

The Q-Net™ Monthly

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What's News

This newsletter's article discusses the management of conflicts of interest in infection control and is to be read in conjunction with the upcoming November-December, 2008, issue of this newsletter, which provides a review of an evaluation of an automated endoscope reprocessor (AER). This month's newsletter and more than 100 other articles are available for downloading at: <http://www.myendosite.com>

Editor-in-Chief

This article was written by this newsletter's editor-in-chief, **Lawrence F. Muscarella, Ph.D.** Email: editor@myendosite.com

What is 'Q-Net'?

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

The main goal of **Q-Net** is to encourage the infection control, endoscopy, and operating room communities to improve patient care by not only asking good questions but also by demanding well referenced, evidence-based answers.

Q-Net addresses the needs of both the healthcare provider, whose goal is to provide the best care possible, and the patient, who deserves affordable quality health care.

"Let sleeping dogs lie?"

The management of conflicts of interest in infection control

THIS ARTICLE:

❖ discusses the "Up Close" column published in the September, 2008, issue of the trade magazine *Healthcare Purchasing News*;

❖ recommends more rigorous management of the working relationships that institutes and organizations, entrusted to evaluate and provide independent advice about the safety and effectiveness of infection-control products, have with manufacturers; and

❖ complements the upcoming November-December, 2008, issue of this newsletter, which features an article entitled "Review of an evaluation of an automated endoscope reprocessor (AER)."

INTRODUCTION: VOICING CONCERNS SIMILAR to those expressed in two articles published this October in the *Wall Street Journal*,^{1,2} the March-April, 2007, issue of this newsletter discusses improper management of conflicts of interest.

This previously published issue reveals that few of the organizations that publish infection-control guidelines (or, the contracted authors writing the guidelines) disclose in the text of their guidelines (or, if insufficient space is available, on appropriate websites) existing financial associations with manufacturers of infection-control products.³ Examples of financial associations with manufacturers include organizations accepting funding from them through educational research grants, honoraria, conference travel, gifts, and free product samples.^{4,5}

This oversight, if omission, suggests that a majority of infection-control (and operating room) organizations undervalue the importance of such disclosures, employing conflict-of-interest policies that arguably are lacking.

UP CLOSE: THE PRESIDENT AND CEO of a non-profit healthcare institute (ECRI Institute; www.ecri.org) discusses the importance of strict conflict-of-interest policies in an article published in the "Up Close" column of the September, 2008, issue of the trade magazine *Healthcare* (Continued on page 18)

BACKGROUND: LETTING SLEEPING DOGS lie is usually prudent. But, awakening these dogs from a lazy afternoon nap and having them stand on all four legs is sometimes warranted and apt, in the idealistic view that important issues worth barking for are at hand. Although recollections and discussions of the past may not always be pleasant, their review is, at times, necessary to teach important lessons about objectivity, scientific integrity, and the prevention of healthcare-acquired infections.

Purchasing News (HPN).⁶ This column, which can be read at: <http://www.myendosite.com/HPNUpClose08.mht>—also discusses this institute’s advertised mission to improve patient care by, among a number of other services, evaluating and rating the safety and effectiveness of medical devices, including those in the field of infection control.

For its evaluations of medical devices (which it publishes in a monthly journal it owns), this healthcare institute claims to have modeled itself after, adopted the strict and uncompromising conflict-of-interest policies of, and employed for its healthcare product evaluations a paradigm, style, and rating scheme similar to those developed and used by, *Consumers Union* (Yonkers, N.Y.)⁶⁻¹¹—the publisher of the popular monthly consumer magazine *Consumer Reports*. (A review of one of this institute’s evaluations of an automated endoscope reprocessor [AER] will be published next month and is available at: www.myendosite.com/htmlsite/2008/sleepingdogs2.pdf.)

The president of this healthcare institute (ECRI Institute) states in this column in *HPN* that “hundreds of hospitals, health insurers, and Ministries of Health get evidence-based guidance and vital insight on the ever-changing healthcare landscape” from this institute’s evaluations of medical devices and other services.⁶ In addition to discussing this institute’s ability to “marry practical experience and uncompromising independence with the thoroughness and objectivity of evidence-based research,”⁶ this president asserts that “accurate, reliable research does not live in environments where conflicts of interest are present. Period.”^{6,7} This observation is both singular and exceptional, and this institute’s advertised commitment to both the “discipline of science”^{6,12} and the “integrity of independence”^{11,12} is outstanding and invites respect, support, and praise. Few endeavors to improve patient care would be as noble and worthwhile.

Integral to its advertised repudiation of conflicts of interest and mission to ascribe in lockstep to the unrivaled standard of objectivity established by *Consumers Union*, this healthcare institute claims to be “completely independent”⁶ of and to have no financial associations with medical device manufacturers (see: the Jan-Feb-Mar 2010 issue of this newsletter).⁶⁻¹³ The integrity and scientific merit of this institute’s published evaluations and ratings of the safety and effectiveness of medical devices, including AERs,¹⁴ are based on the verity, or genuineness, of this advertised ethos.

In addition to noting its claimed approbation of *Consumers Union*’s revered model of uncompromising independence for its evaluations of medical devices,⁶⁻¹¹ the president of this institute details in this “Up Close” column in *HPN* this institute’s existential journeys and the self-actualization of its “DNA.”⁶ The expression of this institute’s genotype would appear at times responsible for the impressive impact of some of its published research. Remnants of the devil can, at times, be entangled in the details,¹⁵ however, and one’s definition of a “conflict of interest” and “uncompromising independence”^{6,7,11,12} may be in stark contrast to another’s. (Please read the accompanying box article: “A conflict of interest?”)

Box article: A conflict of interest? A “conflict of interest” can be simply defined as a person or an organization, institute, or agency in a position of trust and authority having two conflicting duties. (An example would be an attorney representing both the plaintiff and the defendant.) The integrity, objectivity, and usefulness of a healthcare guideline, or the evaluation and rating of a medical device, depend on the sponsoring organization or testing institute, respectively, having in place strict policies to manage and control any conflicts of interest that may arise. Conflicts that are fully acknowledged and disclosed can be appropriately managed and mitigated, if not eliminated. Those that are overlooked, ignored, and not disclosed, however, in addition to betraying the public’s trust and expectations, are inconsistent with objective scientific research and would raise doubts about the organization’s or testing institute’s mission.^{4,5,16,18}

Different interests may define a “conflict of interest”^{6,7} differently, however, clouding waters that are already (unnecessarily) muddy. One perspective may deem its definition, like that of “uncompromising independence,”⁶ to be inexorably fixed, literal, and not subject to compromise or qualification,⁴ viewing a conflict of interest as an emergent contagion of objectivity. (Refer to the main article.) An opposing perspective, however, may interpret the definition of a conflict of interest in more of a contextual and conditional light, permitting sculpturing and compromise to fit inconstant circumstances. This latter perspective may view a conflict of interest instead as a means to an end, a potential opportunity for personal gain that does not require disclosure. These two dichotomic perspectives bring into focus the importance of infection-control (and operating room) organizations and institutes that evaluate medical devices clearly defining and publishing their respective definition of a conflict of interest, to avoid confusion and misunderstanding. ●

A “WORKING RELATIONSHIP”? NOTWITHSTANDING ITS CLAIM to “avoid conflicts of interest like, well, the plague,”⁷ to be “completely independent,”⁶ and to have adopted *Consumers Union*’s model for its product evaluations,⁶⁻¹¹ ECRI Institute (www.ecri.org) acknowledges (arguably, confusingly) having “working relationships”¹³ with manufacturers (albeit “at financial arm’s length”¹³). *But, can an institute that has working relationships¹³ with manufacturers remain “completely independent”⁶ of their influence and control? Can the performance of a medical device be objectively evaluated and dispassionately⁴ rated by an institute that “works”¹³ with its manufacturer? Similarly, can an infection-control guideline be entirely objective if its authors or sponsoring organization have undisclosed financial associations with manufacturers of infection-control products?*

While these questions are significant and provoke thought and debate, each warrants a negative (“no”) answer.

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Some may disagree and counter, if not insist, that cooperating and having working relationships¹³ with manufacturers is all but required of an institute that evaluates and rates the safety and effectiveness of competing medical devices, to ensure the publication of accurate data. At first glance, such an institute's policy would appear reasonable and pragmatic, if not cost-effective. But, it is the execution of this policy, not its written words, that holds the truth and, if their fine details are opaque, cryptic or inadequately disclosed, working relationships¹³ with manufacturers can present conflicts and introduce bias that belie the public's trust and understanding.^{1-5,16-20}

TO BUY OR NOT TO BUY? RECOGNIZING THAT INTERACTIONS (e.g., working relationships) with manufacturers can compromise objectivity and independence, *Consumers Union* does not accept revenue from advertising.^{21,22} Nor does it accept from competing manufacturers gifts or free samples of products for an evaluation, claiming to prohibit these activities to ensure having "no agenda other than the interests of consumers."^{21,22} To "remain unbiased from commercial influence" and maintain its "independence and impartiality," *Consumers Union* instead anonymously purchases "off the shelf" all of the products it evaluates and rates for publication in its monthly magazine *Consumer Reports*.²¹⁻²³

The president of this healthcare institute (ECRI Institute; www.ecri.org) similarly states that its "monthly journal accepts no advertising from any source."⁶ (*But, in fairness, is revenue from advertising the only "currency" of influence?*) This institute's policy vis-à-vis advertising is part and parcel to its aforementioned and frequent claim to employ *Consumers Union's* model of objectivity, excellence, and independence (this institute's "working relationships"¹³ with manufacturers notwithstanding).⁶⁻¹³

Nevertheless, despite claiming to have adopted the model established by *Consumers Union*⁶⁻¹¹—which, as previously mentioned, prohibits accepting gifts or free samples from competing manufacturers for a product evaluation²¹⁻²³—the ECRI Institute typically borrows from each respective manufacturer the medical devices it ordinarily tests and rates for an evaluation.²⁴ (That this institute does not purchase the medical devices it evaluates is not easily identifiable and is not disclosed in the text of its product evaluations.¹⁴)

Although some medical devices can admittedly be expensive to purchase and the costs associated with an evaluation of their safety and effectiveness all but prohibitive, published studies suggest that the acceptance of gifts or free product samples from manufacturers can be "ethically challenging"¹⁶ and pose conflicts of interest that are inconsistent with objectivity and "dispassionate"⁴ critical analysis.^{5,18-20,25} (Whether any of the medical devices submitted for an evaluation might have been modified by its manufacturer to enhance artificially and unfairly its performance and obtain an unfair advantage, potentially skewing the evaluation's ratings and results, is plausible and cannot typically be determined or ruled out.)

Specifically, these published studies suggest that interac-

tions with manufacturers including receiving from them gifts or product samples can introduce bias and cause the benefits of a product to be "overstated."⁴ (Please read the upcoming November-December, 2008, issue of *The Q-Net Monthly*.) Similarly, these and other published studies suggest that interactions with manufacturers can also result in researchers publishing only favorable data, to feel indebted,¹⁶ and to develop "positive attitudes,"⁵ preferences, deference, and irrational behavior⁵ toward the manufacturer or its products.^{4,18-20} (None of these studies suggest that accepting from several competing manufacturers free product samples for an evaluation eliminates the potential for bias.) Indeed, interactions with manufacturers can affect behavior and outcomes, and if not rigorously managed and disclosed, these interactions can result in improper commercial influence and a loss of objectivity.¹⁶ ... *But, let's get back to the sleeping dogs.*

CONFLICTS OF INTEREST IN INFECTION CONTROL?

- ◆ **PROBLEM:** Improperly managed conflicts of interest can introduce bias and favoritism into both infection-control guidelines and evaluations of medical devices.
- ◆ **DISCUSSION:** This article discusses the "Up Close" column of the September (2008) issue of the magazine *Healthcare Purchasing News (HPN)*. The practice of having working relationships¹³ with manufacturers is discussed and questioned.
- ◆ **ACTION:** Sleeping dogs are awoken and recommendations are provided to manage more rigorously potential conflicts of interest, to improve patient safety and minimize the risk of healthcare-acquired infections.

DISCLOSURE AND PERSPECTIVE: AS SOME OF you may know, I was employed in the early 1990s by this healthcare institute (ECRI Institute) discussed in this "Up Close" column in *HPN*,⁶ believing in this institute's advertised mission to improve patient care by doing what is right through a commitment to objectivity and fairness. But, differences in our respective definition of a *conflict of interest*, the execution of "uncompromising independence" (see box: "A conflict of interest?" on p. 18), and the appropriateness of capitulation and showing deference to a manufacturer during the evaluation of its medical device, including the STERIS System 1, soon became apparent.²⁶ (I am presently employed by a manufacturer of medical devices.) Refer to: The July-August-September, 2009, issue of this newsletter.

In my view, the name *Consumers Union* is synonymous with objectivity, a sobriquet for fairness, a moniker for independence. Its name and mission connote an inflexible code of ethics and policies intended to engender an uncompromising passion and commitment to the interests of the public.

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Therefore, healthcare institutes that evaluate infection-control products (and organizations that publish infection-control guidelines) have, in my opinion, a fiduciary responsibility, once they claim to employ *Consumers Union's* model, to have no working relationships¹³ or financial associations with manufacturers of infection-control products, except, possibly, those that are infeasible to eliminate and, to be sure, explicitly and forthrightly disclosed. (An example of such a disclosure might be to publish in its text as a footnote that the published evaluation of medical devices was developed and performed working and in collaboration with manufacturers, who provided their devices as free samples due to their high price.)

Further, because working relationships¹³ or financial associations with manufacturers are not universally defined terms (*see*: box article on p. 18), healthcare institutes and infection-control organizations having neither with manufacturers of infection-control products (except those that are infeasible to eliminate and fully disclosed) would prevent confusion and misunderstanding. Such a prohibition would also all but prevent unscrupulous, mighty manufacturers (with predilections for litigation) from exerting unfair control and securing improper and undisclosed deference for themselves and their products—a scenario that could result in a loss of objectivity, skewed ratings, and an evaluation's or infection-control guideline's overstatement of a product's safety and effectiveness.²⁶ (Whether institutes and organizations that evaluate the performance of medical devices are adequately covered by liability insurance to protect themselves against a lawsuit initiated by a disgruntled manufacturer is unclear, although an important consideration.)

RECOMMENDATIONS AND CONCLUSIONS: THE EFFORTS OF institutes and organizations entrusted to provide independent recommendations and evaluations of the safety and effectiveness of medical devices and infection-control products are to be enthusiastically respected and supported. To enhance the deliverance of their stated missions, however, it is recommended that these institutes and organizations, among other considerations, adopt stricter conflict-of-interest policies that require a stronger, more *bona fide* commitment to patient safety and independence from manufacturers.²⁵ The endorsement or mere mention of a product in an evaluation or infection-control guideline can be a powerful marketing tool expected to benefit financially its manufacturer. More rigorous management and transparency of the interactions and working relationships¹³ between manufacturers and both these institutes and organizations, therefore, are recommended, to prevent “self-serving bias”¹⁶ and improper commercial influence of a product evaluation or guideline.^{4,17,18}

The elimination of every potential conflict of interest is ideal, and not accepting gifts or free product samples from manufacturers to perform an evaluation is an important prohibition. But, as previously acknowledged, this policy may not always be feasible. For example, some medical devices may be prohibitively expensive to purchase for an evaluation.

Similarly, some manufacturers employ healthcare experts whose knowledge is indispensable and whose cooperation with an institute or healthcare organization is important to ensure the accuracy and validity of its evaluation or infection-control guideline, respectively. To preclude these experts from working with these institutes and organizations would be myopic and a public disservice.

Indeed, financial associations and working relationships with manufacturers do *not* preclude the advancement of knowledge and scientific integrity, *provided*, as part of a commitment to and adoption of stricter conflicts of interest policies, such types of interactions—for example, institutes accepting free samples of medical devices from several competing manufacturers for an evaluation, or infection-control organizations receiving funding from manufacturers through educational grants, gifts, or advertisements—are more rigorously managed and fully disclosed in the text of the published evaluation or guideline (for example, as a footnote or, if insufficient space is available, on an appropriate website).^{16,25}

Finally, to avoid confusion and misunderstanding, healthcare institutes and infection-control organizations are encouraged to clarify and publish their respective definitions of a conflict of interest and working relationships or financial associations with manufacturers, explaining which specific practices are expressly permitted and prohibited. These are important times. The public is counting on our commitment to fairness, objectivity, and doing what is right. ● *Continued next month.* Article by: Lawrence F. Muscarella Ph.D.

✓ The REFERENCES to this article are available at:
<http://www.myendosite.com/htmlsite/2008/refs091008.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.*
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