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 observational 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...
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 VAMCs in Murfreesboro (TN), Augusta (GA), and Miami (FL) by the Veterans Affairs Office of Inspector General (VAOIG).

<table>
<thead>
<tr>
<th>Breach</th>
<th>Description</th>
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<tbody>
<tr>
<td>Improper high-level disinfection of transvaginal ultrasound transducers.</td>
<td>Failure to clean and/or to high-level disinfect these devices has been causally linked to patient infection.</td>
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<tr>
<td>Infection risk:</td>
<td>These breaches pose an ‘increased risk of infection’ but do not necessarily have resulted in disease transmission.</td>
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Guidelines, manufacturers’ instructions: Transvaginal ultrasound transducers are semi-critical devices for which high-level disinfection (sterilization) is recommended after each use, whether or not these transducers are covered with a protective sheath.

- Improper reprocessing/sterilization of colonoscopes.

- Lack of a manufacturer’s guidance on the use of a colonoscope after high-level disinfection.

Infection risk: The use of an improperly cleaned colonoscope is associated with disease transmission.

Guidelines, manufacturers’ instructions: Guidelines and manufacturers’ instructions require the cleaning (using aftype detergent and high-level disinfection of flexile

- Improper cleaning and high-level disinfection of flexible laryngoscopes.

- Infection risk: Because the laryngoscope was not properly cleaned, this VAOIG report acknowledges that ‘adequate (high-level) disinfection cannot be ensured.’ The improper cleaning and/or high-level disinfection of the laryngoscope gives rise to disease transmission.

Guidelines, manufacturers’ instructions: VAOIG report recommends that ‘adequate (high-level) disinfection cannot be ensured.’ The improper cleaning and/or high-level disinfection of the laryngoscope gives rise to disease transmission.

- Use of a misbranded flexible laryngoscope.

- Infection risk: The safety and effectiveness of a misbranded medical device cannot be assured.

- FDA regulations: The misbranded device lacks the necessary clearance to be legally marketed in the U.S.

- Infection risk: The use of a misbranded device can cause harm to patients.

Guidelines, manufacturers’ instructions: Guidelines and manufacturers’ instructions require the cleaning and high-level disinfection of flexible endoscopes and other semi-critical items after each use.

- Infection risk: The improper cleaning and/or high-level disinfection of flexible endoscopes can cause harm to patients.

- Improper cleaning and high-level disinfection of flexible laryngoscopes.

- Infection risk: The improper cleaning and/or high-level disinfection of flexible laryngoscopes can cause harm to patients.

EXCLUSIVE!

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at Veterans Medical Center

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