Dear Pediatrics: An Assessment of the Effectiveness of Bundles and Checklists for the Prevention of Central line-associated Bloodstream Infections in the Neonatal Intensive Care Units (NICUs) of New York State Hospitals

A LETTER: The study by Schulman et al. (2011) in *Pediatrics* is a significant contribution to the prevention of central line-associated bloodstream infections (CLABSIs) in neonatal intensive care units (NICUs).[1] This study's design and methods feature a number of limitations, however, four of which are discussed herein.

❖

1. STUDY DESIGN: Like that of other studies also quantitatively evaluating the effectiveness of an intervention for the prevention of CLABSIs,[2-10] the prospective-cohort design of Schulman et al.'s (2011) study necessarily limits its results to displaying associations. Nevertheless, these authors conclude that both the increased use of maintenance checklists and the statewide adoption of standardized bundles *causally* reduced CLABSI rates. In general, such a claimed cause-and-effect relationship would require that the study be that which it is not: both randomized and controlled (and blinded), to minimize or eliminate the potential effects on the study's results of biases, confounding factors and chance. Although common of studies similarly evaluating an initiative's effectiveness for reducing CLABSIs,[2] Schulman et al.'s (2011) depiction of an association as a causal relationship is no less of an overstep.

2. FEEDBACK: Schulman et al.'s (2011) study emphasizes the importance of verbal discussions among NICU staff members about the intervention's intent and progress.[1] Although such dialogue during the study's *post*-intervention period is common and often encouraged to improve the quality of central-line care,[2] it can, like discussions during an "open label" drug study, manifestly compromise the study's validity and quantitative determination of the intervention's performance.[2] Indeed, these verbal discussions (or "social interactions"[1]) not only can introduce biases and confounding factors (e.g., "feedback bias," "confirmatory bias") that result in under-reporting the true incidence of infection, but they can also cause the study to misattribute to the intervention reductions in CLABSIs caused instead unwittingly by the verbal exchange of information between NICU staff members.[5]

3. COMPLIANCE: Schulman et al. (2011) did not confirm that the *actual* use of the checklists by NICU staff members was the same as their *reported* use. Another factor often overlooked,[2] without verification that staff strictly adhered to each of an intervention's prescribed elements, the validity of a study's conclusion that, for example, the use of maintenance checklists reduced CLABSIs[1] may be questioned.[5] (As these authors disclose, "reported checklist use" may not be the same as "actual checklist use."[1]) Consequently, there is the possibility that the reductions in the CLABSI rate reported by Schulman et al. (2011) were caused—not by the studied bundles and checklists—but instead by one or more unrecognized confounding factors.

➔ *A peer-reviewed article I wrote about the validity of infection data can be read at:* http://bit.ly/MSAwht

4. DATA VALIDATION: Schulman et al. (2011) acknowledge that the public reporting of CLABSIs can bias their rates "downward,"[1] which both underscores the importance of data validation and raises the question whether the majority of the CLABSI data that these authors used as the primary metric to evaluate the studied intervention's performance might be unreliable (e.g., might under-report the true CLABSI rate in the participating NICUs[2]). Although they report having audited a sample of the CLABSI data, Schulman et al. (2011) do not discuss whether: (*i*) this sample's size was statistically sound; (*ii*) the number of central-line days, like the number of infections, was audited; and (*iii*) these audited data were valid.

To be sure, an underestimation of the true incidence of infection can cause not only the actual performance of the studied bundles and checklists on CLABSI rates to be over-exaggerated,[11-13] but also the participating NICUs to mischaracterize unwittingly the quality of central-line care and to forgo the adoption of preemptive practices otherwise necessary to the prevention of infection, ironically posing an *increased* risk of CLABSIs and patient harms.

CONCLUSIONS: This box article, which is a letter to the medical journal *Pediatrics,* does not question the objectives of Schulman et al.'s (2011) study, which are laudable and noble. Rather, it emphasizes mitigation of the four aforementioned limitations, which, if overlooked and not addressed, can compromise the quality, significance and validity of a study's both CLABSI data and conclusions (that are based on these data). In short, this letter suggests that prospective-cohort studies (non-randomized, un-controlled) aiming to evaluate quantitatively an intervention's impact on the CLABSI rate in NICUs apply a more circumspective approach and: (1) confirm the validity of their CLABSI data; (2) verify that NICU staff members strictly adhered to all of the intervention's elements (and adhered to none during the *pre*-intervention period[2]); (3) do not advance an association as a causal relationship; and (4) understand that "feedback" among staff members can introduce errors into the study's data and findings. ● LFM *(This letter's references are available for the reader's convenience at:* http://tinyurl.com/842turq*.)*

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

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What's News

Published in the *World Journal of Clinical Infectious Diseases* (WJCID), readers may find of interest an article I recently wrote about infection-control breaches and medical errors. It can be read at: http://tiny.cc/aoevgw. Other topics that this article in *WJCID* discusses include the clinical use of misbranded medical devices, liquid chemical sterilization and instrument reprocessing.

Founder

This newsletter/journal's articles are written by its founder, **Lawrence F. Muscarella, Ph.D.** *Email:* **editor@myendosite.com**

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.

Q-Net's Annual Quiz

A focus on instrument reprocessing, risk assessments, a CDC report about infections, and a FDA guidance document

- This quiz focuses on and teaches all of the topics discussed in this newsletter in 2011.
- These topics include: (a) the risk of infection associated with a number of well-publicized infection-control lapses; (b) reprocessing of the Olympus MAJ-855 auxiliary water tube; and (c) reported trends in the rates of healthcare-associated infections.
- This quiz also focuses on the reprocessing of: (a) sheathed "ENT" laryngoscopes; (b) the handles of rigid laryngoscopes; and (c) vaginal ultrasound transducers.
- This quiz may be used for training or to provide continuing educational units (CEUs). This quiz may also be used in conjunction with a medical facility's patient safety program.

➔ **Page 15: "Dear Pediatrics: Assessment of the Effectiveness of Bundles and Checklists for the Prevention of Central Line–Associated Bloodstream Infections in NICUs." [A Letter]**

PART 1A: Five cases of infection-control breaches. *(Refer to the* ***Jan-Feb-Mar-Apr, 2011****, issue.)*

1. ***In 2011 a Veterans Administration Medical Center (VAMC) in St. Louis reportedly identified "spots" on surgical instrument trays and "water stains" on at least one surgical instrument. These anomalies might indicate faulty:*** **(A)** cleaning; **(B)** reprocessing practices; **(C)** sterilization; **(D)** all of the above.

(Continued on page 15)

Quiz Instructions, Answer Form:

(A) For each of this self-study quiz's questions, please read every one of the provided choices *before* selecting an answer.

(B) To score well, a review of all of this newsletter's articles published in 2011 is recommended *prior* to taking this self-study quiz.

(C) Write the answer to each question on the form provided on p. 18. This form also includes this quiz's correct answers.

(Continued from page 14)

2. ***According to hospital officials, the origin of these spots and water stains might have been any one of the following except:*** **(A)** blood or another potentially infectious body fluid; **(B)** metallic etchings; **(C)** rust; **(D)** corrosive pits on the surfaces of surgical instruments.

3. ***Referring to this incident, which resulted in the closure of the operating suite of this VAMC in St. Louis for 5 weeks and the cancellation of more than 70 surgeries, the press and others stated each of the following except:*** **(A)** that these spots and water stains indicated "sloppy sterilization practices"; **(B)** that infections are "almost never" associated with significant breaches in aseptic technique; **(C)** that this incident is a "national disgrace"; **(D)** that this VAMC in St. Louis has "a great heart and soul."

➔ *The Jan-Feb-Mar-Apr, 2011, issue of this newsletter discusses several infection-control lapses.*

4. ***Which one of the following breaches was identified in 2010 at the dental clinic of this same VAMC in St. Louis?*** **(A)** the low-level disinfection of biopsy forceps; **(B)** the use of an acidic glutaraldehyde formulation to sterilize dental handpieces; **(C)** the failure to use detergent to clean dental instruments prior to their sterilization; **(D)** the misuse of a hydrogen peroxide gas to disinfect sinks.

PART 1B: Five cases of infection-control breaches.
(continued) *(Refer to the **Jan-Feb-Mar-Apr**, **2011**, issue.)*

5. ***Each of the following breaches was confirmed (circa 2008-2009) at one or more of the three VAMCs in Murfreesboro (TN), Augusta (GA), and Miami (FL) except:*** **(A)** the low-level disinfection of dental handpieces and biopsy forceps; **(B)** the improper reprocessing of flexible laryngoscopes; **(C)** the improper use and reprocessing of the Olympus MAJ-855 auxiliary water tube; **(D)** the improper reprocessing of colonoscopes.

6. ***Which one of the following statements is false:*** **(A)** Improper reprocessing of the Olympus MAJ-855 auxiliary water tube may pose an increased risk of infection. **(B)** Leak-testing the flexible laryngoscope prior to its reprocessing is recommended. **(C)** Reprocess the colonoscope's auxiliary water channel only after its first use of the day. **(D)** Soil or debris dripping from a "reprocessed" colonoscope's distal tip may indicate, among other breaches, improper cleaning of its auxiliary water channel.

7. ***Which one of the following statements is true:*** **(A)** Do not visually inspect or leak-test colonoscopes prior to their reprocessing. **(B)** Use of a damaged flexible laryngoscope that failed the "leak test" is acceptable. **(C)** Intermediate-level disinfection is indicated for processing *semi-critical* devices. **(D)** Wiping flexible laryngoscopes and colonoscopes with a gauze soaked in a quaternary ammonium disinfectant is recommended to achieve high-level disinfection. **(E)** Improper reprocessing of vaginal ultrasound transducers may pose an increased risk of infection.

8. ***Which of the following breaches was confirmed in the summer of 2009 at a number of medical facilities within the Caribbean (U.S.) healthcare system including a VAMC in Puerto Rico:*** **(A)** the failure to leak-test colonoscopes; **(B)** the use of a damaged flexible laryngoscope; **(C)** the failure to high-level disinfect transvaginal ultrasound transducers; **(D)** all of the above.

PART 1C: Five cases of infection-control breaches.
(continued) *(Refer to the **Jan-Feb-Mar-Apr**, **2011**, issue.)*

9. ***The Veterans Health Administration's (VHA) decision not to notify affected patients of several infection-control breaches confirmed in 2009 at a number of medical facilities within the Caribbean healthcare system is confusing primarily for which of the following reasons:*** **(A)** this decision is inconsistent with the VHA's published commitment to transparency and to notify patients of potentially adverse medical events; **(B)** the inadequate reprocessing of reusable medical devices has never been linked to the transmission of a virus; **(C)** this decision is inconsistent with the VHA's previous notification of patients affected by similar types of breaches; **(D)** A and C.

➔ *The Jan-Feb-Mar-Apr, 2011, issue of this newsletter provides recommendations to prevent infections.*

10. ***Which of the following statements about the Olympus MAJ-855 auxiliary water tube is false:*** **(A)** This tube may be used during the clinical exam to supply the gastrointestinal endoscope's auxiliary water channel with water. **(B)** This tube may only be reprocessed using an automated endoscope reprocessor—never manually. **(C)** This tube is to be used clinically only when fitted with a one-way valve—not with a two-way connector. **(D)** This tube may be either high-level disinfected or steam autoclaved after its use.

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Topics published in this newsletter in 2011:

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(E) Single-patient irrigation tubing (fitted with a one-way valve) may be used instead.

11. ***A "negligible" risk of infection associated with an instrument-reprocessing breach is seemingly comparable to each of the following risk assessments except:*** **(A)** a "moderate to high" risk; **(B)** a "close to nil" risk; **(C)** an "extremely low" risk; **(D)** a "minimal to non-existent" risk; **(E)** an "extremely remote" risk.

12. ***Which of the following statements is false:*** **(A)** The labeling of some automated endoscope reprocessors (AERs) may claim to be validated for processing the colonoscope's auxiliary water channel using the Olympus MAJ-855 water tube. **(B)** Only flush and prime the auxiliary water channel and system with an irrigant prior to esophago-gastro-duodenoscopy ("EGD"). **(C)** The Olympus "MH-974 washing tube" and the MAJ-855 water tube are approximately 10 in. and 4 ft. in length, respectively. **(D)** Discard daily the short irrigation tube that connects the MAJ-855 water tube to the flushing pump. ●

PART 2A: Review of a CDC report about infections. *(Refer to the **May-Jun-Jul**, **2011**, issue.)*

1. ***Which of the following statements is false:*** **(A)** Each year 5% of hospitalized patients in the U.S. reportedly contract a healthcare-associated infection (HAI). **(B)** The *Centers for Disease Control and Prevention* (CDC) report that the number of central line-associated bloodstream infections (CLABSIs) in intensive care units (ICUs) of U.S. hospitals dropped to 18,000 in 2009. **(C)** CLABSIs are never used to evaluate, rate and/or compare the relative safety and quality of U.S. hospitals. **(D)** The mortality rate associated with CLABSIs may be as high as 25%.

2. ***In a report it published in the March 1, 2011, issue of* Morbidity and Mortality Weekly Report *(MMWR), the CDC estimate that the number of CLABSIs in the ICUs of U.S. hospitals decreased by 58% between 2001 and 2009. According to the CDC, this finding:*** **(A)** demonstrates that the quality of health care in the U.S. is improving; **(B)** indicates that as many as 27,000 patient lives may have been saved; **(C)** is likely due to state and federal efforts, in part coordinated and supported by the CDC, to prevent healthcare-associated infections; **(D)** suggests considerable savings in health-care costs; **(E)** all of the above.

3. ***This newsletter's review of this report by the CDC published in the March 1, 2011, issue of* MMWR *concludes each of the following except:*** **(A)** that some of the conclusions of this report by the CDC are overly-simplistic and more conjectural than scientific; **(B)** that this report by the CDC demonstrates that the number of CLABSIs increased by 103% between 2001 and 2005; **(C)** that the conclusions of this report by the CDC are based on self-reported infection data that have not been validated and may be in error; **(D)** that this report by the CDC may have under-reported the true incidence of CLABSIs in ICUs.

➔ *The May-June-July, 2011, issue of this newsletter raises questions about the soundness of a report by the Centers for Disease Control and Prevention.*

4. ***Which of the following statements is true:*** **(A)** The majority of published CLABSI data have not been validated for accuracy and completeness. **(B)** The *American Hospital Association* has expressed "serious concern" about the public reporting of infection data that lack validation. **(C)** Published infection data require validation, to ensure they do not under-report the true incidence of infection. **(D)** The CDC acknowledges that the CLABSI data on which its analysis in the March 1, 2011, issue of *MMWR* is based are subject to "reporting biases." **(E)** All of the above.

PART 2B: Review of a CDC report about infections. (continued) *(Refer to the **May-Jun-Jul**, **2011**, issue.)*

5. ***Each of the following terms is used to describe a policy embraced by public and private health insurers to improve quality and incentivize the prevention of healthcare-associated infections except:*** **(A)** "value-based purchasing"; **(B)** "pay for performance"; **(C)** "pay to underestimate the risk of infection"; **(D)** "pay for reporting."

6. ***Which of the following is a type of bias that can cause the true incidence of CLABSI to be under-reported and the actual performance of an intervention to be over-exaggerated:*** **(A)** "measurement bias"; **(B)** "confirmatory bias"; **(C)** "sampling bias"; **(D)** "publication bias"; **(E)** all of the above.

7. ***Which of the following is false:*** **(A)** A study's conclusion that an evaluated intervention causally prevented infections does not require confirmation that staff members adhered to the intervention's prescribed elements. **(B)** The U.S. Government Accountability Office (GAO) has expressed concern that published infection data that have not been validated may be "misleading." **(C)** The majority of the reported infection data that *Consumers Union* (like the

(Continued on p. 17)

ANSWER FORM, CORRECT ANSWERS: Remember to write your answers on the form provided on p. 18. This form also features this quiz's correct answers. Extra copies of this newsletter's quiz are available at "The Q-Net Monthly's" website. Visit: www.MyEndoSite.com

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CDC) uses to rate and compare the safety of hospitals have not been validated for accuracy and, therefore, may be invalid. **(D)** A prospective cohort study is generally much less robust than a randomized, controlled study.

8. ***A prospective cohort study:*** **(A)** always demonstrates a causal relationship, ensuring that a studied intervention or initiative was the sole cause of a measured or estimated reduction in the CLABSI rate; **(B)** is generally limited and neither eliminates every potential bias nor controls every unrecognized confounding factor; **(C)** is always blinded, randomized and associated with a placebo; **(D)** uses a predetermined correction factor to account for every confounding factor that might affect the study's results. ●

PART 3A: Five instrument-reprocessing topics and the FDA. *(Refer to the **Aug-Sep-Oct**, **2011**, issue.)*

1. ***This newsletter's Aug-Sep-Oct, 2011, issue addresses each of the following topics except:*** **(A)** infections of the hepatitis C virus linked to "TEE" probes; **(B)** the reprocessing of laryngoscope handles; **(C)** the reprocessing of sheathed "ENT" endoscopes; **(D)** liquid chemical sterilization; **(E)** the FDA's definition of "sterility."

2. ***Which of the following statements is false:*** **(A)** Flexible endoscopes are associated with more healthcare-associated infections (HAIs) than any other type of reusable instrument. **(B)** Laparoscopes are *semi-critical* devices that never enter sterile tissue. **(C)** One cause of HAIs is the improper reprocessing of reusable medical instruments. **(D)** Blood pressure cuffs are *non-critical* devices.

3. ***Which choice completes the sentence: "The FDA considers {blank} to be non-critical, even though during their routine use these devices may contact abraded skin with exposed blood."*** **(A)** laryngoscope blades; **(B)** arthroscopes; **(C)** sink drains; **(D)** skin electrodes.

➔ *An article about medical errors and liquid chemical sterilization was recently published in a peer-reviewed medical journal. Visit: http://tiny.cc/aoevgw*

4. ***Which of the following statements is true:*** **(A)** In May, 2011, the FDA published a draft guidance document that states that the reprocessing instructions of a sheathed instrument "should assume (that) the device (was) used uncovered," without a sheath. **(B)** The FDA recently published that biological indicators (BIs) are "not appropriate" for monitoring liquid chemical sterilization processes (despite clearing a BI for that sole purpose). **(C)** The FDA currently defines *liquid chemical sterilization* less by what this claim actually achieves than by what a device with this claim does *not* achieve. **(D)** All of the above (are true).

PART 3B: Five instrument-reprocessing topics. (continued) *(Refer to the **Aug-Sep-Oct**, **2011**, issue.)*

5. ***Which two choices best complete the sentence: "Guidelines classify the blades of rigid laryngoscopes as {blank #1} devices that require cleaning and {blank #2}."*** **(A)** {*semi*-critical} and {at least high-level disinfection}; **(B)** {*non*-critical} and {sterilization}; **(C)** *{critical}* and {low-level disinfection}; **(D)** {*semi*-critical} and {intermediate-level disinfection}; **(E)** {*non*-critical} and {high-level disinfection}.

6. ***Which of the following is true:*** **(A)** The FDA classifies rigid laryngoscope handles as *critical* devices. **(B)** Standardization of the reprocessing requirements of any reusable instrument is not important either to quality or to prevent both user confusion and disease transmission. **(C)** An example of skin electrodes includes scalp electrodes used during "EEG." **(D)** The FDA requires that staff low-level disinfect laryngoscope blades. **(E)** The FDA classifies rigid laryngoscope blades as *non-critical* devices.

➔ *Page 15 features a review of an article about the effectiveness of infection-control initiatives in NICUs.*

7. ***The FDA defines "sterile" in its draft guidance document published in May, 2011, as a "state of being free from viable microorganisms." The Aug-Sep-Oct, 2011, issue of this newsletter concludes that this definition is incomplete because:*** **(A)** according to this definition, an instrument heavily soiled with non-viable materials, such as endotoxins that could cause patient harm, is "sterile"; **(B)** "sterility" connotes the instrument's cleanliness and its inability to transmit potentially harmful contaminants, infectious or not; **(C)** corneal endothelial decompensation and "TASS," both of which are non-infectious eye disorders that may be caused by ophthalmic instruments contaminated with sterile debris, present two examples of why the FDA's definition of "sterile" should be revised to be a "state clean and free of infectious and non-infectious contaminants capable of causing patient harm"; **(D)** all of the above.

8. ***A box article in this Aug-Sep-Oct, 2011, issue of this newsletter discusses an original article by Passaretti et al. (2011), who wrote each of the following about the public reporting of infections except:*** **(A)** the "public reporting of (infections) is fraught with problems"; **(B)** "the public reporting of infections is flawless, without error and requires no improvement"; **(C)** "the politics of measuring (healthcare-associated infections) may have outpaced the science"; **(D)** the "role of politics (vis-à-vis infections) far exceeds that of science." ●

➔ *The self-study quiz's ANSWER FORM and CORRECT ANSWERS are provided on page 18.*

~ Answer Box and Key ~

INSTRUCTIONS: *(1) After having reviewed all of the articles published in this newsletter in 2011, cover the right-hand column, below, which provides the quiz's correct answers. (2) Write your answer to each question on the lines provided in the left-hand column. (3) Calculate your score to test your knowledge.*

Part 1A.
- Question 1: _____
- Question 2: _____
- Question 3: _____
- Question 4: _____

Part 1B.
- Question 5: _____
- Question 6: _____
- Question 7: _____
- Question 8: _____

Part 1C.
- Question 9: _____
- Question 10: _____
- Question 11: _____
- Question 12: _____

Part 2A.
- Question 1: _____
- Question 2: _____
- Question 3: _____
- Question 4: _____

Part 2B.
- Question 5: _____
- Question 6: _____
- Question 7: _____
- Question 8: _____

Part 3A.
- Question 1: _____
- Question 2: _____
- Question 3: _____
- Question 4: _____

Part 3B.
- Question 5: _____
- Question 6: _____
- Question 7: _____
- Question 8: _____

Part 4—Bonus.
- Question 1: _____
- Question 2: _____

- Answer 2: A
- Answer 1: C

Part 4—Bonus.

- Answer 8: B
- Answer 7: D
- Answer 6: C
- Answer 5: A

Part 3B.

- Answer 4: D
- Answer 3: D
- Answer 2: B
- Answer 1: A

Part 3A.

- Answer 8: B
- Answer 7: A
- Answer 6: E
- Answer 5: C

Part 2B.

- Answer 4: E
- Answer 3: B
- Answer 2: E
- Answer 1: C

Part 2A.

- Answer 12: B
- Answer 11: A
- Answer 10: B
- Answer 9: D

Part 1C.

- Answer 8: D
- Answer 7: E
- Answer 6: C
- Answer 5: A

Part 1B.

- Answer 4: C
- Answer 3: B
- Answer 2: A
- Answer 1: D

Part 1A.

PART 4—Bonus. ***Two Bonus Questions.*** *(Refer to all of the issues of this newsletter published in 2011.)*

1. ***Guidelines typically recommend that reusable "critical" instruments not damaged by pressurized steam be sterilized using:*** **(A)** ethylene oxide gas; **(B)** a liquid disinfectant, such as glutaraldehyde; **(C)** a steam autoclave; **(D)** a plasma, mist or ozone; **(E)** none of the above.

2. ***Which of the following is false:*** **(A)** To reduce costs, guidelines advise staff to reuse the same pair of gloves and syringes (but not needles) from one patient to the next. **(B)** High-level disinfection of reusable *critical* instruments damaged by heat may be permissible. **(C)** "Wiping" an instrument's surfaces once, using a gauze soaked in 70% isopropyl alcohol, may not provide a sufficient exposure time to achieve intermediate-level disinfection. **(D)** "Data validation" evaluates the quality, accuracy, and completeness of reported infection data. ● **{The End}** LFM

➡ ***The REFERENCES to the letter to* Pediatrics *on p. 15 are available at: http://tinyurl.com/842turq***

➡ Each of the articles and quizzes published in *The Q-Net Monthly* are written by Lawrence F. Muscarella, Ph.D., this newsletter's *founder* and *editor-in-chief.* To subscribe to this free educational newsletter, or to download a previously published issue, visit: www.MyEndoSite.com

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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