

The Q-Net™ Monthly

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What's News

- A database error occurred last month affecting the mailing of the March-April (2006) issue of this newsletter to some subscribers. To download a copy of this issue, visit: <http://www.myendosite.com>
- An article entitled "The risk of disease transmission associated with inadequate disinfection of gastrointestinal endoscopes" and written by LFM appears in the July (2006) issue of the *Journal of Hospital Infection* (Volume 63, Number 3, pp. 345-7).

Editor-in-Chief

All of the articles published in this newsletter are written by: **Lawrence F Muscarella, PhD**, Chief, Infection Control at **Custom Ultrasonics, Inc.** Ivyland, PA

What is 'Q-Net'?

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

The mail goal of **Q-Net** is to encourage the infection control, endoscopy, and OR communities to not only ask good questions but to also demand 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.

Double Standards

This article is one in a series that discusses confusing trends in infection control, endoscopy, and instrument reprocessing.

*This article discusses **double standards** and **inconsistencies** in **sterilization** and **infection-control** guidelines.*



Background

An article entitled "Best Practices for Scope Reprocessing" was published in the May (2006) issue of the magazine *Infection Control Today*.¹ Focusing on gastrointestinal (GI) endoscopy, this article highlights double standards and inconsistencies advanced by some sterilization guidelines, as well as reaffirming several conclusions that this newsletter has published during the last ten years.

Quoting a well-respected and published gastroenterologist, who is a spokesman for the *American Society for*

Gastrointestinal Endoscopy (ASGE), this magazine article discusses from a physician's perspective a number of endoscopy-reprocessing practices, if not controversies, the significance of which is frequently overlooked by sterilization and infection-control guidelines.

According to this gastroenterologist:

☛ "It's not my practice to store it (the endoscope) wet. I know that one of my manufacturers insists the finished instrument not be exposed to alcohol and forced air. In that circumstance, you're left with water. Unless you're checking the water quality, you have no guarantee of the reliability of water. In every other aspect of medicine, you don't assume something is sterile because it's been through an autoclave. We have biological indicators, and if they don't prove it's sterile, you assume it's not. I don't think we should assume because the water has gone through the reprocessor, and there's a claim about the water quality — if we're not testing it — we should not assume that it's sterile."¹

Monitoring the rinse water

As part of a complete quality control program designed to reduce the risk of nosocomial infection, this gastroenterologist's comments provide a logical, if not compelling, argument for health-care facilities to monitor, or routinely

(Continued on page 10)

FOCAL POINT: ● *This article discusses double standards that occur as a result of developing and publishing **sterilization** and **infection-control** guidelines to accommodate the labeling of medical devices, rather than designing and labeling medical devices in conformance with published guidelines.*

check, the microbial quality of the rinse water used during endoscope reprocessing. Although most guidelines in the U.S. recommend this practice only during an outbreak investigation—endoscope-reprocessing guidelines in the United Kingdom, however, recommend that the microbial quality of the rinse water be “regularly” monitored²—this newsletter, in agreement with this gastroenterologist’s comments, endorses monitoring the rinse water for both clinical and academic reasons (refer to the *January-February 2004*, *August-September 2002*, and *April 2001* issues of this newsletter).³

Achilles’ heel: Providing a strong rationale for monitoring the rinse water used during endoscope reprocessing—whether tap water, bacteria-free water, or “sterile” filtered water—the success of a manual or automated high-level disinfection or liquid chemical “sterilization” process is dependent on the microbial quality of the rinse water—arguably the *Achilles’ heel* of endoscope reprocessing. Because it contacts the instruments *after* chemical immersion, contaminated rinse water yields contaminated instruments irrespective of the potency, effectiveness, or concentration of the liquid chemical disinfectant/sterilant (LCS). As this physician notes in *Infection Control Today*: “The instrument is only as good as the water quality you rinse it off with.”¹

Failure to monitor “sterile” (or “bacteria-free”) filtered rinse water to evaluate its microbial quality and its endotoxin level invalidates a manufacturer’s claim, assurance, or guarantee that the endoscope was successfully “sterilized” (or high-level disinfected), because the possibility exists that the *un-monitored* filtered rinse water may have unknowingly become contaminated with potentially pathogenic microorganisms, resulting in re-contamination of the endoscope during terminal water rinsing and an increased risk of nosocomial infection. Monitoring the rinse water, therefore, is recommended, to ensure its microbial quality is consistent with its label claim (i.e., “sterile,” “bacteria-free”) and does not adversely compromise the success of the reprocessing procedure and patient safety.

Water filters, bacterial colonization: Water filtration systems are often used by healthcare facilities in conjunction with automated endoscope reprocessors (AERs) and “sterilizing” systems, to treat the tap water and improve its microbial quality. Preemptive determination of when the 0.2 (or 0.1) micron bacterial membrane of these water filtration systems is failing, requires replacement, and is posing an infection risk provides additional rationale for monitoring filtered rinse water.³ (Activation of a visual or audible alarm once a critical, or threshold, water pressure differential is detected across the bacterial filter’s membrane is inadequate and an unreliable indicator of, or gauge for, filter failure and both rinse water and endoscope contamination.) Over time and with repeated usage, the integrity of a 0.2 micron bacterial

membrane can become compromised, break down, and allow potentially pathogenic microorganisms to leak through the filter. To be sure, “filtered” rinse water used during endoscope reprocessing, although labeled as “sterile” or “bacteria-free,” has been linked to nosocomial infection.³⁻⁸

In addition to preventing contamination of the endoscope during terminal water rinsing (after chemical immersion), replacement of the bacterial filter can prevent contamination of the plumbing and internal surfaces and components within an AER or automated system. Reports of colonization of these internal surfaces with bacteria resulting in re-contamination of the rinse water and the endoscope have been reported.^{3,4,9,10} In addition to substantiating the rinse water’s label claim and improving patient safety, monitoring the rinse water is, therefore, recommended to evaluate the bacterial filter’s effectiveness and determine when its 0.2 micron membrane requires replacement, as well as to detect colonization of the AER’s or automated system’s internal components with microorganisms that may pose an infection risk.

“I don’t think we should assume because the water has gone through the reprocessor, and there’s a claim about the water quality—if we’re not testing it—we should not assume that it’s sterile.”¹

Sterilization precedent, double standards: Two other important reasons why this newsletter recommends routine monitoring of filtered rinse water used during endoscope reprocessing are for consistency and to uphold important sterilization precedents. Intimated by this gastroenterologist’s comments in *Infection Control Today*, failure to recommend monitoring the rinse water—especially in the operating room setting where aseptic technique, quality control, and sterility are paramount—advances a double standard.¹

Consider this: Sterilization and infection-control guidelines and federal guidance documents historically and universally understand that the sheer labeling of a device by its manufacturer as a *sterilizer* is insufficient to conclude that the conditions for instrument sterilization are consistently and reliably achieved to within a sterility assurance level, or SAL, of 10⁻⁶. Consequently, these guidelines and guidance documents require that steam autoclaves (and other types of sterilizers) be monitored on-site using biological indicators (BIs), emphasizing that if a sterilizer is *not* microbiologically monitored (or if it yields a *positive* BI result), then its sterilization cycle is deemed to be ineffective, the processed instruments are presumed to be contaminated, and the clinical use of these instruments is considered verboten.

In the context of endoscope reprocessing and the potential for rinse water contamination, however, these guidelines and guidance documents abandon this important evidence-based approach. Healthcare facilities may use a water filtration system that features a 0.2 micron bacterial membrane to produce rinse water labeled as “sterile.” Because this water filtration system is a process labeled to achieve “sterilization” on-site, it is subject to the same requisite sterilization quality controls that apply to steam autoclaves, which include

(Continued on page 11)

microbiologic monitoring. Nevertheless, while recommending monitoring of steam autoclaves using BIs, these guidelines and guidance documents, including a set of sterilization guidelines published in March (2006),¹¹ embrace a double standard and do *not* recommend microbiologic monitoring of water filtration systems labeled to produce “sterile” filtered rinse water.

Failure of a guideline or guidance document to recommend monitoring water filtration systems associated with a sterilization claim—a salient misstep that is the same as failure to recommend monitoring steam autoclaves using BIs—violates infection-control and sterilization principles and precedents, requiring that the water filtration system be deemed ineffective and both the filtered rinse water (despite its “sterile” label claim) and the rinsed instruments be considered contaminated, unsterile, and unsafe for use.

This conclusion notwithstanding, this set of sterilization guidelines published in March (2006) recommends that:

☛ *"Items sterilized in an automated system using peracetic acid should be transported and used immediately. Items sterilized with peracetic acid are wet, and the cassette or container is not sealed to prevent contamination."*¹¹

Referred to as “*Recommended Practice IX*,”¹¹ this recommendation is dubious, because of the dangerous precedent it establishes, if not the double standard and erroneous presumptions it advances. Without recommending monitoring the microbial and endotoxin levels to provide on-site verification of the manufacturer’s claim that the water filtration system produces “sterile” filtered rinse water, or requiring that the manufacturer provide and publish the SAL associated with the water filtration system, *Recommended Practice IX* ignores well established sterilization and infection-control principles and quality controls, choosing instead to take an unprecedented “leap of faith,” accept as an *a priori* truth, and (erroneously) conclude that this automated system produces “sterile” rinse water.¹¹ (Note: Monitoring rinse water is based on an entirely different FDA clearance and set of microbiologic principles than monitoring the effectiveness of peracetic acid or another LCS. Moreover, a SAL associated with a sterilant is independent of and separate from the SAL associated with a water filtration system that claims to produce “sterile” rinse water.)

By concluding without supporting data that the rinse water is “sterile,” *Recommended Practice IX* is inconsistent with the understanding that for the sake of patient safety filtered rinse water, like a processed instrument, is considered contaminated until it is demonstrated to be “sterile” to within a predetermined SAL. The microbial quality (as well as pH and hardness) of rinse water is inconsistent and may vary significantly from one medical facility to another.

*“Filtered filtered rinse water, despite being labeled as “sterile” (or “bacteria-free”), may be contaminated with potentially pathogenic microorganisms.”*³⁻⁸

Because un-monitored filtered rinse water labeled as “sterile” (or “bacteria-free”) may be contaminated with microorganisms and has been linked to nosocomial infections,³⁻⁸ not only is the label claim of “sterility” associated with a water filtration system misleading, but also *Recommended Practice IX* is arguably flawed and compliance with it an infection risk. (It is puzzling how *Recommended Practice IX* expects a *clean* area, where the decontaminated endoscope is placed into the processor prior to initiating its automated cycle, to transform into a *sterile* area, as required to maintain the “sterility” of the endoscope upon its removal from the processor.)

Wet endoscopes, endoscope drying

R*ecommended Practice IX* also raises concern for other reasons. In addition to providing rationale for monitoring the rinse water, the gastroenterologist quoted in *Infection Control Today* points out that not everyone supports endoscope drying. *Recommended Practice IX*, as well as a manufacturer and some other published guidelines, for example, instead recommend that the endoscope be “*transported and used immediately*” after completion of the reprocessing cycle, without first being dried.^{4,7,11,12}

The recommendation to “immediately” use an (un-dried) endoscope after reprocessing is problematic, however, because it acknowledges and accepts that the endoscope and its internal channels will be wet with rinse water when used to treat the patient. Many published studies and clinical investigations raise doubts about the safety of this recommendation, documenting the increased risk of disease transmission and nosocomial infection associated with the insertion of wet endoscopes (and other types of instruments) into, for example, the patient’s biliary tract, lungs, urethra, sinuses, knees, or peritoneal cavity.^{4,7,11-15} Moreover, several of these reports also demonstrate the contribution of endoscope drying to the abrupt termination and prevention of true and pseudo outbreaks.^{4,7-10,13,14} Citing this published association between nosocomial infection and wet (or improperly dried) endoscopes, this newsletter’s editor (LFM) expresses concern about guidelines, manufacturers, and labeling that contraindicate endoscope drying and suggests that “immediate” use of wet flexible (and rigid) endoscopes, in accordance with *Recommended Practice IX*, is an arguably negligent practice tantamount to medical malpractice.^{4,7-10,13-15}

The reasons for a guideline, manufacturer, or agency *not* to recommend endoscope drying after every reprocessing cycle, whether disinfecting or “sterilizing” endoscopes using a LCS, but instead to endorse the “immediate” use of a wet

(Continued on page 12)

“‘Immediate’ use and introduction into patients’ viscera of wet (and, therefore, potentially contaminated) flexible (and rigid) endoscopes is an arguably negligent practice tantamount to medical malpractice.”^{4,7-10,13-15}

endoscope after reprocessing, without first drying all of its surfaces—a practice that is associated with an increased risk of morbidity and mortality^{4,6-10,13-15}—are unclear and perplexing, especially when current reports indicate that as many as 2 million people each year in the U.S. develop nosocomial infections that contribute to as many as 100,000 patient deaths and cost nearly \$5 billion dollars a year to treat.^{16,17}

What's more, almost one third of these nosocomial infections are caused by Gram-negative bacteria,¹⁶ such as *Pseudomonas aeruginosa*—a waterborne bacterium that has been not only cultured in the rinse water used to reprocess endoscopes, but is also associated with disease transmission and both true and pseudo outbreaks following endoscopy (refer to the September, 2001, issue of this newsletter).^{6,8-10,13,14} (It is unclear whether endoscope drying, or microbiologic monitoring of the rinse water, could have prevented these outbreaks.) The importance of endoscope drying, which is simple, inexpensive, and safe, to the reduction of healthcare costs and the prevention of morbidity and mortality associated with waterborne microorganisms, including Gram-negative bacteria, cannot be overstated.^{1,4,7-10,13,14,18-20}

A wet-yet "sterile"—endoscope? Expressing concern about using wet instruments, a healthcare organization aptly wrote:

☛ *"A sterile, wrapped set with moisture or dampness on the inside should be rejected even if there is no evidence of wetness on the outside. Moisture, whether on the inside or the outside, causes a wicking effect and provides access for microorganisms to enter and contaminate the sterile set. The pack may have been wet on the outside and dried before it was opened. Regardless of the location, wetness or dampness creates doubt about the sterility of the set, and it should be considered unsterile."*¹⁵

This recommendation is well-stated, evidence-based, and designed to protect the patient. Supporting the conclusion that wet or inadequately dried endoscopes pose an increased risk of contamination and nosocomial infection (and that a sterile, wet endoscope is an oxymoron), this recommendation calls into doubt the validity of Recommended Practice IX. One might be surprised to learn, therefore, that the same healthcare organization that published this evidence-based recommendation to prevent nosocomial infection associated with moist, wet, or damp instrument sets also published Recommended Practice IX. The publication by the same healthcare organization of these two mutually exclusive recommendations raises the inevitable question:

☛ *"How can a wet, unwrapped endoscope intended for 'immediate' use be considered 'sterile' when a wet, wrapped instrument set is considered contaminated, 'unsterile,' and unsafe for use?"*

Conclusions, Recommendations

Each month newspaper articles are published across the U.S. reporting infection-control lapses and the potential for disease transmission associated with an instrument reprocessing mishap. To reduce the frequency of these lapses, mishaps, and the risk of nosocomial infection, federal, accreditation, healthcare, and non-profit agencies, as well as operating room, endoscopy, and infection-control organizations, are requested to revise their respective guidelines as required to recommend: (1) an improvement of quality controls that include monitoring the rinse water used during endoscope reprocessing, especially if it is produced by a water filtration process and labeled as "sterile"; and (2) endoscope drying after completion of every reprocessing cycle, both between patient-procedures and before storage.

Reaffirmation and clarification of the importance of endoscope drying and the potential for contamination and nosocomial infection associated with wet instruments,²¹ and the elimination of inconsistencies from sterilization and infection-control guidelines that advance double standards are also recommended. Finally, to maintain the integrity and validity of published guidelines and reduce the risk of patient injury, it is imperative that medical devices be designed and labeled in conformance with published guidelines, rather than developing and publishing guidelines to accommodate and placate the designs and labeling of medical devices. ● LFM [The End]

The references for this article are available at:

☛ <http://www.myendosite.com/refs050606.pdf>

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, Ph.D.* Please direct all correspondence to:

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