

The Q-Net™ Monthly

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What's News

Happy New Year! This is this Q-Net's 9th year of publication. Thank you for your interest.

Three important articles that discuss Olympus's recent bronchoscope recall were published in *The New England Journal of Medicine's* January 16th (2003) issue.

Also, several newspaper articles discussing an outbreak following bronchoscopy in Pittsburgh, PA, were recently published. Visit: <http://www.myendosite.com> for the link to each of these articles.

Editor-in-Chief

The articles published in this newsletter are written by: **Lawrence F Muscarella, PhD**, Chief, Infection Control at Custom Ultrasonics, Inc. Ivyland, PA 18974 (215-364-8577).

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 healthcare.

Bronchoscope reprocessing

The following **questions and answers** are from an interview with the editor of this newsletter.

In addition to bronchoscope reprocessing, issues addressed include the importance of drying.

Q1: *Are there any aspects of endoscope reprocessing that you think may not be receiving sufficient attention?*

Yes, particularly with respect to bronchoscope reprocessing. Several outbreaks linking patient colonization and infection to bronchoscopes contaminated with gram-negative bacteria or mycobacteria after automated reprocessing have been reported, including a recent outbreak in Flushing (NY) caused by antibiotic-resistant *Pseudomonas aeruginosa*.

While the cause of some of these outbreaks was reported to be human error – namely, improper connection of the bronchoscope to an automated endoscope reprocessor (AER), resulting in inadequate reprocessing and cross-infection – I believe that the environment, specifically the rinse water used during bronchoscope reprocessing, may have played a more significant role in these outbreaks than acknowledged or reported.

For reasons not entirely clear, I have

found that nursing and reprocessing personnel are sometimes blamed for causing an outbreak, even though the data necessary to support human error are generally lacking. My research suggests that some of these outbreaks may have been due instead to contaminated environmental surfaces within the healthcare facility, and not to patient-to-patient disease transmission caused by a nursing mistake as often cited. This finding should not be surprising, particularly since most outbreak reports following endoscopy are due to environmental (waterborne) bacteria – not HIV, the hepatitis C virus, or another virus or pathogen whose mode of transmission is patient-to-patient.

As a result of my conclusion that some of these recent outbreaks may have been due to environmental contamination and not a nursing mistake, I caution investigators against prematurely asserting that the mode of transmission of a *P aeruginosa* outbreak following bronchoscopy (or gastrointestinal endoscopy) is patient-to-patient simply because, for example, the strain is resistant to antibiotics. Such an assertion can be too simplistic and is often based on insufficient data. Reports

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have shown that environmental surfaces within a healthcare facility, including the water used to rinse instruments during automated (and manual) reprocessing, can be important sources of antibiotic-resistant (as well as –susceptible) *P aeruginosa* and other bacteria (refer to this newsletter's October-November and December 2002 issues).

Contaminated rinse water in my opinion is an increasingly significant, although under-recognized, risk to patients undergoing endoscopy, particularly bronchoscopy. I am concerned that if the contribution of contaminated rinse water to patient infection following bronchoscopy continues to receive inadequate attention, simple measures such as drying the endoscope after reprocessing — a practice that prevents the transmission of waterborne bacteria — will be ignored, and outbreaks linking bronchoscopes contaminated with bacteria to patient infection will continue to be reported.

Q2: *What can be done to reduce the risk of patient infection from P aeruginosa and other waterborne bacteria following bronchoscopy?*

Reports in the medical literature indicate that, assuming there are no design defects in the instrumentation where inaccessible bacteria may colonize (refer to this newsletter's April-May and June-July 2002 issues), drying the bronchoscope after reprocessing significantly reduces, if not eliminates, the risk of infection from gram-negative bacteria and other microorganisms present in rinse water. The incorporation of drying into virtually every guideline for cleaning and disinfecting gastrointestinal (GI) endoscopes is likely responsible for the significant reduction over the past decade of the number of reported infections from waterborne bacteria during GI endoscopy, particularly endoscopic retrograde cholangiopancreatography (ERCP).

It is therefore paramount that bronchoscopes, as with GI endoscopes, be dried after reprocessing. Drying of the endoscope's channels is typically accomplished easily and inexpensively using a 70% alcohol rinse followed by forced-air. Even if not provided ample time to proliferate, bacteria in the rinse water can already be of a sufficiently high number to cause infection. It is important to remember that as the patient's immune system becomes more compromised, the number of bacteria required to elicit infection decreases. Low numbers of bacteria in the rinse water can therefore pose an immediate risk to critically ill patients. *I therefore recommend drying bronchoscopes (and GI endoscopes) not only before storage but also between patient procedures, during which time the endoscope may remain idle before reuse allowing bacteria to proliferate to potentially dangerous levels.*

Whenever an outbreak following bronchoscopy (or GI endoscopy) is linked to *P aeruginosa* or another waterborne microorganism, attention should immediately focus on the healthcare facility's drying process. Indeed, inadequate

drying, possibly in addition to other reprocessing mistakes, is typically at fault whenever waterborne bacteria are transmitted via an endoscope. To be clear, there are no reports of a bacterial infection linked to a thoroughly dried flexible endoscope (refer to the article: "Plan to attack contamination of bronchoscopes proposed," published in the January 20th, 2003, issue of Pittsburgh's *Post-Gazette* newspaper).

I therefore recommend terminally drying the endoscope whether it was reprocessed manually or using an automated device that claims to produce "sterile" or bacteria-free (or distilled) water, or claims to achieve "sterilization" or high-level disinfection of endoscopes.

Q3: *You have clearly stated the importance of drying. Considering the availability, convenience, and low cost of 70% alcohol and forced-air, why do you think a healthcare facility might not dry its bronchoscopes?*

That is a very good question, especially since drying has been shown through the years to prevent the transmission of bacteria during endoscopy (refer to the previous question, above). Although bronchoscopes rinsed with contaminated water pose a significant infection risk, drying them to prevent bacterial transmission is not always practiced.

There may be several reasons for the omission of drying, and one may be due in the United States to a lack of formal reprocessing guidelines published exclusively for bronchoscopes by the pulmonary community. Unlike bronchoscopes, GI endoscopes and their potential for disease transmission are frequently the focus of attention and media reports. To be sure, guidelines published by several different organizations provide step-by-step and clear instructions for reprocessing and drying GI endoscopes.

Perception may be another reason for some facilities not drying their bronchoscopes after reprocessing. While unintentional, recommendations for the prevention of nosocomial pneumonia may at times appear to portray bronchoscopes as "critical" instruments. For example, it is generally recommended that bronchoscopes be rinsed with sterile water (after immersion in a liquid chemical sterilant). The recommendation that the rinse water be sterile, instead of bacteria-free or from a tap, may suggest to some healthcare staff that bronchoscopes require sterilization.

As a result of having concluded (erroneously) that bronchoscopes are critical instruments that require sterilization, some healthcare facilities may not dry their bronchoscopes after reprocessing, because in the healthcare setting neither a solution of 70% alcohol nor forced or compressed air is typically sterile. The practice of using both in tandem to dry the bronchoscope after reprocessing might therefore be perceived to violate aseptic technique and the bronchoscope's presumed sterility, especially if the

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automated device used to reprocess the bronchoscope is labeled for “sterilization” and/or the rinse water used during reprocessing claimed to be “sterile.”

But bronchoscopes (and GI endoscopes) are not critical instruments and do not require sterilization. Rather, they are semi-critical instruments for which high-level disinfection is recommended or deemed acceptable (i.e., high-level disinfection does not pose an infection risk). And most important, drying the endoscope using 70% alcohol and forced air, even though neither is ordinarily sterile, does not compromise the safety of the endoscope nor violate the recommendations of any reprocessing guideline or standard.

Also, although some reprocessing guidelines may state that the drying of bronchoscopes or GI endoscopes is only required before storage when bacteria-free or sterile rinse water is used, I recommend that drying also be performed between patient procedures, irrespective of whether the rinse water is labeled to be sterile (or bacteria-free). In short, drying is an essential practice that significantly reduces the risk of patient infection during endoscopy. This misunderstanding of the classification of bronchoscopes and the intent of published guidelines, as well as misleading labels that claim sterile rinse water can be produced from tap water using a bacterial filter, has contributed to de-emphasizing the importance of endoscope drying.

Q4: *In addition to drying, what other practices can be performed to reduce the risk of patient infection from waterborne bacteria following bronchoscopy?*

Drying the bronchoscope after reprocessing is important, but I also recommend monitoring the microbial quality of the rinse water used during both manual and automated endoscope reprocessing. (The measurement of the level of endotoxins in the rinse water also appears necessary if claimed to be sterile.) Despite being a practice that I recommend for the prevention of patient infection during endoscopy, monitoring the rinse water used during endoscope reprocessing is not currently recommended by any endoscopy or infection control organization in the United States.

For several reasons, I have concluded that monitoring the rinse water is important (*refer to this newsletter's February, March and April 2001 issues*). First, it yields data crucial to evaluating whether the water used by a facility to rinse endoscopes, particularly bronchoscopes and ERCP endoscopes, after chemical immersion is safe for reprocessing, or whether the rinse water could pose a serious risk of infection, especially if the patient is immunocompromised and the endoscope not dried between patient procedures or before storage. Second, in addition to improving infection controls, monitoring the rinse water is necessary to determine whether its quality (e.g., bacteria-free or sterile) is consistent with the label claims of the liquid chemical sterilant (LCS) or the automated endoscope

reprocessor (AER). For manual and automated reprocessing, the process's labeled outcome – whether high-level disinfection or sterilization – is limited by and can only be as good as or as valid as, among other factors, the quality of the terminal water rinse. Although often overlooked, if the rinse water is contaminated, then, because it contacts the endoscope after chemical immersion, so too would the endoscope be contaminated, rendering meaningless the process's high-level disinfection or sterilization claim.

The observation that the manual or automated process's outcome and claim are dependent on and part and parcel of the rinse water's microbial quality underscores the importance of monitoring the rinse water. Simply put, a thoroughly cleaned endoscope that is immersed in a LCS, but is then rinsed with water that has not been monitored and therefore whose microbial quality is unknown, cannot be claimed to be high-level disinfected or sterilized. Whereas processes labeled to achieve high-level disinfection require the rinse water be at least bacteria-free, processes labeled to achieve sterilization require a sterile water rinse. *Rinse water that is not monitored and whose quality is therefore unknown yields reprocessed instruments whose outcome and quality are also unknown, irrespective of the LCS's or AER's label claim (i.e., high-level disinfection, sterilization).*

And, third, as part of an overall quality control program that compares the claims of medical devices to their clinical effectiveness, monitoring the filtered rinse water, which is produced by virtually all AERs on the market, provides data necessary to evaluate whether the bacterial filter is producing rinse water whose quality is in accordance with the filter's labeling claim (i.e., bacteria-free, sterile), or whether the filter is failing and allowing bacteria to pass and re-contaminate the endoscope during rinsing. *Particularly if it is claimed to be sterile, monitoring the filtered rinse water – just like routinely monitoring a steam autoclave using biological indicators, to ensure the process produced conditions appropriate for sterilization – would seem to be a practice required by the FDA and recommended by all appropriate endoscopy and infection control guidelines.*

Current practice and protocol assume that the bacterial filter will not fail or require changing until a pressure differential across its membrane reaches a threshold level (e.g., 25 PSI or pounds-per-square-inch). But the reliability and effectiveness of a pressure differential as the sole indicator for the onset of microbial leakage across the filter's membrane have not been demonstrated. Indeed, data showing a direct correlation between a specific pressure differential, such as 25 PSI, and filter failure are lacking. It is likely that monitoring the microbial quality of the filtered rinse water would be a more reliable indicator for filter failure than a pressure differential, especially if it is possible for bacteria and other types of waterborne microorganisms to pass through the bacterial filter's membrane before reaching a threshold pressure differential.

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Monitoring the rinse water can also provide important data with regard to whether the filter's housing is contaminated with a biofilm and requires decontamination, or whether the internal components of the AER may be colonized with bacteria and require disinfection or sterilization to prevent contamination of the endoscope during rinsing. *For these reasons, I recommend monitoring the rinse water used during endoscope reprocessing.*

Q5: Why do you suggest monitoring the rinse water is particularly important when reprocessing bronchoscopes and ERCP endoscopes?

Lower GI endoscopy, which is often a screening procedure performed on generally healthy patients, poses a very low risk of infection. While still a concern, transmission of waterborne bacteria via an endoscope into a patient's colon (or stomach) does not appear to pose the same infection risk as their transmission during ERCP and bronchoscopy. The medical literature indicates that, while still low, the risk of infection associated with these two relatively invasive endoscopic procedures is higher than the risk of infection associated with lower GI endoscopic procedures like colonoscopy.

The susceptibility of their respective tissues to infection is one of the reasons for the increased bacterial infection risk associated with ERCP and bronchoscopy. ERCP endoscopes are routinely used near or in the common bile duct, which especially if occluded can retain stagnant fluids for long periods of time. If during a procedure the ERCP endoscope were to introduce bacteria into this duct, there is the possibility of bacterial growth, infection and bacteremia. Reports several years ago documented a significant risk of waterborne infections during ERCP. But, in part because drying ERCP endoscopes has become the standard of care, the risk of the transmission of exogenous (waterborne) bacteria into the common bile duct via the ERCP endoscope has become very low.

Similarly, bronchoscopes, which are often used to penetrate deep into the lungs, may also transmit disease if not properly reprocessed and dried. The lungs appear to be particularly susceptible to infection from waterborne bacteria, such as gram-negative bacteria and mycobacteria. Bronchoscopy is also often performed on critically ill patients. Introduction of only a few bacteria into these patients' lungs can be catastrophic. Furthermore, some healthcare facilities may not dry bronchoscopes, having (erroneously) concluded that a bronchoscope is a critical item whose aseptic quality would be violated by drying (refer to question 3, above). Bronchoscopes, like ERCP endoscopes, are semicritical items for which high-level disinfection is recommended. *As a result of the relative invasiveness of bronchoscopy and ERCP, I recommend monitoring the rinse water used during the reprocessing of bronchoscopes and ERCP endoscopes.*

Q6: What can a hospital do to improve the quality of the rinse water it uses during endoscope reprocessing?

If the healthcare facility is manually reprocessing its endoscopes, particularly bronchoscopes and ERCP endoscopes, I recommend rinsing the endoscope not with tap water but instead with bottled, sterile water after chemical immersion in accordance with the liquid sterilant's labeling. (An increased risk of infection associated with rinsing GI endoscopes with tap water has not been demonstrated.) But some liquid sterilants may require several water rinses, each of a large volume. And, because the cost of bottled, sterile water can be prohibitively expensive, its use is often not feasible, especially if the facility's endoscopy unit is large and reprocessing many endoscopes per day.

Automated endoscope reprocessors (AER) provide a convenient alternative not only to manual reprocessing but also to rinsing endoscopes with tap water or expensive bottled, sterile water. Virtually all AERs are equipped with a water filtration system capable of producing large volumes of filtered water that is ordinarily significantly less expensive per volume than bottled, sterile water. Although filters improve the quality of the rinse water, they can fail, which is why I recommend drying the endoscope before reuse and monitoring the filtered rinse water's microbial quality, to ensure: the rinse water is not contaminated; the bacterial filter is functioning properly and not failing; and the filter's housing and the internal components of the AER are not contaminated with a biofilm capable of re-contaminating the endoscope during rinsing. Proper maintenance of these filters, their housing and the AER in accordance with the respective labeling of each is crucial to minimize the risk of patient infection from contaminated rinse water. *The End*

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

LAWRENCE F MUSCARELLA, PH.D.
Author, Editor, Publisher, *The Q-Net™ Monthly*
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: editor@myendosite.com
<http://www.myendosite.info>



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