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SPECIAL CONSIDERATIONS FOR ENDOSCOPY AND VARIANT CREUTZFELDT-JACOB DISEASE (VCJD) GUIDELINE	
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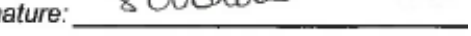
Authorised By Name: Sandra Morton Title: Clinical Nurse Manager III	*Signature:*  *Date: 14 / 2 / 2020*
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Update to: Purpose, Guideline, Procedure, Reference, Appendences	

CONTENTS

		Page Number
1.0	Purpose	03
2.0	Definition of Term	03
3.0	Responsibility	03
4.0	Guideline	03
5.0	Procedure	04
6.0	References	04
7.0	Appendices	05-12

1.0 Purpose

To ensure that the potential risk of transmission of vCJD is minimised. This advice differs depending on the type of CJD diagnosed or for which symptoms are being investigated and for those who are asymptomatic, but for whom an increased risk of developing the disease has been identified. It is important to note that the risks from sporadic CJD (sCJD) and variant CJD (VCJD) are different, as the distribution of infectivity in tissues and body fluids differs (Appendix 1).

2.0 Definition of Term

Creutzfeldt-Jacob Disease (CJD). One of the transmissible spongiform encephalopathies which can occur in people or animals. The disease is characterised by degeneration of the nervous system and is invariably fatal. The precise nature of the agent that causes CJD is not known, but the most likely theory implicates an abnormal form of protein called a "prion". The abnormal prion protein induces the normal protein to alter its shape. This leads to destruction of the nervous tissue. New variant (nvCJD) differs from classic CJD in its clinical presentation, younger age 19-42 years, and neuropathy. The Spongiform Encephalopathy Advisory Committee (SEAC) concluded that the most likely explanation for the emergence of nvCJD was that it had been transmitted to people through exposure to Bovine Spongiform Encephalopathy (BSE). The incubation period for nvCJD is lengthy, between 10-30 years. During this time the affected person has the potential to transmit the disease during the course of an endoscopic procedure. (AORN 2004, BSG 2003).

3.0 Responsibility

All staff involved in endoscopic procedures must ensure that the correct procedures are followed to minimise contamination and maximise cleaning.

4.0 Guideline

- Endoscopy should be avoided, whenever possible in patients with suspected or confirmed vCJD.
- It is the ultimate responsibility of the Consultant in Charge to inform the CNM III / CNM II (Co-Ordinator) / CNM II (Endoscopy) and the Infection Control Team.
- When an endoscopic procedure is deemed absolutely necessary the CNM III / CNM II / CNM I, Infection Control Team and Risk Management must be notified prior to the procedure being carried out.
- A dedicated scope must be used.
- Ideally single use equipment should be used.
- Endoscope is water sampled and quarantined until it is cleared.
- Thermal disinfection of the Endoscope Washer Disinfector (EWD) is done; water sample taken and machine wash done. Then the EWD is safe to use.

5.0 Procedure

- The Clinical Nurse Manager in Endoscopy and the Infection Control Team must be notified of the procedure to be performed. Adequate time must be given to allow the Endoscopy CNM II to decide which endoscope is to be used, prepare the room, obtain the necessary disposable equipment and commence the unit protocol for scope decontamination / storage.
- *A d*esignated wash station (sealed box) must be identified and used solely for the manual washing of scopes used on suspected VCJD cases (Appendix 2).
- *Following the procedure, the e*ndoscope must undergo manual cleaning as per type of endoscope SOP (Leak Test & Manual Cleaning of …). This procedure must be performed in the designated wash station attached to the operating theatre where procedure was carried out.
- It is processed in the EWD (intensive wash). Endoscope is water sampled and quarantined.
- Thermal disinfect cycle is done (chamber is empty) / water sample taken from this chamber and a machine cycle is done on this chamber.
- In the event that a leak test fails and the manufacturer indicate that repairing the scope is not possible, the scope must *be destroyed by incineration.* The scope must be placed in a sealed bio-hazard container for transport.
- As there is not a designated scope to be used for the vCJD in the department the Clinical Nurse Manager III / Clinical Nurse Manager II / Consultant will make a decision which scope will be used. This scope will then be quarantined. The location will be subsequently made known to all those involved in endoscopy procedure, Infection Control Team and Risk Management.
- Where an alternative diagnosis has been made on a suspected case of vCJD, the scope may be removed from quarantine, processed in the normal manner and put back into circulation.
- Where a definitive diagnosis of vCJD has been made, THE SCOPE MUST BE SENT FOR INCINERATION. The scope must be placed in a sealed biohazard container for transport.

6.0 References

HSE Standards and Recommend Practices for Operational Management of Endoscope Decontamination Facilities Version 1 June 2019

Our Lady's Children's Hospital, Crumlin, Dublin, *Infection Control Policies and Guidelines*, 2007

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Appendices

Appendix 1

Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Annex F
Table F2b: Common flexible endoscopic procedures classified as invasive or non-invasive (vCJD and CJD type uncertain)
The term "working channel" applies to the endoscope channel that is used for both the passage of accessories and the suction removal of liquids and gases.

	Procedure	Contamination of Working Channel	Mechanism	Invasive (+) or Non-Invasive (-)	Notes / Expectations
1b	Diagnostic cystoscopy or * bronchoscopy	Providing no biopsy is taken it is very unlikely that the endoscope will become contaminated *.	None. Tissue contamination would not result from a straightforward diagnostic procedure	-	
1d	Bronchoscopy with biopsy to obtain fixed lymphoid tissue	When a biopsy is taken of lymphoid tissue, there is a risk that the working channel could become contaminated with potentially infectious tissue.	Lymphoid tissue could come into contact with the lining of the working channel. Tissue may be deposited in the working channel.	+	Bronchoscopy with biopsy can be considered non-invasive (-) if it can be determined with confidence that there has been no contact with or invasion of lymphoid tissue.
1e	Transbronchial biopsy	There is a risk that the working channel may become contaminated with lymphoid tissue during transbronchial biopsy.	Lymphoid tissue could come into contact with the lining of the working channel. Tissue may be deposited in the working channel.	+	
3a	*Diagnostic gastroscopy	Providing no biopsy is taken it is very unlikely that the endoscope will become contaminated*.	None. Tissue contamination would not result from a straightforward diagnostic endoscopy.	-	

3b	Gastroscopy with biopsy	Even with efficient single use forceps contamination of the working channel with submucosal lymphoid tissue is likely	Contaminated tissue may come into contact with the lining of the endoscope working channel. Tissue may be deposited on the internal surface of the working channel. Decontamination not proven to remove the infective agent.	+ (but see exception, right)	Cytology is a negligible risk provided a sheathed technique is used. Alternatively cytology (using a sheathed cytology device) could be taken at the first gastroscopy if malignancy is strongly suspected. Some larger channel endoscopes allow the passage of a sheath through which biopsy may be done while protecting the endoscope working channel from tissue contamination. Following biopsy, the tip of the biopsy forceps is fully retracted into the sheath, the tip of which is kept protruding from the endoscope tip throughout. The practice of taking a single biopsy and removing the endoscope with the forceps protruding and then severing it with wire cutters is to be discouraged.
3c	Gastroscopy with brush cytology	The cytology brush is sheathed and therefore there is a low risk	No contact of lymphoid tissue with the working	-	

		of the working channel becoming contaminated with lymphoid tissue. Cytology is of negligible risk provided a sheathed technique is used.	channel.		
3d	Gastroscopy and balloon dilatation of stricture (oesophagus or pylorus)	Balloon dilatation may disrupt submucosal lymphoid tissue which could be transferred to the working channel as the balloon is retracted back into this channel.	Contamination would be through 'contact' and would be lower than biopsy. Modifying the technique to include removing the endoscope and used balloon as one (without retracting it back into the working channel) would minimise the risk.	-	This technique should be considered non-invasive ONLY if the endoscope and balloon are withdrawn from the patient as one (i.e. without retracting the balloon into the working channel) and the balloon is cut off and destroyed.
3e	Gastroscopy and bougie dilatation of oesophagus	Bougie dilatation over a guide wire involves disruption of submucosal tissue only when the endoscope has been withdrawn.	No contamination of the working channel with the lymphoid tissue.	-	
3f	Gastroscopy and polypectomy	Polypectomy snares use diathermy, which coagulates tissue and this adheres to the snare. Although the snare is sheathed it is possible for lymphoid tissue to contaminate the working channel.	Polyp tissue fragments are readily sucked into the working channel during and after polypectomy.	+ (but see exception, right)	Some endoscopists advocate the use of slow continuous irrigation of the working channel with water during polypectomy in order to minimise the risk of polyp fragments coming into contact with the internal surface of the endoscope working channel. Experience is, however, limited, and if aspirated into the

					working channel (as is normally the case) the procedure is immediately deemed invasive.
3j	Gastroscopy and injection of ulcer	This may be a necessary procedure and haemostasis may be achieved through a variety of methods. Injection of adrenaline would not disrupt submucosal lymphoid tissue but there is contact between the needle and submucosal tissue.	Good technique would minimise risk. The needle is sheathed and therefore not in contact with the working channel. Poor technique might result in the unsheathed needle coming into contact with the channel, rendering the procedure invasive.	-	
3k	Gastroscopy and injection of varices	This may be a necessary procedure and haemostasis may be achieved through a variety of methods. Injection of a sclerosing agent would not disrupt submucosal lymphoid tissue but there is contact between the needle and submucosal tissue.	Good technique minimises the risk. The needle is sheathed and therefore not in contact with the working channel. Poor technique might result in the unsheathed needle coming into contact with the channel, rendering the procedure invasive.	-	
3l	Gastroscopy and banding of varices	Bands are applied to prominent veins in the oesophagus. Submucosal lymphoid tissue should not be disrupted and in theory the risk should be low.	Tissue does not come into contact with the working channel during banding.	-	
3m	Gastroscopy and mucosal clipping	No disruption of lymphoid tissue	No contamination of biopsy channel with lymphoid tissue	-	

3n	Gastroscopy and insertion of a PEG (Percutaneous Endoscopic Gastrostomy Feeding Tube)	Patients with vCJD may require a PEG feeding tube. Contamination of the biopsy channel is possible with some techniques.	The most common 'pull through' method does involve a needle penetrating the stomach via the abdominal wall. In theory a small amount of submucosal lymphoid tissue might adhere to the needle and transfer to the wire or thread, which is pulled up via the working channel. However, the wire or thread can be withdrawn without entering this channel if the technique is modified so that the endoscope and wire or thread are withdrawn with the grasping device in full view (i.e. not withdrawing the wire or thread into the endoscope).	**-** If modified technique is used	Non-endoscopic (radiological) gastrostomy is recommended if possible. However, if this is not an option, the modified PEG technique must be used. This means that the endoscope and wire or thread are withdrawn with the grasping device in full view (i.e. the wire or thread is NOT withdrawn into the endoscope, the procedure must be considered invasive.
4a	ERCP without sphincterotomy	It is unlikely that the endoscope will become contaminated.	No contamination of the working channel with lymphoid tissue.	**-**	
4b	ERCP with spincteroplasty	There is a significant risk that the biopsy channel will become contaminated with lymphoid tissue.	It is necessary to withdraw the dilatation balloon via the working channel of the endoscope so contamination with lymphoid tissue is possible. Subsequent manoeuvres to remove	**+**	

			stones from the bile duct using retrieval balloons or baskets could contaminate the duodenoscope working channel.		
6a	Colonoscopy without biopsy	A diagnostic colonoscopy is unlikely to contaminate the working channel with submucosal lymphoid tissue.	No contamination would result from straightforward diagnostic colonoscopy.	-	
6b	Colonoscopy and biopsy	It is likely that the working channel will become contaminated with ileal submucosal tissue or colonic submucosal lymphoid aggregates	Contamination of the working channel very likely.	+ (but see exception, right)	Sheathed biopsy, where feasible may allow tissue sampling while avoiding the risk of working channel contamination. Following biopsy; the tip of the biopsy forceps is fully retracted into the sheath, the tip of which is kept protruding from the endoscope tip throughout. The practice of taking a single biopsy and removing the endoscope with the forceps protruding and then severing it with wire cutters is to be discouraged.
6d	Colonoscopy and polypectomy	Coagulation of tissue which then adheres to the snare. Sometimes small polyps retrieved using the suction channel and a biopsy "trap".	Polyp tissue fragments are readily sucked into the working channel during and after polypectomy.	+ (but see exception, right	Some endoscopists advocate the use of slow continuous irrigation of the working channel with water during

		This would increase the risk of contamination with lymphoid tissue.			polypectomy in order to minimise the risk of polyp fragments coming into contact with the internal surface of the endoscope working channel. Experience is however limited and if polyp fragments become aspirated into the working channel (as is normally the case) the procedure is immediately deemed invasive.
7a	Flexible sigmoidoscopy	This diagnostic procedure is unlikely to result in contamination of the working channel.	No contamination of the channel with lymphoid tissue would occur.	-	For 'invasive' procedures the risks are identical to those procedures associated with colonoscopy (see above).

- Where intubation is via the nasal cavity the advice of the endoscopist performing the procedure 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, it is advised to intubate via an oral route or take precautions appropriate for medium infectivity tissues.

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Appendix 2

Management of vCJD Endoscopes

- Use disposal room attached to theatre for manual washing the dedicated contaminated endoscope;
- Remove all bins / containers with consumables out of room;

Disposal Room Requirements for vCJD Positive Scope

- Designate person to wash and process endoscope and do H2O sampling / swab etc.;
- PPE – wear thumbs up gown / Nitra Tex Gloves / Mask IC Visor

Requirements

- Jug (to measure 15 litres of water);
- 75mls Wassenburg endo-cleaner;
- Cleaning brushes BW-412T (GI);
- (PBC1215A) All bronchoscopes except 5.1 respiratory bronchoscope;
- (PB1824A) 5.1 Pentax respiratory bronchoscope;
- J-cloths;
- Relevant leak testers;
- 20ml syringes x 4;
- Small yellow bag (to discard j-cloth / gloves / brushes etc);
- Use large HSSD box to wash and transport scope to washer (use lid when transporting). Return this box when empty back to disposal room for washing and swabbing;
- Leave leak tester in room for washing and swabbing also;
- N.B.: Ensure that Wassenburg washer disinfector is washed down with brial solution and actichlor after scope has been loaded into the dirty side;
- Take environment swab from washer disinfector on affected side, send to lab and record;
- Do not leave any contaminated gloves / gown / mask etc in washroom 6 after use. Bring back into quarantine disposal room and place in clinical waste bag;
- After decontamination – water sample and swab the endoscope, send to lab immediately and record same. Quarantine scope: the location will be subsequently made known to all those involved in this endoscopy procedure, Infection Control Team and Risk Management;
- Do thermal disinfect cycle on Wassenburg washer disinfector;
- Take water sample from tap post cycle.