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What's News

In early March, the FDA posted an updated document entitled, "FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices March 2003." This document includes some notable additions and can be read at: <http://www.fda.gov/cdrh/ode/germlab.html>

In its February 13, 2003, issue, the *Los Angeles Times* published an article that discusses the risk of patient infection associated with contaminated colonoscopes. This newspaper article is referenced in this newsletter's editorial.

Editor-in-Chief

All articles published 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.

Going back to school

An editorial that discusses trends in infection control and a recent bacterial outbreak



Last March (2002), Johns Hopkins Hospital (JHH) in Baltimore (MD) disclosed that several patient infections had been linked to bronchoscopes that unknown to the hospital's pulmonologists had been recalled several months earlier.¹ This outbreak was reportedly due to a manufacturing flaw that allowed the housing of the bronchoscope's biopsy channel port to become loose and colonized with *Pseudomonas aeruginosa*. These bacteria, which were shielded from contact with detergents and disinfectants, were apparently transmitted from inside this loose housing to patients during bronchoscopy, resulting in lung infection despite the facility's strict adherence to endoscope reprocessing guidelines. (Refer to this newsletter's April-May and June-July 2002 issues for a detailed discussion of this bronchoscope recall.)

Several national and local news sources reported this bronchoscope recall and outbreak at JHH. Although most were fair and objective, some of these reports were misleading, suggesting that the outbreak at JHH might have been due—not to a manufacturing or bronchoscope design defect—but rather to an inherent inadequacy in current published guidelines for reprocessing gastrointestinal (GI) endoscopes and bronchoscopes.

This past February (2003) a Los Angeles newspaper reported that state health officials had recently mailed a letter of concern to approximately 1000 health care facilities stressing the importance of reprocessing every one of the endoscope's internal channels²—including the colonoscope's auxiliary water channel—whether or not the channel is used during the procedure.³ Like some of the articles that reported almost a year earlier the *P aeruginosa* outbreak at JHH, this newspaper article caused uneasiness by implying that current endoscope reprocessing guidelines are inadequate and pose a risk to public health, the low risk of infection following endoscopy notwithstanding.

This Los Angeles newspaper article brings to our attention an important question: "What lessons (if any) were learned as a result of the well-publicized outbreak at JHH linked to contaminated bronchoscopes?" The answer to this question appears potentially grim. This past October (2002), Pittsburgh's Allegheny General Hospital (AGH) announced that it was investigating the cause of an outbreak of *P aeruginosa* linked to several

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patient injuries and one death following bronchoscopy.⁴

Although reportedly not due to a recalled bronchoscope or manufacturing defect, AGH's outbreak is similar in many respects to the *P aeruginosa* outbreak at JHH, as well as to several other bacterial outbreaks, including an outbreak following bronchoscopy at a hospital in Flushing (NY).^{5,6} While bacterial infections following endoscopy can have many different causes ranging from defective endoscopes to inadequate drying of the endoscope's channels, one reproducible fact is clear, consistent, and incontrovertible: *There are no reports of a patient infection from a bronchoscope, GI endoscope, or endoscopic accessory that was reprocessed in accordance with and as instructed by current endoscope reprocessing standards and guidelines published by several professional organizations.*

So, what exactly went wrong at AGH?

After having reviewed more than a thousand papers in the field of instrument reprocessing and infection control, I have arrived at the following conclusions: It is my opinion that, although certainly encouraged is the development of future endoscope designs that are more user-friendly and facilitate more efficient reprocessing, years of experience and a plethora of data have taught us that *new and improved* endoscope reprocessing guidelines are not needed. Rather, what is needed is strict adherence to the guidelines already published and currently in place. This was the message that should have been, but was not, conveyed in this recent Los Angeles newspaper article.²

Simply put, to further minimize the already low risk of infection following GI endoscopy and bronchoscopy, I suggest that health care facilities ensure their endoscopy units are in complete compliance with published guidelines that describe in step-by-step detail the three steps of endoscope reprocessing:⁷ (1) cleaning, (2) high-level disinfection, followed by rinsing with a large volume of fresh and clean water (e.g., bacteria-free), and (3) drying, which is typically achieved by rinsing the endoscope's channels with 70% alcohol, followed by forced-air. *Provided each of these steps is properly performed and all of the endoscope's channels are accounted for and reprocessed, there is virtually no risk of disease transmission via an endoscope.*

Officials at AGH in Pittsburgh report that the outbreak was due in large part to the transmission of *P aeruginosa* via bronchoscopes rinsed with contaminated, even though filtered and labeled as "sterile," water during reprocessing.⁸ Because *P aeruginosa* and other waterborne bacteria require a moist environment to survive, bacterial outbreaks like AGH's suggest that, in addition to other possible reprocessing missteps, the facility's bronchoscopes were not being adequately dried (if dried at all) after automated reprocessing.

This possibility raises several inevitable and potentially

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Monitoring an open sterile field

As a operating room nurse, I have two questions regarding the monitoring of open sterile fields.

1. *Provided an open sterile field remains continuously monitored and no compromising event is observed, for how long can it be considered sterile?*

Although there are few published studies that specifically address the amount of time a monitored open field can be expected to remain sterile, a source that provides some guidance on sterile fields is the *Association of periOperative Registered Nurses's* (AORN) "Recommended Practices for Aseptic Technique."[†] This document recommends that a sterile field be prepared as close as possible (if not immediately prior) to its expected time of use. It is therefore recommended, by way of example, that intravenous medications be promptly administered after opening their ampules and vials, rather than the syringes filled and used several hours or days later (*refer to this newsletter's February 2002 and March 2002 issues*). The risk of contamination of an open sterile field increases as the time after its establishment increases, even if the field is continuously monitored by vigilant and trained personnel.

No realistic or accurate time frame can be provided to define how long a continuously monitored open field can remain sterile. The actual time will depend on several factors, including the type of surgical procedure and attention to aseptic technique (as well as the amount of elapsed time since establishment of the sterile field). If there is any doubt about the sterility of an open field, concern that it might have become contaminated, or acknowledgment that an unreasonable amount of time has elapsed since its establishment, it may be necessary to discard the entire open setup.

2. *Is it acceptable once a sterile field is established to cover it with sterile drapes and leave the room, if only for a few minutes?*

This question has a two-part answer. First, according to AORN,[†] sterile fields should not be covered, because the physical act of uncovering them may result in their contamination. As a result, a covered field is considered contaminated. Second, a sterile field requires continuous monitoring and maintenance. Because of the many factors that can contribute to its contamination, the sterility of an open field that is unmonitored, if only for a short while, cannot be guaranteed. As a result, an unmonitored open field is considered unsterile. It is essential to continuously monitor a sterile open field to ensure that no event capable of contaminating the field or compromising its sterility is observed.

[†] AORN. Recommended Practices. *AORN J* 1991 Oct;54(4):819-23.

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troubling questions: *During its P aeruginosa outbreak, was AGH drying its bronchoscopes after each reprocessing cycle? And, if not, why not? Was there anything in the labeling of the automated endoscope reprocessor or bronchoscopes used by AGH that would suggest that the terminal drying step could (or should) be skipped or ignored?* These are important questions that warrant responses due to their significant infection control implications.

Further, I also suggest health care facilities consider dedicating more resources to the recruitment, education, training and support of their nursing and reprocessing staff. Never should the importance of endoscope reprocessing to the prevention of nosocomial infection be minimized or overlooked. It is paramount during training to stress the importance of: (a) understanding the potentially unique internal design presented by different endoscope models; (b) reprocessing every endoscope channel and potentially contaminated surfaces, including the colonoscope's auxiliary water channel and the duodenoscope's elevator forceps channel; and (c) remembering that each reprocessing step is as important as the other—drying is no less important than cleaning.

Of particular concern, some health care facilities may not be entirely aware of the importance of thoroughly drying the endoscope after each reprocessing cycle (and before storage), having concluded or been led to believe that drying is not only superfluous and of no infection control consequence but also violates the presumed aseptic condition of the reprocessed endoscope. To be clear, drying the endoscope is crucial to the prevention of bacterial transmission during endoscopy.⁷ Health care facilities are also encouraged to evaluate the merits of routinely monitoring the microbial quality of the rinse water used during endoscope reprocessing (especially if the rinse water is claimed to be “sterile”),⁹ because *P aeruginosa* and other waterborne bacteria cultured in hospitals' water supplies have been shown to be the cause of bacterial outbreaks. (Refer to this newsletter's October-November 2002 and December 2002 issues.)

As a result of recent *P aeruginosa* outbreak reports,^{1,2,4-6} recall letters, and safety notices,³ certain to be heard will be calls to use only disposable or “sterilized” endoscopes to prevent disease transmission.² *Would a disposable bronchoscope have prevented the outbreak at AGH?* Yes, but so presumably would have drying (as well as cleaning and high-level disinfecting) the bronchoscope's channels, a simple and inexpensive practice. When given a choice, a patient would always prefer a new and sterile instrument. But the rising cost of health care in an environment driven by limited resources and cost reductions does not always afford us this option.

To assess the feasibility of using a more expensive device such as a disposable endoscope, it is recommended that a cost-benefit analysis first be performed.¹⁰ If a more expensive disposable device demonstrates a clinically significant advantage over a less expensive (per use) reusable device, then its use, despite its higher cost, should be considered. But, to date,

data supporting the claim that a more expensive disposable endoscope is safer than a reusable endoscope reprocessed according to published guidelines⁷ have not been published. (Whether health care facilities would feel pressured, like with many other expensive disposable items, to reuse disposable endoscopes to reduce costs is unclear.)

Finally, I suggest that we learn from our reprocessing mistakes and ask ourselves why lessons from published *P aeruginosa* outbreaks following endoscopy, such as those at AGH in Pittsburgh and in Flushing,^{4,6} are apparently not being learned. Unfortunately, probably because something in the message about the causes and prevention of bacterial outbreaks in the endoscopic setting is confusing or is being misinterpreted or improperly conveyed to health care staff, more outbreaks linked to endoscopes contaminated with *P aeruginosa* and other bacteria are likely to be reported.

Are we all to blame for this apparent miscommunication? Perhaps. But we can all contribute to reducing the risk of disease transmission during endoscopy by, among other considerations, encouraging the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to adhere more diligently to their intended respective missions and act as required to ensure that reusable endoscopic instrumentation is used in a manner that is safe, effective, and prevents disease transmission (I say this notwithstanding my being employed by a manufacturer of automated endoscope reprocessors regulated by the FDA).

It is further suggested that the FDA review the current labels of liquid chemical sterilants, flexible endoscopes, and automated endoscope reprocessors to safeguard public health and make certain none in any way misleads users or confuses health care staff into skipping or omitting an essential reprocessing step, such as drying. It is also suggested that infection control, operating room, and endoscopy organizations review and clarify their respective guidelines and recommendations to stress clearly and without equivocation the importance of endoscope drying, irrespective of the rinse water's quality (e.g., tap, “sterile”), to the prevention of the transmission of bacteria. There are lessons out there to be learned. Let's all go back to school and learn them. ○ *The End*

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Perspectives in infection control

The following interview provides the responses of this newsletter's editor to questions about trends in infection control and outbreak management.

1. In your opinion, what is one of the most pertinent issues facing infection control practitioners (ICPs) today?

There are several, but one issue of particular concern to infection control practitioners (ICPs) today is balancing the growing interests of the patient against the never-ending reduction in health care resources. Some health care facilities, under pressure to reduce costs, may reassign their ICPs to other responsibilities or terminate the position altogether. Only after an outbreak or some other infection-related event is identified do some facilities realize the shortsightedness of their downsizing and the true value and importance of ICPs. Surveillance and the analysis of infection-related data are crucial to the detection and termination of outbreaks. Facilities that realize the importance of infection control and all of its related activities are likely to significantly reduce not only the risk of patient infection but also the risk of liability due to inadequate care and nosocomial infections.

2. Where do you see health care headed? Any predictions?

With regard to infection control, I am hopeful that recent reports that suggest the risk of patient injury increases with a reduction in the number of attending nurses will be sufficient to sound an alarm and cause health care facilities to upgrade their infection control capabilities and allocate additional resources to hire more ICPs. Those facilities with foresight understand that ICPs contribute to the reduction—*not* increase—of overall health care costs. The cost to manage an active infection control program that monitors trends to detect when an outbreak has occurred and provides measures to quickly eradicate it is small in comparison to the costs incurred by a facility with a lax infection control program capable of detecting an outbreak only after it has already spread throughout a large unit. Whether facilities with more active infection control programs become in the future the norm or an aberration remains to be determined.

3. As a health care professional, what solution do you see to the nursing shortage?

The answer is simple, but its implementation complex. Basic economic theory provides a simple solution to the current nursing shortage: increase the supply of nursing staff. This goal can be accomplished through many avenues, such as by increasing the benefits and salaries and improving the work conditions of nursing staff. Exactly how to obtain the additional revenue required to satisfy this economic principle and

increase the supply of nurses is not so simple. Certainly, assessing which health care practices are unnecessary (e.g., "sacred cows") is part and parcel to the solution. To be clear, most infection control practices are not superfluous and warrant expansion, not downsizing or elimination.

4. Where should more money be spent to improve patient safety and reduce the risk of outbreaks?

In order to improve patient safety, I believe that, in addition to spending more money on health care worker safety, additional resources must be made available for utilization by ICPs. Of particular concern is the number of bacteria that has mutated and become resistant to what once were effective antibiotics. Additional resources that provide for preemptive infection control activities and practices designed to quickly address and eradicate the spread of infections associated with these resistant bacterial strains are important to patient safety. Antibiotic-resistant strains of bacteria, including MRSA (methicillin-resistant *Staphylococcus aureus*) and VRE (vancomycin-resistant *Enterococcus*), have become problematic because of several factors, including the overuse of antibiotics and lax aseptic technique practices. Increased spending for infection control practices that control the mutation and spread of antibiotic-resistant bacteria is recommended.

An article published in the March 2003 issue of *Health-care Purchasing News* was used as the basis for this newsletter's editorial, which discusses lessons to be learned. Both of these articles were written by Lawrence F Muscarella, Ph.D., this newsletter's editor.

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully,*
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