

The Q-Net™ Monthly

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What's News -

- ✓ This month's issue discusses precautionary measures that minimize the risk of patient infection from atypical (waterborne) mycobacteria.
- ✓ Two new liquid chemical germicides recently received 510(k) clearance from the FDA for reprocessing endoscopes: *Minntech's Peract™ 20* and *Reckitt and Colman's Sporox®*.
- ✓ Q-Net's book, '**Q-Net-97**', a collection of all of 1997's newsletters, will be published this January 1998.

ER: 'Essential Reading'

Two important instrument reprocessing papers were recently published:

1. Agerton T, et al. *JAMA* 1997 Oct 1;278(13):1073-77.
2. Michele TM, et al. *JAMA* 1997 Oct 1;278(13):1093-95.

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.

Mycobacterium chelonae, gordonae

"My facility's water lines are colonized with Mycobacterium chelonae and M. gordonae. How do I prevent these atypical mycobacteria from contaminating my endoscopes during reprocessing?"

Your facility is not alone. The presence of atypical mycobacteria has been identified in the water supply of other institutions as well.^{1,2} (Refer to the November 1996 issue of this newsletter in which a similar question was addressed.)

In general, endoscope reprocessing can be divided into 3 stages:³ (1) cleaning; (2) chemical immersion in a liquid sterilant that achieves high-level disinfection, followed by a thorough water rinse; and, (3) a terminal 70% alcohol rinse, followed by forced air drying, prior to storage.

To protect the patient from contamination with *M. chelonae*, *M. gordonae*, *Pseudomonas aeruginosa*, or any other microorganism, the following 4 precautionary measures are recommended:

(1) Thoroughly clean the entire instrument prior to chemical immersion.^{4,5} Cleaning is necessary to remove layers of organic debris and expose the underlying microorganisms to the biocidal agent.

(2) After thoroughly cleaning the endoscope, immerse it in, and flush each of its channels with, a liquid sterilant (e.g., 2% glutaraldehyde) that achieves high-level disinfection.^{1,6,7} (The liquid sterilant should be monitored daily and discarded when its concentration drops below its

MEC (or, minimum effective concentration).

(3) During automated endoscope reprocessing, filter the rinse water using a 0.2 (or 0.1) micron bacterial filter. (Alternatively, bottled, sterile water may be used as a final water rinse during manual endoscope reprocessing, but its use is impractical and costly.)

Ideally, a 0.2 micron bacterial water filter produces bacteria-free water from a hospital's tap water supply. A bacterial filter is therefore expected to remove all bacteria, including mycobacteria, from the final water rinse, minimizing (if not eliminating) the risk of patient infection from *M. gordonae*, *M. chelonae*, or any other waterborne bacteria.^{3,8,9} (Periodic replacement of these filters and proper maintenance of their housing assembly is necessary to prevent the development of biofilms.)

(4) Bacterial water filters have been reported to fail, however, allowing bacteria to pass through their 0.2 micron membrane,¹⁰ which could result in instrument recontamination during the final water rinse. (Review the August-September 1996 double issue and October 1996 issue of this newsletter for a discussion of bacterial water filters.)

As a result, terminally rinse each of the endoscope's internal channels with 70% alcohol, followed by forced air, to facilitate drying and prevent bacteria growth in the instrument's internal channels during storage.^{3,11-14} (Too often,
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this final 70% alcohol rinse step is skipped, even though it may be as important to the prevention of patient infection as cleaning and high-level disinfection.³⁾

The End

“3 levels of sterilization”?

A follow-up to last summer's double issue

A recently published paper supports last summer's (July-August; 1997) double issue of *The Q-Net™ Monthly* newsletter, which discusses variations in the anticipated reliability of different 'sterilization' processes. This paper evaluates the performance of the AbTox system,¹⁵ a low-temperature chemical system designed to sterilize certain surgical instruments.

The data published in this paper¹⁵ and Alfa et al.'s¹⁶ show that the reliability and effectiveness of different low-temperature sterilization processes vary. As you may recall, Alfa et al.'s¹⁶ data warranted publication of an editorial that asked: 'Do we need to redefine 'sterilization'?'¹⁷

To be sure, sterility is often defined in the context of a SAL ('sterility assurance level') value of 10^{-6} . But this value can be misleading and may be of limited significance when using a low-temperature sterilizing agent to process complex instruments that do not facilitate thorough cleaning.

As discussed in last summer's double issue of *The Q-Net™ Monthly*: (1) **instrument design** (*Is it complex or simple? Does it facilitate cleaning?*); and, (2) **the physical properties of the sterilizing agent** (*Is it heat-based, or is it a low-temperature gas, vapor, plasma, or liquid sterilant?*) can adversely affect the reliability of the sterilization process, the 10^{-6} SAL value notwithstanding.

For example, layers of inaccessible organic debris may remain inside a complex instrument after cleaning. While pressurized steam can typically reach and penetrate this debris, destroying all underlying microorganisms, the physical properties of low-temperature sterilizing agents may limit them from contacting and destroying the underlying microorganisms, resulting in sterilization failure.

Consider the following FDA quote: "Data is not yet available to validate that liquid chemical germicides can achieve a defined sterility assurance level."¹⁸ *Doesn't this suggest that different 'levels' of sterilization do indeed exist? (Doesn't this quote also suggest that data showing that liquid sterilants can be used to 'sterilize' instruments, such as flexible endoscopes, are not currently available?)*

This FDA statement supports the June 1997 issue of *The*

Q-Net™ Monthly, which concluded that, because of their limitations, future liquid chemical sterilants will likely be cleared by the FDA *only* for high-level disinfection, not 'sterilization,' of complex instruments, such as flexible endoscopes, between patient procedures. (Refer to the FDA's recent 510(k) clearances of Minntech's Peract™ 20 (FDA reference No.: K960513) and Reckitt and Colman's Sporox®.)

In summary, different sterilization processes may be categorized into different levels, depending on the probability of instrument contamination associated with the sterilization process. (Refer to the detailed discussion of this topic in the July-August 1997 double issue of this newsletter.) **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:

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