

# The Q-Net™ Monthly

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## What's News

Happy New Year! Welcome to Q-Net's 7th year of publication.

Effective February 14, 2001, the FDA will treat as a manufacturer any hospital or commercial company that reprocesses for reuse single-use 'class III' devices.

The label of Sporidicin, a liquid chemical sterilant discussed in this newsletter's October 1999 issue, has been modified and re-labeled for 14-day (instead of 7-day) reuse. This product's glutaraldehyde content has been increased from 0.95% to 1.12%.

## Editor-in-Chief

Unless otherwise stated, all articles in this newsletter are written by: Lawrence F Muscarella, PhD, *Chief, Infection Control*, Custom Ultrasonics, Inc. Ivyland, PA 18974. This newsletter can be read and downloaded at: [www.myendosite.com](http://www.myendosite.com)

## 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.

## Medical errors in endoscopy

Medical errors are responsible for thousands of patient deaths each year.<sup>1</sup> Two articles published in the *Journal of the American Medical Association* (JAMA) discuss medical errors.<sup>1,2</sup> Clarifying the definitions and parameters of *medical errors* is necessary to evaluate and reduce risk. According to one expert, medical errors are due to: "design and conditions of medical work that lead careful, competent, caring physicians and nurses to make mistakes."<sup>1</sup>

This apt depiction of medical errors provides as many answers as it raises questions. For example: *Does the definition of a medical error include patient injuries caused by a medical device that is difficult to operate, inadequately labeled, or flawed in its design?* Presumably not, if we assume that medical errors are mistakes made by medical staff. It is the responsibility of manufacturers, not medical staff, to design properly labeled devices that are safe, effective and easy to operate.

Several years ago, two models of automated endoscope reprocessors (AERs) were linked to several patient infections and deaths.<sup>3,4</sup> Investigations concluded that the internal designs of both AER models supported the growth of bacteria, which re-contaminated the endoscope during reprocessing. These injuries would therefore not be due to medical errors, because the AERs' flawed designs, not medical staff, were at fault.

According to one expert: "Errors result from faulty systems not faulty people."<sup>1</sup> And, "Errors ... can be eliminated, but only if concern and attention is shifted away from individuals..."<sup>1</sup> Indeed, blaming medical staff when an error or injury occurs can create a working environment more fearful of retribution than motivated toward improvement and correction. Experts agree that, rather than assigning blame when an error occurs, developing and improving quality controls designed to identify and minimize risk reduces significantly the likelihood of patient injury.

But not everyone necessarily agrees that converting the health care setting from one of 'finger-pointing' to individual accountability reduces risk. To exonerate themselves of liability, some manufacturers may blame medical staff and seek to classify as a medical error any patient injury linked to their medical device. Health care workers are human and therefore will make mistakes. But care must be taken not to capitalize on their 'humanness' and indiscriminately shift blame their way.

For their part, health care workers are often busy caring for patients. Rarely are they versed at refuting or challenging a manufacturer's assertion that human error, not the device, was responsible for an injury. Health care workers may yield and accept responsibility even before a thorough investigation, which might absolve them of error and implicate at fault the manufacturer, has been completed.

Consider a recent outbreak that resulted in patient injury (see this newsletter's June 1999 issue).<sup>2,5</sup> During bronchoscopy, 18 patients were infected with *Pseudomonas aeruginosa*, a waterborne microorganism, and one died.<sup>2,5,6</sup> The Centers for Disease Control and Preven-

tion (CDC) and the Food and Drug Administration (FDA) concluded that this outbreak was due at least in part to medical staff improperly connecting bronchoscopes to an AER.<sup>2,5</sup>

*Is this incident an example of a medical error?* Human error likely contributed to this outbreak. But maybe more at fault are the complex designs of flexible endoscope (which may not facilitate cleaning, disinfection or sterilization, and drying) and the designs and labeling of AERs (which may be lacking and confusing, especially if hospital staff is inadequately trained).<sup>6</sup> According to the CDC and FDA, the reprocessing instructions provided by the manufacturers of the bronchoscope and AER, which ideally should have been the same, were at times unclear and in disagreement.<sup>2,5</sup> This outbreak may therefore have been due more to the shortcomings of medical devices than to a medical error (i.e., human error). *A device whose design, instructions and labeling make it prone to human error is arguably a faulty device.*

A review of the FDA's MAUDE database ("Manufacturer and User Facility Device Experience Database") reveals that since 1998 more than a dozen outbreaks of *P. aeruginosa* (or another waterborne microorganism) following bronchoscopy were reported. These outbreaks, which include the MMWR discussed above,<sup>2,5,6</sup> resulted in at least 5 patient deaths and dozens of patient injuries. Investigations have linked these outbreaks to contaminated bronchoscopes reprocessed in an AER. Although limited in detail, each of these MAUDE reports provides the comments of the manufacturers, who often conclude that their respective devices were operating properly and the injuries were likely due to medical errors.

In one of these MAUDE reports, which is similar to the outbreak in the MMWR discussed above,<sup>2,5,6</sup> 13 patients were infected with *P. aeruginosa* during bronchoscopy, 4 of whom died. Suggesting that human error was at fault, one manufacturer concluded that medical staff: (1) may have improperly connected bronchoscopes to its AER during reprocessing; and (2) likely employed an improper microbiologic sampling technique. Another manufacturer confirmed that the hospital was not rinsing the bronchoscopes with 70% alcohol to facilitate drying. After implementing this drying step, the *P. aeruginosa* outbreak stopped. (Although it began in June 1999, this outbreak has not been formally discussed or published, save for two unspecific MAUDE reports.)

*Is this report an example of a medical error? Or were the injuries due to a medical device(s)? Is it a medical error if medical staff connects the endoscope improperly to the AER? Is it a medical error if staff does not rinse the endoscope with 70% alcohol, followed by forced air-drying (even though this practice has become the standard of care before storage)?*

To be sure, medical staff would likely be responsible for these injuries, provided (in addition to satisfying other criteria) the manufacturer(s): (a) properly instructed and adequately trained the medical staff on proper cleaning and connection of the bronchoscope to the AER; and (b) stressed the importance of drying the endoscope to prevent bacterial colonization during storage. If, however, the medical staff

was inadequately trained and/or either of the device's labeling vague or equivocal, then the manufacturer(s) - not the medical staff - would arguably be at fault.

In conclusion, medical device manufacturers may find that in the health care setting directing concern and attention toward reducing risk, rather than shifting blame toward medical staff, yields more fruitful outcomes. Haste to blame medical staff can hamper discovery of every contributor to an adverse event and delay preemptive action crucial to preventing further patient injury. As the burdens of medical staff continue to increase, the importance of health care facilities designing and implementing quality controls that reduce the risk of medical errors cannot be overstated.

Manufacturers are encouraged to simplify the tasks of overworked medical staff by: (a) becoming more attuned to the work-related stresses that diligent health care workers face daily; (b) designing devices that are easier to operate and placarded with clearer labeling; and (c) providing more thorough operator training. Similarly, the FDA is encouraged to continue to apply science and objectivity to its proactive surveillance of medical devices and, when appropriate, to seek fair remedies that protect the public. ■ *The End*

## References

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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, Editor in Chief.* Please direct all correspondence to:

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