

Transmissible Spongiform Encephalopathy

Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection.

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Annex F Endoscopes

Decontamination of endoscopes

F.1 The general procedures set out in the MDA Device Bulletin MDA DB2002(05), available at www.medical-devices.gov.uk, should be followed. In order to decrease the risk of transmission of TSEs through endoscopic procedures, additional precautions for the decontamination of flexible endoscopes are recommended in this annex:

- (a) Channel cleaning brushes and the valve on the biopsy/instrument channel port used with flexible endoscopes should be disposed of as clinical waste after each use. Single use, disposable biopsy forceps should be used routinely in all patients with definite, probable or possible CJD, and in those identified as at risk of developing CJD. This guidance endorses the advice of the MDA Bulletin that other accessories should be single-use wherever possible, but where this is not possible, they must be kept together with the endoscope, forming a unique set, until the accessories are disposed of. It is essential to have systems in place that enable endoscopes, together with all re-usable accessories, to be traced to the patients on whom they have been used.
- (b) Aldehyde disinfectants with fixative qualities (such as glutaraldehyde and OPA) tend to stabilise, rather than inactivate prions. The use of nonfixative disinfectants, if this is in accordance with the manufacturers' instructions, is therefore preferable. Disinfectants with fixative properties should not be used on flexible endoscopes used for any procedure on patients with a diagnosis of definite, probable or possible CJD or where the diagnosis of CJD is unclear (see Annex B, paragraph B12) or the patient is at risk of developing CJD. Contact the endoscope supplier for advice on appropriate alternatives.

F2. PrP-res has been detected in the olfactory epithelium, but not the respiratory epithelium, of sporadic CJD patients (see paragraph 4.5 of Part 4 of this guidance). The olfactory epithelium is normally located deep within the nasal turbinates but its distribution varies between individuals. 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.

Definitions

F3 The definitions of different types of patients are as set out in paragraphs 4.16 – 4.17 in Part 4 and Annex B of this guidance.

Sporadic and other non-variant CJD This includes sporadic CJD, iatrogenic CJD and familial prion diseases.

Symptomatic sCJD patients (definite, probable)

F.4 Neurological endoscopes would not normally be used on patients whose diagnosis is definite or probable sCJD. However, should use be necessary, the endoscope should be single use if possible. If this is not appropriate, the endoscope should be destroyed¹.

F.5 Endoscopes that come into contact with the nasal cavity may, on occasion, be used in patients with definite or probable sCJD. If there is a risk that the endoscope could become contaminated with olfactory epithelium (see paragraph F3 of this Annex), a single use endoscope should be used if

possible. If this is inappropriate, the endoscope should be destroyed.

F.6 For all other types of endoscopy, normal decontamination procedures, as set out in the MDA Device Bulletin MDA DB2002(05) should be followed, with the additional precautions for flexible endoscopes as set out in paragraph F.1 above.

Symptomatic patients with possible CJD or diagnosis unclearⁱⁱ

F.7 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 destroyed¹.

F.8 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 paragraph F3 of this Annex), a single use endoscope should be used where possible. If this is not appropriate, the 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 destroyed¹.

F.9 For all other types of endoscopy, normal decontamination procedures, as set out in the MDA Device Bulletin MDA DB2002(05) should be followed, with the additional precautions for flexible endoscopes as set out in paragraph F.1 above.

Asymptomatic patients at risk of CJD

F.10 No special precautions are required for the use, in at risk patients, of rigid endoscopes without lumens that can be autoclaved. The guidance in Part 4 for all surgical instruments can be followed.

F.11 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 quarantined after use until the absence of CJD can be confirmed by eventual post-mortem. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If confirmation of the absence of CJD is not practicable, the endoscope should be destroyed.

F.12 If there is a risk that an endoscope used in the nasal cavity could become contaminated with olfactory epithelium (see paragraph F3 of this Annex), a single use endoscope should be used where possible. If this is not appropriate, the 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 destroyed¹. For some procedures, the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. In practice, however, 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.

F.13 For all other types of endoscopy, normal decontamination procedures, as set out in the MDA Device Bulletin MDA DB2002(05) should be followed, with the additional precautions for flexible endoscopes as set out in paragraph F.1 above.

ⁱⁱ Instruments that are destined for disposal by incineration may be collected for use in research. Anyone considering such a course of action should contact the Surgical Instruments Store, Health Protection Agency, Porton Down. Tel: 01980 612100.

ⁱⁱ 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 (see also Annex B of this guidance)

Variant CJD

Symptomatic vCJD patients (definite, probable)

- F.14 Neurological endoscopes would not normally be used on patients whose diagnosis is definite or probable vCJD. However, should use be necessary, the endoscope should be single use if possible. If this is not appropriate, the endoscope should be destroyed¹. Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection. Published: September 2004
- F.15 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 paragraph F3 of this Annex), a single use endoscope should be used if possible. If this is inappropriate, the endoscope should be destroyedⁱ.
- F.16 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 technique, for example biopsy, is deemed to be a low risk procedure. If biopsy or other invasive procedure is carried out, the possibility of contamination of the instrument channel with lymphoid tissue means the endoscope should be quarantined pending assessment of likely contact with potentially infected tissue.

Symptomatic vCJD (possible or diagnosis unclear)

- F.17 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 use be necessary, a single use endoscope should be used if possible or the 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 destroyedⁱ.
- F.18 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 appropriate, the endoscope should be 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 destroyedⁱ.
- F.19 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 technique, for example biopsy, is deemed to be a low risk procedure. If biopsy or other invasive procedure is carried out, the possibility of contamination of the instrument channel with lymphoid tissue means the endoscope should be 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 destroyedⁱ.

Asymptomatic patients at risk of vCJD

- F.20 Endoscopes that are used for central nervous tissue investigations may, on occasion, be used on patients at 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 used if possible. Where this is not possible, the endoscope should be quarantined after use until the absence of Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection. Published: September 2004 CJD can be confirmed by eventual post-mortem. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If confirmation of the absence of CJD is not practicable, the endoscope should be destroyedⁱ.

F.21 If there is a risk that an endoscope used in the nasal cavity could become contaminated with olfactory epithelium (see paragraph F3 of this Annex), a single use endoscope should be used where possible. If this is not appropriate, the 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 destroyed¹. For some procedures, the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. In practice, however, 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.

F.22 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 technique, for example biopsy, is deemed to be a low risk procedure. If biopsy or other invasive procedure is carried out, the possibility of contamination of the instrument channel with lymphoid tissue means the endoscope should be 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 destroyed'

Summary of precautions advised for the use endoscopes

Table F1. CJD other than vCJD

Tissue Infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/probable	Possible/diagnosis unclear ¹	At risk ² iatrogenic/familial
High: <ul style="list-style-type: none"> Brain Spinal cord 	single use OR destroy ³ after use	single use OR quarantine ⁴ pending diagnosis	single use OR quarantine ⁴ pending exclusion of CJD
Medium: <ul style="list-style-type: none"> Olfactory epithelium* 	single use OR destroy ³ after use	single use OR quarantine ⁴ pending diagnosis	single use ⁵ OR quarantine ⁴ pending exclusion of CJD
Low/none detectable <ul style="list-style-type: none"> All other tissues 	no special precautions ⁶	no special precautions ⁶	no special precautions ⁶

* 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 (see paragraph F3 of this Annex).

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 (see also Annex B of this guidance).

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 Part 4 of this guidance.

³ Instruments that are destined for disposal may be collected for use in research. Anyone considering such a course of action should contact the Surgical Instruments Store, Health Protection Agency, Porton Down. Tel: 01980 612100.

⁴ Quarantined endoscopes may be re-used exclusively on the same individual patient if required.

⁵ For some procedures, the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. In practice, however, 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 decontamination procedures advised in F1 of this guidance, taken together with the MDA Device Bulletin MDA DB2002(05), should be followed.

Table F2 vCJD

Tissue Infectivity	Status of patient		
	Symptomatic		Asymptomatic
	Definite/probable	Possible/diagnosis unclear ¹	At risk ² iatrogenic
High: <ul style="list-style-type: none"> Brain Spinal cord 	single use OR destroy ³ after use	single use OR quarantine ⁴ pending diagnosis	single use OR quarantine ⁴ pending exclusion of CJD
Medium⁸: <ul style="list-style-type: none"> Olfactory epithelium* Lymphoid tissue** 	single use OR use dedicated endoscope ⁷ OR destroy ³ after use	single use OR quarantine ⁴ pending diagnosis	single use ⁵ OR quarantine ⁴ pending exclusion of CJD
Low/none detectable⁸ <ul style="list-style-type: none"> All other tissues 	No special precautions	no special precautions ⁶	no special precautions ⁶

* 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 (see paragraph F3 of this Annex).

** For the purposes of this Annex, lymphoid tissue refers to the spleen, thymus, tonsils and adenoids, lymph nodes, the appendix and the gastro-intestinal tract sub-mucosa ^{1,2,3,4,5} and ⁶ see footnotes to Table F1 above.

⁷ The NCJDSU holds a few flexible endoscopes dedicated for use on probable CJD 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 CJD, patients for whom the diagnosis of CJD is unclear or patients at risk of CJD.

⁸ All endoscopes used for biopsy or other invasive procedures (e.g. ERCP, diathermy) must be quarantined after use.