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

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What's News

This complete, 8-page on-line version of this newsletter provides several recommendations to reduce the risk of infections associated with a number of different types of instrument-reprocessing breaches. Instructions for reprocessing the Olympus MAJ-855 water tube are featured. All of this newsletter's articles are available for downloading at: http://www.MyEndoSite.com

Editor-in-Chief

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What is 'Q-Net'?

Q-Net is a technology assessment, infection control-based **net**work of **q**uestions, answers, and perspectives. Its newsletter, or journal, 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.

Recommendations to Prevent Healthcare-Associated Infections

Recommendations are provided to reduce the risk of healthcare-acquired infections associated with several infection-control breaches recently identified at a number of medical facilities within the U.S. and Caribbean. Five cases are discussed.

CASE 1: St. Louis, Missouri – Operating room suite:

Introduction: A few weeks ago, in early February, the John Cochran Division of the Veterans Affairs Medical Center (VAMC), located in St. Louis (MO), reportedly identified during a regular inspection "spots" on surgical instrument trays, as well as "water stains" on at least one surgical instrument.[1,2]

Amid concerns that these anomalies might indicate faulty cleaning and sterilization practices, officials closed this VAMC's operating suite of 10 procedure rooms. Indeed, improper reprocessing of surgical instruments and trays can pose a significant risk of infection.[1-3]

Root cause analysis: The specific cause of these visual indicators of apparent instrument contamination has not been determined.[1,2,4] Nevertheless, hospital officials have reportedly concluded that these spots and stains were not of blood or another potentially infectious body fluid or material, but were more likely metallic etchings, rust, or corrosive pits on the instruments' surfaces.[2]

A root-cause analysis's determination of all of the factors that might have contributed to, or caused, the spotting and staining of these instruments, however, is crucial. Such an analysis would establish the mitigations—or corrective actions—necessary to minimize the likelihood of, if not prevent, this breach's recurrence.

The determination of each of a

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How to reprocess the Olympus MAJ-855 water tube: Box A, p. 5

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breach's contributing factors is additionally important to evaluate the number of affected patients on whom suspect surgical instruments might have been used.

Patients not at risk: According to hospital officials, the spotting and staining of these surgical trays and (at least one) instrument were this breach's only instance and did not result in the clinical use of any potentially contaminated instruments.[1,2] Consequently, concluding that no cases of disease transmission would have been associated with this breach, patients were not notified of it.[2,3] The rationale for the resolute conclusion by officials that this breach did not expose any patients to infectious agents or non-infectious materials—such as HIV, the hepatitis B (HBV) or C (HCV) viruses, or metallic debris, such as rust—however, is unclear.

è *Table 1 (p. 3) highlights a number of recommendations that are provided to reduce the risk of infection.*

"Great heart and soul": Nevertheless, because of the potential risk of patient injury, hospital officials cancelled more than 70 surgeries and did not reopen this VAMC's operating suite until 5 weeks later, in mid-March (2011), once its cleaning and sterilization processes were verified to be functioning properly (*see*: Table 2, p. 8).[4]

Raising the rhetoric, a St. Louis newspaper editorialized that there is "no excuse" for such "sloppy sterilization practices,"[5] and whereas some have referred to it as a "national disgrace," others have characterized this VAMC as having "a great heart and soul."[6]

The rationale for the resolute conclusion by officials that this breach in St. Louis (MO) did not expose patients to infectious (or non-infectious) materials is unclear.

CASE 2: St. Louis, Missouri – Dental clinic:

Faulty cleaning: To many (but not all[7]), reports of this St. Louis VAMC's apparent instrument-reprocessing breach would have been a surprise. Less than a year earlier, in March (2010), a similar routine inspection found that for the previous 13 months the dental clinic of this same VAMC (in St. Louis, MO) had been improperly reprocessing dental instruments.[8] In response, this VAMC claimed to be "doing everything possible" to prevent such a breach from recurring.[8]

According to officials, this clinic had failed to use a detergent (as manufacturer instructions require) to clean its dental instruments prior to steam sterilization (*see*: Table 2, p. 8).[8] Improper cleaning of soiled dental (and surgical) instruments poses an increased risk of ineffective sterilization and

Article at a Glance: Prevention of Infections

- **BACKGROUND:** Five publicized cases documenting instrument-reprocessing and infection-control breaches were recently identified in the U.S. and Caribbean.
- **PATIENT NOTIFICATION:** Whereas some of these breaches resulted in patient notification, others were deemed to pose a "negligible" risk of infection that did not warrant their disclosure to affected patients (*see*: Box B).
- **RECOMMENDATIONS:** Recommendations are provided in Table 1 to reduce the risk of infection associated with these several documented breaches. Instructions for re-

healthcare-acquired infections.[9] (*Note*: Last summer the dental clinic of a different VAMC in the Midwest was closed for three weeks because of similar concerns that infection-control standards may have been breached; *see:* case 5, p. 8.[10])

Although it concluded that the risk of infection was "extremely low," the VA, nonetheless, notified (via mailed letters) 1812 patients in June, 2010, of this VAMC dental clinic's breach,[8] in accordance with the Veterans Health Administration's (VHA) patient-disclosure policies.[11,12]

CASE 3: Murfreesboro (TN), Augusta (GA), and Miami (FL) – Flexible endoscopy:

Fundamental defects: The breaches identified in this St. Louis VAMC's operating suite (*case 1*), like in its dental clinic (*case 2*), would not appear to be isolated or necessarily unique. In June, 2009, the VA's Office of Inspector General (VAOIG) issued a report confirming several instrument-reprocessing and infection-control breaches at a number of VAMCs in other regions of the country. The VAOIG concluded in this report that these breaches resulted from the failure of medical facilities to comply with alerts and directives, which displayed "fundamental defects" within the VHA that posed "a risk of infectious disease to veterans."[13]

Improper reprocessing of reusable instruments: The VAOIG confirmed in this report (published in June, 2009) that for as many as 5 years three VAMCs[13]—located in Murfreesboro (TN), Augusta (GA), and Miami (FL)—had been improperly reprocessing colonoscopes, flexible laryngoscopes and other types of reusable equipment. Receiving more media focus than any other of these breaches were the Murfreesboro VAMC's improper use and reprocessing of the Olympus MAJ-855 auxiliary water tube—*see*: Box A, p. 5.

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TABLE 1: *Highlighted recommendations provided to prevent infections associated with the specific types of breaches discussed in the main article.*[†]

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1. **Olympus MAJ-855 water tube:** Clean and high-level disinfect (or steam sterilize) the MAJ-855 auxiliary water tube (in accordance with its manufacturer's instructions).[20]

a) Improper reprocessing, or the misuse, of the MAJ-855 auxiliary water tube may pose an increased risk of infection warranting patient notification.[13]

b) The reader is referred to Box A (*"Reprocessing the MAJ-855 tube and the auxiliary water channel"),* p. 5.

2. **Colonoscope:** After each clinical case, clean and high-level disinfect (at a minimum) the colonoscope (and all other types of GI endoscopes).[23,24] *Refer to the colonoscope's reprocessing manual for detailed instructions.*

a) In addition to its other channels and surfaces, including valves, reprocess the auxiliary water channel regardless of whether this channel was used or flushed with water during the clinical case (*see:* Box A, p. 5).[20] *Do not use the GI endoscope if assurances that this channel (or any other surface) was properly reprocessed cannot be provided.*[23]

b) Soil dripping from a "reprocessed" colonoscope may indicate improper cleaning of the auxiliary water channel. *(Refer to the article about endoscope storage in this newsletter's December, 2009, issue*.)

c) Improper reprocessing of the colonoscope and its auxiliary water channel may pose an increased risk of infection warranting patient notification.[9,13,19] *Do not use a visibly soiled or improperly reprocessed GI endoscope* (*see:* Box A, p. 5).[13,23,24]

d) Prior to its reprocessing, visually inspect (for damage) and leak-test the colonoscope, in accordance with its manufacturer's instructions. *Do not use a colonoscope that has not been leak-tested, has a leak and fails this test, is torn, and/or is otherwise damaged.* Instead, return the damaged colonoscope to its manufacturer, in accordance with its operator's manual.[13,15,23,24]

3. **Flexible laryngoscope:** After each clinical case, clean and high-level disinfect (at a minimum) the flexible laryngoscope, including, if featured, its suction channel, suction valve, and biopsy inlet or port.[13,25]

a) A unique set of step-by-step instructions for reprocessing laryngoscopes is provided in this newsletter's *May-June, 2004,* issue, to which the reader is referred.

b) Prior to its reprocessing, visually inspect (for damage) and leak-test the flexible laryngoscope, in accordance with its manufacturer's instructions. *Do not use a laryngoscope that has not been leak-tested, has a leak and fails this test, is torn, and/or is otherwise damaged.* Instead, return the laryngoscope to its manufacturer, in accordance with its operator's manual.[25]

c) Improper reprocessing of the flexible laryngoscope—for example, failing to use a detergent to clean it; or "cleaning" and "disinfecting" its surfaces by wiping them with a sanitizing cloth or a gauze soaked with a disinfectant, such as 70% alcohol or a quaternary ammonium product—may pose an increased risk of infection warranting patient notification.[13,25]

d) Service and maintain the flexible laryngoscope, like all types of flexible endoscopes, including colonoscopes, as recommended by its manufacturer. *Do not use a flexible laryngoscope (or other type of flexible endoscope) that is misbranded or adulterated.*[16,26]

4. **Transvaginal ultrasound transducer (or probe):** After each clinical case, clean and high-level disinfect (at a minimum) the transvaginal ultrasound transducer regardless of whether this reusable probe was covered with one or two protective sheaths. *Refer to this transducer's reprocessing manual for more detailed instructions.*[16]

a) Improper reprocessing of this transducer—for example, "cleaning and disinfecting" its surfaces by spraying them with a disinfectant; wiping them with a disposable sanitizing cloth; or using running tap water (and no detergent)—may pose an increased risk of infection warranting patient notification.[13,15-17]

5. **Dental, surgical instruments:** After each clinical case, clean and, unless otherwise contraindicated, steam sterilize *critical* (and some *semi*-critical) dental and surgical instruments.[9] *Refer to the operator's manual of each instrument for more detailed reprocessing instructions.*

a) Improper reprocessing of reusable dental and surgical instruments—for example, failing to use a detergent to "clean" them—may pose an increased risk of infection warranting patient notification.[1,2,8-10] *Do not use surgical (or dental) instruments that were not properly reprocessed, or that are spotted or stained with soil or another indicator of potential contamination.*[2,10]

b) High-level disinfection of reusable *semi*-critical instruments damaged by heat is ordinarily recommended.[9] (*Note*: High-level disinfection of some delicate *critical* instruments may be permissible.[9])

c) Low- or intermediate-level disinfection may be sufficient for reprocessing *non*-critical dental (and medical) equipment.[9] Refer to this newsletter's *March-April, 2004,* issue, which discusses device classifications.

d) Don a new pair of gloves for each patient, in accordance with guidelines for proper hand washing and hand hygiene. *Do not wear the same pair of gloves to treat or care for more than one patient.*[10,12] ▮

[†] This is not a complete list of recommendations. *Refer to this newsletter's May-June, 2003, and July, 2003, issues.*

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"Presumptive obligation": As it did for the 1812 patients of the St. Louis VAMC's dental clinic,[8] the VHA disclosed to more than 10,000 patients of these three VAMCs[†] (located in Murfreesboro, Augusta, and Miami) that these breaches posed an increased risk of infection.[13] Demonstrating "respect for the patient, professionalism, and a commitment to improving care," the VHA notified these patients in accordance with its patient-disclosure policies and *Directive 2008-002*—which emphasize the "ethical," "legal" and "presumptive obligation" to inform patients of "harmful or potentially harmful" events, even those that "may not be obvious or severe, or where the harm may only be evident in the future."[11]

***The New England Journal of Medicine*:** This policy of transparency is consistent with the conclusions of a article by Dudzinski et al. (2010).[14] Recently published in the *New England Journal of Medicine*, this article establishes that the notification of patients of an infection-control breach (or another potentially harmful medical error or event) "should be the norm, even when the probability of harm is extremely low."[14]

Although such disclosure can incur averse publicity for the healthcare facility, Dudzinski et al. (2010) add that any consequential difficulties to the healthcare facility "are outweighed by (its) obligation to be transparent and to rectify unanticipated patient harm."[14]

CASE 4: San Juan, Puerto Rico – Flexible endoscopy, Transvaginal ultrasound:

Confirmed breaches: The VAOIG published a similar report in March, 2010, confirming that several medical facilities within the *VA Caribbean Healthcare System*—like the four aforementioned VAMCs in St. Louis, Murfreesboro, Augusta, and Miami[8,13]—had been improperly reprocessing reusable medical instruments and equipment.[15-17]

Specifically, during inspections in the summer of 2009 of a number of medical facilities within this Caribbean healthcare system, which includes a VAMC in San Juan (Puerto Rico), the VAOIG confirmed the:[††] (a) failure to high-level disinfect transvaginal ultrasound transducers, or probes; (b) improper cleaning of flexible laryngoscopes; (c) failure to leak-test colonoscopes and flexible laryngoscopes; and (d) use of both damaged and misbranded flexible laryngoscopes.[15-17]

Negligible" risk? This report by the VAOIG concluded that each of these breaches confirmed within the *VA Caribbean Healthcare System* posed a "negligible"[15-17] risk of infection, and, as a result, affected U.S. veterans were not notified of them. The reader is referred to both the *April-May-June, 2010*, issue of this newsletter and to a front-page article in the June 24-30, 2010, issue of the *San Juan Weekly*.[16,17]

The reader is additionally referred to the comparison of several different risk assessments in Box B—which is available only on p. 7 of this newsletter's *on-line* version and which suggests that such assessments of the risk of infection may, in some instances, be more arbitrary than scientific.

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Commentary: *A distinction without a difference?* The VHA's decision not to notify patients of the *VA Caribbean Healthcare System's* several confirmed breaches is understandably controversial and confusing for a number of reasons, several of which are discussed in Box C, which is available only in this newsletter's *on-line* version, on p. 7.

One reason not discussed in Box C is the contrast between, on the one hand, the VHA's (and VAOIG's) conclusion that these breaches within the *VA Caribbean Healthcare System* posed a *negligible*[15] infection risk *not* warranting patient notification (*see*: case 4, above), and, on the other, the VHA's conclusion that the breach confirmed at the St. Louis VAMC's dental clinic (*see*: case 2, above)—like a Canadian hospital's recent breach*—posed an "*extremely low*"[8] infection risk (and a "*phenomenally remote*"[18] chance of ineffective sterilization) warranting the notification of 1812 patients.

Discussed in Box B (p. 7, on-line), *negligible*, *extremely low*, *extremely remote*,* and *minimal to non-existent*** risks of infection are ordinarily assessments without differences, and to distinguish between them might be to split hairs. If for no other reason than consistency and as a precaution, the notification of patients of a breach associated with one of these risk assessments would seemingly warrant the notification, too, of patients of a breach associated with any of the others.

Respectfully, however, it appears that the VHA would disagree, having distinguished between these risk assessments

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† These breaches and their associated increased risk of infection are detailed in Table 2 of this newsletter's April-May-June, 2010, issue, to which the reader is referred.

†† These breaches and their associated increased risk of infection are detailed in Table 1 of this newsletter's April-May-June, 2010, issue, to which the reader is referred.

* A hospital's failure to disinfect a colonoscope's auxiliary water channel was assessed by Canada's *Interior Health Authority* (IHA) to pose an "*extremely remote*"[19] infection risk, causing the IHA to notify 9000 patients of this breach, in December, 2010, "in the interest of transparency" (*see*: Box B).[19]

** A medical center in Louisiana (USA) notified 360 patients in January, 2011, of the improper disinfection of bronchoscopes and GI endoscopes that, according to this center, posed a *"minimal to non-existent"* infection risk (*see*: Box B).[28,29]

Box A: Reprocessing the MAJ-855 tube and the GI endoscope's auxiliary water channel

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Introduction: As much as any other lesson, the reprocessing breaches identified at the three VAMCs in Murfreesboro, Augusta, and Miami (see: *case 3*, p. 2) teach the importance of proper use and reprocessing of both the Olympus MAJ-855 auxiliary water tube and the colonoscope,† including its auxiliary water channel.[13,20]

Purpose: The MAJ-855 tube has two purposes.[27] First, it may be used to supply the GI endoscope's auxiliary water channel with (sterile) water for flushing the GI tract's mucosa, which may be required to enhance visibility during the clinical exam.[20] (Flushing may be achieved manually via a syringe or using an automated water pump.[27]) Second, the MAJ-855 tube may be used as an adapter to reprocess the GI endoscope's auxiliary water channel.

Recommendations: The following recommendations provide guidance to reprocess the MAJ-855 tube and auxiliary water channel both manually and using an automated endoscope reprocessor (AER). *Refer to the operator's manual of the GI endoscope for more detailed instructions.*

I. Initial quality-assurance verifications:

A. Verify whether any GI endoscopes in inventory feature an auxiliary water channel that uses a MAJ-855 tube for flushing (i.e., Olympus 160 and 180 series: 3 models of gastroscopes, 13 models of colonoscopes).[20]

B. Confirm that the MAJ-855 tube and the GI endoscope's auxiliary water channel are both being reprocessed after each clinical case, in accordance with their manufacturer's instructions.[20]

➡ *Caution: If it was connected to the GI endoscope's auxiliary water channel during the clinical case, the MAJ-855 auxiliary tube requires reprocessing, regardless of whether this channel (and tube) was used or flushed with water.*[20]

C. Prior to GI endoscopy, visually verify that the MAJ-855 tube is fitted with the correct green, *double*-winged (one-way flow) valve (with which the MAJ-855 tube was originally manufactured and shipped).[13,20]

➡ *Caution #1*: *Do not remove this green, double-winged valve from the MAJ-855 tube. This valve is crucial to the MAJ-855 tube's safe and effective use.*[13,20]

➡ *Caution #2: Do not use the MAJ-855 tube if it is fitted with a similarly-shaped, green, single-winged (two-way flow) connector, which is intended for use only with the Olympus MH-974 washing tube. Use of the MAJ-855 tube fitted with the MH-974 tube's single-winged connector is contraindicated.*[13,20]

II. Manual reprocessing of the MAJ-855 tube and the auxiliary water channel using a syringe:

A. Use a (30 ml) syringe to clean and high-level disinfect (and water rinse and forced-air dry), manually and simultaneously, the MAJ-855 tube and the GI endoscope's auxiliary water channel (to which this tube is connected;† *see:* main article) in accordance with the GI endoscope manufacturer's instructions.[13,20]

□ *Note*: The manufacturer's procedure and set-up for manually reprocessing the auxiliary water channel via the MAJ-855 tube are similar to those of the same manufacturer for manually flushing this channel with water during the exam via the MAJ-855 tube.[20]

III. Automated reprocessing of the MAJ-855 tube and the auxiliary water channel using an AER:

A. Some manufacturers suggest that their AER model(s) may be used to reprocess: (a) the auxiliary water channel via (and while simultaneously reprocessing) the MAJ-855 tube; and/or (b) the MAJ-855 tube by itself (i.e., while not connected to the GI endoscope).

➡ *Caution #1:* The use of an AER to reprocess the MAJ-855 tube, whether connected to the GI endoscope's auxiliary water channel or by itself, however, is ordinarily not recommended (*see:* Section III. C, below).

➡ *Caution #2:* The MAJ-855 tube's restrictive one-way valve, though of importance during the exam, can hinder the flow of reprocessing fluids through this tube's lumen, limiting the AER's effectiveness for reprocessing the MAJ-855 tube and, if it is connected to the GI endoscope, the auxiliary water channel.

B. Other manufacturers, however, may recommend that their AER model(s) be used to reprocess the GI endoscope's auxiliary water channel via a different adapter—known as the (Olympus) MH-974 washing tube (or its equivalent)—while the MAJ-855 tube is reprocessed by itself (manually or using an AER).[27]

➡ *Caution*: The MH-974 tube is fitted with a green, single-winged, two-way connector. *Do not confuse this connector, or use it interchangeably, with the MAJ-855 tube's double-winged, one-way valve* (*see*: Section I.C, above).[13,20,27]

□ *Note #1*: According to its manufacturer, the MAJ-855 tube can be manually reprocessed by itself, either using a syringe to achieve high-level disinfection or a steam autoclave, or using an AER.[20] (Steam sterilization of the MAJ-855 tube may require the purchase of

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† A diagram showing the MAJ-855 tube connected to the GI endoscope to flush water through its auxiliary water channel is provided at: *www.MyEndoSite.com*/letters/MAJ-855.pdf

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(Re: Box A: *Reprocessing the MAJ-855, auxiliary water channel*)

additional tubes to maintain an adequate inventory.)

- *Note #2:* Shorter in length (10 in.) than the MAJ-855 tube (4 ft.), the MH-974 washing tube features a connector that does not impede fluid flow and facilitates the AER's connection to the auxiliary water channel, as some manufacturers of AERs recommend.[13,27]

C. The following guidance is provided if the medical facility (e.g., its GI endoscopy unit) is considering to use an AER model to reprocess the MAJ-855 tube either while connected to the auxiliary water channel or by itself, separate from the GI endoscope:

a. Obtain from the AER manufacturer's quality assurance department a statement confirming that it has performed the necessary validation and verification tests (e.g., *microbiologic tests* performed under *worst-case* simulated in-use conditions) demonstrating, per FDA regulations, that the AER model can reprocess (including water rinsing and air-purging) the MAJ-855 tube (with its restrictive one-way valve firmly in place).

b. Alternatively, obtain from the manufacturer a letter confirming that the FDA has granted its AER model a 510(k) clearance to reprocess the MAJ-855 tube.

- If such a statement or letter is obtained, clarify with the manufacturer whether its AER model can be used to reprocess the MAJ-855 tube connected to the auxiliary water channel, or only by itself, separate from the GI endoscope. (If by itself, clarify whether the AER can simultaneously reprocess two MAJ-855 tubes.)

- If such a statement or FDA clearance letter is not provided to the medical facility, then the manual reprocessing of the MAJ-855 tube is advised (after *each* clinical case; *see:* Section II, above), although the automated reprocessing of the auxiliary water channel (using an adapter other than the MAJ-855 tubing, such as the MH-974 washing tube) would presumably be appropriate, unless otherwise indicated.

- *Note:* Some manufacturers may claim that their AER model(s): (a) are validated for reprocessing the auxiliary water channel via the MAJ-855 tube; (b) can reprocess the MAJ-855 tube, but only by itself (i.e., not while connected to the GI endoscope's auxiliary water channel) and one at a time (not two of them simultaneously in the same basin); or (c) cannot reprocess either the auxiliary water channel via the MAJ-855 tube or the MAJ-855 tube separately, by itself. ➡ *Medical facilities are advised to verify which of these scenarios applies to their AER model(s).*

IV. **Additional instructions are provided on p. 7, which is available only in this newsletter's *on-line* version.**

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and concluded that a breach associated with an *extremely low* risk of infection—for example, *case 2*, above, about which 1812 patients *were* notified—is different from and apparently poses a significantly *greater* risk of patient harm[8] than a breach associated with a *negligible* infection risk—for example, *case 4*, above, about which *no* patients were notified.[15]

In short, it is confusing, if not incongruous and unsound, that affected patients were not notified of the *VA Caribbean Healthcare System's* several confirmed breaches. As a precaution and in accordance with the VHA's other published risk assessments, patient-disclosure policies, and directives, notification of these affected patients is recommended.[11,15]

Recommendations: Several highlighted recommendations are provided in Table 1 (p. 3) to reduce the risk of healthcare-acquired infections associated with the specific types of breaches recently identified at a number of medical facilities within the U.S. (and Caribbean) and which are discussed herein. This table's listing of these recommendations—which completes the discussion provided in, and is to be read in conjunction with, this newsletter's *April-May-June, 2010,* issue—complements, and is neither all inclusive nor a replacement for, manufacturers' instructions. **The End** [*Article by*: L.F. Muscarella Ph.D.] *(Continued on pages 7 and 8, which are available only on-line. See: box, below.)*

➡ The **REFERENCES** to this newsletter's main article, box articles, and tables are available at:

www.myendosite.com/htmlsite/2011/refs01-0411.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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(Re: Box A: *Reprocessing the MAJ-855, auxiliary water channel*)

IV. **Additional instructions *(continued from p. 6)*:**

- After connecting the reprocessed ("patient-ready") MAJ-855 tube to the GI endoscope, flush and prime the auxiliary water system *prior* to beginning the clinical case, verifying that water is flowing from the GI endoscope's distal tip. *Connecting the unprimed MAJ-855 tube to the GI endoscope while the procedure is already in progress can be problematic*.[13]
- If using an automated pump to flush the patient's GI tract with water via the auxiliary water channel, discard *daily* the short irrigation tube that connects the MAJ-855 tube to the flushing pump's fluid container, in accordance with the pump's instructions. *Do not reuse from day to day this short irrigation tube*.[13,20,27]
- Sterilize *daily* this automated pump's fluid container.[20] Moreover, the manufacturer recommends using sterile water to flush the GI tract via the MAJ-855 tube.[20,27]
- Consider the use of single-patient irrigation tubing (in lieu of the MAJ-855 tube) featuring a one-way valve to prevent contamination of the water bottle. ●

Box B: *Distinctions with, or without, differences?*

Although the risk assessments below are seemingly without differences, their associated actions were, at times, quite different. Whereas infection-control breaches assessed to have a *negligible* infection risk did not result in patient notification (row 4, below), others associated with similar infection risks did result in such disclosure. (A "case" refers to those 5 discussed in the main article.)

Assessed risk of infection	Number of Patients Notified	Case or Reference
(Reportedly, no risk[1-4])	(No patients notified)	*(Case 1)*
"Extremely low"[8,12]	1812	*Case 2*
"Small but not zero"[13]	More than 10,000	*Case 3*[†]
"Negligible"[15-17]	No patients notified	*Case 4*
Extremely low[10]	More than 500	*Case 5*
"Extremely remote"[19]	9000	*Ref: 19*
"Close to nil"	150	*Ref: 32*
"Minimal to non-existent"[29]	360	*Ref: 29*
"Extremely low risk"[31]	38	*Ref: 31*
"Extremely low"	15	*Ref: 32*

[†] Case 3's breaches were also assessed to have a "*low but significant risk*"[13] of infection and a risk "*substantially less than 1 in 10,000.*"[13]

Box C: San Juan—A controversial risk assessment

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The Veterans Health Administration's (VHA) decision not to notify patients of the several breaches confirmed within the *VA Caribbean Healthcare System* is controversial for a number of reasons (*see*: main article). First, the medical literature and a guideline by the CDC[9] suggest that these breaches—which included the failure to high-level disinfect *semi*-critical instruments[15] (*see: case 4*, p. 4)—pose an *increased* infection risk,[16] notwithstanding both the VAOIG's assessment that they pose a "negligible" infection risk or the VHA's notification of 1069 patients of the similar failure by the Augusta (GA) VAMC to high-level disinfect *semi*-critical instruments (*see: case 3*, p. 2).[13]

Moreover, on balance, several of these breaches confirmed within the *VA Caribbean Healthcare System* might pose *more* of an infection risk than some of those confirmed at the three VAMCs in Murfreesboro, Augusta, and Miami (see: *main article*), about which the VHA notified more than 10,000 patients. For example, whereas the Murfreesboro VAMC's improper use and reprocessing of the MAJ-855 water tube (*see*: Box A), to date, has not been linked to infection,[20] the failure to leak-test flexible endoscopes (which was one of the *VA Caribbean Healthcare System's* confirmed breaches) has been previously associated with patient morbidity and mortality.[16] What's more, this healthcare system's improper disinfection of transvaginal ultrasound transducers (*see: case 4*, p. 4) reportedly poses an *increased* risk of infection of, among other agents, the human papillomavirus (HPV).[16]

Second, whereas it did not notify affected U.S. veterans of the *VA Caribbean Healthcare System's* failure to use a detergent to clean flexible laryngoscopes prior to high-level disinfection,[15,16] the VHA notified 1812 patients of the similar failure by the St. Louis VAMC's dental clinic to use a detergent to clean dental instruments prior to steam sterilization (see: *case 2*, p. 2),[8] which is confusing.

Third, the VHA's failure to notify affected patients of this Caribbean healthcare system's several confirmed breaches is inconsistent with: (a) the VHA's published "obligation" to notify patients of such potentially adverse medical events;[11] (b) the VAOIG's published commitment to "transparency";[21] (c) the VA's mission to "protect the interest of veterans";[22] and (d) "duty-based frameworks."[14] Like the VHA's published policy of a "presumptive obligation" (*see*: main article), Dudzinski et al. (2010) state that: "health care institutions have a duty to inform patients when the delivery of health care has put them at risk."[14]

And, fourth, having not notified or monitored for infection patients who were potentially affected by the *VA Caribbean Healthcare System's* several breaches, the VHA cannot be assured that there were no cases of disease transmission.[14] In closing, it can be respectfully argued that the VAOIG's (and VHA's) assessment that this healthcare system's breaches did not pose a sufficient infection risk to warrant patient disclosure is unsound (*see:* Box A, p. 10 of this newsletter's *Apr-May-Jun, 2010*, *issue*). ı

TABLE 2: *Specific instrument-reprocessing breaches recently identified by officials of the Department of Veterans Affairs (VA) at the John Cochran VA Medical Center (VAMC) in St. Louis (MO).*

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1. *Faulty reprocessing of surgical instruments.*

- **Breach:** In early February, 2011, 10 procedure rooms in this VAMC's operating suite were closed and more than 70 surgical procedures were cancelled amid concerns that "spots" noticed on surgical instrument trays and "water stains" on at least one surgical instrument indicated faulty reprocessing practices.[1,2] This VAMC's operating suite was re-opened almost 5 weeks later once its cleaning and sterilization processes were verified to be functioning properly.[4] *(Refer to the main article for more details;* see: *case 1*, p. 1.)[†]
- **Guidelines, manufacturers' instructions:** After their use, cleaning followed by sterilization of *critical* (reusable) surgical instruments is required. Critical instruments not damaged by heat, pressure, or moisture ordinarily require steam sterilization.[9]
- ➡ **Infection risk:** Failure to clean and sterilize reusable *critical* surgical instruments and trays may pose an increased risk of transmission of infectious (and non-infectious) agents warranting patient notification.[1-3,30]
- u **Recommendations:** *Refer to* Table 1, No. 5.

2. *Faulty reprocessing of dental instruments.*

- **Breach:** For 13 months, this St. Louis VAMC's dental clinic, among other breaches, improperly cleaned dental equipment, failing to use a detergent prior to sterilization.[30] The VA notified 1812 patients in June, 2010, of the potential for this breach to have exposed them to "visibly dirty"[30] dental instruments potentially contaminated with such infectious agents as HIV and both the HBV and HCV.[8] *(Refer to the main article for more details;* see: *case 2*, p. 2.*)*
- **Guidelines, manufacturers' instructions:** Like other medical equipment, dental instruments are classified as *non-*, *semi-*, and *critical* devices, requiring low-, intermediate-, or high-level disinfection, or sterilization. *Semi-critical* and *critical* dental instruments not damaged by heat, moisture, and pressure (e.g., dental hand pieces) ordinarily require after each use cleaning using a detergent followed by steam sterilization.[9]
- ➡ **Infection risk:** Failure to clean using a detergent and to sterilize reusable *critical* dental instruments and equipment may pose an increased risk of infection warranting patient notification.[30]

[†] The VHA did not notify any patients of this breach, concluding that none were affected or potentially harmed by it.

CASE 5: Dayton, Ohio – Dental clinic:

Introduction: Last summer the dental clinic of the VAMC in the Dayton (OH) was closed for three weeks following concerns that infection-control standards may have been breached, posing an increased risk of patient-to-patient disease transmission. Reports indicate that a dentist failed to change gloves between clinical cases and reused dental instruments that had not been sterilized.[10] Table 1 (p. 3) provides recommendations to reduce the risk of infection associated with using improperly reprocessed dental instruments.

Officials notified more than 500 patients (who had been treated at this VAMC's dental clinic for more than 18 years), and, although none have tested positive for HIV, seven of these 500 patients have tested positive for HCV and two for HBV.[10] Whether these nine cases are a result of patient-to-patient disease transmission caused by this dental clinic's breaches (or an un-related event) is unclear.[10] In addition to Table 1 on p. 3, the reader is referred to the discussion provided in Table 2. ●

➡ The **REFERENCES** to this newsletter's main article, box articles, and tables are available at:
www.myendosite.com/htmlsite/2011/refs01-0411.pdf

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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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