

The Q-Net™ Monthly

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What's News

Q-Net welcomes its newest subscribers from Maharashtra, India; Selangor, Malaysia; Jeddah, Saudi Arabia; and Bangkok, Thailand. An article written by this newsletter's editor-in-chief that discusses push enteroscopy and the practice of "shuffling" gastrointestinal endoscopes is published in the March-April 2007 issue of SGNA's journal *Gastroenterology Nursing*. Remember to visit www.myendosite.com for all back issues of this newsletter.

Editor-in-Chief

All of the articles published in this newsletter are written by: **Lawrence F. Muscarella, Ph.D.**, 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 main goal of **Q-Net** is to encourage the infection control, endoscopy, and OR communities not only to ask good questions but also to 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.

A proposal to reduce the risk of nosocomial infections

➔ *This article focuses on infection-control guidelines and the financial associations between the organizations that write and publish them and companies that market and sell infection-control products. The potential for these associations to increase the risk of healthcare-acquired infections (HAIs) is discussed.*

*their official journals and companies that market and sell infection-control products. Infection-control guidelines include those that provide guidance about, among other topics, reprocessing gastrointestinal endoscopes and other types of instruments; cleaning, disinfection, and sterilization; and operating-room techniques (see: **Box A** on page 6 for a definition of a "financial association").*

Newspaper articles and medical reports that discuss the morbidity, mortality, and rising costs associated with healthcare-acquired infections (HAIs) are published every day in local and national newspapers. Many of these articles focus on infection control and the growing number of state legislatures in the U.S. considering the enactment of laws that would mandate hospitals to report to the state the rates of several types of HAIs.¹⁻³

The "factor": While many of these newspaper articles provide timely discussions of HAIs, the public disclosure of their rates, and the importance of infection control to their prevention, none have discussed the potential contribution of an important factor to the estimated 2 million HAIs and 90,000 associated deaths reported each year in the U.S. at an annual cost of \$4.5 billion.⁴ *Financial associations between organizations that publish infection-control guidelines, recommended practices, and standards in*

What's in an infection-control guideline, standard? Healthcare organizations, associations, and societies routinely publish guidelines, recommended practices, policies, and consensus or position statements that provide guidance on a number of clinical topics, ranging from the treatment of diabetes to the lowering of cholesterol levels. Published guidelines are typically treated with biblical-like reverence, and their impact on medi-

(Continued on page 6)

TABLE OF CONTENTS

| | |
|--|---|
| The "factor:" | 5 |
| What's in a guideline, standard?..... | 5 |
| Box A, Box B | 6 |
| Examples of inconsistent guidelines... | 6 |
| Long overdue? | 7 |
| A proposal | 7 |
| A model guideline | 8 |
| Discussion, Conclusion | 8 |
| References | 8 |

➤ A “financial association,” tie, or relationship between organizations that publish guidelines, experts that write them, and industry may be direct or indirect and in the context of this newsletter’s main article includes, but is not limited to, the sponsorship or underwriting of a guideline; educational programs; research grants; funding; donations; honoraria; speakers bureau; and employment or consulting compensation.

Box A. The definition of a “financial association.”

cal practice can be profound. Healthcare professionals generally take it for granted that a guideline is evidence-based, lacks commercial bias, and has been thoroughly reviewed and vetted by experts in the field who are not financially associated with companies that market and sell products whose sales could benefit from the guideline’s recommendations.

The acceptance of a guideline’s recommendations is based on this conclusion and the implicit understanding that their purpose is not to benefit, insulate, or appease industry, or to promote a product, but rather, in addition to clarifying an organization’s position for its membership, to improve patient care and establish an acceptable standard of practice. Failure to comply with a guideline’s recommendations may violate the standard of care and can incur legal exposure and liability.

The costs associated with researching, writing, and publishing a guideline can be significant, and a healthcare organization may woo or be solicited by a company to help underwrite these costs. Despite the potential conflict of interest, the funding company often has a vested interest in the guideline’s content and recommendations (see: **Box B**).⁵⁻⁹ The organization may write the guideline, or it may contract an expert or panel of experts (some of whom may have financial ties to industry) to write the guideline (see: **Box A**). Several recently published newspaper articles have discussed these financial associations, their handling and disclosure, and their potential to affect adversely patient safety.⁵⁻⁸ The recommendations of some guidelines raise concerns that these financial associations may have compromised the scientific merit of these guidelines and jeopardized patient safety (see: **Box B**).⁵⁻⁸

To be sure, the field of infection control is not unique, and it too has organizations, societies, and experts that research, write, and publish infection-control guidelines while having direct or indirect financial relationships with companies that sell infection-control products and could financially benefit from the guideline’s recommendations (see: **Box A**).⁹

As with other medical fields, participants from different clinical perspectives and orientations may actively collaborate during the writing of an infection-control guideline, each vying with one another in an oft-competitive jostle to have their viewpoints and, in some instances, one or more specific recommendations or discussions included, omitted, truncated, or parsed in the guideline. Many of these participants may be financially associated with industry, and their contributions to the guideline and its recommendations could have financial implications for the companies that employ them and that sell

infection-control products. Often because of competing interests, the goal to write an infection-control guideline to prevent HAIs may sometimes lose focus and direction, resulting in the guideline’s published recommendations being less evidence-based and scientifically sound than biased and inconsistent.

Examples of inconsistent guidelines: Infection-control guidelines that provide inconsistent recommendations have been published.¹⁰⁻¹² For example, whereas some guidelines recommend low-level disinfection of a rigid laryngoscope’s handle, others recommend at least high-level disinfection.¹¹ Another example is endoscope drying.^{10,12} Reports that document an increased risk of outbreaks and pseudo-outbreaks of opportunistic microorganisms, including *Pseudomonas aeruginosa*, associated with wet endoscopes (that were otherwise properly reprocessed) are well documented.¹⁰ As a consequence, several organizations including *The Society of Gastroenterology Nurses and Associates* prudently recommend thoroughly drying the endoscope’s internal channels after every reprocessing cycle—whether achieving high-level disinfection or “sterilization,” or whether using tap or “sterile” rinse water—to prevent HAIs during flexible endoscopy.^{10,13}

Nevertheless, despite the increased risk of HAIs associated with wet endoscopes, the guidelines of some other organizations (and the labeling of a few infection-control products) do not recommend endoscope drying, instead instructing clinicians to use the endoscope immediately after reprocessing while its channels are still wet with rinse water.^{10,12,14-18} The implications of this instruction are far-reaching, because it encourages, for example, pulmonologists to introduce wet (and, therefore, potentially contaminated^{12,18}) bronchoscopes into the lungs of patients who may be critically-ill, immunosuppressed, and suffering from respiratory pneumonia. Few (if any) other recommended endoscopic practices are as questionable and present as significant a potential risk of HAI.¹⁰

Infection-control guidelines that recommend the clinical use of *just-reprocessed-and-wet-with-rinse-water* endoscopes instead of endoscope drying assert that wet endoscopes are

(Continued on page 7)

➤ A kidney foundation recently published a guideline for the treatment of anemia in patients with kidney disease. This guideline was underwritten by a company that paid more than \$500,000 to this kidney foundation.⁷ Two thirds of the experts commissioned to write this guideline had financial ties (see: **Box A**) to companies associated with the sale of anti-anemia drugs, including the company that underwrote this guideline. The final recommendations of this guideline favor the use of higher doses of anti-anemia drugs than recommended by the Food and Drug Administration (FDA), to the financial benefit of the company (and others) that underwrote the guideline. A subsequent study, however, reported that this guideline’s recommendation increases the risk of fatal heart attacks and stroke in kidney patients suffering from anemia.⁷

Box B. An example of a guideline that poses a risk?

“sterile” following “sterilization”^{10,15-18}—even though, among other considerations: (1) the endoscopes are terminally rinsed with filtered tap water that is not monitored for microorganisms or endotoxins as required to validate and verify a “sterile” water claim; (2) the location in the medical facility where the dirty endoscopes are placed into the system for terminal processing is not sterile although it is the same as where the wet (unwrapped) “sterilized” endoscopes are removed from the system for immediate patient use, causing the wet processed endoscopes also to be not sterile; and (3) water or moisture identified on the wrapping of surgical instrument sets (and, therefore, presumably *just-reprocessed-and-wet-with-rinse-water* endoscopes) indicates an increased risk of HAI due to the potential for contamination, requiring that the instrument sets be considered un-sterile and re-sterilized before reuse.¹²

In addition to engendering confusion and begetting complacency, inconsistent infection-control guidelines may have played an important role in numerous reports of disease transmission and HAIs, including two well-publicized nosocomial outbreaks and associated deaths linked to inadequate reprocessing of bronchoscopes and rigid laryngoscopes.^{11,19,20}

Long overdue? Although, admittedly, the reasons for guidelines to include inconsistent recommendations may be complex, long overdue is a discussion of these inconsistencies, their potential contribution to an increased risk of HAIs, and whether some of them may in part be due to or explained by financial associations between organizations that publish infection-control guidelines and companies that sell infection-control products that are directly or indirectly discussed or referred to in the guidelines (see: **Box A**).

It is unclear whether such financial associations may explain why some infection-control guidelines claim wet endoscopes are “sterile” and recommend (to be consistent with the labeling of some infection-control devices?) their immediate use after processing,¹⁵⁻¹⁸ despite the increased risk of disease transmission and HAIs associated with wet endoscopes.¹⁰ Guidelines that recommend the use of *just-reprocessed-and-wet-with-rinse-water* endoscopes were reviewed,^{16,17} but none discloses potential conflicts of interest or a financial association between the organization (or its board of directors) that approved and published the guideline and companies selling infection-control products, some of whose labeling contraindicates endoscope drying.

Articles and reports that discuss HAIs and the importance of infection control to their prevention, but that do not address these financial associations, their ubiquitousness, and the potential for them to have an adverse effect on HAIs and patient safety would appear to be incomplete. No doubt, money can affect decisions, introduce bias, and cloud perspectives, and, to be sure, organizations that publish infection-control guidelines neither are exempt from the influences of money nor reside beyond its reaches. Infection-control guidelines can prevent HAIs and save lives, but, if proper measures

are not taken, their recommendations, like those of other clinical guidelines (see: **Box B**),⁵⁻⁸ can be subtly manipulated to become “ingenious marketing tools”²¹ intended more to promote a product than to provide sound clinical guidance.

To the potential detriment of efforts to prevent HAIs, financial associations can blur the line that separates, on the one side, evidence-based recommendations included in a guideline because they have been documented to reduce the risk of HAIs from, on the other side, questionable recommendations that—even though they may be inconsistent with the recommendations of other guidelines and provide no benefit to the patient, sometimes even *increasing* the risk of HAIs and their associated costs—are included in a guideline because of their potential to advance the sale of a product, vindicate a product’s labeling claims, or otherwise maintain a financial association with industry.

◆ **Background:** Organizations often publish in their official journals infection-control guidelines to prevent HAIs.

◆ **What’s the problem?** Some of the recommendations of these guidelines are inconsistent and may increase the risk of HAIs and their associated costs.

◆ **What is proposed?** Disclosure in the text of the guideline of any financial association (see: **Box A**) between the organization publishing the guideline and companies that sell infection-control products and could financially benefit from the guideline’s content is recommended. Whether such disclosure would significantly reduce the risk of HAIs is unclear.

◆ **What’s at stake?** Failure to have in place proper checks and balances—such as disclosure of a financial association—may result in infection-control guidelines being subtly manipulated to recommend practices that are less evidence-based than biased, inconsistent, and potentially unsafe.

A proposal: It is proposed that organizations that publish infection-control guidelines *and* receive financial support (see: **Box A**) from companies that could financially benefit from the guideline’s recommendations adopt a policy of disclosing these financial associations in their guidelines, or, if insufficient space is available, on the organizations’ websites.^{22,23} Disclosure of these financial associations is important to the integrity of the guideline, an evaluation of the guideline’s objectivity and scientific merit, and patient safety. Failure to disclose an existing financial association undermines the contribution, usefulness, and legitimacy of the guideline, in addition to rendering it arguably incomplete.

Alternatively (although potentially not feasible), organizations that publish infection-control guidelines might adopt a policy of refusing to accept funding from or have any type of financial association with any company that sells infection-control products.^{22,23} (Specific rules regarding the proper procedure for publishing advertisements in an organization’s official journal have been published.²⁴)

(Continued on page 8)

A model guideline: Several infection-control guidelines were reviewed for a financial disclosure statement.^{9,13,16-18} One guideline—which provides guidance on the selection and use of disinfectants, including 2% glutaraldehyde, and was published in 1996 in *The American Journal of Infection Control*, the official journal of the *Association for Professionals in Infection Control and Epidemiology* (APIC)⁹—discloses on its first page that its publication was made possible by an “educational grant” provided by a company that sells, among other types of disinfectants, 2% glutaraldehyde.⁹

This commendable example of disclosure in an infection-control guideline of a financial association between the organization that published the guideline and industry is the exception, not the rule. Although many of the organizations that publish infection-control guidelines (or that contract experts or a panel of experts to author them) are financially associated with companies that sell infection-control products discussed directly or indirectly in the guideline (see: **Box A**), few infection-control guidelines acknowledge these financial associations, the importance of their full disclosure to the objectivity, legitimacy, and scientific merit of the guideline notwithstanding.²²⁻²⁴

Indeed, financial associations may at times introduce inadvertent bias into an infection-control guideline, potentially increasing the risk of HAIs (see: **Box B**). According to the *International Committee of Medical Journal Editors*, “all participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential conflict of interest.”²⁴

Discussion: This article discusses financial associations that often exist between the organizations that publish infection-control guidelines and companies that sell infection-control products. The potential for these financial associations to increase the risk of HAIs is also discussed. To be clear, however, this article is not averse to these financial associations. Nor is it suggesting that an infection-control guideline published by an organization financially associated with a company that sells infection-control products lacks legitimacy, or that a financial association should disqualify an organization from publishing an infection-control guideline.

To the contrary, this article encourages these organizations to publish well-researched, comprehensive, evidence-based infection-control guidelines, because these organizations have members that are some of the most knowledgeable in the fields of infection-control, instrument reprocessing, and aseptic technique and can contribute the most to the improvement of patient care and the prevention of HAIs.

What this article does oppose, however, is the failure to disclose in an infection-control guideline (or on the organization’s website) existing financial associations between the organization publishing the guideline (or an expert or panel of experts contracted to write the guideline) and companies that could financially benefit from the guideline’s content and recommendations. Full disclosure of any potential conflicts of

interest is as important to the legitimacy and usefulness of an infection-control guideline as the guideline’s evidence-based recommendations are to the prevention of HAIs.

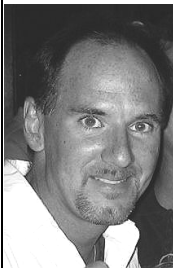
Conclusion: Without proper checks and balances in place to protect the integrity and legitimacy of an infection-control guideline, its intended goal to prevent HAIs can become sidetracked, if not derailed, by participants with financial ties to industry seeking to have some of the guideline’s content written, if subtly, to benefit financially a company that sells infection-control products (see: **Box A**). *Full disclosure in the guideline (or on a website) of all potential conflicts of interest and existing financial associations between the organization publishing, or experts writing, an infection-control guideline and companies that sell infection-control products and could financially benefit from the guideline’s recommendations is proposed, lest patient safety and the objectivity of a guideline’s recommendations be compromised.*

Organizations that publish infection-control guidelines need not take this article’s conclusions as overly critical or too constraining, as this proposal is not a disavowal or repudiation of an organization’s credibility or integrity. Scientific trials are routinely conducted using “blinded” methodologies, not because the investigators conducting the trials cannot be trusted or their integrity is in doubt, but merely to prevent the inadvertent introduction of bias into the trials that might skew the data and invalidate the results. ● **The End** LFM

References for this article are available at:
www.myendosite.com/refs030407.pdf

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

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