

The Q-Net™ Monthly

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What's News?

(1) Several articles comparing the safety and cost of reusable and disposable endoscopic biopsy forceps appear in March's issue of *Gastrointestinal Endoscopy* (2000;51[3]). (2) An article that discusses hepatitis C transmission in Egypt, due possibly to poor sterilization of reusable needles and syringes, is published in the March 11th issue of *The Lancet* (2000;355:887-891). And (3) The April 2000 issue of *Gastrointestinal Endoscopy Clinics of North America* is dedicated to discussions on endoscopic disinfection and reprocessing of endoscopic accessories.

Editor-in-Chief

Lawrence F Muscarella, PhD
Chief, Infection Control
144 Railroad Drive
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.

P. aeruginosa Infection

The problem with waterborne pathogens recontaminating endoscopes

Several media reports that discuss errors in instrument reprocessing practices have been published recently. In February (2-14-2000, p. A1), *Investor's Business Daily (IBD)* published the article, "A new risk for high-tech surgery?" This article discusses multiple patient injuries caused by bronchoscopes contaminated with *Pseudomonas aeruginosa*. (This outbreak was discussed in *The Q-Net™ Monthly's* June 1999 issue.) Some of the issues reported in *IBD's* article are discussed in greater detail below.

Background: A nosocomial infection originates (or is acquired) in a hospital or other health care setting. Microorganisms responsible for causing nosocomial infections are either *endogenous* or *exogenous*.

The patient's own microbial flora contain many different types of endogenous microorganisms. When, for example, those that are indigenous to the gut are transferred by a surgical instrument to the patient's respiratory tract, a nosocomial infection may result.¹ Most surgical wound infections are caused by endogenous microorganisms.²

In contrast, exogenous microorganisms reside in the outside environment and when introduced into the patient may cause nosocomial infection. Examples include environmental microorganisms on contaminated medical instruments.

Pseudomonas aeruginosa: *P. aeruginosa* is a gram-negative bacillus (rod-shaped). It is commonly found in soil and other natural environments and has been reported to cause many different types of nosocomial infections and pseudo-infections,³⁻⁶ including pneumonia, bacteremia,³ and cholangitis.⁷ Although *P. aeruginosa* ordinarily does not cause disease in healthy individuals, it is an opportunistic microorganism that can pose a serious risk to patients with compromised immune systems.

Requiring little more than a moist environment to colonize and proliferate, *P. aeruginosa* can survive exposure to very adverse conditions.⁸ Respiratory equipment, pressure monitoring devices, and other exogenous sources, including whirlpools, sinks, and tap water,^{3,9-13} have been linked to nosocomial outbreaks of *P. aeruginosa* infection.

Flexible endoscopes: Reports have also linked gastrointestinal endoscopes to *P. aeruginosa* infection.^{3,7} One study reported an outbreak of gram-negative bacteremia following endoscopic retrograde cholangiopancreatography (ERCP).³ Even though filtered to yield

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“sterile” water, the tap water, which recontaminated the endoscope with *P. aeruginosa* during rinsing, was identified as a source of this outbreak. Improving the quality of the rinse water is important, as nosocomial infections linked to contaminated tap water may be more common than reported.¹³



The importance of a 70% alcohol rinse, forced-air drying:

Whereas the contribution of cleaning and disinfecting endoscopes to the prevention of patient infection is well established,¹⁴ the importance of drying the endoscope is not as well understood or appreciated (refer to *Investor's Business Daily*, 2-14-00, p. A1). Indeed, the significance of drying the endoscope to prevent nosocomial outbreaks linked to *P. aeruginosa* and other waterborne microorganisms requires revisiting and reemphasis (refer to this newsletter's June 1999 issue). The internal channels of inadequately dried endoscopes provide an ideal environment for the colonization and growth of opportunistic bacteria.^{3,4,15}

In one report, five of seven patients, each of whom was the first patient of the day, died from *P. aeruginosa* (serotype 10) septicaemia following ERCP.⁷ A similar report documented patient infection and death linked to endoscopes contaminated with *P. aeruginosa*.⁴ And investigation of a pseudo-epidemic of *Legionella pneumophila* found that the tap water used to rinse bronchoscopes after chemical immersion was the source of the contamination.¹⁶

- ✓ Only after the endoscope was thoroughly dried using a 70% alcohol rinse, followed by forced air, was each of these outbreaks terminated.

At a time when reports of nosocomial infection caused by mycobacteria and *P. aeruginosa* are reappearing,¹⁷ renewed attention to the prevention of the transmission of waterborne microorganisms via endoscopes and other instruments is warranted. Failure to thoroughly dry each of the endoscope's internal channels can yield a catastrophic outcome.³⁻⁷



Water filtration systems: More and more health care facilities are purchasing automated flexible endoscope reproprocessors (AFERs), designed to reprocess flexible endoscopes between patient procedures. A recently published survey (refer to this newsletter's April-May 1999 issue) found that more than two thirds of the respondents used an AFER.

One salient advantage of AFERs, compared to manual reprocessing, is the ease with which they can be connected to a water filtration system, which includes a 0.1 or 0.2 micron filter, to yield bacterial-free rinse water. For their part, bacterial filters can improve significantly the quality of the rinse water. But bacterial water filters can also fail, and over the course of their use-life, may allow bacteria and other microbial debris to pass through their membrane and recontaminate the endoscope during water rinsing.^{3,18-20}

Therefore, to protect the patient from a water filter failing in clinical practice,^{3,18-20} drying the endoscope is essential.²¹ Proper maintenance and replacement of the filters and their housing are necessary to improve their effectiveness and reliability.^{18,19} Although expensive and not routinely performed, more frequent microbiologic sampling of the facility's rinse water may be necessary to ensure its quality meets certain minimum specifications (eg, < 200 CFUs/ml).



Issues still to be resolved: Published reports and guidelines recommend rinsing the endoscope's channels with 70% alcohol, followed by forced air drying.^{3-5,21} Although this recommendation is usually heeded when tap water is used for rinsing,^{3,17,21} it may not be as readily practiced if the endoscope is rinsed with filtered water labeled as bacterial-free or sterile (refer to this newsletter's September 1997 issue).

- The need for federal regulatory agencies, standards committees, and professional endoscopy and infection control organizations to recommend flushing the endoscope with 70% alcohol, followed by forced-air drying, whether the endoscope is rinsed with tap or filtered water, is encouraged.

In truth, lacking in the medical literature is a clear description of the parameters of *bona fide* “sterile” water, how it is produced, and how it compares to and differs from other types of water, such as: (a) bottled, sterile water, (b) filtered water labeled as sterile or bacterial-free, and (c) tap water.

Such comparisons and distinctions between water types may not be trivial. For example, the label of at least one liquid chemical sterilant recommends using sterile water to rinse bronchoscopes (refer to this newsletter's October and November 1999 issues). Guidelines for preventing nosocomial pneumonia also recommend rinsing bronchoscopes with sterile water (*MMWR* January 03, 1997;46[RR-1]:1-79). Discussions that address the significance of these recommendations, their intent, and what other types of water may be adequate for rinsing bronchoscopes are necessary.

Issues related to endoscope storage also warrant further discussion. If the endoscope will not be used for a day or two, the importance of terminally rinsing the endoscope with 70% alcohol, followed by forced air-drying, is clear and cannot be overstated. *But what if a reprocessed (and wet) endoscope is to be stored for only a few hours: is drying still necessary?* (“Storage” refers not only to a location but also to a period of idle time.) *And if not, how much time (if any) can elapse between patient procedures before drying the endoscope becomes necessary?* The answers to these questions have important infection control implications.

Whereas drying the endoscope's channels before storage is essential to the prevention of nosocomial infection, the importance of performing this practice between patient proce-

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dures is less clear, as data in its support is limited. Nevertheless, because even low numbers of *P. aeruginosa* and other opportunistic bacteria can pose serious infection in immunocompromised patients, drying the endoscope between patient procedures seems a warranted and prudent practice.

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Conclusions and Summary: The internal channels of flexible endoscopes provide an ideal environment for the colonization and growth of *P. aeruginosa*. To all but eliminate the risk of transmitting opportunistic microorganisms to the patient via an endoscope, rinsing the endoscope's channels with 70% alcohol, followed by forced-air drying, is recommended: (a) before storage and, (b) when feasible, between patient procedures. Further, this practice of drying the endoscope is important to perform, whether the endoscope is rinsed with tap water or water filtered through a 0.2 micron bacterial membrane (see adjacent box article).

Finally, discussions that examine under what conditions (if any) disinfecting endoscopes *before* the first patient of the day may be appropriate seem timely and are also encouraged (refer to this newsletter's October-November 1998 issue),²² lest an inadequately dried endoscope be stored wet the previous day and result in patient infection. *The End*

DID YOU KNOW

... that more than half of the reported patient infections and fatalities linked to contaminated gastrointestinal endoscopes were caused by *Pseudomonas aeruginosa*?^{3-5,7,27}

Patient infections linked to bronchoscopes contaminated with *P. aeruginosa* have also been reported.^{17,27} Because many of these reports identified the tap water,^{3,5,11} not another patient, as the source of the *P. aeruginosa*, thorough cleaning and effective chemical immersion of the endoscope would *not* have prevented these patient injuries.

What measures have been shown to prevent P. aeruginosa infection? In virtually every report of infection caused by *P. aeruginosa* (or another waterborne microorganism), rinsing the endoscope with 70% alcohol to facilitate drying, followed by forced air drying, abruptly terminated the outbreak.³⁻⁷

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Editorial Note: *Media reports often focus on the theoretical differences that may exist between high-level disinfection and sterilization of endoscopes, even though no clinical differences between the two have been reported. The public would be better served if these reports were instead to discuss measures proven to reduce the risk of patient infection, such as the importance of thoroughly drying the endoscope before storage.*

THE UNIQUENESS OF LCSs

Liquid chemical sterilants (LCSs), such as glutaraldehyde, hydrogen peroxide, and peracetic acid, are routinely used by health care facilities to reprocess bronchoscopes and gastrointestinal endoscopes. These unique biocidal agents are relatively inexpensive, easy to use, and typically effective in less than an hour. Moreover, the labels of most LCSs offer health care facilities the opportunity to reprocess endoscopes in or near the patient's procedure room, a practice sometimes referred to as "point-of-use" reprocessing.

LCSs have several salient limitations, however.²³⁻²⁶ Unlike processes that use pressurized steam, ethylene oxide (EtO) gas, or hydrogen peroxide plasma to effect their outcome, those that use a LCS rinse the instrument with a large volume of water after chemical immersion to remove potentially toxic chemical residues. Often overlooked, this requirement is arguably the Achilles' heel of LCS-based processes, as the success of their outcome depends significantly on the rinse water's quality, a parameter that is difficult to monitor and control.

In short, rinse water that contains opportunistic microorganisms can recontaminate the instrument and pose an infection risk, even if the preceding cleaning and chemical immersion steps are thoroughly and effectively performed. Nosocomial infections and pseudo-infections linked to tap water, sinks, shower heads and faucet aerators have been reported.^{3-7,11-13}

While rinsing endoscopes with sterile water may be desirable, its use in clinical practice is limited. In addition to being expensive, producing *bona fide* "sterile" water on-site is problematic, requiring that several manufacturing criteria be satisfied. Presumably monitoring the production process using biological monitoring to ensure sterility would also be required. Although sometimes used during manual reprocessing, bottled, sterile water is also expensive and cannot be easily used by or supplied to automated flexible endoscope reprocessors (AFERs), limiting its application.

In lieu of sterile water, endoscopes reprocessed by an AFER are often rinsed with water filtered through a 0.2 micron filter. Under ideal conditions, these filters can produce bacterial-free water, but they are not designed to produce sterile water from a facility's tap water supply. In fact, bacterial water filters have been reported to fail and allow the passage of bacteria.¹⁸⁻²⁰

In conclusion, because of the inherent limitations of LCSs and the risk of infection that contaminated rinse water can pose to patients, drying the endoscope, whether using tap water or a 0.2 micron filtered water rinse, is recommended. *The End*

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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.* 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

<http://www.myendosite.com>



WORKING WITH THE FDA

The end of this century is finally upon us, making this a time to reflect and reassess what we can do to improve the status quo. For while current infection control practices may be adequate, there is always room for improvement. Indeed, our efforts to improve patient care are working and are appreciated ...

And it is in this vein of improving patient care that health care staff routinely spend exhausting days attending to the needs of the patient. Manufacturers of medical devices similarly spend endless days striving to develop the best engineered equipment to simplify the duties of these health care staff. Almost always these companies produce and market devices with the clear interests of the patient in mind. But on occasion misguided and myopic decisions that may place the patient at risk are made.

Are federal regulatory agencies needed to prevent the marketing and sale of unsafe and ineffective medical devices? Not in Utopia. But ours is an imperfect world that seeks fair and impartial guidance, advice and oversight. Without the Food and Drug Administration proactively screening medical devices to ensure they are safe, and to remove (or relabel) them from the marketplace if deemed unsafe, patient safety would be seriously and irrevocably compromised.

To be sure, the FDA's responsibilities are complex, balancing many tangential and opposing forces against one another. Pragmatism and compromise are the tools the FDA uses in its daily endeavors to regulate a rapidly changing environment that links medical technology with the care giver and patient. As we enter this new century, our need to assist the FDA is more paramount than ever. Only by jointly sharing the responsibilities of protecting the patient will timely and preemptive action be possible.

In truth, some practices that may jeopardize patient safety cannot be easily (if at all) regulated by federal agencies. None is a better example than the reuse of single use devices. It is therefore incumbent upon all of us to ensure that health care practices place the patient's interests first. Neither we nor the FDA can flourish in a vacuum isolated from each other. Harmony can only triumph if we join forces and work together.

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