



Western Health
and Social Care Trust

**Policy for the Control of Transmissible
Spongiform Encephalopathy (TSE),
Including Creutzfeldt Jakob Disease (CJD)
and
variant Creutzfeldt Jakob Disease (vCJD)**

*To be used in conjunction with the Guidance issued by The
Advisory Committee on Dangerous Pathogens TSE Risk
Management Sub-Group:*

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

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This policy does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/ or guardian or carer.

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1.0 **INTRODUCTION**

The purpose of this policy is to provide all clinical staff with guidance and advice on safe working practices with the aim of preventing the transmission of Creutzfeldt Jakob Disease (CJD), variant Creutzfeldt Jakob Disease (vCJD) and other human prion diseases in hospital and community healthcare settings.

N.B. This document is intended for use by all clinical staff.

All staff must comply with the current policy. Failure to do so may result in disciplinary action.

1.1 **Background**

CJD is a rare illness and is one of a group of diseases called prion diseases, which affect humans and animals. Prion diseases exist in different forms, all of which are progressive, currently untreatable and ultimately fatal. Their name arises because they are associated with an alteration in a naturally occurring protein: the prion protein.

CJD was first described in 1920. The commonest form is called sporadic CJD and occurs worldwide causing around 1-2 deaths per million population per year. A new form of CJD (variant CJD) linked to bovine spongiform encephalopathy (BSE) in cattle was identified in 1996. There are also inherited forms of human prion disease linked to mutations of the prion protein gene and cases caused by infection via medical or surgical treatments (iatrogenic CJD).

This guidance provides advice on safe working practices with the aim of preventing the transmission of CJD, variant CJD (vCJD) and other human prion diseases in hospital and community healthcare settings.

N.B: It is acknowledged some procedures involving 'high risk tissue', e.g. neurosurgery, are not presently performed within the WHSCT. However, some patients who reside within the WHSCT will have to have such procedures performed at another hospital. Therefore, it is recommended, if possible, that an assessment regarding CJD/ vCJD risk be carried out on such patients prior to them being transferred.

If the patient is found to be at risk, then the Infection Prevention and Control Department at the receiving hospital should be informed immediately via telephone.

All documentation is to accompany the patient to the receiving hospital.

The diagnosis of prion diseases and classification of suspect cases is best made by a Neurologist. All such patients must be referred to a Neurologist for classification.

1.2 **Purpose**

This policy aims to provide guidance for all healthcare workers on the safe

and effective management of patients with CJD, thereby reducing the risk of transmission to other patients and staff within a healthcare setting by identifying staff roles and responsibilities and providing clear procedures to follow.

2.0 SCOPE OF THE POLICY

This policy applies to all healthcare workers employed within the WHSCT and others working within the Trust in a contracted capacity.

3.0 ROLES AND RESPONSIBILITIES

3.1 Trust Board and Chief Executive

Have an overall governance role in Infection Prevention and Control in relation to staff, patients and visitors. They have a collective responsibility to ensure that patients with suspected/ confirmed CJD/ vCJD can be managed according to the procedures set out in this policy.

3.2 Senior Managers

Within directorates should:

- Ensure staff have access to this policy and adhere to the procedures set out in this policy.
- Have a key role in the co-ordination of actions required.
- Ensure records of meetings are maintained.
- Ensure relevant specialties must carry out audits relating to the compliance with CJD/ vCJD risk assessments. Date(s) and score(s) of same to be kept within the relevant speciality.

3.3 Ward Managers

Ensure that:

- Staff within their area of responsibility adhere to the procedures outlined in this policy.
 - Adverse incidents are reported and managed as per Trust policy.
- Staff are provided with suitable information, instruction and training as required.
- Should maintain an accurate record of patient placement within the ward at all times to facilitate accurate retrospective information gathering if required.
- Staff have access to appropriate personal protective equipment (PPE).
- All necessary information requested by an Incident Team is provided as required.
- Ensure necessary documentation has been completed as per policy.

3.4 All Healthcare Employees within the WHSCT

- Must be familiar with this policy.
- Must comply with the WHSCT pre-employment health assessment.

3.5 Infection Prevention and Control Team

- Advise on the infection prevention and control issues for individual patients.
- Contribute to the updating of the Policy for the Control of Transmissible Spongiform Encephalopathy (TSE) (Including CJD / vCJD).

3.6 Consultant Microbiologist

Advise on infection prevention and control issues for individual patients.

3.7 Clinician Responsible for the Patient

Must be familiar with the guidance set out within this policy.

4.0 KEY PRINCIPLES

The overarching principles/ statements for this policy are to ensure that:

- Staff are informed and instructed in the management and control of CJD/ vCJD.
- The relevant personnel/ departments and agencies are notified of the positive patient.
- To give advice on completing risk assessments in relation to health and safety of patients and staff.
- To ensure that all procedures for diagnosis, treatment are implemented appropriately.
- To ensure that PPE use is appropriate.
- To ensure that Trust incidents are investigated appropriately.

5.0 MODE OF TRANSMISSION

- It is important to emphasize that CJD prion diseases are not contagious, but can be transmissible under certain circumstances.
- Normal social and clinical contact and non-invasive procedures **do not** present a risk to healthcare workers (HCWs), visitors, relatives and the community.
- CJD has been transmitted accidentally in human sources including growth hormones, dura mater preparation and transplantation of a corneal graft donated by an affected patient.
- Infection prevention and control measures, therefore, deal primarily with instruments, tissues and the prevention of inoculation injuries.
- CJD is particularly resistant to standard physical and chemical methods of inactivation and decontamination. **Therefore, effective cleaning is of great importance.**

Table 1 – Distribution of TSE Infectivity in Human Tissues and Body Fluid

Further guidance can be accessed via: Annex A1 at

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

Tissue	Presence of abnormal Prion Protein and level of infectivity			
	CJD other than vCJD		vCJD	
	PrP ^{TSE} detected	Assumed level of infectivity	PrP ^{TSE} detected	Assumed level of infectivity
Brain	+ve	High P	+ve	High P
Spinal cord	+ve	High P	+ve	High P
Cranial nerves – specifically <ul style="list-style-type: none"> Entire optic nerve Only the intracranial components of the other cranial nerves 	+ve	High	+ve	High
Cranial ganglia	+ve	High	+ve	High P
Posterior eye – specifically <ul style="list-style-type: none"> Posterior hyaloid face Retina Retinal pigment epithelium Choroid Subretinal fluid Optic nerve 	+ve	High P	+ve	High
Pituitary gland	+ve	High (?)	+ve	High (?)
Spinal ganglia ¹	+ve	Medium	+ve	Medium P
Olfactory epithelium	+ve	Medium	NT	Medium
Dura mater ²	-ve	Low	+ve	Low
Tonsil	-ve	Low	+ve	Medium P
Lymph nodes and other organised lymphoid tissues containing follicular structures	-ve	Low P	+ve	Medium P
Gut-associated lymphoid tissue	-ve	Low	+ve	Medium
Appendix	-ve	Low	+ve	Medium
Adrenal gland	-ve	Low	+ve	Medium
Spleen	+ve	Low P	+ve	Medium P
Thymus	-ve	Low	+ve	Medium
Anterior eye and cornea	-ve	Low	-ve	Low
Peripheral nerve	+ve	Low	+ve	Low
Skeletal muscle	+ve	Low	+ve	Low
Dental Pulp	-ve	Low	-ve	Low
Gingival Tissue	NT	Low	-ve	Low
Blood and bone marrow	NT	Low	-ve	Low
CSF	-ve	Low P	-ve	Low
Placenta	-ve	Low	-ve	Low
Urine	-ve	Low	-ve	Low
Other tissues	-ve	Low P	+ve	Low

Key: +ve = tested positive -ve = tested negative NT = not tested
P = infectivity proven in experimental transmission studies

¹ Spinal ganglia have a high assumed level of infectivity in the WHO Guidelines. However, unpublished results on the infectivity of spinal ganglia indicate that this tissue is of medium infectivity.

² Dura mater is designated low infectivity as virtually no detectable abnormal prion protein has been found in cases of CJD; **however, as grafts of these tissues are associated with CJD transmission, probably as a result of contamination by brain and because of the lengthy period of implantation in the CNS, procedures conducted on intradural tissues (i.e. brain, spinal cord and intracranial sections of cranial nerves) or procedures in which human dura mater was implanted in a patient prior to 1992 remain high risk.**

6.0 PATIENT RISK GROUPS

Further guidance may be accessed via: ‘Infection Prevention and Control of CJD, vCJD and other human prion diseases in healthcare and community settings’, Part 4 at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>. When considering measures to prevent transmission of CJD 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 and ‘**at increased risk**’ patients, i.e. those with no clinical symptoms, but who are at increased risk of developing CJD or vCJD, i.e. because of their medical or family history. Table 2 below details the classification of the risk status of symptomatic and asymptomatic patients.

Table 2 – Categorisation of Patients by Risk

Symptomatic patients	<p>Patients who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD. (For full diagnostic criteria see Annex B at https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group).</p> <p>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.</p>
Patients ‘at increased risk’ from genetic forms of CJD.	<p>Individuals who have or have had two or more blood relatives affected by CJD or other prion disease.</p> <p>Individuals who have a blood relative known to have a genetic mutation indicative of genetic CJD.</p> <p>Individuals who have been shown by specific genetic testing to be at significant</p>

	risk of developing CJD.
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	<p>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.</p> <p>Individuals who underwent intradural neurosurgical or intradural spinal procedures before August 1992 who have 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 <i>dura mater</i> was not used).</p> <p>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.</p> <p>Individuals who have received an organ or tissue from a donor infected with CJD/ vCJD or ‘at increased risk’ of CJD/ vCJD.</p> <p>Individuals who have been identified as having received blood or blood components from 300 or more donors since January 1990.</p> <p>Individuals who have given blood to someone who went on to develop vCJD.</p> <p>Individuals who have received blood from someone who has also given blood to a patient who went on to develop vCJD.</p> <p>Individuals who have been treated with certain implicated UK sourced plasma products between 1990 and 2001.</p>

N.B: Recipients of ocular transplants, including corneal transplants, are not considered to be “at increased risk” of CJD/ vCJD.

7.0 PRE-ANAESTHETIC ASSESSMENT QUESTIONS

Further guidance may be accessed via: Annex J at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group> updated August 2017

There are a number of patients who have been informed that they are at increased risk of CJD or vCJD. Thus it is now recommended that **all** patients about to undergo **any** elective or emergency surgical or endoscopic procedure are to be asked the following question (with the exception of obstetrics and gynaecological procedures, also refer to section entitled Dentistry) to allow appropriate infection control procedures to be followed.

The CJD/ vCJD Questionnaire(s) **must** be completed at the earliest opportunity by the patient's **clinician** and then filed in the patients medical notes for future reference.

It is crucial that the question(s) are asked in a manner that does not cause undue anxiety, and therefore the questioner should be prepared and able to reassure the patient, and provide further information if needed.

Question: 'Have you ever been notified that you are at increased risk of CJD/ vCJD for public health purposes?' (See Appendix 3)

Table 3 – The actions to be taken following the patient's response to the above questions are

Patient Response	Action
No	Surgery or endoscopy should proceed using normal infection prevention and control procedures, unless the procedure is likely to lead to contact with high risk tissue then additional questions must be asked. (See additional questions page 13, Table 4 and Appendix 3.)
Yes	<ul style="list-style-type: none"> • Please ask them to explain further. • If a patient has answered 'yes', there is no additional need to ask the questions in Table 4/ Appendix 3, as the patient's risk status has been established. • Special infection prevention and control precautions should be taken for all surgery or endoscopy involving contact with <u>medium</u> or <u>high</u> infectivity tissues. The Infection Prevention and Control Team should be consulted for advice. • Advice on the precautions to be taken during the treatment of patients with or at increased risk of CJD/ vCJD can be accessed via 'Infection Prevention and Control of CJD, vCJD and other human prion diseases in healthcare and community settings' Part_4 at https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

	<ul style="list-style-type: none"> • Annex F at https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group provides information on endoscopic procedures. • The patient's response must be recorded in their medical notes for future reference. • Record in the 'Needs' section of Patient Centre / PAS.
<p>Unable to respond</p>	<ul style="list-style-type: none"> • Surgery or endoscopy should proceed using normal infection prevention and control procedures unless the procedure is likely to lead to contact with high risk tissue. • In the event that a patient about to undergo emergency surgery or 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 question / and those set out in Table 4, prior to surgery or 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 <u>but all instruments should be quarantined following the procedure.</u> • The patient's GP should be contacted after the surgery or neuro-endoscopy and enquiries made as to whether the patient is at risk of CJD/ vCJD according to the CJD risk questions set out in Table 4.

If a patient answers **no** to the above question, but is already **known** to be at risk and is undergoing **any** elective or emergency surgical or endoscopic procedures likely to involve contact with tissues of potentially **medium/ high** level infectivity, refer to 'Summary of Precautions Advised for the Use of Endoscopes pages 17-20. Also Handling of Instruments – Appendix 1 and 2 of this policy.

8.0 ADDITIONAL RECOMMENDATIONS FOR SURGERY AND NEURO-ENDOSCOPY WHICH MAY/ WILL INVOLVE CONTACT WITH HIGH RISK TISSUE ONLY

As well as asking **all** patients whether they have been notified as being at risk of CJD/ vCJD clinicians assessing patients who are coming in for procedures that are likely to/ will involve contact with **high risk** tissues **must** ask the following supplementary questions to further assess CJD/ vCJD risk. These questions are included in the Questionnaire, Appendix 3.

N.B: It is recommended that patients are asked the questions outlined in Table 4 prior to elective or emergency surgical or neuro-endoscopic procedures likely to involve contact with tissues of potentially **high** infectivity.

Procedures should not be delayed whilst information is being collected and clinicians should be careful not to prejudice overall patient care.

Table 4

	Questions to Patient	Notes to Clinician
1	<p>Have you any history of CJD or other prion disease in your family? If yes, please specify.</p>	<p>Patient should be considered to be at risk from genetic forms of CJD if they have or have had:</p> <ul style="list-style-type: none"> i) Genetic testing, which has indicated that they are at significant risk of developing CJD or other prion disease; ii) A blood relative known to have a genetic mutation indicative of genetic CJD or other prion disease; iii) 2 or more blood relatives affected by CJD or other prion disease.
2	<p>Have you ever received growth hormone or gonadotrophin treatment? If yes, please specify:</p> <ul style="list-style-type: none"> i) whether the hormone was derived from human pituitary glands? ii) the year of treatment iii) whether the treatment was received in the UK or in another country 	<p>Recipients of hormone derived from human pituitary glands, e.g. growth hormone or gonadotrophin, have been identified as potentially at risk of sporadic CJD.</p> <p>In the UK, the use of human derived growth hormone was discontinued in <u>1985</u> but human-derived products may have continued to be used in other countries.</p> <p>In the UK, the use of human-derived gonadotrophin was discontinued in <u>1973</u> but may have continued in other countries after this time.</p>
3	<p>Have you had surgery on your brain or spinal cord?</p>	<ul style="list-style-type: none"> a) Individuals who underwent intradural brain or intradural spinal procedures before August 1992 who have received (or may have received) a graft of human-derived <i>dura mater</i>, are 'at increased risk' of transmission of sporadic CJD, (unless evidence can be provided that human-derived <i>dura mater</i> was not used). Patients who received a graft of human-derived <i>dura mater</i> before 1992 are at increased risk of transmission of sporadic CJD, but not vCJD. b) <u>NICE guidance</u> emphasises the need for a separate pool of new neuroendoscopes and reusable

		<p>surgical instruments for high risk procedures on children born since 1st January 1997 and who have not previously undergone high risk procedures. These instruments should not be used for patients born before 1st January 1997 or those who underwent high risk procedures using reusable instruments before the implementation of this guidance.</p>
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The actions to be taken following the patients response to the questions in Table 4 are:

Patients Response	Action
<p>No to all questions</p>	<p>Surgery or neuro-endoscopy can proceed using normal infection prevention and control procedures.</p>
<p>Yes to any of the questions 1, 2 or 3</p>	<p>Further investigations into the nature to the patients CJD risk should be undertaken and the patients CJD risk assessed. This assessment of CJD risk should be recorded in the patient's medical notes for future reference.</p> <p>If the patient is found to be at risk of CJD or vCJD following investigation or the risk status is unknown at the time of the procedure, special infection prevention and control precautions should be taken for the patient's procedure including quarantining of instruments and the infection prevention and control team should be consulted for advice.</p> <ul style="list-style-type: none"> • Advice on the precautions to be taken during the treatment of patients with or at increased risk of CJD / vCJD can be accessed via 'Infection Prevention and Control of CJD, vCJD and other human prion diseases in healthcare and community settings', Part_4 at https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group • Annex F at https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group provides information on endoscopic procedures. <p>Record in the 'Needs' section of Patient Centre / PAS.</p> <p>If the patient is found to be at increased risk of CJD or vCJD they should be referred to their GP, who will need to inform them that</p>

	<p>they are at risk of CJD or vCJD and provide them with further information and advice. Advice is available from the Public Health England CJD Section, who can be contacted on 02083276090.</p> <p>* 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, Queens Square, London: http://www.nationprionclinic.org</p> <p>* 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 Tel: 020 7404 0536.</p>
<p>Unable to respond</p>	<p>In the event that a patient about to undergo 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 4.</p> <p>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 <u>but all instruments should be quarantined following the procedure</u>. See Annex E at https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group for details on quarantining.</p> <p>The patient's GP should be contacted after the surgery or neuro-endoscopy and enquiries made as to whether the patient is at risk of CJD/ vCJD according to the CJD risk questions as set out in Table 4.</p>

The actions to be taken following the GPs response to the questions in Table 4 are:

<p>GP's Response</p>	<p>Action</p>
<p>No to all questions</p>	<p>The instruments can be returned to routine use after undergoing normal decontamination processes.</p>
<p>Yes to any of questions – 1, 2 or 3</p>	<p>Further investigation into the nature to the patients CJD risk should be undertaken by medical staff, and the patient's CJD risk confirmed or rejected. Confirmation or rejection of CJD risk must be recorded in the patient's medical notes for future reference.</p>

	<p>Record in the 'Needs' section of Patient Centre / PAS.</p> <p>If the patient is found to be at risk of CJD or vCJD following investigation then the quarantined instruments should be <u>destroyed</u>. Alternatively, instruments destined for disposal may instead be retained for research, refer to Annex E at https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group</p> <p>The patient's GP should inform the patient that they are at risk of CJD or vCJD and provide them with further information and advice. Advice is available from the Public Health England CJD Section, who can be contacted on 02083276090.</p> <p>* 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, Queens Square, London: http://www.nationprionclinic.org</p> <p>* 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 Tel: 020 7404 0536.</p>
<p>Uncertain about any of the questions 1, 2 or 3</p>	<p>The instruments should be kept in quarantine. The infection prevention and control team will carry out a risk assessment. The outcome of the risk assessment will determine whether or not to return the instrument to routine use.</p>

9.0 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/ vCJD 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.

10.0 **MANAGING vCJD RISK IN GENERAL SURGERY AND LIVER TRANSPLANTATION**

Further guidance can be accessed via Annex M at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

11.0 **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. This should include assessment of residual post-production organic contamination.

12.0 **PROBLEMS WITH SURGICAL INSTRUMENTS**

If any problems are identified with instruments or sets of instruments, this should be referred to MHRA through the Yellow Card Scheme. (<https://yellowcard.mhra.gov.uk/>).

13.0 **SUMMARY OF PRECAUTIONS ADVISED FOR THE USE OF ENDOSCOPES**

Further guidance can be accessed via Annex F at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

Table 1 - CJD other than vCJD

Tissue Infectivity	Status of Patient		
	Symptomatic		Asymptomatic
	Definite/ Probable	Possible/ Diagnosis Unclear ¹	At Risk ² inherited/ iatrogenic
High: <ul style="list-style-type: none"> • Brain • Spinal Cord 	Single use OR Destroy after use OR Quarantine ³ for re-use exclusively on	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine ³ for re-use exclusively on same

	the same index patient		index patient
Medium: <ul style="list-style-type: none"> Olfactory Epithelium* 	Single use OR Destroy after use OR Quarantine ³ for re-use exclusively on the same index patient	Single use OR Quarantine pending diagnosis	Single use ⁴ OR Destroy after use OR Quarantine ³ for re-use exclusively on same index patient
Low/ None Detectable: <ul style="list-style-type: none"> All other tissue 	No special precautions ⁴	No special precautions ⁴	No special precautions ⁴

Table 2 - vCJD and CJD type uncertain

	Status of Patient			
	Symptomatic		Asymptomatic	
	Definite/ probable	Possible vCJD, possible sCJD or diagnosis unclear ¹	At risk (blood*** recipient from a donor who later developed vCJD)	At risk ² Other iatrogenic
Tissue Infectivity				
High: <ul style="list-style-type: none"> Brain Spinal cord 	Single use OR Destroy after use OR Quarantine ³ for re-use exclusively on same index patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine ³ for re-use exclusively on same patient	Single use OR Destroy after use OR Quarantine ³ for re-use exclusively on same patient
Medium: <ul style="list-style-type: none"> Olfactory epithelium* 	Single use OR Remove from use OR Quarantine ³ for re-use exclusively on same index patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine ³ for re-use exclusively on same index patient	No special precautions unless contaminated with olfactory epithelium*. If contaminated: single use OR Destroy after use OR Quarantine ³ for re-use

				exclusively on same index patient
Medium: <ul style="list-style-type: none"> Lymphoid tissue** 	Single use OR Remove from use OR Quarantine ³ for re- use exclusively on same index patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine ³ for re- use exclusively on same index patient	No special precautions ⁴
Low / none detectable: <ul style="list-style-type: none"> All other tissues 	No special precautions ⁴	No special precautions ⁴	No special precautions ⁴	No special precautions ⁴

* 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.

** Lymphoid tissue refers to the spleen, thymus, tonsils and adenoids, lymph nodes, the appendix and the gastro-intestinal tract sub-mucosa. Further guidance re; Transrectal Prostatic Biopsy in Men at Risk of vCJD can be accessed via: <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

*** 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 CJD but where a diagnosis of CJD is being actively considered. Also see Annex B at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

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. See 'Infection Prevention and Control of CJD, vCJD and other human prion diseases in healthcare and community settings', Part 4 at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

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 in Annex E at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>, should be followed **except** for endoscopes, the bedside clean should take place immediately after the procedure has been carried out and it is recommended that the endoscopes should be manually cleaned according to the manufactures recommendations and passed through an Endoscope Washer Disinfefer as soon as possible 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 paragraph F1 (e), Annex F at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

⁴ The decontamination procedures advised in paragraph F1, Annex F at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group> taken together with the **CFPP 01-06** or equivalent national guidance and **BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy (2014)** should be followed.

14.0 COMMON FLEXIBLE ENDOSCOPIC PROCEDURES CLASSIFICATION – INVASIVE OR NON-INVASIVE

Further guidance can be accessed via; Annex F, Table F 2b. (Table F 2b refers only to vCJD) <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>.

15.0 DECONTAMINATION OF ENDOSCOPES

Further guidance can be accessed via: Annex F & E at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

16.0 QUARANTINING OF SURGICAL INSTRUMENTS

Further guidance can be accessed via: Annex F & E at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

17.0 MANAGING CJD/ vCJD RISK IN OPHTHALMOLOGY AND CJD GUIDANCE FOR OPHTHALMOLOGISTS

Further guidance can be accessed via: Annex L at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

18.0 HOSPITAL CARE OF CJD/ vCJD PATIENTS

- **Sample taking and other invasive medical procedures**
- **Spillages**
- **Clinical waste**
- **Child birth**
- **Bed linen**
- **Occupational exposure**
- **Surgical procedures and instrument management**

Further guidance can be accessed via 'Infection Prevention and Control of CJD, vCJD and other human prion diseases in healthcare and community settings', Part 4 at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

19.0 GENERAL PRINCIPLES OF DECONTAMINATION AND WASTE DISPOSAL

Further guidance can be accessed via: Annex C at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

20.0 DECONTAMINATION OF INSTRUMENTS

Research demonstrates that allowing surgical instruments to dry for more than fifteen minutes before reprocessing greatly increases the amount of residual protein contamination. Therefore instruments should be transported to the HSDU immediately after the close of the procedure for cleaning and reprocessing as soon as practically possible. This will make the cleaning process more effective, hence reducing the risks to the patients and staff handling the devices. If devices cannot be returned in a timely manner, it is important that the instruments are kept moist using appropriate methods approved and verified by the HSDU.

Further guidance can be accessed via Annex C at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

21.0 INCINERATION OF INSTRUMENTS

Further guidance can be accessed via 'Infection Prevention and Control of CJD, vCJD and other human prion diseases in healthcare and community settings', Part 4 at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

22.0 TRANSRECTAL PROSTATIC BIOPSY IN MEN AT RISK OF vCJD

Further guidance can be accessed via

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

23.0 COMMUNITY HEALTHCARE OF CJD/ vCJD PATIENTS

Further guidance can be accessed via 'Infection Prevention and Control of CJD, vCJD and other human prion diseases in healthcare and community settings', Part 4 at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

24.0 TRANSPORTATION OF TSE INFECTED MATERIAL

Further guidance can be accessed via Annex D at

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

25.0 DENTISTRY

If a patient informs a dentist that they have CJD / vCJD or have been notified that they are 'at risk' of CJD, then the dentist **must** include this in the patient's dental records and any referral for surgery.

Further guidance can be accessed via 'Infection Prevention and Control of CJD, vCJD and other human prion diseases in healthcare and community settings', Part 4 at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

26.0 HANDLING OF TISSUES FROM PATIENTS 'WITH' OR 'AT RISK OF' CJD OR vCJD – FOR PATHOLOGISTS AND PATHOLOGY LABORATORIES

Further guidance can be accessed via Annex K at

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

27.0 AFTER DEATH

Further guidance can be accessed via Annex H at

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

28.0 SURVEILLANCE: NATIONAL REFERRAL OF SUSPECTED CASES OF CJD

Local clinicians are asked to report all new cases and suspected cases of CJD and other prion diseases to the NCJDRSU in Edinburgh and the National Prion Clinic (NPC) in London, with a copy to the local health protection team. A reporting form and associated information for patients and clinicians are provided below.

- [National CJD Reporting Form \(updated April 2012\)](#)
- [Patient Information Leaflet \(updated April 2012\)](#)

This system does not preclude a clinician informally discussing a suspect or doubtful case with the NCJDRSU or the NPC. The NCJDRSU are very happy to provide clinical and other advice concerning potential cases of CJD. The NCJDRSU continues to provide a national cerebrospinal fluid (CSF) 14-3-3 service and will arrange collection of CSF samples and prompt results.

29.0 REPORTING NEW CJD CASES TO PUBLIC HEALTH TEAMS

To help prevent any possible spread of CJD between people, local clinicians should also inform their local health protection team (the Consultant in Communicable Disease Control (CCDC) or equivalent) about all new suspect cases of all types of CJD. This is vital as a local response may be required with respect to potential secondary transmission, infection control, and any issues that may arise over time concerning the protection of the wider community. A reporting form for clinicians and further guidance are provided for this purpose below. The health protection team will then investigate and manage any public risk.

- [CCDC reporting form](#)
- [Guidance on local reporting of CJD cases](#)

Further advice and guidance for health protection teams on the actions to be taken upon being informed of a case or suspect case of CJD, is available from the Health Protection Agency (Dr Katy Sinka, Consultant Scientist, tel: 0208 327 6411; e-mail: katy.sinka@hpa.org.uk) or Health Protection Scotland (Dr Oliver Blatchford, Consultant Epidemiologist, tel: 0141 300 1100; e-mail: oliver.blatchford@nhs.net).

30.0 PROTOCOL FOR SURVEILLANCE OF CJD

NCJDRSU has comprehensive mechanisms in place for the ascertainment of all cases of variant and sporadic CJD in the UK. Suspect cases are classified according to internationally recognised published criteria, last updated in 2010 and retrospectively applied to all referrals since January 2010.

- [Diagnostic criteria](#)
- [NCJDRSU protocol for CJD surveillance across the UK](#)

31.0 FREQUENTLY ASKED QUESTIONS – CLINICAL STAFF

Further guidance can be accessed at

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

32.0 IMPLEMENTATION

32.1 Dissemination

This policy applies to all staff.

The policy shall be available for staff to access on the Trust Intranet.

Staff shall be alerted via Trust Communication in relation to the availability of the policy on the Trust Intranet.

32.2 Exceptions

There are no exceptions.

33.0 MONITORING

Compliance with this policy shall be monitored by the Ward/ Department Manager/ Team Leader/ Lead Nurse/ Head of Service. The Infection Prevention & Control Team may also independently monitor compliance.

34.0 REFERENCES

Department of Health: 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. London: The Stationery Office.
www.dh.gov.uk

The National CJD Research & Surveillance Unit (NCJDRSU). The University of Edinburgh. www.cjd.ed.ac.uk

Gateway Approval Reference Number: 8100 Department of Health April 2007. Chief Dental Officer for England.

National Institute for Health and Clinical Excellence: Patient safety and the reduction of risk of transmission of Creutzfeldt-Jakob Disease (CJD) via interventional procedures. Issue date November 2006. <http://www.nice.org.uk>

The Advisory Committee on Dangerous Pathogens' TSE Risk Managements Sub-Group:
<https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

35.0 CONSULTATION PROCESS

Infection Prevention & Control Team
Consultant Microbiologists
Lead BMS, Haematology & Blood Transfusion
Decontamination Managers
Medical Director
Staff Side Consultation Group
Chief Executive HCAI Accountability Forum
Medical Directorate Senior Management Team
Corporate Management Team
Trust Board

36.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1988), Targeting Social Need Initiative, Disability Discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is: **PENDING**

Major Impact

Minor Impact

No Impact

37.0 APPENDICES

Appendices to this policy are as follows:

- Appendix 1 – Handling of Instruments: Patients With or ‘At Increased Risk’ of CJD (Other than vCJD)
- Appendix 2 – Handling of Instruments: Patients With or ‘At Increased Risk’ of vCJD
- Appendix 3 – CJD/ vCJD Risk Questionnaire
- Appendix 4 – CJD/ vCJD Endoscope Identification Form
- Appendix 5 – Information for Patients Undergoing Surgery or Neuro-Endoscopy on High Risk Tissues
- Appendix 6 – 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

38.0 SIGNATORIES

Signed for and on behalf of the Western Health and Social Care Trust:



Clare Robertson

Clare Robertson
Infection Prevention & Control Nurse

01/09/20

Date

Wendy Cross

Wendy Cross
Head of Infection Prevention & Control

01/09/2020

Date

Appendix 1 at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>. 'Infection Prevention and Control of CJD, vCJD and other human prion diseases in healthcare and community settings', Part 4

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
<p>High*</p> <p>Brain</p> <p>Spinal cord</p> <p>Cranial nerves, specifically the entire optic nerve and the intracranial components of the other cranial nerves</p> <p>Cranial ganglia</p> <p>Posterior eye, specifically the posterior hyaloids face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve</p> <p>Pituitary gland</p>	<p>Single use or Destroy or Quarantine for re-use exclusively on the same patient</p>	<p>Single use or Quarantine for re-use exclusively on the same patient pending diagnosis</p>	<p>Single use or Destroy or Quarantine for re-use exclusively on the same patient</p>
<p>Medium</p> <p>Spinal ganglia</p> <p>Olfactory epithelium</p>	<p>Single use or Destroy or Quarantine for re-use exclusively on the same patient</p>	<p>Single use or Quarantine for re-use exclusively on the same patient pending diagnosis</p>	<p>Single use or Destroy or Quarantine for re-use exclusively on the same patient</p>
<p>Low</p>	<p>No special precautions</p>	<p>No special precautions</p>	<p>No special precautions</p>

Appendix 2 at <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>. 'Infection Prevention and Control of CJD, vCJD and other human prion diseases in healthcare and community settings', Part 4

HANDLING OF INSTRUMENTS – PATIENTS WITH, OR 'AT INCREASED RISK' OF vCJD

Tissue Infectivity	Status of Patient		
	Definite or Probable	Possible	At Increased Risk
High* Brain Spinal cord Cranial nerves, specifically the entire optic nerve and the intracranial components of the other cranial nerves Cranial ganglia Posterior eye, specifically the posterior hyaloids face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve Pituitary gland	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
Medium Spinal ganglia Olfactory epithelium Tonsil Appendix Spleen Thymus Adrenal gland Lymph nodes and gut-associated lymphoid tissues	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

* 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.

Appendix 3

CJD/ vCJD Risk Questionnaire

The CJD/ vCJD Questionnaire/s must be completed at the earliest opportunity by the patient's **clinician** and then filed in the patient's medical notes for future reference.

The Questionnaire must also be completed prior to any patient being transferred to the Day Case Unit/ Endoscopy Unit at another hospital for Endoscopic procedures, e.g. ERCP.

Question A: To be asked to **all** patients about to undergo **any** elective or emergency surgical or endoscopic procedures.

Questions 1, 2 & 3: To be asked to patients about to undergo elective or emergency surgical or endoscopic procedures likely to involve contact with tissues of potentially **high** level infectivity.

N.B. If a patient answers **no** to Question A but is already **known** to be at risk and is undergoing **any** elective or emergency surgical or endoscopic procedures likely to involve contact with tissues of potentially **medium/ high** level infectivity, refer to 'Summary of Precautions Advised for the Use of Endoscopes, pages 17-20. Also Handling of Instruments – Appendix 1 and 2 of this policy. **(Please tick the appropriate box)**

Question to Patient		Yes	No	
A	Have you ever been notified that you are at increased risk of CJD or vCJD for public health purposes?			
1	Have you any history of CJD or other prion disease in your family? If yes, please specify.			
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?			
3	Have you had surgery on your brain or spinal cord before August 1992?			
Patient H&C/ Hospital Number	Date	Ward/ Dept. & Hospital	Categorisation – CJD/ vCJD	Signature, Title (PRINT) & GMC No.
Procedure to be performed:				
Outcome of risk assessment:				

Appendix 4

CJD/ vCJD Endoscope Identification Form

To be completed when an endoscope is placed in Quarantine.

Department/ Hospital:

Patient's Name:

Patient's Date of Birth:

H&C/ Hospital Number:

Endoscope ID:

Endoscope Serial Number:

Endoscope Procedure and Date:

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.....
.....
.....
.....
.....
.....

Consultant/ Nurse Endoscopist (Print in full):

.....

Adverse Incident Form Complete: Yes / No

Signature

Endoscopy Clinician:

Appendix 5

The following leaflet can be accessed via

<https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group> Annex J, Appendix B

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?

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.

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.

- 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 6

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

