For IC Practitioners, OR and Endoscopy Staff, Reprocessing Personnel, Materiel Managers, et al.

The Q-Net™ Monthly

Volume 6, Number 10 October 2000

FDA Websites

The FDA recently published on its web site information on reusing single-use devices (SUDs) in hospitals. A list of SUDs (updated 11/13/00) known to be reprocessed is provided at *"http://www.fda.gov/cdrh/reuse/1168a.html"*. Also, a letter to hospitals discussing the reprocessing of SUDs (issued on 9/28/00) is provided at *"http://www.fda.gov/cdrh/reuse/feigal092800_reuse.html"*.

This month's newsletter discusses CJD and prion transmission. A previous discussion on mad cow's disease appears in this newsletter's June 1996 issue.

Editor-in-Chief

Unless noted otherwise, all articles in this newsletter are written by: **Lawrence F Muscarella, PhD**, *Chief, Infection Control* at Custom Ultrasonics, Inc. Ivyland, PA 18974

What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *The* **Q-Net™** *Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

Q-Net addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

Creutzfeldt-Jakob Disease

~ Breaking News ~

Just a few weeks ago in October a hospital reported that last spring as many as 8 patients may have been infected with Creutzfeldt-Jakob disease (CJD), a rare and fatal neurological disease.[1]

Some of the same instruments used during brain surgery on an "index" patient last March were reused on 8 other patients during various neurological procedures between March and May. The potentially contaminated surgical instruments were not removed from service until May, when the index patient who had passed away was found during autopsy to have had CJD.

Reports suggest that, after use on the index patient and each of the other 8 patients, the instruments were washed and sterilized in accordance with the hospital's routine decontamination procedures. Prions, however, which are the agents thought to cause CJD, may survive standard cleaning and sterilization procedures, raising concern.

Therefore, the possibility exists, however remote, that the surgical instruments: (1) were contaminated with prions during the index patient's brain surgery in May; (2) remained contaminated despite the hospital's efforts to clean and sterilize them; and, (3) between March and May transmitted prions, and therefore presumably CJD, to these 8 patients.

Complicating this incident is the lack of a reliable method to assess the risk that any of these 8 patients were infected with CJD. Symptoms of CJD may not develop for many years, and CJD usually can only be confirmed definitively through an autopsy or brain biopsy.

What is CJD, prions?

CJD, or *Creutzfeltd-Jakob disease*, is a fatal degenerative neurological disorder that causes structural changes in human brain tissue. Initial symptoms include depression and poor memory, followed in its latter stages by dementia and loss of physical functioning. Currently there is no treatment for CJD.[2]

CJD is a *transmissible subacute spongiform encephalopathy* (TSE) that affects approximately 1 in 1 million people per year. Examples of other TSEs include *bovine spongiform encephalopathy* (BSE), or "mad cow's disease," and *scrapie,* which infects goats and sheep.

Most cases of CJD occur sporadically,[2] although as many as 15% of all cases may be inherited.[3,4] Less than 5% of CJD cases result from contact with contaminated surgical instruments, tainted hormones from the pituitary gland, and infected neurological tissue.

What is a "prion"? Prions, the agents that cause CJD, are believed to be infectious proteins unusually resistant to standard cleaning and sterilization methods. Unlike all other known pathogens, prions do not contain genetic material.

Prions are produced in cells through the processes known as *transcription* and *translation*. Genes on a specific portion of a DNA molecule ordinarily instruct the cell to synthesize "healthy" proteins. Cellular messengers attach to and

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transport amino acids (the building blocks of proteins) from the cell's cytoplasm to its ribosomes, where protein synthesis occurs. The retrieved amino acids are assembled into a specific order determined by the genes' instructions. Like a chain-linked fence, these amino acids bond to one another, forming a protein molecule. For unclear reasons, a mutated or altered gene can cause the sequence of assembled amino acids to become out of order.[5,6] The result can be the production of "unhealthy" and infectious proteins, or prions.

What decontamination method effectively destroys prions? Reports indicate that prions can be transmitted from one patient to another via contaminated surgical instruments.[2,7,8] Surprisingly, standard processes routinely used to destroy virtually all known pathogens, such as those that use ethylene oxide gas, glutaraldehyde, peracetic acid - and even heat - are reported to be ineffective against prions.[2] And while it reduces bioburden, cleaning may not always effectively remove all of the prions from a contaminated instrument.[2] Although some decontamination methods are recommended for items potentially contaminated with prions (see Box article, below), data demonstrating their efficacies are limited.

Assessing the risk of prion transmission during surgery:

➡ *The risk of being contaminated with prions during a surgical procedure is remote. Only patients exposed to infected pituitary gland hormones and neural tissues, such as the brain, spinal cord, and cornea, appear to be at risk.[2] And to date, CJD following endoscopy has not been reported (see this newsletter's June 1996 issue).*

Published data suggest that patients who come into direct physical contact with the neurological tissues of CJD patients may be at risk. This risk is very low, however, as each year only about one in one million people acquires CJD.

Four scenarios are described below. The first presents the greatest risk of CJD infection, the fourth the least risk. These scenarios, which describe the types of instruments used (*simple or complex in design?*) and the types of tissues encountered (*"at risk" neurological tissues?*), can be used to assess the risk of prion transmission during surgery:

1. *Complex instruments that are difficult to clean and in contact with "at risk" neurological tissues:* Because these instruments pose the highest risk for transmitting prions, only disposables should be used;
2. *Simple instruments that are easy to clean and in contact with "at risk" neurological tissues:* These instruments pose a risk for transmitting prions and therefore should be disposable. If, however, disposables are not available, then thorough cleaning followed by an extended sterilization procedure (see Box article) is recommended;
3. *Complex instruments that are difficult to clean and in contact with "low risk" tissues, such as the gastrointestinal respiratory tracts:* These instruments, which include biopsy forceps, pose a negligible risk of prion contamination (*no reports of prion transmission during an endoscopic procedure have been reported*). The use of disposable instruments is recommended; but if impractical, reprocessing the instruments using normal sterilization procedures preceded by thorough cleaning will all but eliminate any risk of prion transmission; and
4. *Simple instruments that are easy to clean and in contact with "low risk" tissues, such as the gastrointestinal or respiratory tracts:* For these types of surgical (and critical) instruments, there is virtually no risk of prion transmission. Normal sterilization procedures preceded by thorough cleaning are recommended. ■ *LFM*

~ Recommended procedures ~

The minimum requirements for decontaminating surgical instruments potentially contaminated with prions is unclear. Nevertheless, there are at least four available options:[2,9-11] (1) Use only *disposable* surgical instruments; (2) reprocess surgical instruments using a prevacuum steam sterilization cycle at 135° C (275° F) for 18 minutes; or (3) instead, use a standard gravity steam sterilization cycle at 132° C (270° F) for 60 minutes. Both option (2) and (3) have been reported to be effective against prions. And, (4) rather than reprocessing and reusing reusable instruments, incinerate them.

Cleaning, exposing instruments to sodium hydroxide (1N, NaOH, or soda lye) or sodium hypochlorite (NaOCl, or bleach) for 60 minutes, followed by a standard gravity steam cycle, is also an option.[2] Combining two or more different procedures appears to be most effective.[2,12]

References available upon request.

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD.* Please direct all correspondence to:

Lawrence F Muscarella, PhD
Director, Research and Development
Chief, Infection Control

Custom Ultrasonics, Inc.
144 Railroad Drive, Ivyland, PA 18974
Tele: 215.364.8577; *Fax:* 561.258.8051

E-mail: q-net@email.msn.com

www.myendosite.com