy	It is unlikely that the endoscope will become contaminated.	No contamination of the working 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 dilatation balloon via the working channel of the endoscope so contamination with lymphoid tissue is possible. Subsequent manoeuvres to remove stones from the bile duct using retrieval balloons or baskets could contaminate the duodenoscope working channel.	**+**	
4c	ERCP with sphincterotomy	The diathermy papillotomy knife used in this procedure frequently has adherent tissue and it is likely that the working channel could become contaminated with lymphoid tissue.	Adherent tissue may be deposited in the working channel as the sphincterotome is withdrawn. Subsequent manoeuvres to remove stones from the bile duct using retrieval balloons or baskets could also contaminate the duodenoscope working channel.	**+**	

5. Enteroscopy					
5a	Enteroscopy without biopsy	Tissue contamination of the working channel is very unlikely.	No contamination would result from a straightforward diagnostic enteroscopy.	_	
5b	Enteroscopy with biopsies	It is likely that the working channel will become contaminated with lymphoid tissue.	Contaminated tissue may be deposited in the working channel.	**+**	It may become feasible to perform biopsy non-invasively if long-sheathed biopsy forceps become available

6. Colonoscopy

6a	Colonoscopy without biopsy	A diagnostic colonoscopy is unlikely to contaminate the working channel with submucosal lymphoid tissue.	No contamination would result from a straightforward diagnostic colonoscopy.	–	
6b	Colonoscopy and biopsy	It is likely that the working channel will become contaminated with ileal submucosal tissue or colonic submucosal lymphoid aggregates.	Contamination of the working channel very likely.	**+** (but see exception, right)	Sheathed biopsy, where feasible, may allow tissue sampling while avoiding the risk of working channel contamination. Following biopsy, the tip of the biopsy forceps is fully retracted into the sheath, the tip of which is kept protruding from the endoscope tip throughout. The practice of taking a single biopsy and removing the endoscope with the forceps protruding, then severing it with wire cutters, is to be discouraged.
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 working 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 working 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.	Polyp tissue fragments are readily sucked into the working channel during and after polypectomy.	**+** (but see exception, right)	Some endoscopists advocate the use of slow continuous irrigation of the working channel with water during polypectomy in order to minimise the risk of polyp fragments coming into contact with the internal surface of the endoscope working channel. Experience is, however, limited, and if polyp fragments become aspirated into the working channel (as is normally the case) the procedure is immediately deemed invasive.
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. Polyp tissue fragments are readily sucked into the working channel during and after EMR.	**+** (but see exception, right)	Some endoscopists advocate the use of slow continuous irrigation of the working channel with water during EMR in order to minimise the risk of polyp fragments coming into contact with the internal surface of the endoscope working channel. Experience is, however, limited, and if polyp fragments

					become aspirated into the working channel (as is normally the case) the procedure is immediately deemed invasive.
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. Tissue is likely to enter the working channel.	**+**	
6g	Colonoscopy and stenting	No contact between working 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 working channel is unlikely to become contaminated.	–	

7. Flexible Sigmoidoscopy					
7a	Flexible sigmoidoscopy	This diagnostic procedure is unlikely to result in contamination of the working 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)

APPENDIX C

HIGH-RISK PROCEDURES

1. Neurosurgery

The list below gives the OPCS-IV codes used in the Hospital Episodes Statistics (HES) databases associated with intradural operations on the brain.

HES code	Description of procedure
A01	Major excision of tissue of brain
A02	Excision of lesion of tissue of brain
A03	Stereotactic ablation of tissue of brain
A04	Open biopsy of lesion of tissue of brain
A05	Drainage of lesion of tissue of brain
A07	Other open operations on tissue of brain
A08	Other biopsy of lesion of tissue of brain
A09	Neurostimulation of brain
A10	Other operations on tissue of brain
A12	Creation of connection from ventricle of brain
A13	Attention to component of connection from ventricle of brain
A14	Other operation on connection from ventricle of brain
A16	Other open operations on ventricle of brain
A20	Other operations on ventricle of brain
A22	Operations on subarachnoid space of brain
A24	Graft to cranial nerve
A25	Intracranial transection of cranial nerve
A26	Other intracranial destruction of cranial nerve
A29	Excision of lesion of cranial nerve
A30	Repair of cranial nerve
A31	Intracranial stereotactic release of cranial nerve
A32	Other decompression of cranial nerve
A33	Neurostimulation of cranial nerve
A34	Exploration of cranial nerve
A36	Other operations on cranial nerve
A38	Extirpation of lesion of meninges of brain
A39	Repair of dura
A42	Other operations on meninges of brain
B01	Excision of pituitary gland
B02	Destruction of pituitary gland
B04	Other operations on pituitary gland
B06	Operations on the pineal gland
L33	Operations on aneurysm of cerebral artery
L34	Other open operations on cerebral artery

2. Posterior Eye Surgery

The list below gives the HES codes associated with high-risk operations on the posterior eye.

HES Code	Description of procedure
C01	Excision of eye
C79	Operations on vitreous body
C81	Photocoagulation of retina for detachment (only when the retina is handled directly)
C82	Destruction of lesion of retina
C84	Other operations on retina

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	Race	No	
	Ethnic origins (including gypsies and travellers)	No	
	Nationality	No	
	Gender	No	
	Culture	No	
	Religion or belief	No	
	Sexual orientation including lesbian, gay and bisexual people	No	
	Age	No	
	Disability	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	N/A	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
5.	**If so can the impact be avoided?**	N/A	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	N/A	
7.	**Can we reduce the impact by taking different action?**	N/A	

If you have identified a potential discriminatory impact of this key document, please refer it to Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Human Resources.

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval