

The Q-Net™ Monthly

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What's News

Welcome to this newsletter's 16th year of publication. This special triple issue provides a convenient format to discuss current trends in infection control. • The March (2010) issue of *Consumer Reports* features an important report (the review of which is recommended) about hospital infections. A response to this report is provided herein on p. 4 (see: "Dear *Consumer Reports*"). • Previous issues of this newsletter are available on-line.

Editor-in-Chief

This article was written by this newsletter's editor-in-chief, Lawrence F. Muscarella, Ph.D.

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.

Infection Control's "Growing Weeds"?

A discussion of aseptic technique and the standard of care

Background

Almost a year ago several newspaper articles, editorials, and television broadcasts, from local news stations to the national nightly news, reported that three Veterans Administration medical centers (VAMCs)—located in Murfreesboro (TN), Miami (FL) and Augusta (GA)—had been improperly cleaning and disinfecting reusable endoscopic instrumentation, including endoscopes.¹⁻¹²

These reports raised well-publicized fears that more than 10,000 U.S. veterans, who underwent colonoscopy and other endoscopic procedures at these three VAMCs, might have been exposed to potentially infectious microorganisms and viruses, including HIV and the hepatitis viruses.¹⁻¹² Please refer to **Box A** on p. 2 for a discussion of the Veterans Health Administration's (VHA) response to these three reprocessing breaches.

THE MAJ-855 AUXILIARY WATER TUBE:

Having received the most publicity, the VAMC in Murfreesboro disclosed in December (2008) that for as many as five years it had been performing colonoscopy using reusable irrigation tubing—known as the *MAJ-855 auxiliary water tube*—that had been fitted with a faulty two-way valve, instead of the intended

one-way valve designed to prevent the tubing's contamination.^{1-3,10,12}

This error may have facilitated the backward flow of potentially infectious debris and fluids from the colon into this tubing and its accessories, which include an irrigation pump and water bottle. The use of this tubing and accessories—which were shared among different patients without being reprocessed after each use—posed the potential for patient-to-patient disease transmission.^{2,3,10,12}

In addition to this reprocessing breach in Murfreesboro, the VAMC in Miami reported that it had been disinfect-

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"Dear Consumer Reports"

A reply to a recent article published in *Consumer Union's* popular monthly magazine p. 4

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Box A: A response by the Veterans Affairs Office of Inspector General (VAOIG).

In May (2009), officials of the *Veterans Affairs Office of Inspector General* (VAOIG) inspected forty-two (42) randomly-selected (and probability-based) Veterans Administration medical centers (VAMCs) within the U.S.¹² The primary purpose of these inspections was to determine whether the reprocessing breaches previously identified by three VAMCs (in Murfreesboro, Miami, and Augusta) might be exhibitiv of “fundamental defects” within the organizational structure of the Veterans Health Administration (VHA) (see: main article).¹²

What was inspected? This Office’s officials determined during these inspections whether each of these forty-two VAMCs had on file: (a) “model-specific” instructions, known as “standard operating procedures” (SOPs), describing the proper reprocessing of flexible endoscopes; and (b) competency records demonstrating that staff members were trained and performing their reprocessing responsibilities in compliance with these SOPs.¹²

Moreover, even though VAMCs use a number of different types of decontamination methods, including sterilization, to reprocess endoscopes, this Office’s inspections assessed reprocessing compliance only as it applied to those specific SOPs and competency records detailing and documenting *high-level disinfection of colonoscopes and ear-nose-throat (ENT) endoscopes*.¹²

The VAOIG report: One month later in June (2009), the VAOIG published a report detailing the results of these inspections.¹² In addition to other considerations, this report concluded that “facilities have not complied with management directives to ensure compliance with reprocessing of endoscopes, resulting in a risk of infectious disease to veterans.”¹² Among other suggestions, this report understandably and appropriately recommended the improvement of the reliability and quality of endoscope reprocessing within the VHA.

Despite the inspections of these VAMCs focusing only on high-level disinfection, the VHA has notably acknowledged the potential for improper “sterilization” of reusable endoscopic equipment. Though the VAOIG’s report excluded both from its list of “pertinent events and actions,”¹² the VHA published two patient safety alerts, in 2005 and 2008, that publicized the potential for the STERIS System 1 to “sterilize” colonoscopes and other types of flexible endoscopes improperly.^{56,57}

Comment: Missing an important opportunity, if not overlooking a requisite consideration, the VAOIG’s report did not investigate whether any of these forty-two inspected VAMCs used the STERIS System 1 (or the Sterrad

100NX System or another “sterilization” technology) to reprocess endoscopes. The rationale for this oversight is confusing, considering that: (1) these two aforementioned patient safety alerts^{56,57} published by the VHA focus on the STERIS System 1; (2) the STERIS System 1 is commonly used to reprocess reusable endoscopic equipment^{26,45}—notwithstanding the FDA concluding a year earlier (May, 2008) that this device is adulterated and misbranded;²⁴ and (3) a primary goal of the VAOIG’s report was to improve the quality of endoscope reprocessing,¹² the fulfillment of which presumably would have required this Office to confirm that none of the inspected VAMCs were using the STERIS System 1. (Note: A report published by the VAOIG on March 16th, 2010, discussing breaches at the VAMC in San Juan similarly failed to discuss the STERIS System 1’s use.⁶⁸)

The justification for the VAOIG’s report to have not included a discussion of either bronchoscopes or the STERIS System 1 is unclear.

The failure of this VAOIG’s report to investigate whether any of the forty-two inspected VAMCs were improperly reprocessing endoscopes other than colonoscopes and ENT endoscopes—for example, bronchoscopes and cystoscopes, the former of which has been linked to patient injury more often than colonoscopes or ENT endoscopes^{27-37,58-60}—is similarly confusing. These oversights raise valid questions about the focus and completeness of the VAOIG’s report. ● LFM

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ing the MAJ-855 irrigation tubing once at the end of the day, instead of after each procedure as required by its manufacturer. And the VAMC in Augusta reported that it had been wiping and inadequately disinfecting the surfaces of ear-nose-throat (ENT) endoscopes (see: Box A).^{5,6,11,12}

ROOT-CAUSE ANALYSIS: This VAMC in Murfreesboro published a detailed *root-cause analysis*[†] that cited several factors that contributed to its reprocessing breach. In particular, this analysis placed blame for this error on: (a) the manufacturer of the MAJ-855 irrigation tubing and valve (this same manufacturer markets the flexible endoscopes used by this VAMC); (b) “unclear” instructions provided by this manufacturer describing this tubing’s reprocessing requirements; and (c) in addition to human error, inadequate training of gastrointestinal (GI) “lab staff.”¹⁰ Whether this analysis and its list of factors might be incomplete, however, is considered, below.

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[†] A *root-cause analysis* is a method used both to identify all of the factors that may have contributed to or caused an adverse event and to prescribe the appropriate remediation.

Discussion and Editorial

In truth, few of us in the GI endoscopic community were likely in genuine shock upon learning of the reprocessing missteps at these three VAMCs (see: [Box A](#)), as if errors like them are not entirely unexpected. Many of us have come to realize that the potential for these types of infection-control contretemps is with us every day. What's surprising is not that these and other breaches like them occur, but that reports publicizing them are not more frequent—a testament to a number of considerations, including, possibly, both the resilience of the average patient's immune system and the use of antibiotics. Please read the article "[Dear Consumer Reports](#)" on p. 4.

What's surprising is not so much that reprocessing breaches like these occur, but that reports publicizing them are not more frequent.

A fair question to ask is whether some of the blame for the breaches identified at these three VAMCs (and possibly at as many as 16 others^{9,12}) may, in part, ironically fall on (in addition to a manufacturer and human error¹⁰) the lap of, not so much the healthcare community itself as, the current "standard of care" that it has adopted and advanced.

MISSION STATEMENTS. The mission statements of both healthcare and accreditation organizations are laudable and specific, steadfastly pledging to promote patient safety and advance the quality of health care.¹³⁻¹⁸ Some claim to promote a "culture of zero tolerance" for practices that pose an increased risk of healthcare-acquired infections.¹³ Others similarly seek to inspire healthcare organizations "to excel in providing safe and effective care of the highest quality"¹⁸ and to improve "the safety, quality and cost-effectiveness of patient care."¹⁶

Indisputably, these organizations are irreplaceable parts in a complex and dynamic system of "checks and balances"—one important aspect of which is the oversight by these organizations of the safety and effectiveness of infection-control devices, ensuring, too, that the labeling and advertised claims of these products are neither false nor misleading.

But, sustained motion requires a committed and intransigent force, the absence of which can beget stasis, complacency and laxity, and the extent to which the mission statements of these organizations are more customary and routine than truly proactive and resolute is fair ground to excavate. More questions arise: (1) Do these organizations unqualifiedly denounce any practice that could increase the risk of healthcare-acquired infections? (2) Could these organizations provide better nursing- and patient-oriented guidance to improve health care? (3) And, is the publicity surrounding an infection-control breach too often the primary impetus for improvements in practice? Fair responses to these questions might be, respectively: *Not always; yes; and on occasion.*

WHO'S TO BLAME? The root-cause analysis performed by the VAMC in Murfreesboro lists, as factors that contributed to its breaches, apparent missteps by both the manufacturer of the MAJ-855 tubing and GI lab staff (see: [Box A](#)).¹⁰ But, respectfully, this analysis would appear to be incomplete, because it did not also list, as another potentially significant factor, confusion engendered by today's inconsistent standard of care.

Some examples that suggest the current standard of care is more compromising and conflicted than committed and evidence-based include its: (a) **endorsement** of inconsistent guidelines—see: the article "[Double Standards](#)" published in this newsletter's May-June, 2006, issue; (b) **acceptance**, if not **advancement**, of the use in operating rooms of automated "sterilizing" devices whose labeling claims are untenable and have been censured by the Food and Drug Administration (FDA; see below); and (c) **advocating**, on occasion, of surgical practices that pose an *increased* risk of infections.

ASEPTIC TECHNIQUE, DOUBLE STANDARDS: Together, these examples portray a standard of care whose commitment to aseptic technique is confused and flawed. Appropriately asserting that water or moisture on a set of wrapped surgical instruments poses an increased risk of microbial contamination, requiring that the set be re-sterilized before its reuse,¹⁹ this same standard of care paradoxically asserts the "sterility" of endoscopes and surgical instruments that during clinical use are *wet* with water (which may be contaminated;²⁰ see: [Box B](#), p. 5) after having been reprocessed and rinsed by the STERIS System 1²¹⁻²³—a device that, as the FDA concluded in May, 2008 (and again in 2009 and 2010), has been adulterated and misbranded since 1988.²⁴

That the current "standard of care"—which healthcare organizations through their publications, in part, define—lacks quality and a commitment to aseptic technique can be argued.

As if water or moisture on its surfaces were no longer to compromise a surgical instrument's "sterility," operating-room guidelines^{21,25,26} endorse the clinical use of wet surgical instruments—notwithstanding this dubious practice's association with an increased risk of healthcare-acquired infections, patient morbidity and mortality.^{20,27-38} The advancement of this double standard raises important questions about healthcare's quality and commitment to aseptic technique.

STERIS SYSTEM 1: In agreement with conclusions provided in this newsletter for more than a decade, the FDA published a letter, dated December 3, 2009, doubting the safety and effectiveness of the STERIS System 1—as well as the validity of its dual claim to achieve "liquid sterilization" and to produce "sterile" rinse water.^{24,38-41} This letter reaffirmed concerns the FDA had previously expressed in two letters pub-

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Dear “Consumer Reports”

The March (2010) issue of *Consumer Reports* features an article about healthcare-acquired infections (HAIs).⁴⁸ This article also discusses a checklist of practices that have been shown to reduce the risk of “central-line infections,” which are bloodstream infections associated with large intravenous catheters.

Respectfully, a fair question to ask Consumer Union, however, is whether its article about central-line infections provides more of a convenient and palatable introduction to the topics of HAIs and their prevention than a complete and useful discussion about aseptic technique, infection control, and the validity of infection rates publicly reported by hospitals.

Notably, Consumers Union does not clarify that the infection rates reported by hospitals account for only a few specific types of HAIs, such as, for example, central-line infections identified in intensive care units (ICUs).^{47,61} Indeed, several states have enacted laws requiring the disclosure of (some types of) HAIs,⁶² but these laws do not mandate that *all* identified HAIs be reported. For example, infections caused by a contaminated bronchoscope or GI endoscope these laws would not ordinarily require be reported.⁶² (Also not discussed by Consumers Union, these state laws generally apply only to hospitals⁶¹ and not to other types of medical facilities, such as dialysis centers or ambulatory surgical centers.)

Nor does Consumers Union clarify that the infection rates it lists in its article for comparisons are based on data that have been reported by the hospitals *themselves* and ordinarily have not been acquired, validated or standardized by independent health officials. While its analysis aptly adjusted for data collected from “varying mixtures” of ICUs,⁴⁷ Consumers Union did not similarly account for the possibility that some of the reported infection rates listed in its article (e.g., “no infections”) may be inaccurate due to bias.^{61,63-65}

Through the disclosure of their HAIs, hospitals may become legally exposed and, following the advice of *Consumer Reports*,⁴⁷ patients may seek medical care at other competing⁶³ hospitals with lower reported infection rates.⁶¹ According to the U.S. Government Accountability Office (GAO), these and other tendencies may provide hospitals with an “incentive” to “underreport” infections.⁶³ Though not discussed by Consumers Union, *reported* infection rates may be partial, “manipulated”⁶⁴ and *lower* than the *actual* infection rates.⁶¹⁻⁶⁷ That the masking of HAIs by antibiotic therapy also may contribute to the reporting of a “zero,”⁶⁴ low, or overly-optimistic infection rate Consumers Union similarly did not address.

Which raises a fair question: Could the infection rate this article lists for New York University Langone Medical Center—*Consumer Reports* states that this is a “poorly performing” hospital whose infection rate is twice the na-

tional average—be a reflection more of the accurate reporting of data by this hospital than necessarily of breaches in aseptic technique and infection control?

Further, Consumers Union does not discuss a potential contributor to HAIs and breaches in sterile conditions that may be as significant a factor as those it discusses. An unavoidable topic, U.S. hospitals have been using unwittingly for as many as two decades (without the patient’s knowledge) an adulterated and misbranded device to “sterilize” surgical instruments (*see*: main article).^{26,45}

Raising legitimate questions about the quality of health care, the FDA published in 2008, 2009, and 2010 that this “sterilizing” device—known as the STERIS System 1—has been without a regulatory clearance since 1988. According to the FDA, the safety and effectiveness of this device—as well as its ability to achieve “sterilization” and maintain sterile conditions—cannot be assured.^{24,38-41,43} Indeed, the FDA has associated this device with HAIs (*see*: main article’s **Box B** on p. 5).³⁸

As many as 20,000 STERIS System 1 devices are reported to be in use in the U.S.,⁴⁵ and one notice estimates that the cost to replace these devices with a legally marketed sterilization technology may exceed *half a billion dollars*.⁴⁵ Though not necessarily legally sound, that this device can continue to be used, if only until August 2011, has been suggested (*see*: main article).⁴³

This article by Consumers Union displays a laudable instruction about HAIs and “public accountability.”^{47,61} But, this article would have been more complete, accurate, and earnest, had it—in addition to acknowledging that *reported* infection rates not only account for only a few types of HAIs but also may be lower than the *actual* rates—provided a brief perspective, as much as of central-line infections, of the STERIS System 1, whose use since 1988 could represent the most potentially significant compromise of aseptic technique by an infection-control device in U.S. history (*see*: main article).

That the use of any faulty “sterilizing” device could jeopardize aseptic technique and pose an increased risk of HAIs is self-evident. Yet, many of the types of HAIs that might be associated with the STERIS System 1⁶⁸ state laws would not typically require be reported.⁶² And, further, the disclosure of an HAI linked to such a censured device could itself be legally problematic.⁴²

In closing, that the STERIS System 1’s common use^{26,45} in the U.S. demonstrates that the current standard of care is confused and off-course can be reasonably argued (*see*: main article). Indeed, for *Consumer Reports* to discuss breaches in infection control and HAIs without also addressing, if only briefly, the implications of the STERIS System 1’s use to aseptic technique is to have missed an important opportunity. *Consumer Union* is requested to complete its discussion about HAIs and address not only the validity of reported infection rates but also whether the current oversight of infection-control devices is sufficiently adequate to prevent HAIs. ■ LFM

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lished in 2001³⁸ and in 2008²⁴ (see: Box B). In its 2008 letter, the FDA wrote that the STERIS System 1 has been without a regulatory clearance for the past two decades—which would suggest that aseptic technique has not been maintained and the process not monitored using a legal biological indicator (BI). The FDA added in December (2009) that the use of this faulty device is to be discontinued within 3 to 6 months.³⁹⁻⁴²

That the use of an adulterated and misbranded “sterilizing” device could compromise aseptic technique and pose an increased risk of health-care-acquired infections is self-evident.

But, having “heard (since December, 2009) from ‘outside constituents’” including several healthcare providers and organizations claiming that 3 to 6 months is insufficient, the FDA in February (2010) revised its previous instruction, extending to 18 months the recommended timeframe to discontinue the use of the STERIS System 1 and transition from it to a legally-marketed sterilization technology.^{43,44}

OVERSIGHTS AND MISSTEPS: The recent acknowledgement that for the past twenty years a device labeled to “sterilize” surgical instruments for use in the operating room has been adulterated and misbranded²⁴ (without the patient’s knowledge) is as significant and concessional vis-à-vis the standard of care as the implications of this device’s common²⁶ use to the integrity of aseptic technique are far-reaching and unprecedented. (Please review: [i] both the July-August-September, 2009, and October-November, 2009, issues of this newsletter; [ii] an article in the March [2010] issue of *Consumer Reports* about healthcare-acquired infections; and [iii] a letter entitled “Dear *Consumer Reports*” on p. 4 herein.)

Nevertheless, to date, no healthcare organization, association, or agency has addressed the significance to aseptic technique of the FDA’s censure of the STERIS System 1 (and of its biological indicator, or BI).⁴⁵⁻⁴⁸ Nor has any discussed whether the continued use of the STERIS System 1, or of any adulterated and misbranded device, would warrant patient notification. To the contrary, and a most notable example of the current standard of care’s misdirection, a Canadian health agency—while acknowledging that the STERIS System 1 is an “unapproved” device that “violates U.S. federal law”—stated in a letter, dated January 5, 2010, that the agency has “no objection” to this device’s continued sale and use.⁴⁶

These oversights and missteps are significant for a number of reasons, including because: (1) these healthcare organizations, through their publications, to a significant extent define the “standard of care”; and (2) the use of the STERIS System 1 (and its faulty BI) since 1988 may be the most costly and potentially significant compromise of aseptic technique by an infection-control device in U.S. history. A notice published in January, 2010, suggests that as many as 20,000

Box B: “STERILE” FILTERED RINSE WATER?

Though overlooked by recent reports^{39-41,43-46} discussing the STERIS System 1’s federal censure, the FDA published a letter in April, 2001, expressing its concerns about this device’s association with “continued reports of patient infections.”³⁸ Stressing in this letter that this “sterilizing” device may be potentially unsafe, the FDA wrote that “the association of the STERIS System 1 with patient infections usually caused by waterborne organisms leads us (the FDA) to question the ability of the processor to provide a sterile water rinse.”³⁸ The FDA added: “We (the FDA) believe that (the System 1) may not be functioning as it is labeled.”³⁸ ● LFM

STERIS System 1 devices are in use in the U.S., requiring as much as *half a billion dollars* (\$500,000,000) to replace.⁴⁵

A MISGUIDED STANDARD OF CARE? The current standard of care’s apparent failure through the years to heed the concerns about the safety of the STERIS System 1 expressed by the FDA and others⁴⁹—including Muscarella, first, in 1993^{20,50} and on the front pages of *Investors Business Daily* in 2000⁵¹ and the *Wall Street Journal* in 2004²⁰ (see: Box B)—is both revealing and foreboding.²⁷⁻³⁸ Having condoned the use of this device and acceded to its unsound guarantee to achieve “liquid sterilization,” a fair question to ask is whether this conflicted standard of care, and the confusion it has sowed, might have contributed, in part, to the reprocessing breaches identified at the three aforementioned VAMCs (see: Box A).

*As many as 20,000 of the STERIS System 1 devices are in use in the U.S., requiring as much as half a billion dollars to replace.*⁴⁵

To be clear, however, no published data or reports suggest that the STERIS System 1 was associated with any of the reprocessing breaches identified at these three VAMCs (in Murfreesboro, Miami and Augusta).¹⁻¹² But, such oversights, missteps, and inattentiveness displayed through the years by:

- published healthcare guidelines* that are inconsistent and, providing inadequate oversight, endorse, for example, such potentially inimical and paradoxical practices as the insertion into a patient’s lungs of a *wet* bronchoscope, having just been reprocessed and rinsed with water by the censured STERIS System 1 (see: Box B),^{21-23,25,26,29-31}
- the *labeling* of some surgical instruments that, by their manufacturers having referenced and, at times, recommended their reprocessing using the STERIS System 1, render these reusable instruments *misbranded*—a conclu-

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sion published by the FDA in February, 2010 (but first published in this newsletter in the fall of 2009);^{48,52,53}

- (c) *healthcare, consumer, and accreditation organizations*—including the VHA itself (see: **Box A** on p. 2), Centers for Disease Control and Prevention (CDC), and Consumers Union—that, to date, have not addressed the implications to aseptic technique of the use of the STERIS System 1—and its misbranded biological indicator^{49,53}—since 1988 (see: “*Dear Consumer Reports*”);^{47,48,52} and
- (d) *health agencies and associations* that have not published statements contraindicating the use of any adulterated and misbranded device, but instead, in some instances, condone the continued use of the STERIS System 1 (without such qualifications as patient notification)^{46,48}

are exhibitiv of a standard of care that is abidingly off-course and lacking in quality, consistency, and a true commitment to aseptic technique. That each of these oversights and missteps is also a reflection, and a consequence, of a reticent standard of care that is want for the zeal and authority required to advance patient safety could be soundly argued.

The use of the STERIS System 1 since 1988 represents a most potentially significant compromise of aseptic technique.

PERSPECTIVES: Due to the current standard of care’s demonstrated paradoxes and confused commitment to patient safety and aseptic technique, it is not entirely surprising, therefore, to have learned that a VMAC had been using for as many as five years the MAJ-855 irrigation tubing fitted with the wrong valve,¹⁻¹² or that several weeks *after* the reprocessing mishaps were disclosed by the three aforementioned VAMCs, fewer than half of the forty-two VAMCs inspected by the Veterans Affairs Office of Inspector General (VAOIG) were in compliance with directives published by the VHA (see: **Box A**).^{12,54}

Nor would it likely be of much surprise if breaches in infection control similar to those disclosed by these three VAMCs were soon to be reported, or if the infection rate—including those infections associated with “central lines” (see: “*Dear Consumer Reports*” on p. 4)—was to remain high, with as many as 99,000 patients reportedly dying each year in the U.S. as a result of a healthcare-acquired infection.^{23,47}

Conclusions

In conclusion, a manufacturer of endoscopic instrumentation, human error, and inadequate training of reprocessing staff in a GI department arguably are not the only causes of the reprocessing breaches identified at the VAMC in Murfreesboro, or at the two VAMCs in Augusta and Miami, and to place all of the blame for these mishaps at their respective

doorstep would be a myopic oversimplification. Indeed, the current standard of care and its displayed confusion, too, must bear some of the responsibility for these breaches.

Indeed, it is fair to observe that the current standard of care has stood by for years, watching weeds grow (along side “broken windows”⁵⁵) with a distracted, if tardy, countenance that is incongruous with the: (a) integrity of aseptic technique; (b) fulfillment of published missions statements; and, among other considerations, (c) prevention of both healthcare-acquired infections and the types of reprocessing breaches reported by the three aforementioned VAMCs.

The current standard of care has stood by for years, watching weeds grow.

Worse, today’s standard of care continues to water these weeds, instead of unqualifiedly pulling their roots.^{21,25,43,44,46,48} It, therefore, should be of no surprise to learn that some of these weeds are now flourishing. Before they can be replaced with blooming flowers, however, not only would errors and missteps have to be acknowledged, but also significant improvements in infection control would have to be both endorsed and commissioned. By working together and pledging a focused and unconditional commitment to patient safety, aseptic technique, and evidence-based practices, all of us can solidly and rewardingly put back on-track today’s errant standard of care. Patients and veterans alike are expecting nothing less from us. ● **The End** (By: *Lawrence F. Muscarella Ph.D.*)

➔ The **REFERENCES** to this article are available at:

www.myendosite.com/htmlsite/2010/refs01020310.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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