

<b>Reference Number:</b> UHB 349 <b>Version Number:</b> 1	<b>Date of Next Review:</b> 2 <sup>nd</sup> Dec 2019 <b>Previous Trust/LHB Reference Number:</b> T39
<b>Creutzfeldt-Jakob Disease (CJD) and Variant CJD (Vcjd)</b> <b>Minimising the Risk of Transmission</b> <b>Infection Prevention &amp; Control Procedure</b>	
<b>Introduction and Aim</b>  <p>These guidelines are to assist in the identification and management of all aspects of infection risk involving CJD and vCJD, to enable staff to minimise the risk of transmission.</p>	
<b>Objectives</b> <ul style="list-style-type: none"> <li>• To provide guidance on the Infection Prevention and Control measures required to manage a patient in hospital and at home.</li> <li>• To assist with identification of patients known to have CJD / vCJD or to be “at risk of infection” prior to surgery / endoscopy.</li> <li>• To guide on actions required to manage surgical equipment and endoscopes being used on patients known to have CJD / vCJD or to be “at risk of infection”.</li> </ul>	
<b>Scope</b>  <p>This procedure applies to all staff in all locations including those with honorary contracts and students on placement at Cardiff and Vale UHB.</p> <p>Cardiff And Vale UHB accepts its responsibility under the Health and Safety at Work Act etc. 1974 and the Control of Substances Hazardous to Health Regulations 2002, to take all reasonable precautions to prevent exposure to hepatitis in patients, staff and other persons working at or using its premises.</p>	
<b>Equality and Health Impact Assessment</b>	An Equality and Health Impact Assessment (EHIA) has / been completed and this found there to be no impact.
<b>Documents to read alongside this Procedure</b>	Decontamination Policy Transmission Based Precautions Procedure Hand Decontamination Procedure Standard Precautions Procedure
<b>Approved by</b>	Infection Prevention & Control Group
<b>Accountable Executive or Clinical Board Director</b>	Director of Nursing
<b>Author(s)</b>	Director of IP&C

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**Disclaimer**

**If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the [Governance Directorate](#).**

<b>Summary of reviews/amendments</b>			
<b>Version Number</b>	<b>Date of Review Approved</b>	<b>Date Published</b>	<b>Summary of Amendments</b>
1	02/12/2016	23/02/2017	Procedure re-written due to numerous updates in the CJD field previous version was a Trust procedure

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# 1 INTRODUCTION

## 1.1 Key Points

- When caring for patients with suspected or confirmed CJD / vCJD Standard Infection Prevention and Control precautions are required, patients do not need to be isolated. Always wear gloves and apron when handling body fluids and eye protection if splashing of body fluids is likely.
- Pre-operative assessment of all patients due to have surgery or endoscopy should include the question: **“Have you ever been notified that you are at increased risk of CJD or vCJD for public health purposes?”**
- Pre-operative assessment of patients about to undergo elective or emergency surgical or neuro-endoscopic procedures likely to involve contact with tissues of potentially high level infectivity should include three more detailed supplementary questions in addition to the question above. (see page 14)
- Surgical equipment and endoscopes may need to be quarantined following use on a patient with known CJD or who is at risk of CJD – see tables below.

Detailed advice is available and regularly updated on the website linked below:  
<https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

# 2 GENERAL INFORMATION

## 2.1 What is CJD?

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

CJD in its classical form is the commonest of the human TSEs but it is still rare with an annual incidence across the world of 0.5 to 1 .0 cases per million population. In the UK about 60 cases are reported per year. The average age of onset of classical CJD is between 55 and 75 years. Classical CJD has no known cause in the majority of cases. However, about 10% of cases are inherited and are caused by gene mutations. About 1% in the past have been transmitted as a result of medical treatments such as human pituitary derived growth hormone injections, corneal transplants and brain surgery involving contaminated instruments.

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## 2.2 What is Variant CJD?

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

Analysis of the incidence data indicates that the vCJD epidemic reached a peak in mid-2000 and has since declined. However, it is important to note that although a peak has passed, it is possible that there will be future peaks, possibly in other genetic groups. There is also the possibility of ongoing person-to-person spread.

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

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

## 2.3 What are the Symptoms?

### ***a) Classical Sporadic Creutzfeldt-Jakob Disease***

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

### ***b) Variant Creutzfeldt-Jakob Disease***

Distinguishing features from classical sporadic CJD are:

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

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

## 2.4 Can Person-to-Person Spread Occur?

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

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

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

## 3 RISK ASSESSMENT

### 3.1 Patient risk groups

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

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**Table 1a Categorisation of patients by risk patient groups**

<b>Symptomatic patients</b>	<ul style="list-style-type: none"> <li>• Patients who fulfil the diagnostic criteria for definite, probable or possible CJD or</li> <li>• Patients with neurological disease of unknown aetiology, who do not fit the criteria for possible</li> <li>• CJD or vCJD, but where the diagnosis of CJD is being actively considered</li> </ul>
<b>Patients “at increased risk” from genetic forms of CJD</b>	<ul style="list-style-type: none"> <li>• Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD</li> <li>• Individuals who have a blood relative known to have a genetic mutation indicative of genetic CJD</li> <li>• Individuals who have or have had two or more blood relatives affected by CJD or other prion disease</li> </ul>
<b>Patients identified as “at increased risk” of vCJD through receipt of blood from a donor who later developed vCJD</b>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Patients identified as “at increased risk” of CJD / vCJD through iatrogenic exposures</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• However use of human –derived products may have continued in other countries after these dates.</li> <li>• Individuals who underwent intradural brain or intradural spinal surgery before August 1992 who received (or might have received) a graft of human-derived dura mater are “at increased risk” of transmission of sporadic CJD (unless evidence can be provided that human-derived dura mater was not used).</li> <li>• 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;</li> <li>• Individuals who have received an organ or tissue from a donor infected with CJD/vCJD or “at increased risk” of CJD/vCJD;</li> <li>• Individuals who have been identified as having received blood or blood components from 300 or more donors since January 1990;</li> <li>• Individuals who have given blood to someone who went on to develop vCJD;</li> <li>• Individuals who have received blood from someone who has also given blood to a patient who went on to develop vCJD;</li> <li>• Individuals who have been treated with certain implicated UK sourced plasma products between 1990 and 2001</li> </ul>

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

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## 4. HOSPITAL CARE OF CJD/vCJD PATIENTS

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

### 4.1 Sample taking and other invasive medical procedures

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

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

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

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

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

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

- use of disposable gloves and eye protection where splashing may occur;

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

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

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

## 4.2 Spillages

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

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

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

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

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

## 4.3 Clinical waste

General guidance on the safe management of clinical waste is given in the guidance document ‘Welsh Health Technical Memorandum 07-01: Safe Management of Healthcare Waste’, available at <http://www.wales.nhs.uk/sites3/Documents/254/WHTM%2007-01.pdf>

According to this guidance, “Waste known or suspected to be contaminated with transmissible spongiform encephalopathy (TSE) agents, including CJD, must be disposed of by high temperature incineration in suitable authorised facilities.”

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Additional guidance on the management of TSE-infected waste is given in the Department of Health's 'Transmissible spongiform encephalopathy: Safe working and the prevention of infection.'

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

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

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

#### **4.4 Childbirth**

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

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

#### **4.5 Bed linen**

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

#### **4.6 Occupational exposure**

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Although cases of CJD/vCJD have been reported in healthcare workers, there have been no confirmed cases linked to occupational exposure. However, it is prudent to take a precautionary approach.

The highest potential risk in the context of occupational exposure is from exposure to high infectivity tissues through direct inoculation, for example as a result of sharps injuries, puncture wounds or contamination of broken skin, and exposure of the mucous membranes.

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

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

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

#### **4.7 Surgical procedures and instrument management**

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

- Wherever appropriate and possible, the intervention should be performed in an operating theatre.
- Where possible, procedures should be performed at the end of the list, to allow normal cleaning of theatre surfaces before the next session.
- Only the minimum number of healthcare personnel required should be involved; Protective clothing should be worn, i.e. liquid repellent operating gown, over a plastic apron, gloves, mask and goggles, or full-face visor; this protective clothing should be single use and disposed of in line with local policies.
- Single-use disposable surgical instruments and equipment should be used where possible, and subsequently destroyed by incineration or sent to the instrument store.
- Effective tracking of re-usable instruments should be in place, so that instruments can be related to use on a particular patient.

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## 5. PRE-OPERATIVE / PRE-ENDOSCOPY ASSESSMENT

### 5.1 Assessment Questions

All patients about to undergo surgery or endoscopy should be asked if they have ever been notified as at risk of CJD or vCJD for public health purposes. In addition those patients about to undergo surgery or neuro-endoscopy which may involve contact with tissues of potentially high TSE infectivity should be assessed for risk through a set of detailed questions relating to possible exposure to CJD/vCJD (see table J1 below)

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

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

Actions to be taken based on the response are:

Patient's	Action
No	Surgery or endoscopy can proceed using the normal infection control procedures unless the procedure is likely to lead to contact with high risk tissue.
Yes	<p>Please ask the patient to explain further the reason they were notified. See Table <b>J1</b> for further questions</p> <p>Special infection control precautions should be taken for all surgery or endoscopy involving contact with medium or high infectivity tissues) and the local infection prevention &amp; control team should be consulted for advice.</p> <p>The patient's response should be recorded in their medical notes for future reference.</p>
Unable to respond	<p>Surgery and endoscopy can proceed using the normal infection control procedures unless the procedure is likely to lead to contact with high risk tissue.</p> <p>If this is the case, refer to precautions to be taken for high risk procedures</p>

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

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

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

Question to patient		Notes to clinician
1	Have you a history of CJD or other prion disease in your family? If yes please specify.	<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"> <li>▪ Genetic testing, which had indicated that they are at significant risk of developing CJD or other related prion disease</li> <li>▪ A blood relative known to have a genetic mutation indicative of genetic CJD or other prion disease</li> <li>▪ 2 or more blood relatives affected by CJD or other prion disease</li> </ul>
2	<p>Have you ever received growth hormone or gonadotrophin treatment?</p> <p>If yes, please specify:</p> <p>i. Whether the hormone was derived from human pituitary glands</p> <p>ii. The year of treatment</p> <p>iii. Whether the treatment was received in the UK or in another country</p>	<p>Recipients of hormone derived from human pituitary glands e.g. growth hormone or gonadotrophin, have been identified as at risk of CJD.</p> <p>In the UK, the use of human-derived growth hormone was <b>discontinued in 1985</b> 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 <b>discontinued in 1973</b> but may have continued in other countries after this time.</p>
3	Have you had surgery on your brain or spinal cord?	<p>(a) Individuals who underwent intradural brain or intradural spinal surgery before August 1992 who received (or might have received) a graft of human-derived dura mater are “at increased risk” of transmission of sporadic CJD (unless evidence can be provided that human-derived dura mater was not used).</p> <p>(b) NICE guidance emphasises the need for a separate pool of new neuroendoscopes and reusable surgical instruments for high risk procedures on children born since 1st January 1997 and <b>who have not previously undergone high risk procedures</b>. These instruments and neuroendoscopes should not be used for patients born before 1st January 1997 or those who underwent high risk procedures using reusable instruments before the implementation of this guidance.</p>

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

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

Patient's response	Action
No to all questions	Surgery or neuro-endoscopy can proceed using normal infection control procedures.
Yes to any of the questions 1, 2 or 3 in Table J1	<p>Further investigation into the nature of the patient's CJD risk should be undertaken, and the patient's CJD risk assessed. This assessment of CJD risk should be recorded in the patient's medical notes for future reference.</p> <p>If the patient is found to be at increased risk of CJD or vCJD following investigation, or the risk status is unknown at the time of the procedure, special infection control precautions should be taken for the patient's procedure including quarantining of instruments, and the local infection control team should be consulted for advice.</p> <p>If the patient is found to be at increased risk of CJD or vCJD they should also be referred to their GP, who will need to inform them of their increased risk of CJD or vCJD and provide them with further information and advice. This is available from Public Health England: <a href="http://www.hpa.org.uk/cjd">http://www.hpa.org.uk/cjd</a></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, Queen Square, London: <a href="http://www.nationalprionclinic.org/">http://www.nationalprionclinic.org/</a></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: <a href="mailto:L.Davidson@ich.ucl.ac.uk">L.Davidson@ich.ucl.ac.uk</a>, 020 7404 0536</p>
Unable to respond	See below

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

If the family member or someone close to the patient, is not able to provide a definitive answer to the CJD risk questions, the surgery or neuro-endoscopy should proceed but all instruments should be quarantined following the procedure (see table

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5a & 5b and point 5.3 below). The patient's GP should be contacted after the surgery or neuro-endoscopy, and enquiries made as to whether the patient is at increased risk of CJD/vCJD according to the questions as set out in **Table J1**.

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

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

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

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

The clinician undertaking the pre-surgery assessment should:

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

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

## 5.2 Handling of instruments – patients with, or “at increased risk” for CJD

**Tables 5a and 5b** separately set out the actions to be taken for instruments used on patients with, or “at increased risk” of, CJD/vCJD. The differences in instrument management are due to differences in tissue infectivities between CJD/vCJD. These actions are also summarised in the algorithm at the end of this document.

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**Table 5a: 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><b>High*</b></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 hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve</p> <p>Pituitary gland</p>	<p>Single use</p> <p>or</p> <p>Destroy</p> <p>or</p> <p>Quarantine for re-use exclusively on the same patient</p>	<p>Single use</p> <p>or</p> <p>Quarantine for re-use the same patient pending</p> <p>Diagnosis</p>	<p>Single use</p> <p>or</p> <p>Destroy</p> <p>or</p> <p>Quarantine for re-use exclusively on the same patient</p>
<p><b>Medium</b></p> <p>Spinal ganglia</p> <p>Olfactory epithelium</p>	<p>Single use</p> <p>or</p> <p>Destroy</p> <p>or</p> <p>Quarantine for re-use exclusively on the same patient</p>	<p>Single use</p> <p>or</p> <p>Quarantine for re-use exclusively on the same patient pending diagnosis</p>	<p>Single use</p> <p>or</p> <p>Destroy</p> <p>or</p> <p>Quarantine for re-use exclusively on the same patient</p>
<p><b>Low</b></p>	<p>No special precautions</p>	<p>No special precautions</p>	<p>No special precautions</p>

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**Table 5b: Handling of instruments – patients with, or “at increased risk” of vCJD**

Tissue Infectivity	Status of patient		
	Definite or probable	Possible	At increased risk
<b>High*</b> 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 hyaloid 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
<b>Medium</b> Spinal ganglia Olfactory epithelium Tonsil Appendix Spleen Thymus <b>Adrenal gland</b> <b>Lymph nodes and gut-associated lymphoid tissues</b>	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
<b>Low</b>	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

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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.

### 5.3 Quarantining of surgical instruments

Quarantining of instruments may be needed if they have been used for procedures involving tissues designated as high or medium infectivity, on patients either;

- with, or at increased risk of, CJD/vCJD, for reuse exclusively on the same patient; or
- with a possible CJD/vCJD diagnosis, pending a confirmed diagnosis.

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

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

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

Re-usable instruments that have come into contact with tissues designated as high or medium infectivity and that are intended to be quarantined should be washed to remove gross soil. Care should be taken to avoid splashing and generating aerosols, by holding instruments below the surface of the water in a sink into which water is running and draining out continuously, for example in a sink in the theatre sluice room. Instruments should not be held directly under a flowing tap as this is likely to generate splashes. Operatives should wear protective gloves and either a visor or goggles, and care must be taken to avoid penetrating injuries. The sink does not require high level decontamination afterwards – the dilution effect from the running water will be sufficient to remove contamination.

After washing, instruments should be placed on a disposable instrument tray and allowed to air-dry. They should then be placed in an impervious rigid plastic container with a close-fitting lid. The lid should be sealed with heavy duty tape and labelled with the patient's identification details (*i.e.* name, date of birth and hospital number). The label should also state the surgical procedure in which the instruments were used and the name of the responsible person (*e.g.* the Team or Unit Manager). The disposable instrument tray should be disposed of by incineration with normal clinical waste. The sealed box can be stored indefinitely in a suitable designated place until the outcome of any further investigations is known, or the instruments are required for another surgery on the same patient.

For patients with a possible CJD/vCJD diagnosis, if the patient is confirmed as suffering from CJD or vCJD, the box and its contents should be incinerated, or retained for use in research, without any further examination. If an alternative diagnosis is confirmed, the instruments may be removed from the box by the

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responsible person (or a named deputy) and reprocessed according to best practice and returned to use. Additional decontamination procedures are not required.

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

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

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

#### 5.4 Handling of Endoscopes – patients with, or “at increased risk” for CJD

The full guidance on CJD / vCJD and endoscopes is contained in Annex F of the ACDP guidance. Available via the link below:

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/470292/ACDP\\_TSE\\_Annex\\_F\\_Oct\\_2015.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/470292/ACDP_TSE_Annex_F_Oct_2015.pdf)

The general procedures set out in the *Welsh Health Technical Memorandum (WHTM) 01-06 – Decontamination of flexible endoscopes: Parts A - D* and the updated *BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy* (2013) should be followed.

In order to decrease the risk of transmission of TSEs through endoscopic procedures, additional precautions for the decontamination of flexible endoscopes used in all patients with definite, probable or possible CJD/vCJD, and in those identified as “at increased risk” of developing CJD/vCJD, are recommended:

- a. Channel cleaning brushes and, if biopsy forceps or other accessories have been passed, the rubber valve on the endoscope biopsy/instrument channel port should be disposed of as clinical waste after each use. Single use (i.e. disposable) biopsy forceps should be used routinely in all patients. This guidance endorses the advice of the BSG guidelines that endoscope accessories should be single use wherever possible. It is essential to have systems in place that enable endoscopes, together with all their detachable components and any reused accessories, to be traced to the patients on whom they have been used.
- b. As defined below, endoscopes used for certain procedures in the CNS and nasal cavity in individuals with possible sporadic CJD, or in whom the diagnosis is unclear, should be removed from use or quarantined pending diagnosis or exclusion of CJD. The principles and procedures recommended for

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quarantining of surgical instruments should be followed, except the endoscope should be fully cleaned and decontaminated immediately after use, before being quarantined.

- c. Endoscopes other than those used in the CNS and nasal cavity, which have been used for invasive procedures in most individuals designated as “at increased risk” of vCJD, can be decontaminated to the standards set out in *WHTM 01-06* and the *BSG guidelines* and returned to use. The endoscope should be put through all the normal stages of cleaning, and be disinfected separately from other equipment within an automated Endoscope Washer Disinfector (EWD).
- d. Aldehyde disinfectants with fixative qualities (such as glutaraldehyde and OPA) tend to stabilise rather than inactivate prions, and are no longer recommended for use in the UK. Non- fixative disinfectants are used instead.
- e. When decontaminating the endoscope cleaning equipment, the EWD should be put through an “empty” self-disinfection cycle as per recommended routine. Provided that the cleaning equipment is decontaminated as indicated, there is no known risk of transmission of TSE agents via this route.
- f. Following use in patients at risk of vCJD endoscopic accessories (including normally reusable devices such as heater probes) and cleaning aids such as brushes should be disposed of by incineration.

Prion protein has been detected in the olfactory epithelium, but not the respiratory epithelium, of sporadic CJD patients. The olfactory epithelium is normally located along the roof of the nasal cavity but its distribution varies between individuals. On the lateral wall it may extend inferiorly onto the superior turbinate and the anterior insertion of the middle turbinate; on the medial wall it may extend onto the uppermost part of the septum.

The advice of the consultant carrying out the endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination of the endoscope with olfactory epithelium can be excluded with confidence. If such contamination cannot be excluded, precautions should be taken appropriate for medium infectivity tissues.

#### **5.4.1 Symptomatic patients (possible sporadic, or diagnosis unclear but variant CJD is not being considered)**

Neurological endoscopes would not normally be used on patients whose diagnosis is possible CJD or for whom the diagnosis of CJD is unclear. However, should use be necessary, a single use endoscope should be used if possible. If this is not appropriate, the re-usable endoscope should be quarantined pending a more definitive diagnosis. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be removed from use.

Endoscopes that are used in the nasal cavity may, on occasion, be used in patients with CJD. If there is a risk that the endoscope could become contaminated with olfactory epithelium (see above), a single use endoscope should be used where possible. If this is not appropriate, the endoscope should be decontaminated singly as

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above, then quarantined pending a more definitive diagnosis. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be removed from use.

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

#### **5.4.2 Asymptomatic patients at increased risk of CJD (other than variant CJD)**

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

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

If there is a risk that an endoscope used in the nasal cavity could become contaminated with olfactory epithelium (see above), a single use endoscope should be used where possible. If this is not appropriate, the endoscope should be removed from use. Alternatively the endoscope can be quarantined after use to be re-used exclusively on the same individual patient if required. For some procedures, the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. However, this does not obviate the need for routine decontamination following use on a patient. Additionally, in practice, it may be difficult to ensure effective protection, and advice should be sought from the surgical staff carrying out the procedure and the manufacturer of the endoscope to determine the practicality of this option.

For all other types of endoscopy, decontaminate according to *WHTM 01-06* and the *BSG guidelines*.

#### **Variant CJD & CJD type uncertain**

##### **5.4.3 Symptomatic vCJD patients (definite, probable,)**

Neurological endoscopes would not normally be used on patients whose diagnosis is definite or probable vCJD. However, should such use be necessary, the endoscope should be single use if possible. If this is not feasible or appropriate, the endoscope should be removed from use.

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

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

#### **5.4.4 Symptoms consistent with vCJD (possible or unclear diagnosis)**

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

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

For all other types of endoscopy, providing decontamination of the endoscope is to approved standards, the use of the instrument for inspection in the absence of invasive procedures as defined in Table F2b within Annex F (link above), is deemed to be a low risk procedure. If an invasive procedure is carried out, the possibility of contamination of the instrument channel with lymphoid tissue means the endoscope should be decontaminated singly as above, then quarantined pending assessment of likely contact with potentially infected tissue. If this is considered possible and an alternative diagnosis is not obtained, the endoscope should be removed from use.

#### **5.4.5 Asymptomatic patients “at increased risk” through receipt of labile blood components (whole blood, red cells, white cells or platelets) from a donor who later developed vCJD)**

No special precautions are required for the use, of rigid endoscopes without lumens that can be autoclaved. The guidance for all surgical instruments can be followed.

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

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

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

**5.4.6 All other asymptomatic patients at increased risk of vCJD (This group includes people with inherited bleeding disorders such as haemophilia.)**

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

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

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

For all other types of endoscopy, decontaminate according to *WHTM 01-06* and the *BSG guidelines*. The endoscope should be put through all the normal stages of cleaning, and be disinfected separately from other equipment within an automated Endoscope Washer Disinfector (EWD).

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#### **5.4.7 Endoscopes currently in quarantine**

Advice is given below regarding endoscopes that have been held in quarantine following previous use on patients who are “at increased risk” of vCJD.

Endoscopes that have been placed into quarantine on or after 1 January 2010, assuming they have not been used to treat patients with or at risk of CJD / vCJD that has resulted in endoscope contact with high risk tissues, olfactory epithelium, or an invasive procedure in the gut for vCJD, should be reviewed as follows:

- 1) Was the endoscope properly decontaminated using a validated process prior to quarantine?
- 2) Is there tracking to demonstrate (1)?
- 3) Has the endoscope been stored properly whilst in quarantine (in a drying cabinet or at least positioned vertically, not coiled up in a case)?

If all of the above are met, the endoscope can be returned to use. If the endoscope has been out of use for more than a few months it is recommended that it is returned to the manufacturer for service and a check of handling characteristics before returning to use.

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## SUMMARY OF PRECAUTIONS ADVISED FOR THE USE OF ENDOSCOPES

**Table 5c. CJD other than vCJD Tissue**

Infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/ probable	Possible / diagnosis unclear <sup>1</sup>	At risk <sup>2</sup> inherited/ iatrogenic
<b>High:</b> • Brain • Spinal cord	single use OR destroy after use	single use OR quarantine pending diagnosis	single use OR destroy after use OR quarantine <sup>3</sup> for re-use exclusively on same patient
<b>Medium:</b> • Olfactory epithelium*	single use OR destroy after use	single use OR quarantine pending diagnosis	single use <sup>4</sup> OR destroy after use OR quarantine <sup>3</sup> for re-use exclusively on same patient
<b>Low/none detectable:</b> • All other tissues	no special precautions <sup>5</sup>	no special precautions <sup>5</sup>	no special precautions

### Notes

\* The advice of the consultant carrying out the endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination of the endoscope with olfactory epithelium can be excluded with confidence. If such contamination cannot be excluded, take precautions appropriate for medium infectivity tissues.

1. This includes patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD but where a diagnosis of CJD is being actively considered.
2. This advice refers to the use of flexible endoscopes in patients at risk of developing CJD. For guidance on the use of rigid endoscopes that can be autoclaved, refer to the guidance for the use of all surgical instruments in at risk patients in this guidance.
3. Quarantined endoscopes may be re-used exclusively on the same individual patient if required. The principles behind the procedures recommended for quarantining of surgical instruments should be followed except the endoscope should be fully cleaned and decontaminated immediately after use, before being quarantined. The endoscope should be decontaminated alone using an Automatic Endoscope Washer Disinfector (EWD). The EWD should be decontaminated as per this guidance.
4. For some procedures, the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. However, this does not obviate the need for routine decontamination following use on a patient. Additionally, in practice, it may be difficult to ensure effective protection, and advice

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should be sought from the surgical staff carrying out the procedure and the manufacturer of the endoscope to determine practicality.

- The decontamination procedures advised taken together with the **WHTM 01-06** and **BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy** (2013), should be followed.

**Table 5d. vCJD and CJD type uncertain**

Tissue Infectivity	Status of patient			
	Symptomatic		Asymptomatic	
	Definite /probable	Possible vCJD, possible sCJD or diagnosis unclear <sup>1</sup>	At risk (blood <sup>***</sup> recipient from a donor who later developed vCJD)	At risk <sup>2</sup> Other iatrogenic <sup>**</sup>
<b>High:</b> • Brain • Spinal cord	single use OR destroy after use	single use OR quarantine pending diagnosis	single use OR destroy after use OR quarantine <sup>4</sup> for re-use exclusively on same patient	single use OR destroy after use OR quarantine <sup>4</sup> for re-use exclusively on same patient
<b>Medium:</b> • Olfactory epithelium* • Lymphoid tissue**	single use <sup>5</sup> OR use dedicated endoscope <sup>6</sup> OR remove from use	single use <sup>5</sup> OR quarantine pending diagnosis	single use OR destroy after use OR quarantine <sup>3,4</sup> for re-use exclusively on	no special precautions
<b>Low/none detectable:</b> • All other tissues	no special precautions <sup>7</sup>	no special precautions <sup>7</sup>	no special precautions <sup>7</sup>	no special precautions <sup>7</sup>

**\*\* This group includes people with inherited bleeding disorders such as haemophilia.**

The advice of the consultant carrying out the endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination of the endoscope with olfactory epithelium can be excluded with confidence. If such contamination cannot be excluded, take precautions appropriate for medium infectivity tissues.

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

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

1. This includes patients with neurological disease of unknown aetiology who do not fit the criteria for possible vCJD but where a diagnosis of vCJD is being actively considered.
2. This advice refers to the use of flexible endoscopes in patients at risk of developing vCJD. For guidance on the use of rigid endoscopes that can be autoclaved, refer to the guidance for the use of all surgical instruments in at risk patients.
3. Flexible gastrointestinal endoscopes may be suitable for refurbishment by their manufacturers/distributors to allow their return to later use. This refurbishment process may be considered as an alternative to quarantining the instrument if a flexible gastrointestinal endoscope has been used in the performance of an invasive procedure in patients at risk of vCJD because they received blood from a donor who later developed vCJD. Refurbishment is not available for endoscopes that have been used for invasive endoscopy in patients with definite or probable vCJD. The decision to undertake refurbishment will be made on a case by case basis by the manufacturer/distributor, taking into account the age and condition of the endoscope, the reprocessing methods and methods of storage following last use.
4. Quarantined endoscopes may be re-used exclusively on the same individual patient if required. The principles behind the procedures recommended for quarantining of surgical instruments should be followed except the endoscope should be fully cleaned and decontaminated immediately after use, before being quarantined. The endoscope should be decontaminated alone using an Automated Endoscope Washer Disinfector (EWD). The EWD should thereafter be decontaminated as per this guidance.
5. For some procedures, the working channel of the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. However, this does not obviate the need for routine decontamination following use on a patient. Additionally, in practice, it may be difficult to ensure effective protection and advice should be sought from the surgical staff carrying out the procedure and the manufacturer of the endoscope to determine practicality.
6. The NCJDRSU holds a few flexible endoscopes dedicated for use on probable vCJD cases. If these are suitable for the clinical purpose intended, they may be borrowed from the Unit. They should not be used on patients with possible vCJD, patients for whom the diagnosis of vCJD is unclear or patients at risk of vCJD.
7. The decontamination procedures advised in this guidance, taken together with the **WHTM 01-06** and **BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy** (2013) should be followed.

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## **6. COMMUNITY HEALTHCARE OF CJD PATIENTS**

People should not be dissuaded from routine contact with CJD patients as both CJD and vCJD are not thought to present a risk through normal social or routine clinical contact.

No special measures over and above standard infection prevention and control precautions are generally required for caring for CJD patients in the community, as it is unlikely that procedures will be adopted that will lead to contact with high or medium risk tissues.

### **6.1 Caring for symptomatic patients at home**

Those caring for patients at home should be advised of the standard infection prevention and control practices that would apply to any patient. They should be provided with disposable gloves, aprons, paper towels, waste bags and sharps containers, as appropriate. Provision should be made with the Local Authority for the removal and disposal of clinical waste and sharps from the home.

Late stage CJD patients may experience tissue breakdown and the development of extensive pressure sores. These lesions should be dressed regularly, using standard infection prevention and control precautions, and contaminated dressings disposed of as normal clinical waste.

### **6.2 Spillages**

It is assumed that all spillages in the community will be of low risk material, for example blood and urine. Standard infection prevention and control precautions should be followed to clear up spillages of material from patients with, or “at increased risk” of, CJD in the community. Spillages should be cleared up as quickly as possible, keeping contamination to a minimum. Disposable gloves and an apron should be worn when removing such spillages, goggles/ eye protection should be considered if risk of splashing. The surface should then be washed thoroughly with detergent and warm water.

For spillages of large volumes of liquid, absorbent material should be used to absorb the spillage. A number of proprietary absorbent granules are available for such use, including those containing sodium dichloroisocyanurate, but it should be noted that these do not deactivate TSE agents.

Any waste (including cleaning tools such as mop heads, and PPE worn) should be disposed of as normal clinical waste.

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## 7. ADDITIONAL INFORMATION

The Department of Health website below carries all the guidance on Prevention of CJD and vCJD produced by the Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Subgroup

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

List of guidance documents available on the website (as at 4<sup>th</sup> July 2016)

- Health and Safety Management of Transmissible Spongiform Encephalopathy (TSE).
- Laboratory containment and control measures.
- Infection Control of CJD, vCJD and other human prion diseases in healthcare and community settings.
- Annex A1: Distribution of TSE infectivity in human tissues and body fluids.
- Annex A2: Distribution of infectivity in animal tissue and body fluids.
- Annex B: Diagnostic criteria
- Annex C: General principles of decontamination and waste disposal
- Annex D: Transport of TSE infected material
- Annex E: Quarantining of surgical instruments
- Annex F: Endoscopy
- Annex H: After death
- Annex I: Outline protocol for management of instruments and tissues from brain biopsy procedures.
- Annex J: Assessment to be carried out before surgery and / or endoscopy to identify patients with, or at risk of CJD / vCJD.
- Annex K: Guidelines for pathologists and pathology laboratories for the handling or tissues from patients with, or at risk of CJD / vCJD.
- Annex L: Managing CJD / vCJD risk in ophthalmology
- Annex M: Managing vCJD risk in general surgery and liver transplantation.
- CJD guidance for ophthalmologists.
- Information sheet for funeral directors, relatives and others following a CJD death.
- Alert to urological surgeons regarding the equipment used for patients at risk of vCJD requiring trans-rectal prostatic biopsy.
- Frequently asked questions.

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## 8. NOTIFICATION OF NEW CASES OF CJD TO THE CJD SURVEILLANCE UNIT IN EDINBURGH

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

Contact details for the CJD Surveillance Unit are:-

Professor R G Will  
 Director  
 National CJD Surveillance Unit  
 Western General Hospital  
 Crewe Road  
 Edinburgh  
 EH4 2XU

Tel: 0131 537 2128

Fax: 0131 343 1404

## 9. MANAGEMENT OF A POSSIBLE EXPOSURE TO CJD THROUGH MEDICAL PROCEDURES

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

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

Advice should be sought at the earliest opportunity when an incident is identified. Within Cardiff and Vale UHB, this should be done with full involvement of the Infection Prevention & Control Team, and local Consultant in Communicable Disease Control.

## 10. NATIONAL ORGANISATIONS ABLE TO GIVE ADVICE

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

- Patients who are at increased risk of sporadic CJD due to receipt of human-derived growth hormone or gonadotrophin should be offered the opportunity of referral to the UCL Institute of Child Health, London. Contact: [L.Davidson@ich.ucl.ac.uk](mailto:L.Davidson@ich.ucl.ac.uk), 020 7404 0536
- The National CJD Surveillance Unit in Edinburgh can provide advice on all clinical and

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neuropathological aspects of CJD. It can be contacted at:

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

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

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

<http://www.nationalprionclinic.org/>

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

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

<http://www.cjdsupport.net/>

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

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

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## Equality & Health Impact Assessment for

### Creutzfeldt-Jacob Disease (CJD) and Variant CJD (Vcjd) Minimising the Risk of Transmission Infection Prevention & Control Procedure

**Please read the Guidance Notes in Appendix 1 prior to commencing this Assessment**

**Please note:**

- The completed Equality & Health Impact Assessment (EHIA) must be
  - Included as an appendix with the cover report when the strategy, policy, plan, procedure and/or service change is submitted for approval
  - Published on the UHB intranet and internet pages as part of the consultation (if applicable) and once agreed.
- Formal consultation must be undertaken, as required<sup>1</sup>
- Appendices 1-3 must be deleted prior to submission for approval

Please answer all questions:-

1.	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	IPCD Policy No 2
2.	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact details	Corporate Dr Eleri Davies Ext: 41772
3.	Objectives of strategy/ policy/ plan/ procedure/ service	<ul style="list-style-type: none"> <li>• To provide guidance on the Infection Prevention and Control measures required to manage a patient in hospital and at home.</li> <li>• To assist with identification of patients known to have CJD / vCJD or to be “at risk of infection” prior to surgery / endoscopy.</li> <li>• To guide on actions required to manage surgical equipment and endoscopes being used on patients known to have CJD / vCJD or to be “at risk of infection”.</li> </ul>
4.	Evidence and background information considered. For example <ul style="list-style-type: none"> <li>• population data</li> </ul>	An internet search was conducted on 15/02/17. The search revealed several equality impact assessments. Examples can be found by following the links below:

[http://www.cardiffandvale.wales.nhs.uk/portal/page?\\_pageid=253,73860407,253\\_73860411&dad=portal&\\_schema=PORTAL](http://www.cardiffandvale.wales.nhs.uk/portal/page?_pageid=253,73860407,253_73860411&dad=portal&_schema=PORTAL)

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	<ul style="list-style-type: none"> <li>• staff and service users data, as applicable</li> <li>• needs assessment</li> <li>• engagement and involvement findings</li> <li>• research</li> <li>• good practice guidelines</li> <li>• participant knowledge</li> <li>• list of stakeholders and how stakeholders have engaged in the development stages</li> <li>• comments from those involved in the designing and development stages</li> </ul> <p>Population pyramids are available from Public Health Wales Observatory<sup>2</sup> and the UHB's 'Shaping Our Future Wellbeing' Strategy provides an overview of health need<sup>3</sup>.</p>	<p><a href="http://www.dbh.nhs.uk/Library/Patient_Policies/PAT%20IC%20v%20-%20vCJD%20Policy%20-%20Final.pdf">http://www.dbh.nhs.uk/Library/Patient_Policies/PAT%20IC%20v%20-%20vCJD%20Policy%20-%20Final.pdf</a></p> <p><a href="http://www.rdash.nhs.uk/wp-content/uploads/2014/05/vCJD-and-TSE-Policy-v6-EIA.pdf">http://www.rdash.nhs.uk/wp-content/uploads/2014/05/vCJD-and-TSE-Policy-v6-EIA.pdf</a></p> <p><a href="http://webcache.googleusercontent.com/search?q=cache:frLIPMEwDKAJ:www.worcsacute.nhs.uk/EasysiteWeb/getresource.axd%3FAssetID%3D31185%26type%3Dfull%26servicetype%3DAttachme nt+&amp;cd=4&amp;hl=en&amp;ct=clnk&amp;gl=uk">http://webcache.googleusercontent.com/search?q=cache:frLIPMEwDKAJ:www.worcsacute.nhs.uk/EasysiteWeb/getresource.axd%3FAssetID%3D31185%26type%3Dfull%26servicetype%3DAttachme nt+&amp;cd=4&amp;hl=en&amp;ct=clnk&amp;gl=uk</a></p> <p><a href="http://www.rdehospital.nhs.uk/docs/patients/services/infection_control/creutzfeldt-jakob-disease-and-other-transmissible-spongiform-encephalopathies-policy.pdf">http://www.rdehospital.nhs.uk/docs/patients/services/infection_control/creutzfeldt-jakob-disease-and-other-transmissible-spongiform-encephalopathies-policy.pdf</a></p> <p><a href="https://www.hampshirehospitals.nhs.uk/media/233935/creutzfeldt-jakobdisease_cjd_policy.pdf">https://www.hampshirehospitals.nhs.uk/media/233935/creutzfeldt-jakobdisease_cjd_policy.pdf</a></p> <p><a href="http://www.newcastle-hospitals.org.uk/downloads/policies/Infection%20Control/CJDInfectionControlPolicy201310.pdf">http://www.newcastle-hospitals.org.uk/downloads/policies/Infection%20Control/CJDInfectionControlPolicy201310.pdf</a></p>
5.	Who will be affected by the strategy/ policy/ plan/ procedure/ service	These guidelines are to assist in the identification and management of all aspects of infection risk involving CJD and vCJD, to enable staff to minimise the risk of transmission

## 6. EQIA / How will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

<sup>2</sup> <http://nww2.nphs.wales.nhs.uk:8080/PubHObservatoryProjDocs.nsf>

<sup>3</sup> <http://www.cardiffandvaleuhb.wales.nhs.uk/the-challenges-we-face>

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<b>How will the strategy, policy, plan, procedure and/or service impact on:-</b>	<b>Potential positive and/or negative impacts</b>	<b>Recommendations for improvement/mitigation</b>	<b>Action taken by Clinical Board / Corporate Directorate.</b> Make reference to where the mitigation is included in the document, as appropriate
<b>6.1 Age</b> For most purposes, the main categories are: <ul style="list-style-type: none"> <li>• under 18;</li> <li>• between 18 and 65; and</li> <li>• over 65</li> </ul>	No negative impact	N/A	
<b>6.2 Persons with a disability as defined in the Equality Act 2010</b> Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes	No negative impact	N/A	
<b>6.3 People of different genders:</b> Consider men, women, people undergoing gender reassignment  <b>NB</b> Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender	No negative impact	N/A	
<b>6.4 People who are married or who have a civil partner.</b>	No negative impact	N/A	

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<b>How will the strategy, policy, plan, procedure and/or service impact on:-</b>	<b>Potential positive and/or negative impacts</b>	<b>Recommendations for improvement/mitigation</b>	<b>Action taken by Clinical Board / Corporate Directorate.</b> Make reference to where the mitigation is included in the document, as appropriate
<b>6.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding.</b> They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	No negative impact	N/A	
<b>6.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers</b>	No negative impact	N/A	
<b>6.7 People with a religion or belief or with no religion or belief.</b> The term 'religion' includes a religious or philosophical belief	No negative impact	N/A	
<b>6.8 People who are attracted to other people of:</b> <ul style="list-style-type: none"> <li>• the opposite sex (heterosexual);</li> <li>• the same sex (lesbian or gay);</li> <li>• both sexes (bisexual)</li> </ul>	No negative impact	N/A	

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<b>How will the strategy, policy, plan, procedure and/or service impact on:-</b>	<b>Potential positive and/or negative impacts</b>	<b>Recommendations for improvement/mitigation</b>	<b>Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate</b>
<p><b>6.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design</b></p> <p>Well-being Goal – A Wales of vibrant culture and thriving Welsh language</p>	No negative impact	N/A	
<p><b>6.10 People according to their income related group:</b> Consider people on low income, economically inactive, unemployed/workless, people who are unable to work due to ill-health</p>	No negative impact	N/A	
<p><b>6.11 People according to where they live:</b> Consider people living in areas known to exhibit poor economic and/or health indicators, people unable to access services and facilities</p>	No negative impact	N/A	
<p><b>6.12 Consider any other groups and risk factors relevant to this strategy, policy, plan, procedure and/or</b></p>	No negative impact	N/A	

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<b>How will the strategy, policy, plan, procedure and/or service impact on:-</b>	<b>Potential positive and/or negative impacts</b>	<b>Recommendations for improvement/mitigation</b>	<b>Action taken by Clinical Board / Corporate Directorate.</b> Make reference to where the mitigation is included in the document, as appropriate
<b>service</b>			

**7. HIA / How will the strategy, policy, plan, procedure and/or service impact on the health and well-being of our population and help address inequalities in health?**

Questions in this section relate to the impact on the overall health of individual people and on the impact on our population. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

<b>How will the strategy, policy, plan, procedure and/or service impact on:-</b>	<b>Potential positive and/or negative impacts and any particular groups affected</b>	<b>Recommendations for improvement/mitigation</b>	<b>Action taken by Clinical Board / Corporate Directorate</b> Make reference to where the mitigation is included in the document, as appropriate
<b>7.1 People being able to access the service offered:</b> Consider access for those living in areas of deprivation and/or those experiencing health inequalities  Well-being Goal - A more equal Wales	No negative impact	N/A	
<b>7.2 People being able to improve /maintain healthy lifestyles:</b> Consider the impact on healthy lifestyles, including healthy eating, being active,	No negative impact	N/A	

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<b>How will the strategy, policy, plan, procedure and/or service impact on:-</b>	<b>Potential positive and/or negative impacts and any particular groups affected</b>	<b>Recommendations for improvement/mitigation</b>	<b>Action taken by Clinical Board / Corporate Directorate</b> Make reference to where the mitigation is included in the document, as appropriate
<p>no smoking /smoking cessation, reducing the harm caused by alcohol and /or non-prescribed drugs plus access to services that support disease prevention (eg immunisation and vaccination, falls prevention). Also consider impact on access to supportive services including smoking cessation services, weight management services etc</p> <p>Well-being Goal – A healthier Wales</p>			
<p><b>7.3 People in terms of their income and employment status:</b> Consider the impact on the availability and accessibility of work, paid/unpaid employment, wage levels, job security, working conditions</p> <p>Well-being Goal – A prosperous Wales</p>	No negative impact	N/A	
<p><b>7.4 People in terms of their use of the physical environment:</b> Consider the impact on the availability and accessibility of transport, healthy food, leisure activities, green spaces; of the design of the built environment on the</p>	No negative impact	N/A	

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<b>How will the strategy, policy, plan, procedure and/or service impact on:-</b>	<b>Potential positive and/or negative impacts and any particular groups affected</b>	<b>Recommendations for improvement/mitigation</b>	<b>Action taken by Clinical Board / Corporate Directorate</b> Make reference to where the mitigation is included in the document, as appropriate
<p>physical and mental health of patients, staff and visitors; on air quality, exposure to pollutants; safety of neighbourhoods, exposure to crime; road safety and preventing injuries/accidents; quality and safety of play areas and open spaces</p> <p>Well-being Goal – A resilient Wales</p>			
<p><b>7.5 People in terms of social and community influences on their health:</b> Consider the impact on family organisation and roles; social support and social networks; neighbourliness and sense of belonging; social isolation; peer pressure; community identity; cultural and spiritual ethos</p> <p>Well-being Goal – A Wales of cohesive communities</p>	No negative impact	N/A	
<p><b>7.6 People in terms of macro-economic, environmental and sustainability factors:</b> Consider the impact of government policies; gross domestic product; economic development; biological diversity; climate</p>	No negative impact	N/A	

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<b>How will the strategy, policy, plan, procedure and/or service impact on:-</b>	<b>Potential positive and/or negative impacts and any particular groups affected</b>	<b>Recommendations for improvement/mitigation</b>	<b>Action taken by Clinical Board / Corporate Directorate</b> Make reference to where the mitigation is included in the document, as appropriate
Well-being Goal – A globally responsible Wales			

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**Please answer question 8.1 following the completion of the EHIA and complete the action plan**

<p><b>8.1 Please summarise the potential positive and/or negative impacts of the strategy, policy, plan or service</b></p>	<p>These guidelines are to assist in the identification and management of all aspects of infection risk involving CJD and vCJD, to enable staff to minimise the risk of transmission and in doing so ensure their safety and well being as well as those of patients</p>
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### **Action Plan for Mitigation / Improvement and Implementation**

	<b>Action</b>	<b>Lead</b>	<b>Timescale</b>	<b>Action taken by Clinical Board / Corporate Directorate</b>
<p><b>8.2 What are the key actions identified as a result of completing the EHIA?</b></p>	<p>No negative impacts identified therefore no actions identified</p>			
<p><b>8.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment required?</b></p> <p>This means thinking about relevance and proportionality to the Equality Act and asking: is the impact significant enough that a more formal and full consultation is required?</p>	<p>N/A</p>			

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	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
<p><b>8.4 What are the next steps?</b></p> <p>Some suggestions:-</p> <ul style="list-style-type: none"> <li>• Decide whether the strategy, policy, plan, procedure and/or service proposal: <ul style="list-style-type: none"> <li>○ continues unchanged as there are no significant negative impacts</li> <li>○ adjusts to account for the negative impacts</li> <li>○ continues despite potential for adverse impact or missed opportunities to advance equality (set out the justifications for doing so)</li> <li>○ stops.</li> </ul> </li> <li>• Have your strategy, policy, plan, procedure and/or service proposal approved</li> <li>• Publish your report of this impact assessment</li> <li>• Monitor and review</li> </ul>	<p>The EQIA process has not identified any evidence that different groups will be affected disproportionately or any evidence or concern that this procedure may discriminate against a particular population group.</p>			