The Royal Wolverhampton NHS Trust

IP21

Control and Management of Transmissible Spongiform Encephalopathies including Creutzfeldt Jakob Disease (CJD)

Contents

1.0 Policy Statement (Purpose / Objectives of the policy)

This policy provides advice on safe working practices with the aim of preventing the risk of Health Care occupational exposure to Transmissible Spongiform Encephalopathies (TSEs) and to prevent the transmission of TSEs. A summary is given in Attachment 1.

TSE describes a group of rare and fatal degenerative conditions of the central nervous system. TSEs are thought to be caused by infectious proteins known as prions. TSEs can occur in human and certain animal species. There is currently no known effective treatment or prophylaxis for TSEs.

The human TSE diseases occur in three groups.

- Idiopathic diseases - sporadic Creutzfeldt Jakob disease (CJD) and sporadic fatal insomnia.
- Familial disease – familial CJD, Gertsmann-Straussler-Scheinker disease (GSS) and Fatal Familial Insomnia (FFI).
- Acquired Diseases - human agents: kuru and iatrogenic CJD. Bovine agent: variant CJD (vCJD).

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

2.0 Definitions

- Healthcare Worker: a person who delivers healthcare and may be exposed to risk during the course of their duties.
- Decontamination: a process which removes or destroys contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to initiate a harmful response.
- Single Use: a medical device that must not be reprocessed or re-used under any circumstances.
- Source Isolation: the segregation of individuals who are deemed to pose a risk of infection to others.
- Standard Precautions: a set of precautions used to minimise risk of transmission of infection from a patient.
- Personal Protective Equipment: specialised clothing or equipment worn to protect against health and safety hazards, usually consisting of gloves, waterproof aprons, gowns, masks and visors.

3.0 Accountabilities

3.1 The Consultant Microbiologist/ Director of Infection Prevention and Control (DIPC)

- Ensuring that Guidance from the Department of Health and other expert groups is followed.
- Advising the Trust on the appropriate use of single use disposable equipment for any required invasive medical/surgical procedures.
- Notifying all confirmed or strongly suspected cases to the National CJD Research and Surveillance Unit (NCJDRSU) and the Consultant in Communicable Disease and Control (CCDC).

3.2 The Infection Prevention Team

- Arranging a tabletop review of cases identified.
- Updating the policy to reflect current guidance.
- Providing education to support the implementation of this policy.
- Alerting required staff of the need to implement actions in line with this policy.

3.3 Matrons

- Being fully aware of suspected or confirmed cases within their identified areas.
- Attending tabletop reviews relating to the cases.
- Ensuring Senior Sisters, Charge Nurses and departmental managers have a robust understanding of the policy and are held to account for any shortfalls.

3.4 Senior Sisters, Charge Nurses and Departmental Managers

- Ensuring that staff members in their area are aware of this policy.
- Facilitating education on the content of this policy.
- Alerting the Infection Prevention Team to potential breaches of this policy.
- Notifying the DIPC or, out-of-hours, the on-call Consultant Microbiologist if a patient has been identified as suspected CJD/vCJD.
- Ensuring that the healthcare professionals responsible for the patient's care are aware that they MUST ask ALL patients about to undergo elective or emergency surgery or endoscopy whether they have been notified that they are at increased risk of CJD/vCJD for public health purposes. This is to identify patients with known or suspected CJD, or potentially at risk of acquiring CJD, prior to an invasive procedure on high or medium risk tissues, or an intervention involving contact with the eye. In addition, patients undergoing surgery or neuro-endoscopy which may involve contact with "high risk tissues" must be assessed for their possible CJD and vCJD

risk exposure This assessment must be included in the initial patient consultation and the results placed into the patient's notes (Attachments 2 and 3).

- Ensuring that a Datix incident report is completed where employees have been exposed to CJD infective material.

3.5 Occupational Health and Wellbeing Department

- Keeping records of employees that are known to have been exposed to CJD infective material. Due to the length of incubation period of human TSEs, records must be kept for 40 years from the date of exposure.

3.6 Decontamination Lead

- Implementing systems and processes to ensure that decontamination of re-usable medical devices and surgical instruments takes place in appropriate facilities.
- Ensuring that staff are trained in decontamination processes and hold appropriate competencies for their role.
- Ensuring that there is a monitoring system in place to ensure that the decontamination processes are fit for purpose and meet the required standard.
- Ensuring there is an effective tracking system for all re-usable medical instruments and packs.
- Ensuring the isolation of surgical instruments used on patients at high risk of developing a TSE (see Section 4.1, Attachment 4).

3.7 Pathology Laboratories

- The laboratories MUST complete a COSHH assessment every 2 years for handling specimens from patients with known or suspected CJD, vCJD or another prion disease.
- Laboratories MUST follow standard operating procedures for handling specimens from patient known, suspected or at risk of having CJD.
- Special measures MUST be taken when handling Central Nervous System (CNS) specimens from known, suspected or at-risk patients. In patients with known or suspected vCJD, certain specimens outside of the CNS may also need to be handled with special precautions (see Table 1, Attachment 1).

An overview of the individual, departmental and committee responsibilities.

4.0 Policy Detail

4.1 TSEs occur in humans and certain animal species. There is currently no effective treatment or prophylaxis for TSEs.

4.2 Standard infection prevention precautions will minimise the exposure of healthcare workers involved in the care of patients who have, or may have developed, CJD or related disorders. There are a number of general measures to prevent the transmission of CJD and vCJD which must be undertaken. Attachment 5 details the areas covered and the measures to be taken. For patients with known or suspected CJD and vCJD, Attachment 4 details measures to be taken.

4.3 Detailed information regarding care of patients with or at increased risk of CJD or vCJD can be found at:

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

For practical advice for care workers and key workers who will be a named professional allocated to coordinate the care of the patient with a clinical diagnosis of CJD /vCJD in either a hospital or in a community setting please link to:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/427854/Infection_controlv3.0.pdf.

Practical advice on the development of care packages can be obtained from the National Care Coordinator at the CJD Surveillance Unit, Western General Hospital, Crewe Road Edinburgh Tel: 0131 537 2128.

The National Care Team | CJD (ed.ac.uk)

4.4 Annex J of the National guidance was revised in May 2013 to remove pre-surgical assessment of blood transfusion history for those undergoing surgery or neuro-endoscopy on high-risk tissue access link:

ANNEX J - PRE-SURGERY ASSESSMENT TO IDENTIFY PATIENTS WITH, OR AT RISK OF, CJD (publishing.service.gov.uk).

4.5 Guidance from the vCJD Clinical Governance Advisory Group available at https://www.gov.uk/government/collections/creutzfeldt-jakob-disease-cjd-guidance-data-and-analysis recommends that GPs should remain their clinical guardian and anchor supported by the consultant neurologist and the specialist national centres. The national CJD Research & Surveillance Unit (NCJDRSU) http://www.cjd.ed.ac.uk/ and the Medical Research Council Prion Unit at UCL, Institute of Prion Diseases **http://www.prion.ucl.ac.uk/clinic-services/**.

4.6 Part 3 of the National guidance, Laboratory containment and control measures, was updated in November 2021.

Laboratory containment and control measures (updated November 2021) (publishing.service.gov.uk).

5.0 Financial Risk Assessment

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

6.0 Equality Impact Assessment

An equality analysis has been carried out and it indicates that:

Tick	Options
X	There is no impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.
	There is some likely impact as identified in the equality analysis. Examples of issues identified, and the proposed actions include:

7.0 Maintenance

This policy will be reviewed by the Infection Prevention Team every 3 years. Earlier review may be required in response to exceptional circumstances, organisational change or relevant changes in legislation or guidance. The link to the website for the latest guidance will ensure the latest information is available.

8.0 Communication and Training

8.1 This policy will be communicated and circulated via the Infection Prevention and Control Group, the Divisional Leads and Matrons for dissemination in the Divisions. It will be available on the Trust intranet.

8.2 Any breaches of this policy which are not risk assessed, documented

and reported as identified must be reported according to the Trust's Incident Reporting Policy. Advice must also be sought from the Infection Prevention Team on the immediate remedial action necessary.

9.0 Audit Process

Criterion	Lead	Monitoring method	Frequency	Committee
If a suspected case or confirmed case is reported.	Infection prevention DIPC	Tabletop investigation and report	If a suspected or confirmed case were reported	IPCG

10.0 References

BSG Guidance for decontamination of equipment for gastrointestinal endoscopy (2017)

2020 Guidance on Decontamination of Equipment for Gastrointestinal Endoscopy - The British Society of Gastroenterology (bsg.org.uk)

Choice Framework for local policy and Procedures (CFPP) 01-06: Decontamination of endoscopes

Choice framework for local policy and procedures (CFPP) 01-01: part A. Management and decontamination of surgical instruments **https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148519/CFPP_01-01A_Final.pdf**

Collinge J (2001) Prion diseases of humans and animals: their causes and molecular basis. Annu Rev Neurosci. 2001; 24: 519-50.

Control of Substances Hazardous to Health Regulations (Sixth Edition): The Control of Substances Hazardous to Health Regulations 2002. Approved Code of Practice and Guidance. HSE Books. ISBN 0-7176-2534-6

Creutzfeldt-Jakob Disease International Surveillance Network https://www.eurocjd.ed.ac.uk/data_tables

DeArmond SJ, Prusiner SB (2003) Perspectives on prion biology, prion disease pathogenesis, and pharmacologic approaches to treatment. Clin Lab Med 23 (1): 1-41

Department of Health (2021) Minimise transmission risk of CJD and vCJD in healthcare settings

Department of Health, (2005) "The decontamination of surgical instruments in the NHS in England update report: A Step Change".

Department of Health, (2003) "Guidance from the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee"

Department of Health (Publications – 2008) Creutzfeldt-Jakob Disease (CJD)

November 2021- REVISED GUIDANCE

Guidance on prevention of CJD and vCJD by Advisory Committee on

Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Risk Management Subgroup Department of Health Updated 18 November 2021

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

Annexe A: Distribution of transmissible spongiform encephalopathy infectivity in human tissues and body fluids

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/444243/Annex_A1_update.pdf

Annexe B : Diagnostic criteria

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209761/Annex_B_-_Diagnostic_criteria.pdf

Annexe E: Quarantine of surgical instruments

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209764/Annex_E_-_Quarantining_of_surgical_instruments.pdf

Annexe F: Endoscopy

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/470292/ACDP_TSE_Annex_F_Oct_2015.pdf

Annexe H: After Death

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209766/Annex_H_-_After_death.pdf

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209773/Information_sheet_for_funeral_directors__relatives_and_others_following_a_CJD_death.pdf

Annexe J: Patient assessment prior to Surgery and or Endoscopy

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/270735/Annex_J_Assessment_to_be_carried_out_before_surgery_and_or_endoscopy_to_identify_patients_with__or_at_risk_of__CJD_or_vCJD.pdf

Annexe L: Ophthalmology

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209770/Annex_L_-_Managing_CJD_vCJD_risk_in_ophthalmology.pdf

Background Information for Healthcare Staff

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/727294/Information_for_people_who_have_an_increased_risk_of_CJD.pdf

Urology Surgeon Guidance note:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/427854/Infection_controlv3.0.pdf

http://www.prion.ucl.ac.uk/clinic-services/

Microsoft Word - Alert re. transrectal prostatic biopsy in men at risk of

vCJD - FINAL UPDATED (publishing.service.gov.uk)

Social Workers

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/719058/creutzfeldt-jakob_disease-guidelines-for-social-workers-in-england.pdf

Blood, tissue and organ donors: surveillance schemes

https://www.gov.uk/guidance/blood-tissue-and-organ-donors-surveillance-schemes

Lasmezas CI (2003) The transmissible spongiform encephalopathies. Rev Sci Tech 22 (1): 22-36.

Medical Devices Agency bulletin Decontamination of Endoscopes July 2002 MDA DB(05)

Medical Devices Agency (1999) Single use of ophthalmic medical devices: implications for clinical practice. MDA AN 1999 (04)

National CJD Research & Surveillance Unit, University of Edinburgh. Creutzfeldt-Jakob Disease Surveillance in the UK, 29th Annual Report 2019.

https://www.cjd.ed.ac.uk/sites/default/files/Report28.pdf

NICE Interventional procedures guidance IPG666 (January 2020) “Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues”.

Public Health England (2015) Public Health action following a report of a new case of CJD or a person at increased risk of CJD

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/474338/CJD_public_health_action_new_case_301015.pdf

World Health Organisation (2010) WHO tables on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies

https://www.who.int/bloodproducts/tablestissueinfectivity.pdf?ua=1

Royal Wolverhampton NHS Trust; Isolation Policy (IP10) 2021

Royal Wolverhampton NHS Trust; Linen Policy (IP05) 2021

Royal Wolverhampton NHS Trust; Decontamination of Re-usable Medical Devices Policy (HS12) 2020

Royal Wolverhampton NHS Trust: Management of Health & Safety (HS01) 2022

Royal Wolverhampton NHS Trust; Standard Precautions Policy (IP12) 2022

Royal Wolverhampton NHS Trust; Management of the Deceased Patient (OP20) 2020

Part A - Document Control

Policy number and Policy version: IP21 V6	**Policy Title:** Control and Management of Transmissible Spongiform Encephalopathies including Creutzfeldt Jakob Disease (CJD)	**Status: FINAL**		**Author: Infection Prevention Nurse** **Chief Officer Sponsor: Chief Nurse**
Version / Amendment History	Version	Date	Author	Reason
	1	June 2010	DIPC	Guidance required
	2	April 2013	DIPC	Updated DH guidance 2013
	3	July 2013	DIPC	Updated DH Guidance May 2013
	3.1	April 2014	DIPC	Reclassified from CP55 to **IP21** at request of DIPC – approved by PQAG 04/04/14
	4	Jan 2017	Infection Prevention Nurse	Review
	4.1	October 2019	Infection Prevention Nurse	Reviewed by Chief Nurse – extended to April 2020 pending full review
	5	Jan 2020	Infection Prevention Nurse	Review
	6	December 2022	Infection Prevention Nurse	Review

Intended Recipients:

- Healthcare staff in operating departments, endoscopy, ophthalmology, emergency departments, infection prevention, microbiology, laboratory staff, acute medical and surgical units, pre-assessment clinics and Central Sterile Supply Departments (CSSD).
- Those working in laboratories dealing with specimens from patients in whom CJD is confirmed or considered to be a 'possibility' or 'high possibility';
- Mortuary and funeral personal, who may need to deal with a confirmed or suspected CJD case

Consultation Group / Role Titles and Date:

Director of Infection Prevention (DIPC)
Consultant Microbiologists
Infection Prevention and Control Group

Name and date of Trust level group where reviewed	Infection Prevention & Control Group – November 2022 Trust Policy Group – February 2023
Name and date of final approval committee	Trust Management Committee – February 2023
Date of Policy issue	March 2023
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	February 2026 (3 yearly)
Training and Dissemination: This policy will be launched onto the IP Policy suite on Trust internet Senior managers will be informed at the Matron Group and IPCG. Staff will be informed of the IP policy suite at induction.	
To be read in conjunction with: Hand Hygiene IP01 Linen Policy IP05 Glove Policy IP09 Standard Precautions IP12 Waste Management Policy HS10 Decontamination of re-usable Medical Devices, Surgical Instruments and Scopes Policy HS12 Blood and body fluid Spillage Management Policy IP19 Management of the deceased patient OP20 Transportation of Clean and Contaminated Instruments, Equipment and Specimens Policy IP04	
Initial Equality Impact Assessment (all policies): Completed Yes **Impact assessment (as required): Completed Yes** If you require this document in an alternative format e.g., larger print please contact Policy Administrator 8904	
Monitoring arrangements and Committee	IPCG
Document summary/key issues covered. This policy provides advice on safe working practices with the aim of preventing the risk of occupational exposure to Transmissible Spongiform Encephalopathies (TSEs) and to prevent the transmission of TSEs.	
Key words for intranet searching purposes	TSE CJD Transmissible Spongiform Encephalopathies Creutzfeldt Jakob Disease

IP21 Attachment 1

Summary

The Infectious Agent and Distribution of TSE Infectivity in Human Tissue and Body Fluids

Transmissible spongiform encephalopathies (TSEs), otherwise known as prion diseases, are rare, fatal, degenerative diseases affecting the central nervous system, that occur in humans and certain other mammals.

TSEs are in many ways unique, and they exhibit biological properties that are different from those of other microbial diseases. The exact nature of the infectious agent is not known; TSEs are currently thought to be caused by unconventional infectious proteins known as prions, which do not share the normal properties of viruses or bacteria.

TSE agents exhibit an unusual resistance to conventional chemical and physical (heat) decontamination methods.

TSE agents are not uniformly distributed in the tissues of the affected individuals. In general, during the clinical disease, CNS tissues (including the retina) pose the highest risk; lymphoid tissues, the cornea and dura mater are of lower risk, and body fluids and other tissues are of negligible risk.

There are several recognised TSEs, including Creutzfeldt-Jakob disease (CJD) in humans. The commonest form of CJD occurs as a sporadic disease, the cause of which is unknown, although genetic factors influence disease susceptibility.

The human TSEs have a pre-clinical phase that lasts for years. This is followed by a rapidly progressive dementia, loss of memory and personality changes or progressive unsteadiness or clumsiness. In most cases, death occurs within a few months of onset of symptoms and the patient is usually mute and immobile in the terminal stages of illness.

All human TSEs are very rare

The human TSEs occur in 3 groups:

• idiopathic diseases: sporadic CJD and sporadic fatal insomnia,

• familial diseases: familial CJD, Gerstmann-Sträussler-Scheinker disease (GSS) and fatal familial insomnia, and

• acquired diseases: human agents: kuru and iatrogenic CJD Bovine agent: Variant CJD.

The worldwide incidence of CJD is about 1 per million people each year. The usual age of onset for CJD is late middle age (average age 65 years). In 1996, however, a new variant of CJD (vCJD) was reported, affecting individuals in a younger age group with a relatively longer duration of illness (up to 2 years). As of July 2021, twenty-five years from the first descriptions of vCJD, 178 clinical cases of definite or probable vCJD have been reported in the UK. Cases of vCJD have declined over the last two decades, having reached a peak in 2000 with 28 recorded deaths. The last known UK case of vCJD was reported in 2016 with a clinical onset in 2014.

The other human TSEs are exceptionally rare, affecting approximately 1-10 people per 100 million per year.

Transmission

Whilst approximately 85% of CJD cases are sporadic (i.e., of unknown origin), 10 – 15% are familial in origin (i.e., inherited). Some cases, however, are the result of medical treatment (iatrogenic transmission). A number of cases of CJD have been associated with administration of hormones prepared from human pituitary glands and from the use of dura mater grafts. A case has been reported as being associated with corneal grafts. Iatrogenic transmission has also been identified following neurosurgical procedures with inadequately decontaminated instruments. Since 2003 there have been four cases of presumed vCJD transmission through blood transfusions. All evidence suggests that both human and animal TSEs are **not** transmissible by normal social contact.

If TSEs could be transmitted in the occupational setting to staff, this would be most likely to occur from exposure to infected tissues by direct inoculation (e.g., puncture wounds, 'sharps' injuries or inoculation of broken skin), by splashing of the mucous membranes or, exceptionally, by swallowing. Taking the unique features of TSE into account, however, the exposure of employees and others to TSE agents must be minimized.

The likely infectivity associated with specific tissues is in Table A1 – Distribution of TSE infectivity in human tissues and body fluids Department of Health and Social Care guidance, Annex A1.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/444243/Annex_A1_update.pdf.

IP21 Attachment 2

FORM 1: PRE-ASSESSMENT QUESTIONNAIRE
For All Surgical and Endoscopy Patients

Patients who have been notified they are at increased risk of CJD or vCJD must be identified before surgery or endoscopy, thus allowing the appropriate infection control procedures to be followed.

All patients about to undergo any elective or emergency surgical or endoscopic procedure must be asked the following question:

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

Please complete patient details or insert label.

Name:				Consultant:	
Hosp No:		DOB:		Clinician completing form:	
Address:				Date:	
				Signature:	Stamp:

The actions to be taken following the patient's response to the above question are:

Patient Response	**Action Required**
No	Surgery or endoscopy can proceed using normal infection prevention procedures unless the procedure is likely to lead to contact with high-risk tissue. If this is the case, please refer to Attachment 3.
Yes	1. Please ask the patient to explain further the reason they were notified. 2. Special infection prevention precautions must be taken (please refer to Attachment 5 for further information). 3. Contact the Infection Prevention Team (IPT) for advice on ext. 88754
Unable to respond	Surgery or endoscopy can proceed using normal infection prevention procedures **unless** the procedure is likely to lead to contact with high-risk tissue. If this is the case, please refer to Attachment 3.

Name of IPT member contacted:	
Date:	
Time:	
Action advised/taken:	

Please retain this form in the patient's medical records for future reference.

IP21 Attachment 3

FORM 2: PRE-ASSESSMENT QUESTIONNAIRE
For those assessing patients for intradural and posterior ophthalmic surgical procedures, or for intradural neuro-endoscopic procedures, i.e., procedures likely to involve contact with tissues of potentially high-level infectivity (Posterior Eye, Spinal and ENT patients).

As well as asking all patients whether they have been notified as being at risk of CJD/vCJD for public health purposes (Attachment 2), clinicians assessing patients who are coming in for procedures that will involve contact with high-risk tissues must ask the supplementary questions from the table below to further assess CJD risk.

Tissues assumed or proven to have high level infectivity for CJD and vCJD are:

- Brain
- Spinal cord
- Implanted dura mater grafts prior to 1992
- Cranial nerves, specifically:
  - the entire optic nerve
  - the intracranial components of the other cranial nerves
- Cranial nerve ganglia
- Posterior eye
- Pituitary gland

Please complete patient details or insert patient label:

<table>
<tr><td>Name:</td><td colspan="3"></td><td>Consultant:</td><td></td></tr>
<tr><td>Hosp No:</td><td></td><td>DOB:</td><td></td><td>Nurse completing form:</td><td></td></tr>
<tr><td>Address:</td><td colspan="3"></td><td>Date:</td><td></td></tr>
<tr><td colspan="4"></td><td rowspan="2">Signature:</td><td rowspan="2">Stamp:</td></tr>
<tr><td colspan="4"></td></tr>
</table>

The following table outlines the questions to further assess CJD risk. The actions to be taken based on the patient's responses are outlined in the table following the questions. Record the patient's answers in the table. Appropriate actions are given overleaf.

No.	Question to Patient	Notes to Clinician	Patient response
1.	Have you any history of CJD or other prion disease in your family? Yes/No If yes, please specify.	Patient must be considered to be at risk from familial forms of CJD linked to genetic mutations if they have or have had: 1. Genetic testing, which has indicated that they are at significant risk of developing CJD or other prion disease; 2. A blood relative known to have a genetic mutation indicative of familial CJD; 3. 2 or more blood relatives affected by CJD or other prion disease.	
2.	Have you ever received growth hormone or gonadotrophin treatment? Yes/No If yes, please specify: a) whether the hormone was derived from human pituitary glands. Yes/No b) the year of treatment; c) 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 at any time in the past? Yes/No	Patients who underwent neurosurgical procedures or operations for a tumour or cyst of the spine **before August 1992** may have received a graft of *dura mater* and should be treated as at risk, unless evidence can be provided that *dura mater* was not used. Patients who received a graft of human-derived dura mater **before 1992** are at increased risk of transmission of sporadic CJD, but **not** vCJD.	

		NICE guidance emphasises the need for a separate pool of new neuroendoscopes and reusable surgical instruments for high-risk procedures on those born since 1st January 1997 and **who have not previously undergone high risk procedures**. These instruments and neuroendoscopes must 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 patient's response to the above questions are:

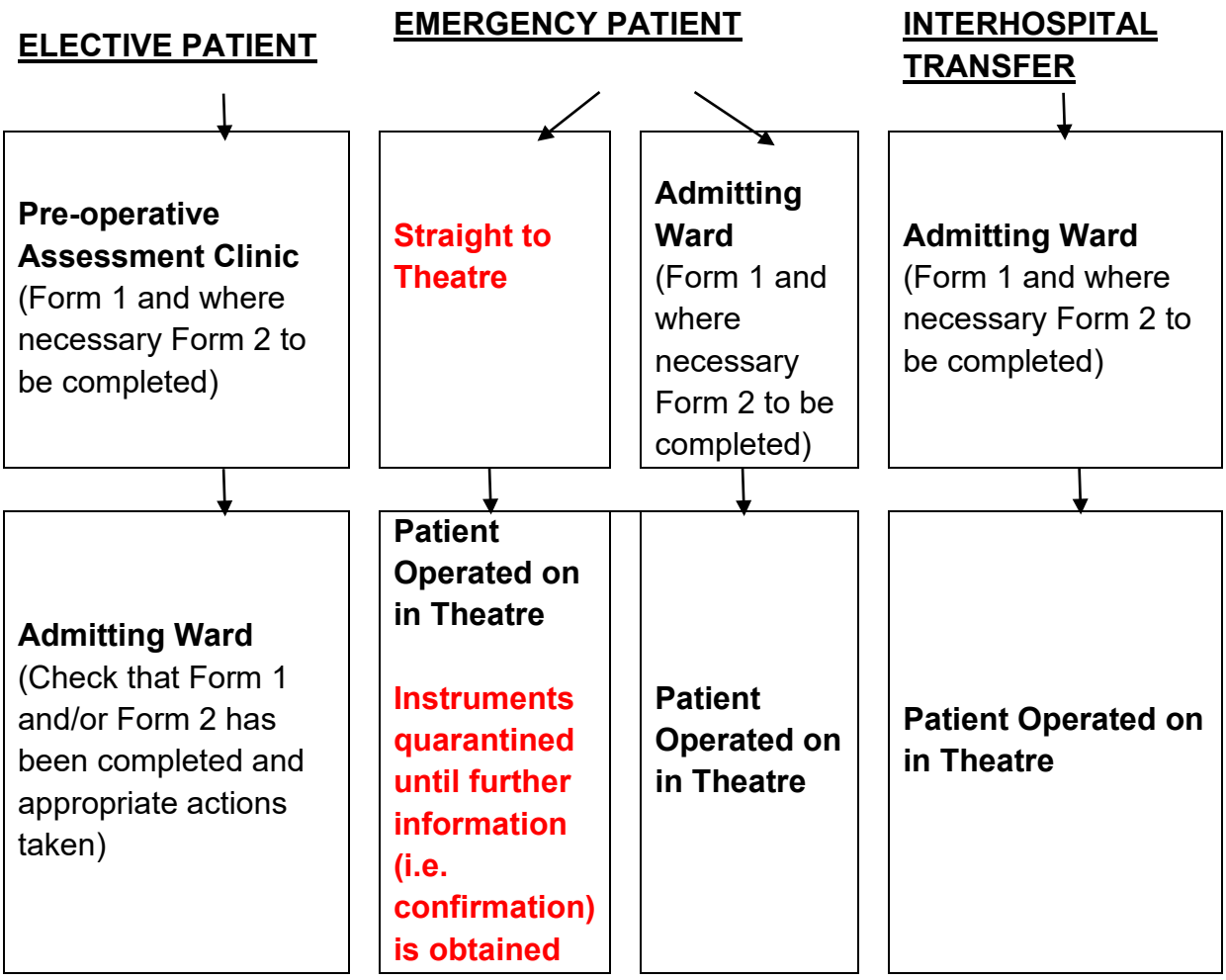
<table>
<tr><th>Patients Response</th><th>Action</th></tr>
<tr><td>No to ALL questions</td><td>Surgery or endoscopy can proceed using normal infection prevention procedures.</td></tr>
<tr><td>Yes to any of the questions 1, 2 or 3</td><td>1. Further questions into the nature of the patient's CJD risk must be asked by medical staff.
2. The patient's CJD risk must be confirmed or rejected. Confirmation or rejection of CJD risk must be recorded in the patient's medical notes for future reference.
3. If the patient is found to be at risk of CJD or vCJD following further questions, or the risk status is unknown at the time of the procedure, special infection control precautions must be taken. (Please refer to Attachment 5 for further information).
4. Please contact the Infection Prevention Team (IPT) for advice

<table>
<tr><td>Name of IPT member contacted:</td><td></td></tr>
<tr><td>Date:</td><td></td></tr>
<tr><td>Time:</td><td></td></tr>
<tr><td colspan="2">Action advised/taken:</td></tr>
<tr><td colspan="2"></td></tr>
</table>
If the patient is found to be at risk of CJD or vCJD they must be referred to their GP, who will need to inform them that they are at risk of CJD or vCJD and provide them with further information and advice.</td></tr>
</table>

	This is available from the CJD Section: UKHSA https://www.gov.uk/government/collections/creutzfeldt-jakob-disease-cjd-guidance-data-and-analysis
Unable to respond	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) must be asked the CJD risk questions (as set out in Attachment 3), prior to the 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 endoscopy can still proceed **but all instruments must be quarantined following the procedure.** The patient's GP must be contacted after the surgery or 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 Attachment 2.

Please retain this form in the patient's medical records for future reference.

When will the risk assessment take place?



IP21 ATTACHMENT 4

MEASURES TO BE TAKEN WITH KNOWN, SUSPECTED or AT RISK CJD AND vCJD PATIENTS

1. GENERAL MEASURES

1.1 Contact the Consultant Microbiologist or Infection Prevention Team if patients with or suspected of having CJD or vCJD are identified.

1.2 Normal social or routine clinical contact with CJD patients is not a risk to healthcare workers, visitors, or relatives in the community.

1.3 Isolation of patients with CJD is not necessary.

1.4 Notify all confirmed or strongly suspected cases to:

Creutzfeldt-Jakob disease (CJD) section, Public Health England
UK Health Security Agency
61 Colindale Avenue
London NW9 5EQ
Tel 020 8327 6090
Email: cjd@phe.gov.uk or PHE.cjd@nhs.net
Web: Creutzfeldt-Jakob disease (CJD): guidance, data and analysis - GOV.UK (www.gov.uk).

1.5 Spillage of blood or body fluids from a patient suspected or known to have CJD or another prion disease can be cleaned up following standard infection precautions. In exceptional circumstances (e.g., spillage of high or medium risk tissue, see Table 1, Attachment 1) the spillage must be disinfected with hypochlorite solution (10,000 ppm available chlorine; note: prevent splashes).

1.6 Blood specimens and specimens from the Central Nervous System (CNS), e.g., CSF, must only be collected by trained staff who are aware of the hazards.

1.7 Blood, tissue and CSF specimens from patients known, suspected, or at risk of CJD must be marked “Danger of Infection”. The suspected diagnosis must be indicated in clinical data on the request card. Care must be taken to maintain patients’ confidentiality.

1.8 Linen and patient care equipment that are contaminated with high infectivity tissues (see Table 1, Attachment 1) must be disposed of as clinical waste and incinerated. No special precautions are required for handling body fluids or body fluid contaminated linen and equipment.

1.9 Personal protective equipment must be worn if contact with blood, CSF and other body fluids are anticipated. This personal protective equipment will include water repellent gown, eye and face protection and disposable gloves.

1.10 If a known, suspect or at-risk patient becomes pregnant, childbirth must be managed using standard infection control precautions. Instruments must be handled as outlined below.

1.11 If the patient has had a surgical procedure deemed medium or high risk, the Outbreak/SI plan must be instigated (IP13).

2. SURGICAL PROCEDURES AND BRAIN BIOPSIES

2.1 When a patient is diagnosed with or suspected of having CJD, the Infection Prevention Team must be notified, and the patient's notes must be checked for details of any prior surgical intervention. If reusable surgical instruments have been used on a patient known to have CJD, they must be withdrawn from use and incinerated; if they have been used on a patient suspected of having CJD, the instruments must be put in quarantine until a definitive diagnosis has been made. The CJD Section, UKHSA must be informed by the DIPC or Microbiologist with details of the incident.

2.2 If surgical interventions are being considered, discuss the infection prevention measures with the Consultant Microbiologist. Single use instruments must be used wherever possible provided their use does not compromise patient safety.

2.3 Re-usable instruments used on high or medium-risk tissues on patients with a possible diagnosis of CJD of any type or used for a brain biopsy must be quarantined in a lockable cabinet situated in Nucleus Theatre pending confirmation of the diagnosis (see Tables 3 & 4 below). Inform the Trust Decontamination Unit Manager prior to the procedure).

2.4 If diagnostic high or medium-risk tissue samples are to be obtained from a patient with possible CJD, inform the laboratories prior to the procedure. The samples must be marked "Danger of Infection".

2.5 Patients at risk of vCJD requiring transrectal prostatic biopsy must have the procedure performed by means of single use equipment that runs alongside (rather than through) the ultrasound probe. Where a unit does not have such equipment and intends to carry out a biopsy procedure on a patient at risk of vCJD, their options are as follows:

- To refer the patient to a unit offering the alternative technique that does not pose a risk of contaminating the internal channels with traces of biopsy tissue;
- To borrow the alternative equipment from another unit;
- To undertake the procedure with equipment that has internal biopsy channels and quarantine the reusable components of that equipment after decontamination. It must be accepted that this equipment would be unlikely to return to general use, except for dedicated re-use in the same patient.

Table 3 CJD other than vCJD Table 3

Tissue Infectivity	Status of patient		
	Definite	Possible	Asymptomatic and at risk
High • Brain • Spinal Cord • Posterior eye	Destroy by incineration	Quarantine	Destroy by incineration
Medium • Olfactory epithelium	Destroy by incineration	Quarantine	Destroy by incineration
Low/non detectable	No special precautions	No special precautions	No special precautions

Table 4 Variant CJD (vCJD)

Tissue Infectivity	Status of patient		
	Definite	Possible	Asymptomatic and at risk
High • Brain • Spinal Cord • Posterior eye	Destroy by incineration	Quarantine	Destroy by incineration
Medium • Lymphoid tissue • Olfactory epithelium	Destroy by incineration	Quarantine	Destroy by incineration
Low/non detectable	No special precautions	No special precautions	No special precautions

2.6 Wherever possible any surgical intervention must be performed in an operating theatre. The procedure must be scheduled at the end of the list.

2.7 The number of health care personnel involved in the procedure must be kept to the minimum required for safe conduct of the procedure.

2.8 A one-way flow of instruments must be maintained during the procedure.

3.0 Endoscopy (Annex F)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/470292/ACDP_TSE_Annex_F_Oct_2015.pdf

3.1 Definitive UK guidance for decontamination of flexible endoscopes and TSE infection control and are complementary to national guidance Choice Framework for local Policy and procedures 01-06.

3.2 Every patient must have a risk assessment (see Attachment 2). People who do not have proven or suspected CJD / vCJD and are not flagged as at risk can proceed as normal.

3.3 For patients considered at risk either because of a possible diagnosis or identified as at risk from the risk assessment, Infection Prevention or a Microbiologist MUST be involved with the decision as to whether and how to proceed, based on Tables 5 & 6 below.

Table 5: CJD other than vCJD

Tissue infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/probable	Possible/diagnosis unclear	At risk iatrogenic/familial
High • Brain • Spinal cord	Single use OR destroy after use	Single use OR quarantine pending diagnosis	Single use OR destroy after use OR quarantine for re-use exclusively on same patient
Medium • Olfactory epithelium	Single use OR destroy after use	Single use OR quarantine pending diagnosis	Single use OR destroy after use OR quarantine for re-use exclusively on same patient
Low/none detectable • All other tissues	No special precautions	No special precautions	No special precautions

Table 6: vCJD

Tissue Infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/probable	Possible/diagnosis unclear	At risk /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 for re-use exclusively on same patient
Medium • Olfactory epithelium • Lymphoid tissue	Single use OR use dedicated endoscope OR remove from use	Single use OR quarantine pending diagnosis	Single use OR destroy after use OR quarantine for re-use exclusively on same patient
Low/none detectable All other tissues	No special precautions	No special precautions	No special precautions

3.4 Exclusive re-use of a flexible scope

The endoscope must be fully cleaned and decontaminated on its own in an Automated Endoscope Reprocessor (AER) then placed in quarantine with the patient's name, date of birth, hospital ID number, surgical procedure undertaken and the name of the clinician who performed the procedure.

4. QUARANTINING OF SURGICAL INSTRUMENTS (Annex E)

4.1 The Decontamination Lead must inform the Infection Prevention Team that sets/instruments will need to be held in quarantine in a lockable metal cabinet in the Nucleus Theatre. The sets/instruments must be stored in a sealed container labelled with the incident number allocated by the CJD Incident Panel, the date of surgical procedure and the date the sets/instruments were placed in quarantine. The decontamination lead will hold the keys to the lockable metal cabinet and will be responsible for ensuring safe storage.

4.2 Gross soilage must be removed from reusable surgical instruments using disposable paper towels and by staff wearing appropriate Personal Protective Equipment (PPE), then washed in theatre and placed in a sealable container before quarantine.

4.3 Single use items must be separated, placed in a yellow limb box and destroyed by incineration.

4.4 The Trust Decontamination Unit Manager must be given the details of the trays or instruments in quarantine for their information.

4.5 If the patient is confirmed as having CJD the instruments must be destroyed by incineration.

4.6 If an alternative diagnosis is made, the instruments can be released from quarantine after written approval by the DIPC and reprocessed in the usual way.

4.7 Records of all decisions made must be kept and the Trust Decontamination Unit manager must be informed of the final outcome before the instruments are sent for processing. The DIPC must inform the Trust Decontamination Unit manager in writing regarding whether the instruments have been released from quarantine for reprocessing or whether they have been destroyed, for their records. Instruments that have been quarantined for more than 5 years must be destroyed.

5. LABORATORY PROCEDURES

5.1 Each laboratory must complete a COSHH assessment at least every 2 years for handling specimens from patients known or suspected of having CJD, vCJD, or another prion disease.

5.2 Laboratories MUST follow standard operating procedures (if available) for handling specimens from patients known, suspected or at risk of having CJD or a related disorder. The Royal Wolverhampton NHS Trust Infection Prevention and Control Group will keep a copy of the standard operating procedures linked to the Code of Practice for HCAI 2015 on file.

5.3 Special measures must be taken when handling CNS specimens from known, suspect or at-risk patients. In patients with known or suspected vCJD, certain specimens from outside the CNS may also need to be handled with special precautions (see Appendix 1).

6. STAFF SURVEILLANCE

6.1 In the majority of clinical situations there is no significant risk of exposure to CJD of any type.

6.2 All staff handling tissues and specimens must receive training appropriate to their role.

6.3 Examples of staff who are at risk of significant exposure to CJD infective material include:

- All those involved in laboratory research work with the agent of CJD of any type;
- Any staff performing invasive clinical procedures on patients suspected to be suffering from CJD of any type, particularly where there is a risk of exposure to central nervous tissue or other tissues known to contain CJD infectivity;
- Laboratory staff handling tissue specimens from such patients, in either routine or specialist neuropathology laboratories;
- Staff undertaking post-mortem examinations of patients who have died of CJD or any type or where CJD of any type is suspected.

6.4 After any incident where employees have been exposed to CJD infective material, an adverse incident form must be completed.

6.5 The incident must be discussed with the Consultant Microbiologist who will carry out a risk assessment. If the risk assessment identifies significant exposure, the Occupational Health Department must keep a list of employees involved.

6.6 The list must include the type of work done and, where known, record of any significant exposure, accident or incident (some of which may be reportable under RIDDOR).

6.7 The list must be kept for at least 40 years after the last known exposure.

7. AFTER DEATH (Annex H)

7.1 Viewing the deceased - relatives, friends or carers of the deceased may wish to view or have some final contact with the deceased. Such viewing or superficial contact, such as touching or kissing need not be discouraged even if a post mortem has taken place. Body bags may be rolled down temporarily to allow superficial contact.

7.2 The body must be placed in a sealed cadaver bag and labelled “High – Risk or Danger of Infection”. The mortuary must be informed of the type of infection risk and this information must be passed onto the undertakers - see Management of Deceased Patient of Deceased Policy (OP20).

7.3 If a post-mortem is required this may be carried out in designated units, but any mortuary can carry out post-mortems on patients with CJD or other prion diseases provided that they follow the guidance given in;
Microsoft Word - Annex H FINAL revision May 2010 (publishing.service.gov.uk)

IP21 Attachment 5

1. GENERAL MEASURES TO PREVENT THE TRANSMISSION OF CJD and vCJD

1.1 Standard infection prevention precautions (see Infection Prevention Operational Policy IP08) will minimise the exposure of healthcare workers involved in the care of the patients who have, or may develop CJD or related disorders. Standard infection prevention precautions, which must be taken with all patients, will protect them from the theoretical risk of infection. The following guidance must be followed.

1.2 Personal Protective Equipment (PPE) must be worn when carrying out any procedures where contamination with blood or other body fluids is anticipated.

1.3 Before any invasive procedure on high or medium-risk tissue (see Attachment 1, Table 1) or any procedure involving contact with the eye, clinicians must identify patients with known or suspected CJD or those potentially at risk of acquiring CJD (see Table 2 below and pre-assessment questionnaire Attachment 3).

1.4 Special consideration must be given to diagnostic brain biopsies. This applies to all patients who have unexplained progressive dementia (or ataxia or neuro-psychiatric syndromes) and in whom neuroradiology shows no evidence of a space-occupying lesion. If a diagnostic brain biopsy is considered in such a patient, the same precautions must be taken as for possible CJD cases, even though the patient does not fulfil the World Health Organisation (WHO) criteria for probable or possible CJD. Indeed, CJD may not have been considered on clinical grounds.

2. Invasive Procedures – i.e., any procedures involving endoscopy or procedures where surgical instruments are used in body areas.

2.1 The Trust must have systems in place to ensure that all surgical instruments are thoroughly cleaned before sterilization and reuse. All reusable medical devices must be reprocessed by the Trust Decontamination Unit or by departments using a validated, accredited system; see Decontamination of Medical Devices Policy (HS12).

2.2 Instruments must be returned to the Trust Decontamination Unit and reprocessed as soon as possible after use. Where there is likely to be a delay (e.g., at the weekend and out of hours), processes such as the use of a purpose designed detergent spray must be used to keep instruments moist prior to the cleaning process and to prevent proteins from sticking to the surface.

2.3 Under no circumstances can any items marked “single use” be reused.

2.4 Single use kits must be used for:

a) lumbar punctures
b) epidurals and
c) any other procedure where a needle or trocar is introduced into the brain, spinal cord or eyes.

2.5 To comply with national guidance and recommendations, the Trust has introduced single use biopsy forceps for biopsies that are performed during flexible endoscopic procedures.

2.6 Where items are difficult to clean effectively, single use options must be used if they are available. This is especially important for instruments with fine lumens used in moderate and high-risk tissues (Attachment 1, Table 1).

2.7 Replace damaged instruments where the damage compromises the cleaning process.

2.8 A comprehensive medical history must be obtained for donors of blood, organs and tissue.

2.9 The Trust must develop a separate pool of reusable surgical instruments for high-risk procedures for use on individuals born since 1 January 1997. These instruments must not be used for patients born before 1 January 1997 or those who have previously undergone high-risk procedures.

3. INSTRUMENT TRACKING SYSTEMS

3.1 A robust system must be in place for the tracking of surgical instruments, and this must be audited. Local reprocessing of instruments must not routinely occur unless with prior approval by the Decontamination Lead.

3.2 The barcode label of instruments processed in the Trust Decontamination Unit must be placed in the patient's operation notes.

3.3 All flexible endoscopes must have a unique identifier, and this must be recorded in the patient's notes on every patient usage. A record of all instruments used and who they have been used on must be kept by each department.

3.4 In the exceptional circumstances where a bench top sterilisation is used, records must be kept of all instruments processed in autoclaves in accordance with the specific recommendations of the Decontamination Lead. These records must be kept in the department where the procedure was performed.

3.5 Instrument sets used in medium and high-risk tissues (see Attachment 4, Table 3&4) must not be split up or mixed. Supplementary instruments that come into contact with high-risk tissues must either be single use or remain with the set to which they have been introduced. There must be an adequate supply of instruments available to meet both regular and unexpected needs.

Categorisation of Patients at Risk for CJD Table 2

1. Symptomatic patients.	1.1 Patients who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD (see Annex B for diagnostic criteria) Annex B (publishing.service.gov.uk 1.2 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.
2. Asymptomatic patients at risk from familial forms of CJD linked to genetic mutations.	2.1 Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD or other prion disease. 2.2 Individuals who have a relative known to have a genetic mutation indicative of familial CJD. 2.3 Individuals who have or have had two or more blood relatives affected by CJD or other prion disease.
3 Asymptomatic patients identified as potentially at risk due to iatrogenic exposure.	3.1 Recipients of hormone derived from human pituitary glands e.g., growth hormone or gonadotrophin. In the UK, cadaver-derived human growth hormone was banned in 1985 but use of human-derived products may have continued in other countries. 3.2 Individuals who have received a graft of *dura mater*. (People who underwent neurosurgical procedures or operations for a tumour or cyst of the spine before August 1992 may have received a graft of *dura mater*, and should be treated as at risk, unless evidence can be provided that *dura mater* was not used.) 3.3 Patients who have been contacted as potentially at risk, including individuals considered to be: a) at risk of CJD/vCJD due to exposure to certain instruments used on a patient who went on to develop CJD/vCJD, or was at risk of vCJD; b) at risk of vCJD due to receipt of blood components or plasma derivatives;

	c) at risk of CJD/vCJD due to receipt of tissues/organs; d) at risk of vCJD due to the probability they have been the source of infection for a patient transfused with their blood who was later found to have vCJD.