Reprocessing of Instrumentation Exposed to Creutzfeldt-Jakob Disease (CJD)/TSEs

Note: The International Association of Central Service Materiel Management (IAHCSMM) and the Massachusetts Chapter for Central Service Professionals (MCCSP) are not standards-making organizations; therefore, this research paper is not a standard, but rather a tool to provide guidance and help facilities develop their own CJD-related instrumentation policies and procedures. The paper is based on referenced materials at the time of publication and those reviewing the paper should consider new research or other guidance at the time of development of facility-specific policies.

OVERVIEW

Healthcare facilities face the challenge of caring for patients who may have Transmissible Spongiform Encephalopathies (TSEs) caused by prions. Processing surgical instrumentation that may have come in contact with prions requires unique processing guidance. The most widely-referenced document that addresses this concern, published by the World Health Organization (WHO), is, unfortunately, outdated for practical clinical application.[1]

DEFINITIONS

Creutzfeldt-Jakob Disease (CJD) is a prion disease found in both humans and animals, and is caused by a proteinaceous infectious agent or prion. CJD is a neurodegenerative disorder with characteristic clinical and diagnostic features. This disease is rapidly progressive and always fatal; infection with this disease leads to death usually within one year of onset of illness. CJD's incidence rate in the United States is approximately 1 case per million per year.[2]

CJD was thought to exist in only three forms until the identification of Variant Creutzfeldt-Jakob disease (vCJD).[3] vCJD is a rare and fatal human neurodegenerative condition. The consumption of food of bovine origin contaminated with the agent of Bovine Spongiform Encephalopathy (BSE), a disease of cattle, has been strongly linked to the occurrence of vCJD in humans.[4] CJD/vCJD has three-risk categories[5]:

IA: HIGH-INFECTIVITY TISSUES: Central Nervous System (CNS) tissues that attain a high titer of infectivity in the later stages of all TSEs, and certain tissues that are anatomically associated with the CNS.

IB: LOWER-INFECTIVITY TISSUES: peripheral tissues that have tested positive for infectivity and/or PrPTSE in at least one form of TSE.

IC: TISSUES WITH NO DETECTABLE INFECTIVITY: tissues that have been examined for infectivity and/or PrPTSE with negative results to date.

Table 1A: High-infectivity tissues

Tissues	Humans			
	vCJD		Other TSEs	
	Infectivity[1]	PrP^{TSE}	Infectivity[1]	PrP^{TSE}
Brain	+	+	+	+
Spinal cord	+	+	+	+
Retina	NT	+	+	+
Optic nerve[2]	NT	+	NT	+
Spinal ganglia	+	+	NT	+
Trigeminal ganglia	+	+	NT	+
Pituitary gland[3]	NT	+	+	+
Dura mate'r[3]	NT	(+)	+	-

Table 1B: Lower-infectivity tissues

Tissues	Humans			
	vCJD		Other TSEs	
	Infectivity[1]	PrP^{TSE}	Infectivity[1]	PrP^{TSE}
Peripheral Nervous system				
Peripheral nerves	+	+	(-)	+
Autonomic ganglia*	NT	+	NT	(-)
Lymphoreticular tissues				
Spleen	+	+	+	+
Lymph nodes	+	+	+	-
Tonsil	+	+	NT	-
Nictitating membrade	NA	NA	NA	NA
Thymus	NT	+	NT	-
Alimentary tract[5]				
Esophagus	NT	-	NT	-
Fore-stomach[6] (ruminants only)	NA	NA	NA	NA
Stomach/ abomasum	NT	-	NT	-
Duodenum	NT	-	NT	-
Jejunum[7]	NT	+	NT	-
Ileum[7]	NT	+	NT	-
Appendix	(-)	+	NT	-
Colon/ caecum[7]	NT	+	NT	-
Rectum	[+]	+	NT	NT
Reproductive tissues				
Placenta[8]	NT	-	(+)	-
Ovary[3]	NT	-(+)	NT	-
Uterus[3]	NT	-(+)	NT	-

Table 1B: Lower-infectivity tissues (cont.)

Tissues	Humans			
	vCJD		Other TSEs	
	Infectivity[1]	PrP^{TSE}	Infectivity[1]	PrP^{TSE}
Other tissues				
Mammary gland/ udder[9]	NT	-	NT	-
Skin[3,10]	NT	-(+)	NT	-
Adipose tissue	NT	-	(+)	-
Heart/ pericardium	NT	-	-	-
Lung	NT	-	+	-
Liver[3]	NT	-(+)	+	-
Kidney[3,11]	NT	-(+)	+	-
Adrenal	NT	+	-	-
Pancreas[3]	NT	-(+)	NT	-
Bone marrow[12]	-	-	(-)	-
Skeletal muscle[13]	NT	+	(-)	+
Tongue[14]	NT	-	NT	-
Blood vessels	NT	+	NT	+
Nasal mucosa[15]	NT	NT	NT	+
Salivary gland	NT	-	NT	-
Cornea[16]	NT	-	+	-
Body fluids, secretions and excretions				
CSF	-	-	+	-
Blood[17]	+	?	-	?
Saliva	NT	-	-	NT
Milk[18]	NT	NT	(-)	NT
Urine[19]	NT	-	-	-
Feces[19]	NT	NT	-	NT

Table 1C: Tissues with no detected infectivity or PrP^{TSE}

Tissues	Humans			
	vCJD		Other TSEs	
	Infectivity[1]	PrP^{TSE}	Infectivity[1]	PrP^{TSE}
Reproductive tissues				
Testis	NT	-	(-)	-
Prostate/ Epididymis/ Seminal vesicle	NT	-	(-)	-
Semen	NT	-	(-)	-
Placenta fluids	NT	NT	(-)	(-)
Fetus[20]	NT	NT	NT	NT
Embryos[20]	NT	NT	NT	NT
Musculo-skeletal tissues				
Bone	NT	-	NT	-
Tendon	NT	-	NT	-
Other tissues				
Gingival tissue	NT	-	-	-
Dental pulp	NT	-	NT	-
Trachea	NT	-	NT	-
Thyroid gland	NT	-	(-)	-
Body fluids, secretions and excretions				
Colostrum[21]	NT	NT	(-)	NT
Cord blood[21]	NT	NT	(-)	NT
Sweat	NT	NT	-	NT
Tears	NT	NT	-	NT
Nasal mucus	NT	-	-	NT
Bile	NT	NT	NT	NT

MAJOR CATEGORIES OF CJD:

- Sporadic CJD: Sporadic CJD presents even though the person has no known risk factors for the disease. This is, by far, the most common type of CJD and accounts for at least 85% of cases.
- Hereditary CJD: In hereditary CJD, the person has a family history of the disease and/or tests positive for a genetic mutation associated with CJD. About 5-10% of CJD cases in the U.S. are hereditary.
- Acquired CJD: In acquired CJD, the disease is transmitted by exposure to brain or nervous system tissue, usually through certain medical procedures. There is no evidence that CJD is contagious through casual contact with a CJD patient. Since CJD was first described in 1920, fewer than 1% of cases have been categorized as acquired CJD.[6]

Summary tables (Tables 1A, 1B and IC) of tissues types for each category are given below with the following key[7]:

+ Presence of infectivity or PrPTSE
- Absence of detectable infectivity or PrPTSE
NT Not tested
NA Not applicable
? Uncertain interpretation
( ) Limited or preliminary data
[ ] Infectivity or PrPTSE data based exclusively on bioassays in transgenic
(Tg) mice over-expressing the PrP-encoding gene or PrPTSE amplification methods.

A word of caution is offered about tissues in Table IB for which positive results are so far limited to either detection of PrPTSE using amplification techniques (PMCA), or infectivity bioassays in Tg mice that over-express PrP. The amounts of pathological protein or infectious agent detected by these sensitive assays may well fall below the threshold of transmissibility for normal animals and humans.[8]

Note: These risks are constantly under review and change based on scientific investigation. World Health Organization 2010 Tables on Tissue Infectivity Distribution in transmissible Spongiform Encephalopthies[9] are already considered outdated.

OTHER CONSIDERATIONS

All instrumentation that has not been tracked within a facility (for example loaned instruments) should be processed in accordance with guidelines as established by the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), IAHCSMM, the World Health Organization (WHO), and the U.S. Centers for Disease Control and Prevention (CDC).

Instruments that are loaned to a healthcare facility from a distributor or manufacturer complicate the tracing of instrument sets from one healthcare facility to the next, thus increasing the likelihood for potential concern. In addition to loaner instruments, traceability within a healthcare facility can also be problematic. Loaner sets that have been at risk of contamination with high-risk tissues at another facility (i.e., brain, spinal cord, posterior eye, pituitary tissue) may need to be treated as being potentially exposed to high-risk tissues.

The reprocessing of contaminated instruments that may have been exposed to CJD/TSE in healthcare facilities today need to be assessed. Due to the resilience of prions and potential of the unknown possibility that a patient may have CJD, instrument reprocessing becomes more challenging.

Protocols and specific policies may be put in place to effectively reprocess all instruments used on the brain, spinal cord, dura, pituitary gland, and eyes. Device contact with all of these tissues should be considered potentially prion-contaminated.

Given the nature and extended time of recommended prion decontamination processes, the facility may wish to incorporate additional "lead time" for loaner instruments.

Alternatively, disposable neurosurgical instruments should be used for such patients, or instruments could be quarantined pending pathologic findings.[10] Prion-contaminated medical devices that are nearly impossible to clean or difficult to fully expose to steam and other sterilization processes should be discarded.[11]

A well-established policy can be used as a guideline to help manage CJD high-risk categories and potential exposure situations for instrumentation.[12] An interdisciplinary team should develop processes to minimize the risk of prion disease transmission.[13] Designated staff responsible for the management of instruments through the CJD decontamination process must be trained and knowledgeable of all aspects of this process. Instrument tracking software is becoming increasingly common in modern reprocessing departments and can play a major role in managing instrumentation, including loaner instrumentation. Efficiencies may be gained from the ease of documentation of specific medical devices and/or trays, including implants and the need for biological testing, usage history, inventory control of implants, and proper cleaning and sterilization parameters built into the system to prevent non-conformance with quality production.[14]

The U.S. Food and Drug Administration (FDA) does not currently recognize any method of "reducing prion infectivity" to be adequately validated and to date has not approved statements about specific decontamination recommendations in device labeling.[15] Cleaning with certain defined formulations in combination with steam sterilization can be an effective prion decontamination process, in particular with alkaline formulations. Cleaning cannot be assumed to reduce the risk of prion contamination. However, the correct use of defined cleaning, disinfection and sterilization methods that have been specifically tested to reduce the risk of prion contamination (by a defined infectivity assay) may provide a standard precaution against prion contamination.[16]

Results from some published studies would suggest that low concentrations of NaOH (0.15 M) and cleaning with the alkaline formulations tested can be efficient in high-risk cases, but, even more importantly, could provide a safe process to be used on all device types as a standard precaution. For example, some high-alkaline formulations have been tested to be compatible with a wide range of device types (including flexible endoscopes), but like all high alkalines, can be incompatible with many anodized aluminum containing devices (depending on the quality and finish of the materials used). Others, such as the mild alkaline series described, can be safely used on all device types to provide a safer prion decontamination process in combination with standard steam sterilization (represented in some studies by 134°C for 4 minutes as a standard steam exposure condition). Even certain tested enzyme-based formulations can be partially effective using worst-case assay conditions when combined with typical steam sterilization to reduce the risk, but this is clearly product specific and should not be taken for granted.[17] Healthcare facilities should consult with both the equipment and chemistry manufacturer to ensure that the cleaning process is attainable.

Disinfectants (including thermal disinfection processes) are not known to have any impact in reducing the risks of prion contamination. Any agents with a cross-linking mechanism of action, such as glutaraldehyde, should not be used on a device as this may fix the infectious material to a surface. In some countries and in many guidelines, recommended steam sterilization cycles to reduce the risk of prion contamination are 275°F/134°C for an 18-minute exposure in a pre-vacuum sterilizer and 250°F/132°C for 60 min (1 hour) in a gravity sterilier.[18] The healthcare facility should consult with the sterilizer manufacturer to ensure that proper programming of the sterilizer has been achieved. Testing of the cycle should also be completed, with facilities ensuring that such testing is within the capabilities of their sterilizers. Other sterilization processes, such as some hydrogen peroxide gas processes, may also reduce the risk, but this should be consulted with the sterilizer's manufacturer. Processes should not be used if not supported with prion infectivity reduction studies that support effectiveness.[19]

The following may be taken into consideration when developing an instrumentation policy for CJD/vCJD:

- Reprocessing devices based on risk level[20]
- Care and handling of instrument during surgery (point of use)[21]
- Care and handling of instruments post-procedure[22]
- Discard if difficult to clean or switch to disposable (i.e., suctions)[23]
- Identification of high-risk cases[24]
- Transportation to decontamination area[25]
- Identification of cleaning agents (alkaline/enzyme detergent, with data to support risk reduction)[26]
- Post-decontamination procedure for sterilization
- Post-sterilization process for inspection of instrumentation[27]
- Sterilization guidelines/Instructions for Use (IFU) from the manufacture that validate the extended cycle times[28]
- Sterilization guidelines/Instructions for Use (IFU) for containers that may house the instruments[29]
- Initial and ongoing training to include care and handling of instruments potentially exposed to CJD
- Required personal protective equipment (PPE) during handling
- Tracking system
- Legal factors, using equipment and instrumentation ("off-market use")

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RECOMMENDED READING

- CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
- EPA: Regulating Pesticides, EPA's Registered Sterilizers, Tuberculocides, and Antimicrobial Products against Certain Human Public Health Bacteria and Viruses
- WHO/CDS/CSR/APH/2000.3 WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies Report of a WHO consultation, Geneva, Switzerland, March 23-26, 1999.
- OSHA Blood borne Pathogen Standard, 29 CFR 1910.1030
- IAHCSMM Central Service Technical Manual, Seventh Edition
- SHEA Guideline, Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments
- ANSI/AAMIST79: 2010 &a1: 2010 &A2: 2011 & A3: 2012
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