Exclusive

Infection Control Breaches Unveiled at Veterans Medical Center

By JANNETTE RIOS

On March 2, 2010, Lawrence Muscarella, PhD, an infection-control expert committed to the advancement of public health, was contacted by the Veteran's Affairs Office of Inspector General (VAOIG) to consult on an investigation held from August 25 to the 28 of 2009 at the VA Caribbean Healthcare System in San Juan.

The investigation was ignited by a complaint that alleged that "transvaginal ultrasound transducer equipment was not being properly disinfected at the Mayaguez outpatient clinic (OPC), and that leak tests were not performed on endoscopes in three other areas in the system," as is written in the report issued by the VAOIG on March 16, 2010. It further explains that all of the allegations in the complaint were "substantiated" as the "endovaginal transducers at the Mayaguez OPC were not submitted to high-level disinfection [as required to prevent disease transmission] after each patient procedure for approximately 2 years." The same condition was seen in the San Juan facility.

In simple terms what does all this mean? The VAOIG investigated unsafe practices in the cleaning and disinfection, or sterilization of reusable medical instruments. The investigation proved specific instruments, namely, flexible laryngoscopes, colonoscopes, and transvaginal ultrasound transducers, were not being properly disinfected according to the CDC's Guideline for Disinfection and Sterilization in Healthcare, which is precisely why Dr. Muscarella was contacted by a health official from the Office of Inspector General in St. Petersburg, Fl. The official was seeking a professional opinion as to the risk posed by infection control breaches and how to handle a possible outbreak among patients.

"In reply to the VAOIG's request for information, I informed several of its healthcare officials, who thanked me for the information I provided them, that, among other important considerations, the cleaning of reusable medical instruments prior to disinfection or sterilization is a separate and crucial step to prevent diseases from being transmitted from one patient to another; and that the use of a "misbranded" laryngoscope or other type of medical device could pose an increased risk of patient injury," Dr. Muscarella said during an interview.

"I also told these officials that it was my professional opinion that, based on the available data, the risk of infection associated with these specific breaches (confirmed within the VA Caribbean System) would be, not "negligible," but sufficiently significant to warrant the notification of veterans and other patients of the potential for their exposure to infectious agents. Ironically, my conclusion is consistent, not only with the VHA's policies on the disclosure of adverse events to patients, but also with the assessment of risk that the VAOIG published in its report issued in 2009 discussing markedly similar infection-control breaches identified in Murfreesboro (TN), Augusta (GA), and Miami (FL)."

The VAOIG apparently completely disregarded Dr. Muscarella's insight and concluded the findings posed a "negligible risk of exposure" and "no patients were notified".

If you take into consideration Tables 1 and 2, taken from Dr. Muscarella's article "Patient Safety Concerns in Puerto Rico: A 'negligible' risk of healthcare-acquired infection?" featured in The Q-Net Monthly 2010 for the

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months of April, May and June, it is clear similar breaches found in Murfreesboro, TN; Augusta, GA; and Miami, FL required patient notification to over 10,000 patients. Why were patients in Puerto Rico not notified?

There are approximately 63,000 veterans enrolled in the VA Caribbean Healthcare System. Of these, about 1,800 are women who may have been subjected to a vaginal ultrasound. When looking at the numbers from the facility in Miami, where from the 44,300 patients enrolled in the system, 3,260 were notified of possible infection risk; it is alarming to calculate the thousands that can be at risk in Puerto Rico and the Virgin Islands.

"While these infection-control breaches pose, in my opinion, an 'increased risk of infection warranting patient notification,' that is not to say these breaches necessarily have resulted in multiple infections or pose a substantially high risk of infection. In my opinion, notification of patients is warranted whenever a breach poses an 'increased risk of infection,' not necessarily only when a breach is known or determined to have posed a 'significant' risk for disease transmission that most likely will result in infection," Dr. Muscarella concluded.

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.[1,4,5,16]

➡ **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]

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]

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]

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.[7-9]

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.)

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] ●

Muscarella LF. "Patient Safety Concerns in Puerto Rico: A 'negligible' risk of healthcare-acquired infection?" The Q-Net Monthly 2010 April-May-June;16(4-6):7-12 [an educational newsletter].

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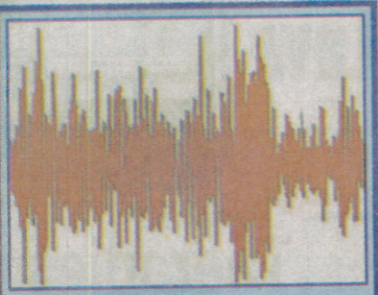

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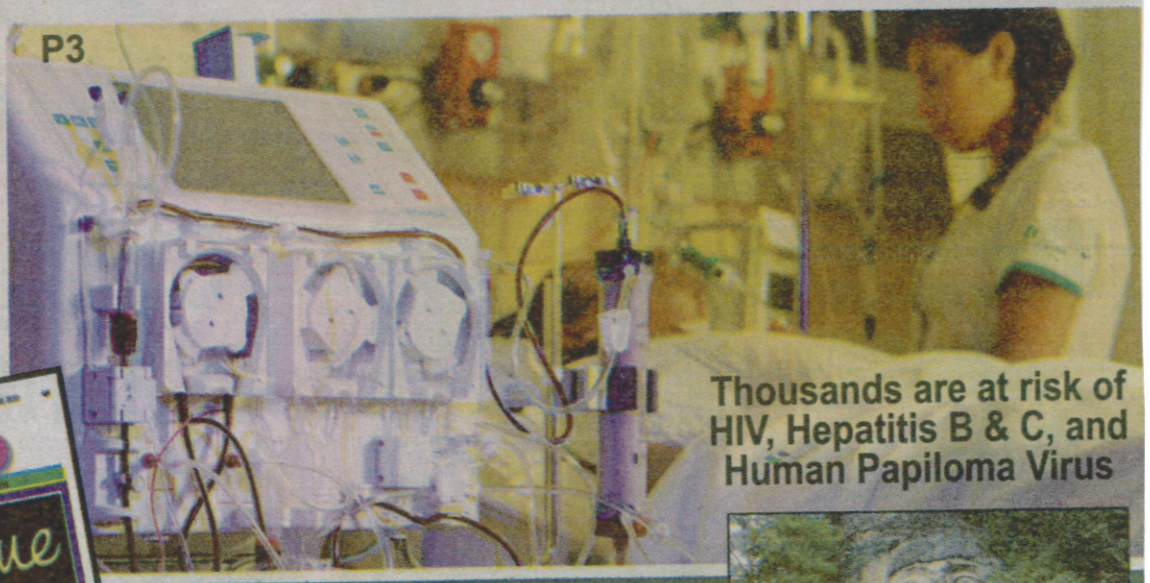

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