Patients with or Suspected of Having a Transmissible Spongiform Encephalopathy (TSE)/ Creutzfeldt Jakob Disease (CJD) Management Policy

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Purpose of Agreement	This policy provides necessary guidance for clinical staff to recognise the need for and implement control measures as required.
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Please fill the table below:

Amend No	Issued	Page	Subject	Action Date
1	03.17	5	Change to risk assessment	Immediate
2	03.17	7	Change to contact details	Immediate
3	03.17	18	Endoscope procedures amended	Immediate

Review Log:

Include details of when the document was last reviewed:

Version Number	Review Date	Lead Name	Ratification Process	Notes
2	March 2014	Dr H Chesterfield	Policy Group / AC	ACDP guidance
3	December 2016	Dr H Chesterfield	Policy Group / AC	Updated Guidance
4	April 2020	Debbie Larkin	Approved as part of the Covid-19 review of policies	Expiry date extended to March 2021

SUMMARY OF POLICY

Transmissible Spongiform Encephalopathies (TSEs) are rare degenerative diseases of the nervous system, which can exist in both man and animals. TSEs are believed to be found mainly in the brain and spinal cord, although lower levels may be found in some lymphoid tissues such as the spleen and tonsils. TSEs have long incubation periods which makes identification and prevention difficult In TSE-infected people or animals.

In most routine clinical contact, no additional precautions are needed for care of known, suspected or at risk patients. However when certain invasive interventions are performed there is potential for exposure to TSEs. In these situations control measures are put in place to prevent iatrogenic transmission. Currently these invasive interventions are not undertaken within Solent NHS Trust.

CONTENTS

1. INTRODUCTION AND PURPOSE

1.1. Transmissible Spongiform Encephalopathies (TSEs) are rare degenerative diseases of the nervous system, which can exist in both man and animals. TSEs are believed to be caused by the cellular prion protein, PrP, which is found mainly in the brain and spinal cord, although lower levels may be found in some lymphoid tissues such as the spleen and tonsils.

1.2. TSEs have long incubation periods which makes identification and prevention difficult In TSE-infected people or animals, these proteins become altered to form an abnormally folded prion protein, which is more resistant to degradation and is associated with infectivity.

1.3. In most routine clinical contact, no additional precautions are needed for care of known, suspected or at risk patients. However when certain invasive interventions are performed there is potential for exposure to TSEs. In these situations control measures are put in place to prevent iatrogenic transmission.

1.4. The human form of disease, known as Creutzfeldt Jacob Disease (CJD), is classified according to whether it is sporadic, inherited, or acquired:

- **Sporadic** - this is the most common affecting approximately 60 people in the UK each year. The change in protein structure occurs spontaneously as a chance event with no known cause.
- **Inherited or familial (genetic)** – this is very rare and results from a genetic mutation in the prion gene. There are three recognised forms of the disease: Inherited CJD, Gerstmann-Straussler-Scheinker Disease and Fatal Familial Insomnia.
- **Acquired** - prion disease has been transmitted to people in a few very specific ways *which are outlined below*
  - ***Kuru***. First identified in 1950s in Papua New Guinea. Transmitted from infected bodies as a result of the practice of ritualistic cannibalism.
  - ***Iatrogenic***. All cases have involved use of or contamination with high-risk tissue as a result of a surgical or medical procedure e.g. cornea or dura mater grafts from infected donors. Other iatrogenic routes have included the use of inadequately sterilised neurosurgical instruments, and the use of human derived pituitary gonadotrophin and growth hormones.
  - ***Variant CJD (vCJD).*** This was first identified in 1996 and is associated with the consumption of Bovine Spongiform Encephalopathy (BSE) infected cattle. Most of the cases have been in people under 30 years of age. It differs from other forms of the disease in that the atypical protein has been found in lymphoid tissue such as the appendix and tonsils.

1.5 Diagnosis of CJD/vCJD is difficult and is usually not confirmed until examination of the brain after death. There is currently no non-invasive test which can diagnose CJD during the incubation period and no effective treatment.

1.6 This policy defines the actions that should be taken by Solent NHS Trust to reduce the transmission of TSEs and to ensure the clinical needs of patients are met.

2. SCOPE & DEFINITIONS

2.1. This policy applies to all directly and indirectly employed staff within Solent NHS Trust and others persons working within the organisation in line with Solent NHS Trusts Equality, Diversity

and Human Rights Policy. This document is also recommended to Independent Contractors as good practice.

2.2 **Decontamination:** A term used for the removal and destruction of microorganisms which then renders an item (medical device) ready for reuse and safe for staff to handle (NHS Estates, 2000).

2.3 **Endoscopy*:*** A procedure in which a lighted viewing instrument (endoscope) is used to look inside a body cavity or organ to diagnose or treat disorders

2.4 **Iatrogenic:** Induced inadvertently by the medical treatment or procedures or activity of a physician or surgeon e.g. infections acquired by the patient during the course of treatment.

2.5 **Incubation Period:** The time interval between the initial infection with an infectious agent and the appearance of the first symptom or sign of disease.

2.6 **Mutation:** This is an abnormality or fault found in genes which produces an altered code, which results in the production of abnormal proteins.

2.7 **Risk assessment:** The evaluation of an individual's personal and family history, often by using questionnaires to estimate the degree to which that person is at risk for developing certain diseases.

2.8 **Single use items:**

This is a device designated for 'single-use' and must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient. The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk. The reuse of single-use devices has legal implications.

2.9 **Standard precautions:** Standard (previously known as universal) precautions are the practices adopted by all healthcare workers when potentially coming into contact with any patient's blood or body fluids. They are a set of principles designed to minimise exposure to and transmission of a wide variety of micro-organisms. Since every patient is a potential infection risk, it is essential that standard precautions are applied to all patients at all times. Such precautions involve the use of safe work practices, protective barriers, and the safe disposal of blood and body fluids.

3. PROCESS/REQUIREMENTS

3.1 Identifying the patient at risk

3.1.1 Infection control measures to prevent transmission to patients or staff depend on how likely the patient is to be carrying the infectious agent - **RISK CATEGORY.**

3.1.2 Symptomatic patients are categorised as **HIGH RISK.**

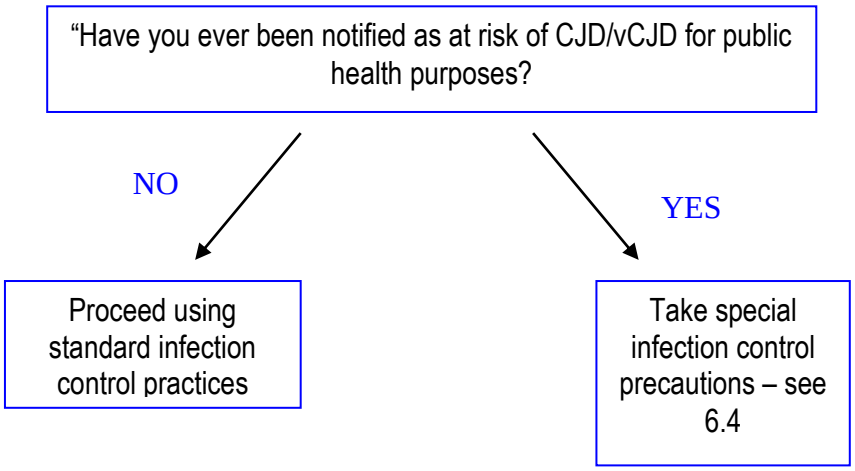
3.1.3 There are also a number of asymptomatic patients who have been informed that they are at increased risk of developing CJD/vCJD due to family history or iatrogenic exposure. These patients are categorised as **MEDIUM** or **LOW RISK** – see table below.

Table 1 – Categorisation of patients by risk

HIGH - 1	Symptomatic	• Patients who fulfil the diagnostic criteria for definite, probable or possible CJD/vCJD • Patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD or vCJD but where the diagnosis of CJD is actively being considered
MEDIUM - 2	Asymptomatic patients who are at risk from familial CJD	• Individuals who have had two or more blood relatives affected by CJD or other prion disease or a relative known to have a genetic mutation indicative of familial CJD • Individuals who have shown by specific genetic testing to be at significance risk of developing CJD or other TSEs
LOW - 3	Asymptomatic patients potentially at risk from iatrogenic exposure	• Recipients of hormone derived from human pituitary glands e.g. growth hormone, gonadotrophin • Individuals who have received a graft of dura mater (Patients who underwent neurosurgical procedures/operations for spinal tumour or cyst prior to August 1992 may have received dura mater and should therefore be treated as a risk unless there is proof that dura mater was not used • Individuals who have received an organ or tissue from a donor infected with CJD/vCJD or 'at increased risk' or CJD/vCJD • Individuals who have been identified prior to high risk surgery as having received blood or blood components from 80 or more donors since January 1980. • Individuals who have received blood from someone who went on to develop vCJD. • Individuals who have given blood to someone who went on to develop vCJD. • Individuals who have received blood from someone who has also given blood to a patient who went on to develop vCJD • Individuals who have been treated with certain implicated UK sourced plasma products between 1980-2001

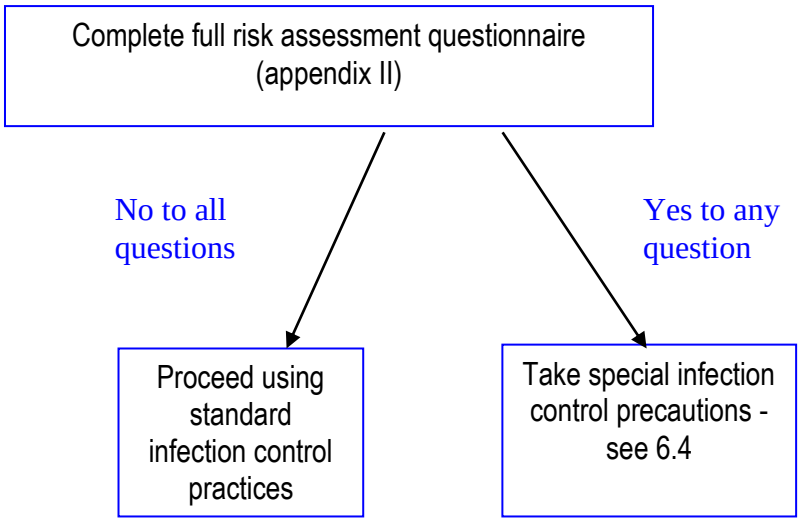
3.2 **Risk assessment of patients prior to endoscopy or surgery (Transmissible Spongioform Encephalopathy Agents:Safe working and the Prevention of Infection. Annex J Updated January 2014)**

3.2.1 **All** patients about to undergo surgery or endoscopy should be asked the following question?



Record patient's response in notes

3.2.2 **All patients** undergoing surgery and endoscopy which may involve **HIGH RISK tissues*.**



**These recommendations are applicable in particular to those assessing patients in neurosurgical and ophthalmic surgical departments.*

Tissues assumed or proven to have high level infectivity for CJD/vCJD are
Brain or spinal cord
Entire optic nerve and intracranial components of other cranial nerves
Cranial nerve ganglia
Posterior eye
Pituitary gland

- If patient is unable to respond ask family member or patients GP to answer questions. If no definitive answer and patient requires emergency endoscopy or surgery, proceed, but all instruments must be quarantined after use.
- The clinician should also check patients' medical notes and/or referral letter for any mention of CJD status.
- Consider whether there is a risk that the patient may be showing early signs of CJD/vCJD, i.e. consider whether patient may have an undiagnosed neurological disease involving cognitive impairment.
- Record patient's CJD/vCJD risk in notes.

3.3 Management of patients known, suspected or at risk of CJD/vCJD

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- There is no evidence that TSEs have been spread from person to person by close contact or through occupational exposure.
- There is no need to isolate the patient provided standard precautions are followed.
- The Infection Prevention Team (IPT) should be informed if the patient is going to be or has been admitted. All cases of clinically suspected CJD of any type should be reported by the clinician caring for the patient to the local Consultant, Health Protection Unit and the National CJD Research and Surveillance Unit. (NCJDRSU), Edinburgh and the National Prion Clinic (London).

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Crewe Road,
Edinburgh EH4 2XUT, Tel: , (0)131 537 1980/2128/3103
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The National Prion Clinic
The National Hospital for Neurology & Neurosurgery
Queen Square,
London
WC1N 3BG

020 3448 4037 / 020 3448 4038

- For further advice regarding management refer to **Public Health Action following a report of a new case of CJD or a person at increased risk of CJD** : PHE Guidance January 2014

3.4 Precautionary measures for surgical procedures

3.4.1. Theatre management

- IPT must be informed BEFORE any procedure is carried out.
- Wherever appropriate procedures should be carried out in an operating theatre at the end of the list to ensure thorough cleaning of all surfaces before the next session.
- Only the minimum number of healthcare personnel should be in the theatre.
- Protective clothing should be used:
    - a liquid repellent gown over a plastic apron
    - gloves
    - Masks and goggles or a full face visor

If patient is 'symptomatic' protective clothing should be single use and disposed of in line with local policy. If the patient is 'at increased risk' the protective clothing need not be single use and may be reprocessed.

- Single use disposable surgical instruments and equipment must be used where possible and incinerated after use.
- Where practical, expensive reusable equipment e.g. drills should be protected from contamination by using shields, guards or similar protective covering which should be destroyed by incineration at the end of the operation. However in practice effective protective covering may not be feasible and therefore advice should be sought from the manufacturer.
- Drapes contaminated with cerebrospinal fluid (CSF) or other neural tissue from patients in the high and medium risk category should be incinerated.
- The facility must be to the standard set in HBN 1.

3.4.2 **Management of surgical instruments**

- See **Algorithm for management of surgical instruments – Appendix IV**
- *Instruments that have been used in procedures involving tissues designated as high or medium infectivity (see Appendix III), on patients with known, suspected or at risk of, CJD/vCJD should be disposed of by incineration or quarantined pending a confirmed diagnosis.*
- The options available should be discussed either with the HSDU (Hospital Sterilisation & Disinfection Unit) manager or Infection Prevention wherever possible single use instruments should be used.
- Instruments which are to be destroyed should be discarded directly into burn bins which must be sealed and sent for incineration at the end of the operation.
- Instruments to be reprocessed should be sent to HSDU as soon as the procedure is completed.
- If the procedures involve low risk tissues (see appendix III) single use instruments should be used wherever feasible. Reusable instruments should be reprocessed within HSDU observing current best practice. When reusable instruments have to be used the HSDU manager must be informed before the operation.

3.4.3 **Surface decontamination and the management of spillages**

- Surfaces in contact with high risk material from definite, probable or high-risk cases should be thoroughly cleaned with detergent wipes or soap and water. Personal protective clothing must be worn. The use of high concentration sodium hypochlorite is unlikely to be practical in the ward/theatre area. It should only be considered in exceptional circumstances to clean high risk material spillages – advice should be sought from IPT. 10,000ppm rather than 20,000ppm sodium hypochlorite is recommended for practical purposes.
- Minor spillages of low risk material e.g. blood from definite, probable or high-risk cases should be dealt with according to the local spillage procedure.
- Absorbent material should be used first to deal with large spillages.
- All materials should be incinerated.

3.4.4. **Collection of blood, biopsy and CSF samples**

- If these procedures are carried out in the ward area then every effort must be made to ensure the environment is easy to clean
- Blood specimens should be collected using standard precautions as for any patient
- All lumbar punctures should be carried out wearing disposable gloves and aprons using single-use disposable instruments

- The laboratory must be informed in advance these samples are being sent

3.4.5. Linen contaminated with CSF or other neural tissue from patients in the high and medium risk category should be incinerated.

3.4.6. **Clinical Waste**
Clinical waste should be disposed of as in the following table

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

* Tissues and material deemed to be low risk include body fluids such as urine, saliva, sputum, blood and faeces. Blood from vCJD patients is considered to be low risk except when transfused in large volumes

3.5. Endoscopy procedures

- Currently there is no evidence of CJD transmission due to an endoscopic procedure; the risk is probably extremely low provided scrupulous decontamination occurs between patients. Gastrointestinal endoscopy is unlikely to be a vector for the transmission of sporadic CJD because the infected material (CNS and retina) is not breached during the procedure.
- In v CJD the lymphoreticular system throughout the body may contain significant levels of infectivity during the incubation period.
- Any endoscopic procedure that breaches gut mucosa and is followed by the withdrawal of an unsheathed accessory through the working channel of an endoscope is deemed "invasive". Procedures that cause tissue vaporisation (diathermy) are also deemed invasive.
- The performance of an "invasive" procedure in a patient with known, suspected or at risk of variant CJD, will necessitate the subsequent quarantining of the endoscope used.
- Endoscopic procedures carried out on most asymptomatic patients "at increased risk" of CJD, where contact with medium risk gut lymphoid tissue may have occurred and be decontaminated and reprocessed according to best practice.
- If a patient with suspected vCJD is inadvertently scoped, or a patient with suspected vCJD is retrospectively discovered, the instrument used should be quarantined.
- Action following a report of a new case of CJD or a person at increased risk of CJDPHE Guidance January 2014 must be followed. Additional resources and advice can be accessed via Public Health England website .
- If vCJD is diagnosed the scope should be quarantined or sent to the National CJD Surveillance Unit for research purposes, or for dedicated use for patients known to have vCJD. If a unit keeps a quarantined endoscope they should inform nearby units.
- It is possible to obtain special endoscopes for patients known to have vCJD from the National CJD Surveillance Unit in Edinburgh (Tel: 0131 537 1868; email elaine.lord@ed.ac.uk).
- The British Society of Gastroenterologists advise a biopsy should only be taken if absolutely necessary and then disposable biopsy forceps and port rubber cap should be used.
- Rubber valves covering the working channel must be discarded after all procedures involving the passage of biopsy forceps, guidewires and/or other accessories through the endoscope. The optimum method for decontaminating air/water and suction valves is currently under review.

- Manual cleaning is essential; the channels should be brushed through with a single use purpose-made catheter or brush tipped wire assembly that is of an appropriate length and diameter for each channel.
- Reusable accessories should only be used in situations where no single use equivalent accessory exists (e.g. oesophageal bougies) and procedures should be available for tracking each patient use in these circumstances.
- All units should have a process for tracking equipment used during each procedure in the event that a patient is subsequently suspected of having, or being at risk of, the disease.
- Rigid metal sigmoidoscopes and proctoscopes should be thoroughly cleaned and then autoclaved.
- For more detailed guidance on endoscopy refer to **Guidance from the Advisory Committee on Dangerous Pathogens and SEAC (2003) Transmissible Spongiform encephalopathy agents: Safe working and the prevention of infection Annex F (updated October 2015) and BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy**

3.6 Maternity Care

- Childbirth should be managed using standard infection prevention procedures and single use instruments. The placenta and all other associated fluids and materials are designated low risk and disposed of as clinical waste.

3.7. Dental Care

- The risks of transmission of infection from dental instruments are thought to be very low provided optimal standards of infection prevention and decontamination are met.
- Instruments used on patients with known or suspected disease can be handled in the same way as those used in other low risk surgery, that is reprocessed according to best practice and returned to use – see Algorithm (Appendix IV).
- The Spongiform Encephalopathy Advisory Committee (SEAC) in 2006 recommend endodontic reamers and files were considered to be single use because these instruments cannot be reliably decontaminated. This was endorsed by the Chief Dental Officer for England in April 2007.
- In 1999 the Department of Health recommended that difficult to clean instruments which in dentistry include matrix bands should be single use.
- Dentists are reminded that any instrument labelled as ‘single use’ by the manufacturer must not under any circumstance be reused.
- Dentists are reminded that information about patients ‘at risk’ of CJD should be included in any surgical referral and recorded in their notes. Head and neck surgery may involve contact with tissues of high/medium infectivity.

3.8. Management of the Deceased Patient

- If the patient is known or suspected of having a TSE the mortuary must be informed
- Post mortem - contact lead histopathologist or mortuary for advice

3.9. Caring for the patient in the community

- No special measures over and above standard infection control precautions are necessary.
- Those caring for patients at home should be advised of the standard infection control practices that would apply to any patient.

4. ROLES AND RESPONSIBILITIES

- **The IPT** will work with Matrons, Clinical Directors, Clinical Leads, Heads of Specialties and infection prevention link staff to improve adherence to infection prevention guidelines / policies.
- **All staff** have a duty of care to the patients and themselves to ensure they deliver high standards of infection prevention practice at all times. Wherever they identify a deficiency in their knowledge they must inform their line manager who is responsible for ensuring the member of staff receives the appropriate training, education or advice.
- **Matrons, Clinical Directors, Clinical leads and Heads of Specialties** have a duty of care to ensure that staff receive education on all aspects of infection prevention.
- **Patients** have a responsibility to ensure that the lead clinician is aware if they are within any of the risk categories for any form of TSE.
- **The consultant/clinician in charge of clinically suspected CJD** has a responsibility to inform the local Consultant, Health Protection Unit and the National CJD Surveillance Unit.

5. TRAINING

5.1. No formal training is currently required. Should high risk activities commence within Solent NHS Trust training needs must be discussed with the IPT prior to introduction.

6. EQUALITY IMPACT ASSESSMENT AND MENTAL CAPACITY

6.1 An Equality Impact Assessment was conducted and no negative impact was identified. (See Appendix VI)

7. SUCCESS CRITERIA / MONITORING EFFECTIVENESS

7.1 Not currently applicable within Solent NHS Trust. Should high risk procedures be introduced services must follow this policy.

8. REVIEW

8.1 This document may be reviewed at any time at the request of either staff side or management, but will automatically be reviewed 3 years from initial approval and thereafter on a triennial basis unless organisational changes, legislation, guidance or non-compliance prompt an earlier review.

9. REFERENCES (AND LINKS TO OTHER DOCUMENTS

Guidance from the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee (2003 and 2011, Revision October 2015) Transmissible spongiform encephalopathy agents: Safe working and the prevention of Infection, The Stationery Office (also available on line at http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm

Public Health Action following a report of a new case of CJD or a person at increased risk of CJD : PHE Guidance January 2014 https://www.gov.uk/government/publications/cjd-public-health-action-following-report-of-new-case-or-person-at-increased-risk

TSE2000 HSC 1999/178. Variant Creutzfeldt Jakob Disease (vCJD): Minimising the Risk of Transmission. Department of Health. London (and http://www.open.gov.uk/doh/coinh.htm)

Creutzfeldt Jakob Disease: Guidance for Health Care Workers. Department of Health. London (and http://www.doh.gov.uk/cjd/cjdguidance.htm)

Royal College of Ophthalmology Creutzfeldt – Jakob Disease and Ophthalmology http://www.rcophth.ac.uk

National Institute for Health and Clinical Excellence Patient safety and reduction of risk of transmission of Creutzfeldt – Jakob disease (CJD) via interventional procedures November 2006

The vCJD Working Party of the Standing Advisory Committee on Transfusion Transmitted Infections. Creutzfeldt- Jakob Disease Policy statement 5th June 2006

Department of Health. Winning Ways: Working together to reduce healthcare associated infection in England. Report from the Chief Medical Officer. 2003

Department of Health Spongiform Encephalopathy Advisory Committee (SEAC): Position statement of vCJD and endodontic dentistry 2006.

Department of Health: Potential vCJD transmission risk via dentistry: an interim review Dec 2007

Health Building Note 13 (HBN) Sterile Services Departments, NHS Estates Publications

10. GLOSSARY

BSE Bovine Spongiform Encephalopathy
CNS Central Nervous System
EEG Electroencephalogram
HBN Health Building Note
IPT Infection Prevention Team
MRI Magnetic Resonance Imaging
PHE Public Health England
HSDU Hospital Sterilisation and Disinfection Unit
PrP Prion Protein
SEAC Department of Health Spongiform Encephalopathy Advisory Committee
TSE Transmissible Spongiform Encephalopathies
vCJD Variant Creutzfeldt Jacob Disease
CSF Cerebrospinal Fluid

Appendix I

Diagnostic Criteria for CJD

Cases should be classified by a neurologist from the National CJD Surveillance Unit on an on-going basis. It is recorded at four key stages.

- At notification
- When the patient is first seen by the neurologist
- The highest classification on the sole basis of clinical information – not including neuropathological information
- When the Surveillance Unit review is completed

Sporadic CJD

Definite	Neuropathological/ immunocytochemical confirmation needed
Probable	Rapidly progressive dementia with at least two of the following symptoms • Myoclonus • Visual or cerebellar problems • Pyramidal or extrapyramidal features • Akinetic mutism **Plus** typical EEG with generalised triphasic periodic complexes at approx 1 per second **Or** clinical criteria for possible sporadic CJD and a positive assay for 14-3-3 protein in the CSF
Possible	Rapid progressive dementia with two of the above symptoms and a duration of less than 2 years

Variant CJD

Definite	Progressive neuropsychiatric disorder and neuropathological confirmation of the disease showing spongiform change and extensive PrP^c deposition with florid plaques throughout the cerebrum and cellebellum
Probable	Can be classified under two sets of criteria: 1) Progressive neuropsychiatric disorder of longer than 6 months where routine investigations do not suggest an alternative diagnosis. Must have at least four of the following symptoms • Early psychiatric symptoms – depression, anxiety, apathy, withdrawal, delusions • Persistent painful sensory symptoms • Ataxia • Myoclonus or chorea or dystonia • Dementia EEG does not show the typical appearance of sporadic CJD AND there is a symmetrical high signal in the posterior thalamus on a MRI brain scan. There is no history of potential iatrogenic exposure 2)Progressive neuropsychiatric disorder of longer than 6 months where routine investigations do not suggest an alternative diagnosis. There is no history of potential iatrogenic exposure A tonsil biopsy is positive for PrP-res
Possible	Progressive neuropsychiatric disorder of longer than 6 months – routine investigations do not suggest an alternative diagnosis. Must have at least four of the following symptoms • Early psychiatric symptoms – depression, anxiety, apathy, withdrawal, delusions

	• Persistent painful sensory symptoms • Ataxia • Myoclonus or chorea or dystonia • Dementia EEG does not show the typical appearance of sporadic CJD

The CJD unit have three additional categories for patients who have been referred to the unit but do not meet the criteria for *possible* CJD

Diagnosis unclear
The diagnostic criteria are not met BUT there is no reasonable alternative diagnosis therefore CJD remains a possibility

CJD thought unlikely
Patient has atypical disease features/ atypical course/atypical clinical investigation results and/or a reasonable alternative diagnosis is made but not confirmed

Definitely not CJD
CJD is not the diagnosis and there is alternative definite diagnosis proven on the basis of clinical examination or investigation

Appendix II

Risk Assessment Questionnaire

1 *Have you any history of neurological disease in your family e.g. CJD or other prion disease?*	Notes to clinician Patients should be considered to be at risk from familial CJD if they have or have had • Genetic testing, which has indicated they are at significant risk of developing CJD or other prion disease • A blood relative is known to have a genetic mutation of indicative of familial CJD • Two or more blood relatives affected by CJD or other prion disease
2. *Have you ever received growth hormone or gonadotrophic treatment? If yes, was this in the UK before 1985 or did you receive this abroad?*	Notes to clinician Recipients of hormone derived from human pituitary glands e.g. growth hormone or gonadtotrophin have been identified as potentially at risk of CJD. In the UK, the use of human growth hormone was stopped in 1985 but human-derived products may have been continued to be used in other countries
3. *Did you have surgery on your brain or spinal cord before August 1992?*	Notes to clinician People who underwent neurosurgical procedures or operations for a tumour or cyst of the spine before August 1992 may have had a graft of dura mater and should be treated as at risk unless there is evidence dura mater was not used

Appendix III

Distribution of Tissue Infectivity
TSE Agents:Safe working and Prevention of Infection Annex A1 (updated 2012/2015)

Tissue Infectivity Levels		
High	**Medium**	**Low**
Brain	Olfactory epithelium	Anterior eye and cornea
Spinal cord	Spinal ganglion	Peripheral nerve
Dura mater		Dental pulp
Cranial nerves	**Variant CJD only**	Gingival tissue
Cranial ganglia	Tonsil	Blood and bone marrow
Posterior eye procedures *	Appendix	CSF
Neuroendoscopy	Spleen and thymus	Placenta
Pituitary gland	Adrenal gland	Urine
	Other lymphoid tissues	Other tissues

* Posterior segment eye surgery is defined as any surgery or procedure that involves potential contact with the posterior hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve

Appendix IV: Summary of Precautions Advised for the Use of Endoscopes

(Annex F Revised and updated 2014))

A) Remove from use or Quarantine

1) Endoscopes used for certain procedures in the CNS or nasal cavity in patients with definite CJD/vCJD, asymptomatic patients at risk of CJD/vCJD or unknown diagnosis

2) Gastrointestinal endoscopes used for "invasive procedures" in patients with symptoms consistent with vCJD

3) Gastrointestinal endoscopes used for "invasive procedures" in patients at increased risk of vCJD because they have received blood products from a donor who went on to develop vCJD

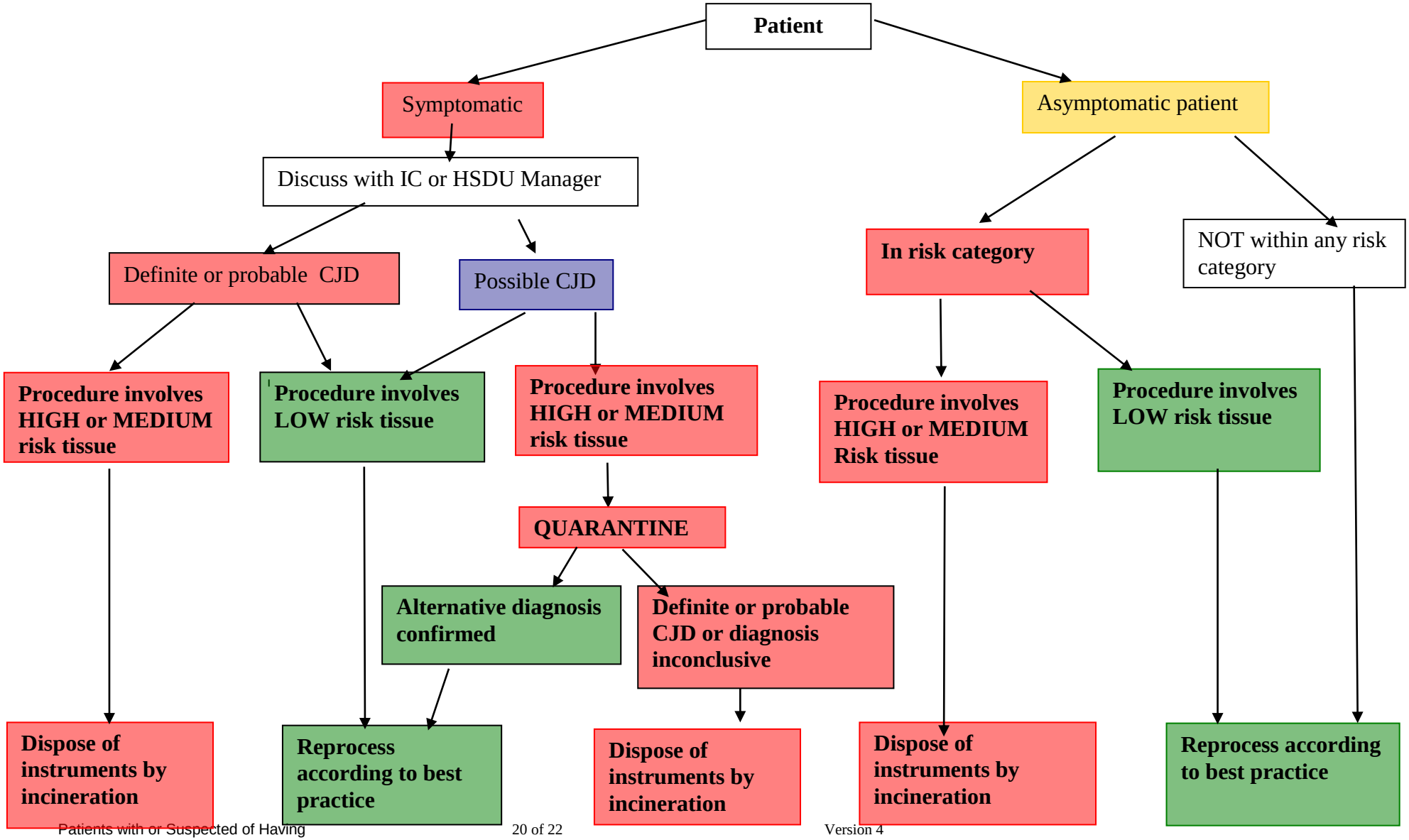
B) Reprocess according to Best Practice

1) Gastrointestinal endoscopes used for inspection, in the absence of "invasive procedures" is considered to be a low risk procedure

2) Gastrointestinal endoscopes used for "invasive procedures" in asymptomatic patients at increased risk of vCJD excluding those at increased risk because they have received blood products from a donor who went on to develop vCJD.

An invasive procedure *is an endoscopic procedure that breaches gut mucosa and is followed by the withdrawal of an unsheathed accessory through the working channel*

Appendix V: Algorithm for the Management of Instruments on known, Suspected or at Risk Patients



Appendix: VI Equality Impact Assessment

Step 1 – Scoping; identify the policies aims	Answer		
1. What are the main aims and objectives of the document?	To provide guidance to staff regarding how to minimise risk of transmission.		
2. Who will be affected by it?	Currently high risk procedures are not carried out within Solent NHS Trust services		
3. What are the existing performance indicators/measures for this? What are the outcomes you want to achieve?	This Overarching Policy is a national requirement upon all organisations		
4. What information do you already have on the equality impact of this document?	No high risk procedures are currently being undertaken within Solent NHS Trust		
5. Are there demographic changes or trends locally to be considered?	No		
6. What other information do you need?	None		
Step 2 - Assessing the Impact; consider the data and research	**Yes**	**No**	**Answer** (Evidence)
1. Could the document unlawfully discriminate against any group?		X	National Guidance
2. Can any group benefit or be excluded?		X	No high risk procedures currently being undertaken within Solent NHS trust
3. Can any group be denied fair & equal access to or treatment as a result of this document?		X	No high risk procedures currently being undertaken within Solent NHS trust
4. Can this actively promote good relations with and between different groups?		X	No high risk procedures currently being undertaken within Solent NHS trust
5. Have you carried out any consultation internally/externally with relevant individual groups?	X		Infection Prevention Group, Consultant Microbiologist
6. Have you used a variety of different methods of consultation/involvement	X		Email, face to face, meetings
7. Mental Capacity Act implications			
8. Will this document require a decision to be made by or about a service user? (Refer to the Mental		X	No high risk procedures currently being undertaken

Capacity Act document for further information)			within Solent NHS trust, Trust would follow National Guidance if adopting high risk procedures.

If there is no negative impact – end the Impact Assessment here.