

The Q-Net™ Monthly

Volume 11, Numbers 9, 10

September-October 2005

What's News

A reprocessing mishap was recently reported in a central supply department. Surgical instruments were inadvertently washed using a petroleum-based hydraulic fluid instead of detergent. Reports of this mishap can be read at: <http://www.myendosite.com>. This topic, as well as the reprocessing of sheathed instruments and a discussion of new disinfection and sterilization technologies will be published in upcoming issues of this newsletter.

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.

Quality control measures that prevent pseudo outbreaks

~ Fifth in a series ~

➔ *This is the fifth and final article in this series that provides a basic understanding of the clinical significance of, factors associated with, and recommendations that prevent, true and pseudo outbreaks associated with bronchoscopy.*

➔ *This article complements last month's article and focuses on quality, quality control, and quality assurance and their application to endoscope reprocessing and the prevention of the contamination of respiratory specimens due to pseudo outbreaks.*

➔ *Although this series of articles focuses on contaminated respiratory specimens, mycobacteria, and bronchoscopy, its recommendations are applicable to true and pseudo outbreaks associated with other types of patient specimens, microorganisms, and flexible endoscopic procedures, including gastrointestinal (GI) endoscopy, cystoscopy, and flexible laryngoscopy.*

Background

Last month's newsletter provides recommendations that prevent pseudo outbreaks of mycobacteria (and other microorganisms) associated with bronchoscopy. These recommendations are divided into three sub-sections, but, due to space limitations, only the first two—entitled: (1) *bronchoscope reprocessing*, and (2) *processing and analysis of respiratory specimens*—were published in last month's newsletter.

This month's article provides the recommendations of the third sub-section, entitled: (3) *quality assurance, quality control*. (A corresponding set of quality-control measures that prevent true outbreaks was published in the *May-June, 2005, issue* of this newsletter.) **Table 1** summarizes the discussion of each of the five articles in this series. The definitions of *quality control* is provided in **Table 2**. **Table 3** lists focal points of each of the articles in this series. ☞

~ Table of Contents ~

1. Background	17
2. Recommendations.....	18
3. Table 1: Summary	18
4. Table 2: Definitions	18
5. Table 3: Focal Points	19

Recommendations

The following set of recommendations focuses on *quality control* measures that prevent the contamination of respiratory specimens due to a *pseudo* outbreak (Table 2). This set is a continuation of the recommendations published in the *July-August, 2005, issue* of this newsletter. Recommendations that prevent *true* outbreaks associated with bronchoscopy were published in the *May-June, 2005, issue* of this newsletter. The combination of the recommendations published in this article with the recommendations provided in these two previously published newsletters provides an all-inclusive set.

II. PSEUDO OUTBREAKS OF MYCOBACTERIA (continued):

3. Quality assurance (QA), quality control (QC):

A. Develop and implement a comprehensive quality assurance program that ensures all reprocessing staff members, among other considerations, are trained, supervised, and understand the basic principles of endoscope reprocessing, infection control, and disease transmission.

B. If the medical facility uses an automated endoscope reprocessor (AER) or system, ensure reprocessing staff members are trained, supervised, and know how to properly operate each AER model in inventory.

C. Whether reprocessing endoscopes manually or using an AER or system, ensure all reprocessing staff members are trained, supervised, and know how to properly adapt to and reprocess every endoscope model in inventory.

a. Ensure these staff members understand and perform *all*

- **ARTICLE 1:** Background information and a detailed example of a pseudo outbreak. (*January-February, 2005*)
- **ARTICLE 2:** Discussion of factors associated with both true and pseudo outbreaks. (*March-April, 2005*)
- **ARTICLE 3:** Recommendations to prevent *true* outbreaks of mycobacteria. (*May-June, 2005*)
- **ARTICLE 4:** Recommendations to prevent *pseudo* outbreaks of mycobacteria. (*July-August, 2005*)
- **ARTICLE 5:** Recommendations and quality control measures that prevent *pseudo* outbreaks of mycobacteria, *continued*. (*The current issue of this newsletter.*)

Table 1: A summary of the five articles in this complete series, and the issue of this newsletter that each article was published. Visit this newsletter's website at: <http://www.myendosite.com> to download and read each.

(A) Quality describes the degree or extent to which a process or task, such as endoscope reprocessing, meets or exceeds expectations as defined by the standard of care and published guidelines.

(B) Quality assurance is a managerial program of actions designed to assure medical staff members have the skills, knowledge, equipment, and resources required to comply with and to practice the medical facility's policies and procedures. The goal of this program is to provide and maintain quality health care.

(C) Quality control is a similar program of managerial activities that controls, monitors, and inspects the activities of medical staff members to prevent practices that are flawed, in error, or otherwise do not meet the minimum requirements of quality health care or the standard of care.

Table 2: Definitions of quality assurance and quality control in the context of medical practices in the healthcare setting.

of the required manual endoscope-reprocessing steps—such as leak testing and cleaning the endoscope's suction channel and valve(s) with a brush and detergent—as described by, for example, *SGNA's* guidelines.^{59,81}

- b. Ensure these staff members have reviewed the operator's manuals and reprocessing instructions of every endoscope model in inventory.
- c. Ensure reprocessing staff members can distinguish one endoscope model from another and are familiar with the different internal channels, designs, and reprocessing steps required for each different model in inventory.
- d. Ensure the equipment and resources required to reprocess every endoscope model in inventory are available to staff members. Specialized and model-specific channel-tubing adapters, or "quick-connect kits," connectors, fittings, and caps are typically required to properly adapt and connect to each endoscope model, to ensure effective reprocessing.^{25,68} A different set of adapters and connectors may be required to reprocess different endoscope models. The endoscope manufacturer, the AER manufacturer, or both, may supply these reprocessing adapters, connectors and equipment. Refer to the *May-June, 2005, issue* of this newsletter, *sections I.2.B and I.2.G*.
- e. In general, during *manual* reprocessing, use the reprocessing instructions, adapters, connectors, and other equipment provided by the *endoscope manufacturer*, and, during *automated* reprocessing, use the reprocessing instructions and equipment provided by the *AER (or system) manufacturer*. Contact the manufacturer of the AER (or system) or endoscope as required to resolve any confusing or contradictory instructions and to ensure use of the required reprocessing adapters and equipment ☞

for each model in inventory. *Confusion about which adapters and connectors to use during reprocessing has resulted in pseudo (and true) outbreaks.*^{9,50,66}

- f. Ensure reprocessing staff members understand the risk of *true* and *pseudo* outbreaks associated with inadequate endoscope reprocessing.

D. Develop and implement a comprehensive quality assurance program that ensures all clinical microbiology (and pathology) staff members, among other considerations, are trained, supervised, and understand the basic principles of aseptic technique, microbiology, infection control, and good laboratory practices.^{11,17,28,33,69,74}

E. Ensure these staff members are trained, supervised, and know how to process and analyze respiratory specimens and to properly operate the instrumentation used during these procedures.

F. As part of this quality assurance program, monitor all endoscope reprocessing activities, and the collection, processing, and analysis of respiratory specimens.

- a. Monitor reprocessing staff members to ensure their practices are in compliance with the medical facility's written policies and procedures as required for effective reprocessing of every model in inventory.
- b. Monitor reprocessing staff members to ensure that, for both *manual* and *automated* reprocessing, every endoscope model in inventory is reprocessed using the required channel-tubing adapters and connectors.²⁵
- c. Monitor clinical microbiology (or pathology) staff members, to ensure their practices are in compliance with the medical facility's written policies and procedures as required to yield accurate microbiological results.

G. Periodically conduct competency tests to evaluate the knowledge and practices of both reprocessing and microbiology staff members, to prevent *pseudo* (and *true*) outbreaks.

- a. Require reprocessing staff members to periodically demonstrate proper reprocessing of every endoscope model in inventory, including how to properly adapt and connect to each model as instructed by the endoscope's manufacturer (or the AER's or system's manufacturer).
- b. Require reprocessing staff members to periodically demonstrate proper operation of each AER model in inventory. Additional training and testing may be indicated whenever a new endoscope model or AER model is introduced into clinical use.
- c. Similarly, require clinical microbiology (or pathology)

staff members to periodically demonstrate proper operation of the instrumentation used to process and analyze respiratory specimens. Additional training and testing may be indicated whenever new instrumentation or a new procedure is introduced in the microbiology laboratory.

H. As part of this comprehensive quality assurance program, establish an active surveillance program.

- a. Consider periodically sampling the internal components, plumbing, and tubings of the AER (or system), to evaluate whether any of these surfaces are colonized with bacteria, which can result in re-contamination of the endoscope during reprocessing and terminal water rinsing.^{25,32,34,78,79} (Some organizations recommend microbiological sampling of environmental surfaces only during an outbreak investigation.)

1. JANUARY-FEBRUARY, 2005: ● *Contaminated respiratory specimens do not necessarily indicate a nosocomial (true) outbreak.* ● *Whereas respiratory specimens contaminated with M. tuberculosis typically indicate a true outbreak, their contamination with atypical mycobacteria usually indicates a pseudo outbreak.* ● *In general, tuberculocidal mycobacteria are transmitted from patient-to-patient, while atypical mycobacteria are transmitted from the environment to the patient via, for example, a contaminated bronchoscope.*

2. MARCH-APRIL, 2005: ● *Factors linked to the contamination of respiratory specimens due to both true and pseudo outbreaks of mycobacteria are discussed.*

3. MAY-JUNE, 2005: ● *Although this series of articles focuses on true and pseudo outbreaks associated with bronchoscopy, some of its discussions may also apply to gastrointestinal endoscopy, flexible laryngoscopy, and other types of flexible endoscopic procedures.* ● *A table of factors linked to the contamination of respiratory specimens due to true and pseudo outbreaks of mycobacteria is provided.* ● *Recommendations that prevent the contamination of respiratory specimens due to a true outbreak are provided.*

4. JULY-AUGUST, 2005: ● *The contribution of automated endoscope reprocessors (AERs) and systems to the contamination of respiratory specimens is discussed.* ● *Recommendations that prevent the contamination of respiratory specimens due to a pseudo outbreak are provided.*

5. SEPTEMBER-OCTOBER, 2005 (CURRENT ARTICLE): ● *More recommendations are provided that prevent the contamination of respiratory specimens due to a pseudo outbreak.* ● *This article, the final in this series, focuses on the development and implementation of a comprehensive quality assurance program, to prevent pseudo (and true) outbreaks.*

Table 3: *Focal points of each of the articles in this series.*

b. Monitor the concentration of the liquid chemical sterilant/disinfectant (LCS), to ensure it is effective.

c. Consider periodic sampling all necessary environmental surfaces in the clinical microbiology laboratory and the solutions and instrumentation used to collect, process, and analyze respiratory specimens.²⁵

I. Document all important reprocessing parameters, including the date; the immersion time and temperature of the LCS; whether the reprocessing cycle was completed or aborted; the endoscope's serial number; and the physician's name. Documentation of these parameters can assist in identifying the source of an outbreak. Most AERs or systems provide a print-out that can be saved in the patient's file.¹⁶

J. Monitor and document the use, service, maintenance, and repair of each AER or system model in inventory. Perform all service and maintenance steps as required by its manufacturer.⁸ Failure to properly service, maintain, and repair the AER or system and its water filtration assembly—and to replace the AER's (or system's) bacterial water filter—can result in bacterial colonization; failure of the bacterial filter; contamination of the rinse water, the endoscope, and respiratory specimens; and a *pseudo* (and *true*) outbreak.³⁵

a. Replace the AER's water filters, particularly the 0.2 (or 0.1) micron bacterial filter, as indicated by its manufacturer (e.g., every 6 months; or, whenever: the pressure differential across the bacterial filter equals 20-25 PSI; bacteria is identified in the rinse water; bacterial colonization of the internal components of the AER (or system) is identified or suspected; or a diagnostic or visual alarm is activated).^{32,71,75} Refer to the AER's (or system's) operator's manual for more information.

b. When replacing the bacterial filter, the AER's (or system's) manufacturer may recommend that several additional maintenance procedures be performed, including decontamination (i.e., cleaning and disinfection or sterilization) of the housings of the AER's water filtration assembly.²⁴ Refer to the AER's (or system's) operator's manual for more information.

c. Proper service and maintenance of the AER (or system) may require routinely performing, among other procedures, an "auto-disinfection" or "auto-sterilization" cycle as instructed by the manufacturer.^{25,26,34,78} This cycle can usually be activated overnight and will not ordinarily

interfere with the busy schedule of most endoscopy units.

d. Consider monitoring the water used to rinse the endoscope, during either *manual* or *automated* reprocessing, to ensure the rinse water does not contain bacteria that could re-contaminate the endoscope, causing a pseudo (or true) outbreak.^{69,70} In addition, this practice may be important to determine failure of the bacterial filter. Measurement of the pressure differential across the bacteria filter (e.g., 20-25 PSI) may not be a reliable indicator of filter failure. Several factors influence filter failure, including the volume of water and the amount of bacteria and sediment in the tap water supply. Replace the filter whenever its failure is determined or suspected.

K. Prior to purchasing an AER (or system), review the schematics of its internal design, to evaluate the potential for bacterial colonization of its internal components. Review other information provided by its manufacturer, the medical literature, and the *Food and Drug Administration's* databases, to assess whether the device has been associated with outbreaks of mycobacteria or gram-negative bacteria.⁶²

L. Consider purchasing models of AERs manufactured by the same company, to avoid confusion, enhance familiarity with their proper use, and minimize the risk of user error and improperly connecting the AER or system to the endoscope, which has been linked to disease transmission.^{9,50}

M. Appoint a staff member to frequently interact with the manufacturer of the AER or system, to learn quickly of any device recalls or alerts, and to resolve any confusing reprocessing instructions. Use of the correct reprocessing adapter(s) is essential to prevent an outbreak (*refer to sections II.3.C.c and II.3.C.d, above*). LFM ■ *The End.*

References

The references for this article are available at:
<http://www.myendosite.com/refs010405.doc>

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:

Lawrence F. Muscarella, Ph.D.
Editor-in-Chief, The Q-Net™ Monthly
Director, Research and Development



Custom Ultrasonics, Inc.
144 Railroad Drive, Ivyland, PA 18974
Tele: 215.364.8577; **Fax:** 215.364.7674

E-mail: editor@myendosite.com
Internet: <http://www.myendosite.com>

Copyright © 1995-2005. All rights reserved. *It is a violation of federal copyright laws (17 U.S.C. Sec. 101 et seq.) to copy, fax, or reproduce any portion of this newsletter without its editor's consent. Q-Net is a registered trademark of Custom Ultrasonics, Inc.* septoct05_v6.1