

The Q-Net™ Monthly

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September-October 2008

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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The Q-Net™ Monthly

Volume 14, Numbers 11, 12

November-December 2008

What's News

Happy New Year. **Note:** After the publication of this newsletter in 2008, the *Olympus Corporation*, on 12-08-09, issued a letter—which can be read on-line at: www.MyEndoSite.com/letters/Olympus120809.pdf—questioning the compatibility of the *STERIS Reliance EPS* with Olympus flexible endoscopes. The letter's findings would seem to impact the ratings of the evaluation reviewed in this issue.

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'?

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Review of an Evaluation of the **STERIS Reliance EPS**

This article is the **second** in a series and complements last month's double issue entitled "**Let sleeping dogs lie?**"



BACKGROUND: THIS ARTICLE REVIEWS a published evaluation of the *STERIS Reliance™ Endoscope Processing System* ("EPS"; Steris Corp., Mentor, OH), which is a newly marketed automated endoscope reprocessor, or **AER**, labeled to wash and high-level disinfect gastrointestinal (GI) endoscopes.¹

The second in a series, this article complements and *is to be read in conjunction with* the first article in this series—"Let sleeping dogs lie?"—which can be read at: <http://www.myendosite.com/htmlsite/2008/sleepingdogs.pdf>.²

Discussing a topic similar to the one recently addressed in a front-page newspaper article about "watchdog" firms and their working relationships with the companies whose products these firms evaluate and rate,³ this series of articles encourages non-profit healthcare institutes and organizations (in the field of infection control) to manage more rigorously potential conflicts of interest.

This series of articles acknowledges, however, that not every conflict can necessarily be eliminated. In these instances, these institutes and organizations are encouraged to disclose in the text of their product evaluations or infection-control

guidelines, respectively, the details of any working relationships⁴ and financial associations, or interactions, they may have with manufacturers.⁵⁻¹³ Examples of such interactions that would warrant full disclosure include these healthcare institutes and organizations receiving money from manufacturers through educational research grants, advertising, honoraria, gifts, and/or free product samples.^{6,7}

INTRODUCTION: THE SEPTEMBER-OCTOBER, 2008, double issue of this newsletter reviews the "Up Close" column published in the September, 2008, issue of *Healthcare Purchasing News* (HPN).^{2,14} This column in *HPN* provides insight into the workings of the ECRI

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Institute (“ECRI”; Plymouth Meeting, PA; www.ecri.org), a non-profit healthcare institute that advertises itself to be modeled after, to have adopted the strict and uncompromising conflict-of-interest policies of, and to employ for its evaluations of medical products a rating scheme similar to that developed and used by *Consumers Union* (Yonkers, N.Y).^{2,14-21}

To avoid the conflicts of interest that working relationships with manufacturers can pose, *Consumers Union*, among other practices, anonymously purchases “off the shelf” all of the products it evaluates. The results of its evaluations are published in its monthly magazine *Consumer Reports*.^{2,3,6-12} To maintain its independence and objectivity and to ensure “no agenda other than the interests of consumers,” *Consumers Union* neither accepts free samples nor borrows from manufacturers the products it evaluates and rates.² Its assertion that it models itself after *Consumers Union* notwithstanding,² ECRI acknowledges having “working relationships”⁴ with manufacturers, which typically include borrowing from these manufacturers the medical devices it evaluates and rates (rather than purchasing these devices anonymously, or independently testing them in the clinical setting).

AIM: IN JANUARY, 2007, the ECRI Institute published the results of its evaluation of the STERIS Reliance EPS.¹ Because interactions and working relationships with manufacturers reportedly can introduce bias and result in the overstatement of a product’s performance,^{2,5-11,22} ECRI’s evaluation of the STERIS Reliance EPS was reviewed, to assess this evaluation’s clarity, validity and objectivity. (Note: This article does not evaluate the performance of the Reliance EPS.)

THE RATING OF AN AER: ECRI’S EVALUATION PROVIDES a dual, if nuanced, rating for the STERIS Reliance EPS—the first of which is “preferred” for most healthcare facilities.¹ ECRI’s evaluation provides a second rating, however, of “not recommended” (which is one of this institute’s three “acceptable” ratings) for healthcare facilities that use GI endoscopes marketed by Pentax (Montvale, NJ). (Pentax is one of the three primary manufacturers of GI endoscopes sold in the U.S. The other two are Olympus [Center Valley, PA] and Fujinon [Wayne, NJ].) According to ECRI, this second, less enthusiastic rating is warranted because of “compatibility concerns” and the potential for the STERIS Reliance EPS to cause endoscope damage that might void Pentax’s warranty.¹

DISCUSSION: THIS HEALTHCARE INSTITUTE’S evaluation rates the presumed performance and safety of the STERIS Reliance EPS.¹ Whether this new model may prove in time to be the most effective and safest AER on the market, surpassing all others, remains to be determined. But ECRI’s evaluation is, at times, confusing, if not inconsistent, and its rating and conclusions are challenging to reconcile and understand. **Table 1** lists several of this evaluation’s salient shortcomings, oversights and omissions—two of which, in particular, not

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Table 1. Some of this evaluation’s shortcomings.

1. **None** of the “traditional AERs”¹ to which the Reliance EPS was compared were included in this evaluation.[†]
2. **Neither** microbiological tests required by the FDA **nor** any other performance tests—such as pressure-flow tests—were performed to evaluate the effectiveness and safety of the STERIS Reliance EPS.^{27,28 †}
3. This evaluation appears to confuse a manufacturer’s claim with an evidence-based finding and does **not** provide the necessary effectiveness and safety data to:
 - justify its rating and inferential suggestions that either the STERIS Reliance EPS improves clinical outcomes or an AER that uses fewer endoscope adapters or connectors reduces the risk of infection;¹
 - support its intimation that the Reliance EPS’s filtered rinse water is bacteria-free and that its air-pressure integrity test is effective, reliable, fail-safe, and activates an audible alarm once bacteria leak through this new AER’s bacterial-retentive water filter;¹
 - conclude that the fumes of the Reliance EPS’s disinfectant were *eliminated* (see **Box B**);¹ and
 - conclude that the STERIS Reliance EPS “disinfects (the GI endoscope’s) suction valves.”¹
4. The Reliance EPS is rated *not recommended*¹—one of ECRI Institute’s three *acceptable* ratings—instead, arguably, of the more apt rating of *unacceptable* for reprocessing Pentax’s contraindicated endoscopes.
5. ECRI’s evaluation downplays the significance of **cost considerations** (see: **Box D**), and it does **not** list as a disadvantage that the STERIS Reliance EPS does not facilitate **drying** by flushing the endoscope’s internal channels with 70% alcohol followed by forced air.
6. Regarding the STERIS System 1, this evaluation does **not** cite independent, published studies that:
 - provide findings antithetical to its conclusions. For example, ECRI’s evaluation does **not** reference studies that associate the System 1^{29,45}—not *aldehyde-based* disinfectants (such as 2% glutaraldehyde)—with endoscope damage (see: **Box A**);
 - support its discussion that reports of endoscope damage linked to the STERIS System 1 “may be the result of the peracetic acid removing protein residue that was not being removed during previous reprocessing with an aldehyde-based chemistry”¹ (as the STERIS System 1’s manufacturer claims^{35,36}); and
 - support its discussion that the System 1 “uncovered prior defects that had resulted from wear and tear and/or improper care and handling and that had been masked by aldehyde-based” disinfectants¹ (as the System 1’s manufacturer claims^{35,36}). ●

[†] Notwithstanding this evaluation’s definition of *preferred*.

only compromise this evaluation's published aims, but also call into question its validity and objectivity. (Please review the *September-October, 2008*, issue of this newsletter.)

A. A singularly evaluated AER: FOR EXAMPLE, ONE of this evaluation's primary aims was to assess the STERIS Reliance EPS's "advantages and disadvantages compared with other (HLD) AER units" and to determine whether the Reliance EPS both "offers meaningful advantages" compared to other marketed AER models and "is any more or less likely than 'traditional AERs'* to be used correctly."¹ Per this comparison and stated aim, ECRI rates the STERIS Reliance EPS *preferred* (for compatible endoscopes)—its highest rating awarded only to a product that "meets all major performance and safety criteria(,) has no serious shortcomings(,) and offers significant advantages over other alternatives."^{1*}

Despite rating the Reliance EPS *preferred* (for compatible endoscopes) "based on a comparison with"¹ these *traditional AERs*,* this evaluation confusingly fails to include any of these other marketed AER models, or "alternatives"* (see: **Table 1**), sold in the U.S. by Olympus, Medivators (Minneapolis, MN), and Advanced Sterilization Products (Irvine, CA), among others. (The author of this review article is employed by another manufacturer of a *traditional AER*, one that is labeled to clean and high-level disinfect GI endoscopes and that also was not included in this evaluation.)

Explaining its exclusion of these *traditional AERs*,*

* This evaluation uniquely refers to these other marketed AER models as "*traditional AERs*" primarily because they use "multiple endoscope-specific connectors" to flush the endoscope's channels with disinfectant.¹ The Reliance EPS uses some of these connectors, but it also uses a "boot" to enclose the GI endoscope's control head and flush the suction and air/water channels with disinfectant.¹

Table 2. Accolades that this evaluation uses to describe the Steris Reliance EPS.^{1,*}

1. Rated "preferred over traditional AERs for facilities that use compatible endoscopes";
2. An "excellent choice" (for compatible endoscopes);
3. A "significant step forward in AER technology";
4. "Strongly encourage(s) healthcare facilities ... that do not have Pentax endoscopes ... to purchase the Reliance EPS rather than a traditional AER";
5. "Significantly reduces the risk that an endoscope would be reprocessed incorrectly";
6. Offers "compelling patient and staff safety advantages";
7. May "chang(e) the AER landscape"; and
8. "Should contribute significantly to patient and staff safety." ● (* This, despite the FDA's determination in 2010 that this device was without a regulatory clearance.)

ECRI's evaluation states that "most of the models that are available function similarly to one another" and "AER technology has changed little in recent years."¹ But, the technologies employed by some of these *traditional AERs*, indeed, *have* markedly changed in recent years (which might have been revealed had ECRI's evaluation included them and tested their performance). The EvoTech™ Endoscope Cleaner and Reprocessor ("ECR"; Advanced Sterilization Products), for example, which was cleared by the FDA the same year as the Reliance EPS (2006), is uniquely labeled to automate the pre-cleaning of GI endoscopes.²³ To be sure, the EvoTech ECR uses several endoscope-specific channel connectors, not a boot,* to flush the endoscope's internal channels with disinfectant—a specific characteristic that this evaluation uses to classify a model as a disfavored *traditional AER*.^{1*} One of this evaluation's most confusing qualities is its rating of the STERIS Reliance EPS *preferred* (for compatible endoscopes) in comparison with the EvoTech ECR and these other *traditional AERs*—*none* of which were evaluated and tested.

B. No microbiological tests performed: THE FOOD AND Drug Administration (FDA) requires that simulated in-use microbiological (and some clinical in-use) tests be performed to evaluate the performance and safety of an AER.²⁴⁻²⁸ Conducted under worst-case conditions using complex (GI) flexible endoscopes artificially contaminated with soil containing resistant microorganisms, these tests (designed to simulate the clinical setting) yield microbial log reductions that are the standard for evaluating the effectiveness of an AER's disinfection cycle.²⁴⁻²⁸ This federal requirement notwithstanding, ECRI's evaluation of the STERIS Reliance EPS, unlike other published evaluations of this same AER,^{24,25} did not perform these microbiological tests.¹ In fact, this evaluation did not perform *any* performance tests, not even pressure-flow tests.

To be sure, the failure of ECRI's evaluation to conduct these most important microbiological tests would certainly seem to belie its rating of the STERIS Reliance EPS *preferred*, compared to the presumed performance and safety of these other *traditional AERs*.* (For example, ECRI's evaluation concludes that the STERIS Reliance EPS "offers compelling staff patient and staff safety advantages over traditional automated endoscope reprocessors"¹ and, too, "includes some unique features that distinguish it from"¹ the *traditional AERs*.) But, this evaluation's failure to perform any microbiological or performance tests—and, most certainly, its confusing exclusion of *traditional AERs** (to which the STERIS Reliance EPS is somehow directly compared)—all the more moots the instruction in ECRI's evaluation "strongly" recommending that healthcare facilities "purchase the Reliance EPS rather than a traditional AER"¹ (see: **Table 2**).

C. A general comment: NEITHER PERFORMING DISINFECTION-effectiveness tests nor including *traditional AERs* (as required for a true and fair comparison) would not necessarily

(Continued on page 24)

have precluded ECRI's evaluation from providing a meaningful discussion about the safe and proper use of AERs. Indeed, its evaluation, in addition to providing some insights into the field of endoscope reprocessing, features a list of some of the STERIS Reliance EPS's noteworthy "pros" and "cons."

But, this evaluation's salient omissions (Table 1) restrain its capabilities, reach and application. Remembering that ECRI rates a device *preferred* if it "meets all major performance and safety criteria ... and offers significant advantages over other alternatives,"¹ * this evaluation's failure both to have performed any efficacy tests and to have included any *traditional AERs* presents obvious limitations and inconsistencies that arguably invalidate its conclusions and rating.

Arguably invalidating this evaluation's design and rating, there remains the possibility that this singularly evaluated STERIS Reliance EPS, rated *preferred*, could prove to be less safe and perform worse than ASP's Evotech ECR or any of the disfavored (and excluded) *traditional AERs*.

D. Accolades: DISPLAYED IN TABLE 2 (see: p. 23), ECRI's evaluation uses a litany of hyperbolic phrases to laud the presumed advantages of the STERIS Reliance EPS. These unambiguous expressions imply, if not require, that clinical data had been published convincingly demonstrating that this new AER significantly reduces the risk of healthcare-acquired infections (compared with *traditional AERs*). But, despite this evaluation's statement that the Reliance EPS "should contribute significantly to patient and staff safety"¹ (see: Table 2), no such clinical data have been published.

That ECRI's evaluation uses such expressions: (a) to describe and praise the STERIS Reliance EPS; (b) to claim its technology is a significant advancement; (c) to suggest inferentially that it may reduce the risk of infection—for example, this evaluation states that the Reliance EPS "significantly reduces the risk that an endoscope would be reprocessed incorrectly";¹ and (d) to justify its *preferred* rating (for compatible endoscopes)—without having either demonstrated that this new AER improves clinical outcomes or performed any tests to evaluate its disinfection effectiveness—is most confusing and suggests an overstatement of the performance and safety of the STERIS Reliance EPS. (Note: STERIS wrote in 2010 that the FDA advised it that "incremental modifications" to the STERIS Reliance EPS rendered it without a legal clearance to be marketed.)

E. A manufacturer's claims? SOME OF THIS evaluation's conclusions suggest that it, at times, may have confused a manufacturer's claim with scientifically-acquired data. For example, first, ECRI's evaluation discusses a possible, though implausible, cause of endoscope damage associated with peracetic acid, which is the Reliance EPS's active ingredient, without clarifying that the explanation it provides is an unsub-

stantiated claim advanced by the Reliance EPS's manufacturer itself and is not a finding independently verified by ECRI during this evaluation (see: Box A on p. 24S₁¹).

Second, ECRI's evaluation lists as a "pro" that the STERIS Reliance EPS "disinfects (the) suction valves"¹ of GI endoscopes. But this, too, is the manufacturer's claim—not an independently determined finding (remember that ECRI's evaluation did not perform any microbiological tests to assess the effectiveness of this new AER for disinfecting GI endoscopes or their suction valves).¹ A distinction with an important difference that would have altogether distinguished the manufacturer's claim from an evidence-based result, ECRI's evaluation might have more aptly stated this ostensible "pro" as: "According to its manufacturer, the STERIS Reliance EPS disinfects suction valves." (ECRI's evaluation does not discuss whether this new AER can reprocess *air/water* valves.)

Third, ECRI's evaluation states that the STERIS Reliance EPS "eliminates personnel exposure to toxic LCG (liquid chemical germicide) agents and fumes."¹ Discussed in Box B (p. 24S₃), however—apparently, again, having confused the manufacturer's claim from a scientifically-determined finding—this evaluation appears not to have performed the air sampling tests necessary to render this definitive conclusion.

Fourth, discussing the STERIS Reliance EPS's two automated "self-decontamination" cycles (a short and long cycle), ECRI's evaluation suggests that both are safe and effective. But, although one of its aims (see: Box C; p. 24S₃), this evaluation did not test or evaluate the safety and effectiveness of either cycle. Instead, this evaluation provides the manufacturer's own specifications for both cycles.³⁰ (Note that box articles B, C, and D are on p. 24S₃, which is *only* available at: <http://www.myendosite.com/htmlsite/2008/3boxes.pdf>)

F. Water filter maintenance: AND, FIFTH, ECRI'S evaluation states that the STERIS Reliance EPS "sounds an alarm and displays a maintenance message when filters should be changed,"¹ adding that this new AER "measures pressure across the water feed filter during filling, and it tests the integrity of this filter with an air pressure test at the end of each cycle. If the filter does not pass either of these tests, the unit will alarm until the cycle is canceled. Traditional AERs do not have an alarm for this."¹ (It is unclear how this evaluation determined that none of these *traditional AERs* feature this alarm, having not included or tested any of them.)

Notably, this evaluation's discussion and listing of this audible alarm and air-pressure integrity test as a "pro" inferentially suggest that the STERIS Reliance EPS monitors the microbial quality of the "filtered" rinse water. But, while this would be a significant advantage, *no* AER, including the evaluated STERIS Reliance EPS, features such an alarm, or integrity test, to monitor its filtered water for microbial contamination. In truth, alarms, air-pressure filter integrity tests, and diagnostic cycles can detect a marked reduction in the flow of tap water through a water filter, often indicating that

(Continued on page 24S₁)

the “feed” filter’s bacterial membrane has become clogged requiring replacement. But, these alarms, tests, and cycles do not detect what is most clinically important—when bacteria and other waterborne microorganisms are leaking through the filter re-contaminating the endoscope during terminal water rinsing, posing an increased risk of infection.

Indeed, terminally rinsing the endoscope with water of a pristine quality is crucial to patient safety.³¹ But, by (again) not distinguishing between a manufacturer’s claim and an independently-determined result, ECRI’s evaluation missed an opportunity to provide important insight into the capabilities and limitations of these alarms and air-pressure filter integrity tests. To be sure, *no* verification and validation data have been published demonstrating that the activation of an alarm, the result of an air-pressure integrity test, or having reached a specific pressure differential indicates microbial contamination of the rinse water, due to a breached filter.

Overlooked in ECRI’s evaluation, microorganisms can leak through the bacterial membrane of any AER’s (or “sterilizing” system’s) water filter *without* activating an audible, visual, or diagnostic alarm *and* despite the water filter *passing* an air-pressure (or comparable) integrity test (known as a “false-negative” result). By not detecting microorganisms in filtered rinse water claimed to be “sterile” or “bacteria-free,” these alarms and filter tests are limited in function and can provide a false sense of security and a misleading result that paradoxically may pose an increased risk of infection.³¹⁻³³

G. Other details and considerations: ECRI’S EVALUATION PROVIDES a second rating for the STERIS Reliance EPS—*not recommended* for reprocessing Pentax endoscopes—which, oddly, is one of ECRI’s three “acceptable” ratings (the other two are *preferred* and *acceptable*, in descending order). Understanding that ECRI’s evaluation states that Pentax contraindicates the use of the STERIS Reliance EPS for reprocessing *any* of its endoscopes, it is most confounding that this evaluation did not instead rate the STERIS Reliance EPS *unacceptable* for reprocessing Pentax’s flexible endoscopes.

Similarly, ECRI’s evaluation notably diminishes the significance of some of the STERIS Reliance EPS’s other acknowledged disadvantages—for example, as discussed in **Box D** (see: p. 24S₃), that both the initial and associated operating costs of the STERIS Reliance EPS are significantly higher than the disfavored *traditional AERs* (though, likely, not ASP’s EvoTech EPS); or, that the STERIS Reliance EPS does not facilitate endoscope drying after each completed cycle (**Table 1**), a shortcoming that this evaluation mentions but does not list as a specific disadvantage. Indeed, ECRI’s evaluation does not emphasize the importance of endoscope drying—a measure as crucial to the prevention of healthcare-acquired infections as manual cleaning of the endoscope.³¹

ECRI’s evaluation also arguably downplays the potential significance of the STERIS Reliance EPS’s inability “to detect two significant user errors” that “an advanced reprocessor should be able to prevent” (this new AER’s *preferred* rating

Box A. A competing “sterilizing” system? ECRI’s evaluation of the STERIS Reliance EPS briefly discusses *The STERIS System 1*—a reprocessor labeled to achieve “sterilization.” The System 1 ironically competes with, and is marketed by the same company as, the Reliance EPS. Nevertheless, ECRI’s evaluation does not compare or contrast these two competing models as part of a critical discussion of automated reproprocessors. Nor does ECRI’s evaluation clarify whether the STERIS System 1—which is also marketed for GI endoscopy and is more compact, easier to use, and costs significantly less than the Reliance EPS (see: **Box D**)—is one of the *traditional AERs* over which the STERIS Reliance EPS is *preferred*.

Instead, ECRI’s evaluation provides a manufacturer’s account,^{35,36} which has not been scientifically verified, to rationalize (if not indemnify) a possible, if implausible, cause of endoscope damage that ECRI’s evaluation acknowledges is associated with the STERIS System 1’s chemical agent^{1,29,43}—peracetic acid, which both the System 1 and the Reliance EPS use at the same concentration and immersion temperature.³⁵ This evaluation’s discussion of endoscope damage associated with the System 1, and, possibly, with the Reliance EPS (see: main article), is a confusing distraction that palliates this potentially significant shortcoming.³ The topic of endoscope damage will be discussed in a future issue of this newsletter. ●

notwithstanding).¹ According to ECRI’s evaluation, one of these two errors (which is not listed as a disadvantage) is the STERIS Reliance EPS’s failure to notify the user when a channel connector has become disconnected from the colonoscope’s auxiliary water channel—one of the specific concerns with *traditional AERs* that this evaluation suggests can result in ineffective disinfection and an increased risk of disease transmission. The other error (which this evaluation does acknowledge as a disadvantage) is the STERIS Reliance EPS’s failure to detect inadequate fluid flows through the internal channels of a second endoscope, if the operator (inadvertently) presses this AER’s “one-endoscope cycle” button when simultaneously reprocessing two GI endoscopes.

CONCLUSION: THE OMISSIONS, OVERSIGHTS, and shortcomings that this review identifies herein (**Table 1**) raise fair questions about the validity and objectivity of ECRI’s evaluation of the STERIS Reliance EPS. As *Consumers Union* understands well,² the establishment of working relationships with manufacturers to evaluate and rate their products—whether a drug, medical device, or a consumer item—may pose conflicts of interests that, unless rigorously and transparently managed, can compromise objectivity.^{5-11,22,34} Studies suggest that interactions with manufacturers can introduce bias and the publication of only favorable data about a product.^{2,3,5-11,22} Whether ECRI’s acknowledged working relationships⁴ with manufacturers may have influenced its conclu-

(Continued on page 24S₂)

sions and rating of the STERIS Reliance EPS is debatable.

Interactions and working relationships with manufacturers can cause researchers to aggrandize a product's benefits; to overlook its flaws and shortcomings; and to develop positive attitudes,⁷ preferences, deference, and irrational behavior^{5,7} toward, and to feel dependent on or indebted or obligated^{3,5,8} to, a manufacturer or its products (Table 2).^{3,5-11,22}

Another aspect of ECRI's evaluation that raises additional questions about whether working relationships with manufacturers can introduce bias^{5-11,22} is its discussion of peracetic acid, the active ingredient used by the STERIS Reliance EPS at the same concentration and temperature as the STERIS System 1 (see: **Box A**).³⁵ Rather than addressing arguably more important patient-safety concerns—such as: the proneness of bacterial water filters to breakage;³¹ the false sense of security an AER's air-pressure integrity test can provide about the microbial quality of filtered rinse water; or, the lack of verification and validation data demonstrating that the STERIS System 1's (or any automated reprocessor's) 0.2 micron bacterial water filter reliably and consistently produces "sterile" rinse water from a hospital's tap³¹⁻³³—ECRI's evaluation instead dubiously and without independent corroboration advances the manufacturer's assertion³⁵ that peracetic acid is not the cause of damage that has been linked to endoscopes reprocessed by the STERIS System 1 (and, possibly, the STERIS Reliance EPS).¹ Worse, ECRI's evaluation does not reference specific studies that challenge the manufacturer's claim that, not peracetic acid, but rather 2% glutaraldehyde may be responsible for the noted endoscope damage (see: **Box A**).²⁹ (Due to space constraints, this topic of endoscope damage linked to peracetic acid is discussed in detail in this newsletter's *January-February, 2009*, issue.)

ECRI Institute discloses in its evaluation of the STERIS Reliance EPS that it will address in an upcoming report "issues related to sterilization versus HLD (high-level disinfection)." Publication of this report is most welcomed, as, too, is a re-evaluation of the STERIS Reliance EPS. Ideally, this re-evaluation would address the shortcomings cited herein (see: **Table 1**); include *traditional AERs*; and would both compare and contrast the STERIS Reliance EPS's effectiveness and safety to these *traditional AERs*, which would include ASP's EvoTech ECR and the STERIS System 1.

This re-evaluation would also discuss the manufacturer's rationale for marketing the STERIS Reliance EPS, thereby abandoning its long-standing (though unsubstantiated) claim that high-level disinfection of GI endoscopes, compared to "sterilization" using the STERIS System 1, poses an increased infection risk.³⁶⁻³⁹ This re-evaluation would therefore provide insight into why the Reliance EPS—despite using a 0.2 micron bacterial retentive filter and the same concentration and temperature of peracetic acid as the STERIS System 1—is

marketed and labeled as a *washer-disinfector*—not as a *washer-sterilizer*, which is the more coveted label claim.

Last, ECRI is encouraged to provide guidance in this upcoming report about the FDA's warning letter, dated May 15, 2008, stating that the STERIS System 1 and its chemical agent are "adulterated" and "misbranded."^{40,41} In truth, few discussions about infection control, endoscope reprocessing, and the safety of AERs would be of greater importance to public health and to the prevention of infections, both in the flexible endoscopic (e.g., GI, urology, pulmonary) and operating room settings, than such timely guidance.⁴⁰

A FINAL WORD: THE FINDINGS OF this review suggest that ECRI's evaluation lacks balance and objectivity, overstating the STERIS Reliance EPS's safety and effectiveness. The shortcomings and accolades identified in **Tables 1** and **2**, respectively, were unexpected in part because ECRI Institute's advertised mission, which is impressive and intriguing—see: ECRI's recently published list of "hospital hazards,"⁴²—would appear to be well-suited to satisfying the public's ardency for independent¹⁴ and objective evaluations of infection-control products. Greater transparency and more rigorous management of conflicts of interest are recommended, to improve the quality, validity and objectivity of all types of product evaluations and healthcare guidelines. ●

[The End] (Article by: Lawrence F. Muscarella Ph.D.)

✓ **Box articles B, C and D are available on p. 24S₃ or: www.myendosite.com/htmlsite/2008/3boxes.pdf**

✓ **This article's REFERENCES are only available at: www.myendosite.com/htmlsite/2008/refs111208.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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Box B. Eliminates exposure to vapors? This evaluation states that the Reliance EPS “eliminates personnel exposure to toxic LCG (liquid chemical germicide) agents and fumes.”¹ Such a finding, if true, would be an advantage. But, this evaluation appears not to have performed the necessary air-sampling tests to conclude that in the surrounding environment the disinfectant’s fumes were *eliminated*—as opposed to maybe just *reduced*, which is the more common attribute of AERs and, ironically, more consistent with the manufacturer’s advertised claims.^{30,41} Without having performed these air-sampling tests, this evaluation’s conclusion that the Reliance EPS “eliminates” its disinfectant’s fumes is questioned. Similarly, ECRI’s evaluation does not provide any references to support its conclusion that “most” facilities use Olympus’s or Fujinon’s GI endoscopes—not Pentax’s contraindicated endoscopes. ●

✓ The REFERENCES to this article are available at:
www.myendosite.com/htmlsite/2008/refs111208.pdf

Box C. Self-decontamination? The FDA requires manufacturers of AERs to demonstrate that the internal design of their AERs are not prone to bacterial colonization. This is a necessary requirement, because the flawed internal designs of AERs have been linked to bacterial colonization and to both patient morbidity and mortality.^{31,44} An important aim of ECRI’s evaluation, therefore, was to determine whether the Reliance EPS “possesses any design flaws that could lead to reprocessing failures.” This aim is typically achieved by artificially contaminating the AER’s internal surfaces with waterborne bacteria, if not biofilms, and verifying the proliferation and colonization of these bacteria. A determination that the AER’s internal surfaces are no longer colonized with these specific bacteria after operation of the AER’s “self-decontamination” cycle would indicate this cycle’s effectiveness.

Nevertheless, although it describes some details about the STERIS Reliance EPS’s two automated “self-decontamination” cycles, ECRI’s evaluation does not provide data or results to demonstrate that the effectiveness and safety of either cycle was evaluated. Instead, this evaluation provides the manufacturer’s published specifications for these two cycles. Having not performed the necessary tests to evaluate objectively the Reliance EPS’s two “self-decontamination” cycles—despite rating this AER *preferred* and “strongly” recommending its use (for compatible endoscopes)—is confusing and suggests that this evaluation may have confused a manufacturer’s claim with an independently acquired finding. (See: **Box A**, **Box B**. Also, please refer to this newsletter’s main article). ●

Box D. Cost considerations: ECRI’s evaluation states that the list price of the Reliance EPS is \$38,000, which, according to this evaluation, is “about \$6000 to \$7000 more” expensive than *traditional AERs*.¹ Further, this evaluation acknowledges that the cost of the Reliance EPS’s single-use disinfectant (per cycle) is \$8.50 (and \$10.50 “per cycle for all consumables”).¹ As noted by ECRI in another of its published evaluations (but not disclosed in this one),⁴² the cost associated with using 2% glutaraldehyde (per cycle) in the disfavored *traditional AERs* is \$1.75—which is almost 80% less.

Paying a higher price for a *preferred* product may be prudent, but doing so would require that some circumspect performance and safety criteria be clearly satisfied. Although it lists both the higher initial and per-cycle costs associated with the Reliance EPS as a *con*, this evaluation does not justify these higher costs by citing any published studies, or performing tests and including any simulated in-use or clinical performance data, demonstrating that, compared to the *traditional AERs*, the STERIS Reliance EPS more effectively (or reliably) achieves high-level disinfection. Arguably placing insufficient weight on cost considerations, this evaluation’s awarding of the rating “preferred” to a device that is significantly more expensive, but for which data showing that it improves clinical outcomes (i.e., reduces the risk of infections) have not been published, is another of this evaluation’s confusing qualities. ●

✓ Wishing you a Happy Holiday and New Year.

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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