For: *Infection Control, Operating Room, Endoscopy, Instrument Reprocessing, Risk Managers, et al.*

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What's News

This triple issue presents the first of two articles that focus on a report, issued by the *Veterans Affairs Office of Inspector General* (VAOIG) in March 16, 2010, that discusses confirmed infection-control breaches within the *VA Caribbean Healthcare System* (Puerto Rico).

The second article in this series, which will be published in a future issue of this newsletter, provides recommendations to prevent disease transmission.

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 **net**work of **q**uestions, 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.

Patient Safety Concerns in Puerto Rico

A "negligible" risk of healthcare-acquired infection?

This article questions the Veterans Health Administration's (VHA) assessment that the risk of healthcare-acquired infections associated with several instrument-reprocessing breaches recently identified within the VA Caribbean Healthcare System (located in San Juan, Puerto Rico) is "negligible."

BACKGROUND: For the second time in as many years, the *Veterans Affairs Office of Inspector General* (VAOIG) issued a report in March (2010) documenting the improper cleaning and disinfecting of reusable medical equipment, including flexible endoscopes and transvaginal ultrasound transducers, by medical facilities within the *Veterans Health Administration* (VHA).[1,2]

Specifically, this report by the VAOIG details the findings of its *Office of Healthcare Inspections*, which—based on a complaint alleging adverse events that posed a risk of patient-to-patient disease transmission—inspected, during the summer of 2009, a number of medical facilities within the VHA's *VA Caribbean Healthcare System*.

This healthcare system includes a Veterans Affairs medical center (VAMC) located in San Juan, Puerto Rico, and outpatient clinics located in the surrounding municipalities, including Ponce and Mayaguez, and in St. Thomas and St. Croix (both of the U.S. Virgin Islands).[1]

Described in its report, the VAOIG confirmed during the inspections of these facilities several infection-control breaches, including the: (*a*) failure to high-level disinfect transvaginal ultrasound transducers; (*b*) improper cleaning of flexible laryngoscopes; (*c*) failure to leak-test colonoscopes and flexible laryngoscopes; and (d) the (routine) use of both a damaged flexible laryngoscope and a misbranded flexible laryngoscope.

Also described in this report is the VHA's assessment of the risk of infection associated with these several breaches.

Déjà vu? These confirmed instrument-reprocessing breaches—which are summarized in Table 1 (p. 9)—do not appear to be isolated or necessarily rare

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events. As if a case of *déjà vu*, these breaches are markedly similar in type and detail to those substantiated, and discussed in meticulous detail, in another report the VAOIG published just one year earlier, in June, 2009.[2]

The infection-control breaches confirmed by the VAOIG within the VA Caribbean Healthcare System do not appear to be isolated or necessarily rare.

Documented in this earlier report, the VAOIG determined that, during 2008 and 2009, three other medical facilities within the VHA—namely, VAMCs located in Murfreesboro (TN), Augusta (GA), and Miami (FL)—had similarly failed to reprocess flexible endoscopes and other reusable medical equipment, as required.[2] These infection-control breaches—which were the focus of several national news reports and congressional hearings (and, too, a *box article* presented in this newsletter's *January-February-March, 2010*, issue)—are summarized in Table 2 (p. 11).

"Fundamental defects": The VAOIG published in this earlier report that the instrument-reprocessing breaches it substantiated at these three VAMCs (in Murfreesboro, Augusta, and Miami) were a consequence of "fundamental defects" within the structure of the VHA that posed "a risk of infectious disease to veterans."[2]

The VHA's policies of patient disclosure laudably emphasize a "presumptive obligation" to inform patients of potentially harmful adverse events.

The VHA, therefore, notified more than 10,000 patients of the risk of their exposure to infectious agents, including HIV and the hepatitis B (HBV) and C (HCV) viruses,[2] as prescribed by its policies of patient disclosure.[1,3] Demonstrating "respect for the patient, professionalism, and a commitment to improving care," the VHA's policies of patient disclosure emphasize its "ethical," "legal" and "presumptive obligation" to inform patients of "harmful or potentially harmful" adverse events, even those that "may not be obvious or severe."[3]

A "negligible" risk of infection: Although markedly similar to those that the VAOIG substantiated one year earlier at these three VAMCs (in Murfreesboro, Augusta, and Miami) and that the VHA concluded posed a significant risk of infection,[2] the VHA, in contrast, concluded that the instrument-reprocessing breaches confirmed by the VAOIG within the *VA Caribbean Healthcare System* (*see*: Table 1) posed a "negligible"[1] risk of infection (and, therefore, did not warrant patient disclosure).[1]

KEYWORDS: *endoscope reprocessing, leak test, transvaginal ultrasound transducers, colonoscopes, flexible laryngoscopes, VA Office of Inspector General, misbranded devices, VA Caribbean Healthcare System Veterans Health Administration, infection control, contamination*

Abstract: Infection-control breaches in Puerto Rico

◆ **BACKGROUND**: A report issued by the VAOIG in March, 2010, identified several infection-control breaches within the VHA's *VA Caribbean Healthcare System*.[1]

◆ **"NEGLIGIBLE" RISK OF INFECTION**: This report by the VAOIG provides the VHA's assessment that the risk of infection associated with these breaches is "negligible," and, therefore, does not warrant patient notification.[1]

◆ **INCONSISTENCIES**: A review of the medical literature suggests, however, that these breaches posed an *increased* risk of disease transmission. This assessment of an *increased* risk is consistent with an earlier report published by the VAOIG in June, 2009, which concludes that similar infection-control breaches identified at three other VAMCs (in Murfreesboro, Augusta and Miami)—in one instance, the same breach: namely, the improper reprocessing of flexible laryngoscopes—posed a "a risk of infectious disease to veterans."[2]

◆ **CONCLUSION**: The risk of infection associated with the breaches confirmed by the VAOIG within *VA Caribbean Healthcare System* would appear *not* to be negligible and, therefore, the VHA's assessment in error. The notification of patients of these breaches would seem warranted.[3]

PURPOSE AND METHODOLOGY: The medical literature and these two reports issued by the VAOIG one year apart (in June, 2009,[2] and March, 2010[1]) were reviewed: *first*, to evaluate the correctness of the VHA's assessment that the instrument-reprocessing breaches confirmed within the *VA Caribbean Healthcare System* (*see*: Table 1) posed a negligible risk of infection; and, *second*, to provide recommendations to prevent disease transmission vis-à-vis these specific breaches (because the VAOIG's report[1] did not include any such recommendations). *Note*: These recommendations will be provided in a future issue of this newsletter.

RESULTS: At odds with the VHA's assessment of a negligible risk of infection,[1] this review identified studies that suggest that the several breaches confirmed within the *VA Caribbean Healthcare System* (*see*: Table 1) would pose an *increased* risk of disease transmission warranting patient notification.

DISCUSSION: This conclusion notably contrasts with—and calls into question the soundness of—the VHA's assessment,

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Table 1: *A list of several of the breaches identified within the **VA Caribbean Healthcare System**, in Puerto Rico, by the Veterans Affairs Office of Inspector General (VAOIG).*[†]

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1. ***Improper high-level disinfection of transvaginal ultrasound transducers.***

- **Breach:** For approximately 2 years, the VAMC (in San Juan) and one outpatient clinic (in Mayaguez) did not high-level disinfect transvaginal ultrasound transducers after each use.[1] Instead, staff sprayed these instruments with an ineffective disinfectant (and then, at least in Mayaguez, covered them with two latex sheaths before use). Whether these transducers were properly cleaned prior to being sprayed is unclear.

❒ **Guidelines, manufacturers' instructions:** Transvaginal ultrasound transducers are *semi-critical* devices for which high-level disinfection (or sterilization) is recommended after each use,[5,8] whether or not these transducers are covered with a protective sheath.[1,4,5,13,16]

➡ **Infection risk:** Failure to clean and/or to high-level disinfect these types of *semi-critical* devices has been causally linked to patient infection.[4,6,7,23] Further, improperly reprocessed transvaginal ultrasound transducers, even when covered with a protective sheath during the procedure, may pose an increased risk of transmission of infectious agents, including HPV.[4,5,16]

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2. ***Failure to leak-test colonoscopes.***

- **Breach:** Colonoscopes used in this VAMC's operating room were not leak-tested for (at least) 9 months.[1]

❒ **Guidelines, manufacturers' instructions:** Leak testing of the colonoscope is required after each procedure, just prior to cleaning.[1,8,9,12] This test detects leaks that can permit fluids to invade and damage the endoscope's internal structures.[1] Manufacturers' instructions contraindicate the use of a colonoscope (or flexible laryngoscope) that fails this crucial test.[9]

➡ **Infection risk:** Leak testing of the colonoscope is also critical to infection control.[1] Reports causally associate use of a torn or damaged flexible endoscope, with a leak, to disease transmission.[1,10,11]

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3. ***Failure to leak-test flexible laryngoscopes; and the use of a damaged laryngoscope.***

- **Breach:** Having not leak-tested these instruments for 9 months, this VAMC (namely, its radiotherapy department) routinely used a damaged flexible laryngoscope, with a leak. Similarly, an outpatient clinic (in Ponce) did not leak-test its flexible laryngoscopes for 3 years.[1]

❒ **Guidelines, manufacturers' instructions:** Leak testing of the laryngoscope is required after each procedure, just prior to cleaning.[1,8,12] Manufacturers' instructions contraindicate the use of a laryngoscope that is damaged and/or fails the leak test.[1,9]

➡ **Infection risk:** Both the use of damaged flexible endoscopes and the failure to leak test them have been causally associated with disease transmission.[9-11]

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4. ***Improper cleaning (and high-level disinfection) of flexible laryngoscopes.***

- **Breach:** For possibly as many as 9 months, this VAMC (namely, its radiotherapy department) was not properly cleaning a flexible laryngoscope after each procedure using a detergent.[1] Instead, it was rinsed with running water (followed by drying with a clean gauze pad). Further, for 3 years one of the outpatient clinics (in Ponce) was not properly cleaning (nor leak testing; *see:* #3, above) its flexible laryngoscope after each use, and this clinic, too, may not have been properly high-level disinfecting the laryngoscope.[1]

❒ **Guidelines, manufacturers' instructions:** Guidelines and manufacturers' instructions require the cleaning (using a detergent) and high-level disinfection of flexible endoscopes after each use.[1,2,4,8,9,12] The importance of these reprocessing measures cannot be overstated. The use of an improperly cleaned or high-level disinfected laryngoscope is contraindicated.[1,2,4,8]

➡ **Infection risk:** Because the laryngoscope was not properly cleaned, this VAOIG report acknowledges that "adequate (high-level) disinfection cannot be ensured."[1] The improper cleaning and/or high-level disinfection of flexible endoscopes have been causally associated with disease transmission.[4,6-9,23]

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5. ***Use of a misbranded flexible laryngoscope.***

- **Breach:** For possibly as many as 3 years, the outpatient clinic (in Ponce) used a misbranded flexible laryngoscope (brand: Karl Storz).[1,12,20,24]

❒ **FDA regulations:** A misbranded device lacks the necessary clearance to be legally marketed in the U.S.[24,25] The use of a misbranded (or adulterated) device is expressly prohibited by the Food, Drug and Cosmetic Act, unless the "unapproved" device has received, for example, an approved "investigational device exemption" (or, IDE)—which, among other considerations, requires for its use informed patient consent.[22,24]

➡ **Infection risk:** The safety and effectiveness of a misbranded medical device cannot be assured,[21,22,24] and its use could pose an increased risk of infection. ●

[†] The Veterans Health Administration (VHA) concluded that each of these listed breaches posed a "negligible" risk of infection.[1] Consequently, patients were not notified of the potential for their exposure to infectious agents, including HIV and other blood-borne pathogens. (To date, reports causally linking these listed breaches to infection have not been published.)

Box A: A Tale of Two Risk Assessments

The VHA concluded that the risk of infection associated with the breaches confirmed within the *VA Caribbean Healthcare System* is "negligible."[1] This assessment, however, is not consistent with published studies, which suggest that these instrument-reprocessing breaches would pose an *increased* risk of infection (*see*: main article).

Nor is this assessment of risk by the VHA consistent with other assessments it has previously published. Whereas it concluded that the risk of infection associated with the improper reprocessing of flexible laryngoscopes at the VAMC in San Juan (Puerto Rico) was negligible,[1] the VHA dissimilarly concluded that this same breach, identified one year earlier at the VAMC in Augusta (GA), posed a risk of disease transmission sufficiently significant to warrant the notification of 1069 patients.[2]

Such incongruous risk assessments by the VHA are puzzling and would appear not to be consistent with one of the VA own policies, which state that the "treatment, control, and prevention of infectious diseases in all VA health care facilities be similar."[26] Moreover, the VHA's notification of patients of the VAMC in Augusta of this infection-control breach, but not the patients of the VAMC in San Juan of the same breach, is a problematic contrariety that suggests, in addition to one of these two risk assessments being invalid, "defects" within the VHA (*see*: main article).

Further, that the VHA notified (in 2008) more than 6000 patients of the VAMC in Murfreesboro (TN) of the potential risk of infection associated with the improper use and reprocessing of the MAJ-855 irrigation tubing (*see*: Table 2),[2] despite this breach, to date, having not been linked to infection, while, in contrast, deciding *not* to notify patients within the VA *Caribbean Healthcare System* of an apparently more hazardous breach, one that *has* been directly linked to infection—namely, the routine use of a damaged flexible endoscope—suggests not only, again, the VHA's violation of its own policies (including those of patient disclosure),[3,26] but also the unreliability, inconsistency, and unsoundness of its assessments of risk.

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advanced by the VAOIG,[1] that the risk of infection associated with the infection-control breaches confirmed within the *VA Caribbean Healthcare System* (and listed in Table 1) is negligible (not warranting patient disclosure).[1]

Moreover, the similarities between the instrument-reprocessing breaches confirmed within the *VA Caribbean Healthcare System* and those substantiated one year earlier at the three VAMCs in Murfreesboro, Augusta and Miami—in one instance, the same breach was identified: the improper reprocessing of flexible laryngoscopes (*compare*: Table 1 and Table 2)—suggest, *first*, that important lessons within the VHA are not being adequately taught and/or learned; *second*, the aforementioned "fundamental defects" identified by the VHA within its own structure remain intact; and, *third*, that the VHA's commitment to quality assurance, to complying with its own policies vis-à-vis patient disclosure,[3] and to public health would appear lacking. *Please refer to Box A.*

As this review confirmed, transvaginal ultrasound transducers, colonoscopes, and flexible laryngoscopes are *semi*-critical instruments that pose an increased risk of infections if not properly cleaned and high-level disinfected (or sterilized) after each use.[1,2,4-15] Moreover, the leak testing† of flexible endoscopes is a reprocessing step that is necessary to detect damage that could result in the contamination of the endoscope's internal structures and disease transmission.[1,8-12]

Calling into doubt the VHA's assessment, this review suggests that the breaches confirmed by the VAOIG within the VA Caribbean Healthcare System posed an increased—not negligible—risk of infection.

A. *Failure to high-level disinfect transvaginal ultrasound transducers*: Acknowledging that at least one of the medical facilities within the *VA Caribbean Healthcare System* (i.e., the outpatient clinic in Mayaguez) failed to high-level disinfect (or sterilize) transvaginal ultrasound transducers after each use (*see*: Table 1), the VAOIG states in its report that staff covered these transducers with a sheath, presumably to minimize the risk of contamination and disease transmission.[1]

But, a study by Kac et al. (2010) reports that transvaginal (and transrectal) ultrasound transducers, *including* those covered with a sheath, were contaminated after use with potentially infectious agents, including *Klebsiella* spp., *Pseudomonas* spp. and the human papilloma virus (HPV)—the latter of which has been linked to cervical and anogenital cancers.[5] And, according to the FDA and CDC, because sheaths can have a high rate of perforations and failure, at least high-level disinfection of these transducers, therefore, is necessary, whether or not a sheath is used to cover them.[13,14,16,17]

In agreement with the FDA,[13] Kac et al. (2010) write that "micro-perforations" may form within the sheath before or during the procedure, permitting blood and other potentially infectious materials to contaminate the "covered" transducer via the sheath's "open rim."[5] These authors conclude: *first*, that sheaths may fail and are "inefficient at preventing contamination";[5] *second*, like flexible laryngoscopes, these transducers may become contaminated during handling, or when the sheath is placed onto, or removed from, them;[13,14] and, *third*, improper reprocessing of these transducers may result

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† During leak testing, equipment is used to pressurize with air the flexible endoscope's internal structures. This equipment, which may be little more than a manometer, typically features a gauge to display the air's pressure. A drop in air pressure generally indicates a leaking and damaged endoscope.

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in "HPV cross-transmission."[5]

Inconsistent with the VHA's assessment of a negligible risk of infection,[1] these reports suggest that the improper reprocessing of transvaginal ultrasound transducers within the *VA Caribbean Healthcare System* would pose an *increased* risk of infection warranting the disclosure of this potentially adverse event to patients.[3,5,13-19]

B. *Improper reprocessing of laryngoscopes*: Like Kac et al.'s (2010) study discussing transvaginal ultrasound transducers, several studies similarly indicate that flexible (and rigid) laryngoscopes may become contaminated with and transmit blood and other potentially infectious materials.[5,16,17] Similarly inconsistent with the VHA's assessment of a negligible risk of infection,[1] these published studies suggest that the improper reprocessing of flexible laryngoscopes within

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Table 2: *A list of several of the breaches identified at three VAMCs in* ***Murfreesboro*** *(TN),* ***Augusta*** *(GA), and* ***Miami*** *(FL) by the Veterans Affairs Office of Inspector General (VAOIG).*[†]

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1. ***Improper reprocessing of irrigation tubing used during colonoscopy*** *(Murfreesboro, TN).*

- **Breach:** For as many as 5 years, the VAMC in Murfreesboro (TN) had been using the Olympus MAJ-855 "auxiliary water tube" that was: (a) fitted with an improper "two-way" connector; and (b) reprocessed once at the end of the day, not after each patient procedure, as required.[2] Further, the short "irrigation tube" that connects the MAJ-855 to a flushing pump was not discarded at the end of the day, also as required.[2,27]

❒ **Guidelines, manufacturers' instructions:** According to its manufacturer: *first*, the MAJ-855 is to be used only with the "one-way" valve with which this tubing is manufactured and shipped. The removal of this valve and its replacement with the two-way connector used by the Olympus MH-974 "washing tube" is contraindicated. *Second*, the MAJ-855 is to be reprocessed after *each* procedure. And, *third*, the short irrigation tube is to be discarded at the end of each day.[2,27]

➡ **Infection risk:** Use of the MAJ-855 fitted with the MH-974's two-way connector (instead of the correct one-way valve) can result in: the auxiliary water tube's malfunction, its contamination due to the "back-flow" of potentially infectious debris from the patient's colon, and patient-to-patient disease transmission.[2] Further, failure to clean and high-level disinfect (or sterilize) the MAJ-855 after each patient procedure, or to discard the short irrigation tube at the end of each day, also poses an increased risk of infection.[2,27]

2. ***Improper reprocessing of colonoscopes*** *(Miami).*

- **Breach:** For as many as 5 years, the VAMC in Miami (FL): *first*, failed to reprocess the MAJ-855 after each procedure, instead merely flushing or rinsing this tubing with (sterile) water; *second*, often connected the MAJ-855 to the colonoscope while the procedure was already in progress; and, *third*, did not discard the short irrigation tube (that connects the MAJ-855 to a flushing pump) at the end of the day.[2] In addition, "debris" had been identified in the auxiliary water channel of "reprocessed" colonoscopes.[2]

❒ **Guidelines, manufacturers' instructions:** According to its manufacturer: *first*, the MAJ-855 is to be cleaned and high-level disinfected (or sterilized) after each procedure; *second*, the MAJ-855 is to be connected to the colonoscope, with the auxiliary water system primed, *prior* to the procedure; and, *third*, the short irrigation tube is to be discarded at the end of the day.[2,27] Most important, the use of an endoscope whose channels are soiled with patient debris is contraindicated.[2,7,8,23]

➡ **Infection risk:** The failure to clean and high-level disinfect the colonoscope thoroughly, including its auxiliary water channel, or to discard the short irrigation tube at the end of each day; or, the practice of neither cleaning and high-level disinfecting (or sterilizing) the MAJ-855 after each patient procedure nor connecting the MAJ-855 to the colonoscope, with the auxiliary water system primed, prior to the procedure, poses an increased risk of disease transmission.[2,27]

3. ***Improper cleaning and high-level disinfection of flexible laryngoscopes*** *(Augusta, GA).*

- **Breach:** For almost a year, the VAMC in Augusta (GA) had been improperly reprocessing flexible laryngoscopes after each procedure, instead merely wiping them down with a disposable "sanitizing" cloth.[2]

❒ **Guidelines, manufacturers' instructions:** Guidelines and manufacturers' instructions require cleaning and high-level disinfection (or sterilization) of flexible endoscopes and other *semi*-critical items after each use.[4,8,10,16-19] The use of an improperly cleaned or disinfected flexible laryngoscope is contraindicated.[1,2,4,19]

➡ **Infection risk:** The improper cleaning and/or high-level disinfection of flexible endoscopes have been causally associated with disease transmission.[5-7,23] ●

[†] The Veterans Health Administration (VHA) concluded that each of these listed infection-control breaches posed an increased risk of infection.[2] Consequently, patients were notified of the potential for their exposure to infectious agents. (To date, reports causally linking these listed breaches to infection have not been published.)

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the *VA Caribbean Healthcare System* would pose an *increased* risk of infection warranting patient notification.[3,16-19]

The VHA's assessment of a negligible risk of infection notwithstanding,[1] these studies discussing the contamination of flexible laryngoscopes are consistent with another of the VHA's risk assessments, which, published by the VAOIG one year earlier, concluded that the infection-control breaches identified at the three VAMCs in Murfreesboro, Augusta and Miami posed a *significant* risk of infection.[2]

A re-assessment by the VHA of the risk of infection associated with the breaches confirmed within the VA Caribbean Healthcare System is recommended.

These published studies also corroborate the conclusions presented by the VAOIG in June, 2009, when, testifying about the breaches substantiated at these three VAMCs, it stated that: "the impact of improper high level disinfection of reusable endoscopes places veterans at risk of infection," adding that viruses, including HBV and HCV, "have been transmitted through endoscopes."[18,19] That the VHA provided two such incongruous assessments of risk for the same breach—namely, the improper reprocessing of flexible laryngoscopes at a VAMC in San Juan (a negligible risk[1]) and at one in Augusta (a significant risk[2]) identified a year apart—would also suggest, not only that one of these two assessments is unsound, but also that there are deficiencies in the process by which the VHA evaluates the risk of infection associated with infection-control breaches. *Please refer to Box A, p. 10.*

Also notable, the VAOIG's report discussing the infection-control breaches within the *VA Caribbean Healthcare System* failed to disclose a most critical consideration: that one of this healthcare system's outpatient clinics (in Ponce; *see*: Table 1) was using on patients a *misbranded* flexible laryngoscope.[20] According to the FDA, the safety and effectiveness of this flexible laryngoscope† cannot be assured.[21,22]

C. *Failure to leak testing flexible endoscopes:* DiazGranados et al. (2009) causally linked the use of a damaged flexible endoscope (a bronchoscope) to an outbreak (or pseudo-outbreak) of *P. aeruginosa.*[10] Similarly, Ramsey et al. (2002) reported the patient-to-patient transmission of respiratory tuberculosis due to the use of a damaged flexible endoscope (also a bronchoscope).[11] Routine leak testing of the endoscope—a crucial reprocessing step that Ramsey et al. (2002) acknowledged might have preemptively detected this damage and the accumulation within the endoscope of inaccessible infectious materials—was not performed.

Similarly inconsistent with the VHA's assessment of a negligible risk of infection,[1] these studies by DiazGranados et al. (2009) and Ramsey et al. (2002) suggest that, like the use of a misbranded flexible laryngoscope, the *VA Caribbean Healthcare System's* both failure to perform leak testing and (routine) use of a damaged flexible laryngoscope would pose an *increased* risk of infection warranting the disclosure to patients of this potentially adverse event.[10,11,18,19]

CONCLUSION: Suggesting that the VHA's assessment advanced by the VAOIG in its report—namely, that the risk of infection associated with the several instrument-reprocessing breaches confirmed within the *VA Caribbean Healthcare System* (*see*: Table 1) was negligible[1]—is in error, the findings of this review conclude that these breaches would pose an *increased* risk of disease transmission[4-8,10-22] warranting patient notification as prescribed by the VHA's own policies.[3]

A re-assessment by the VHA of the risk of infection associated with these breaches, therefore, would appear necessary—lest healthcare staff erroneously (though understandably) interpret the VAOIG's report to be perilously suggesting that, if, as the VHA claims, their improper reprocessing posed a negligible risk of infection,[1] then the proper reprocessing of reusable medical equipment is superfluous and unnecessary.[15,16] ● **The End** (*By:* Lawrence F. Muscarella PhD)

➡ *Recommendations will be provided in a future issue.*

➡ The **REFERENCES** to this article are available at:
www.myendosite.com/htmlsite/2010/refs04050610.pdf

Thank you for your interest in this newsletter, which I founded. *I have addressed each topic to the best of my ability. Respectfully, Lawrence F. Muscarella, Ph.D.*
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† Whether the *VA Caribbean Healthcare System* uses the STERIS System 1, another misbranded device,[20-22,24,25] is unclear, though is likely and warrants consideration, discussion, and disclosure, because VAMCs use this device.[28-30] *To date, the VHA has not published any safety notices or alerts discussing the federal censure of the STERIS System 1.*[24]