

The Q-Net™ Monthly

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What's News

Happy New Year! *Welcome to this newsletter's 12th year of publication.* ● This month's newsletter provides the second and final article in a series that discusses *push enteroscopy* and *endoscopic shuffling*. ● This month's newsletter also includes an article that questions the conclusion of a FDA-CDC public health advisory. ● Remember that recent media reports and all of the back issues of this newsletter can be searched by topic and read at:

<http://www.myendosite.com>

Editor-in-Chief

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What is 'Q-Net'?

Q-Net is an internet-based technology-assessment network of questions and answers. Its newsletter is: *The Q-Net™ Monthly*.

The main goal of **Q-Net** is to encourage the infection control, endoscopy, and OR communities to not only ask good questions but to also demand well referenced responses.

Q-Net addresses the needs of both the health care provider, whose goal is to provide the best care possible, and the patient, who deserves affordable quality health care.

"Endoscopic shuffling," Part 2

This is the second and final article in a series that discusses push enteroscopy and endoscopic shuffling. Important recommendations are provided.



Background and answer: Last month's issue of this newsletter provides the first of two articles that discuss *push enteroscopy* and the controversial practice of *endoscopic shuffling*. This article, which is the second and final article in this series, provides important recommendations for gastrointestinal (GI) endoscopy units considering endoscopic shuffling. Together, these two articles provide a response to a question submitted by a GI nurse asking about the appropriateness of using a colonoscope to examine the proximal small bowel.

During push enteroscopy, a long, narrow flexible GI endoscope, known as a push enteroscope, is pushed, or

advanced, through the oral cavity into the upper GI tract to examine the proximal (first one third) small bowel. This procedure may be indicated for patients on whom colonoscopy and upper GI endoscopy, such as EGD (or, esophagogastroduodenoscopy), fail to identify and diagnose the cause of obscure bleeding or another GI ailment.

Despite its clinical versatility and usefulness, many GI endoscopy units do not have a push enteroscope in inventory and available for use, primarily due to its infrequent use and relatively high cost. These GI endoscopy units may, nevertheless, perform push enteroscopy using instead a less expensive and readily available adult or pediatric colonoscope. The use of a colonoscope, or another endoscope indicated for use in the lower GI tract, to perform push enteroscopy, or another upper GI procedure, (or, vice versa), is defined for this series of two articles as endoscopic shuffling.

As discussed in last month's issue of this newsletter, endoscopic shuffling

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FOCUS POINTS: ■ The use of a lower GI endoscope, such as a colonoscope, to perform an upper GI procedure, such as push enteroscopy, (or, vice versa), is defined as *endoscopic shuffling*. ■ The primary impetus for endoscopic shuffling is not necessarily to improve patient care but often to compensate for limited equipment availability. ■ Lessons learned in last year's series of 5 articles on contaminated respiratory specimens and both true and pseudo outbreaks are applied to a FDA-CDC public health advisory.

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may, for some types of procedures, be practiced with the intent to improve clinical outcomes. For instance, a push enteroscope, which is thinner, longer, and more flexible than a colonoscope, may sometimes be used in the lower GI tract, in lieu of a colonoscope, to prevent incomplete or unsuccessful colonoscopy.⁵⁻⁷ But, for other types of GI procedures, endoscopic shuffling may instead jeopardize patient safety. Compared to a push enteroscope, use of a (shorter) colonoscope to perform push enteroscopy can result in reduced diagnostic yields and an increase in the risk of misdiagnosis (i.e., a *false-negative* result) and patient injury, due to the colonoscope's limited advancement into, and inadequate visualization of, the proximal small bowel.⁴

What's more, endoscopic shuffling is controversial, because – in addition to raising questions and concerns vis-à-vis infection control and hygiene, patient expectations, the standard of patient care, published reprocessing guidelines, and the endoscope's labeling, instructions, and intended uses – the primary impetus for its adoption and implementation generally has to do less with improving patient safety and clinical outcomes than with compensating for limited endoscope availability, reducing health care costs, improving efficiency, and increasing patient throughput.⁹

Some GI endoscopy units performing endoscopic shuffling may reserve and mark, or label, a colonoscope or EGD endoscope exclusively to perform push enteroscopy or colonoscopy, respectively, among other considerations, to prevent the per-oral introduction of a GI endoscope that has been used previously in the lower GI tract. Depending, in part, on patient demand, endoscope availability, and management, however, other GI endoscopy units may instead interchangeably use (unmarked) colonoscopes or other types of GI endoscopes to perform *both* upper and lower GI procedures. For instance, GI endoscopy units may perform a variation of endoscopic shuffling and use the same GI endoscope to perform in sequence on the same patient during the same sitting both an upper and lower GI procedure, without reprocessing the endoscope between the two procedures. No doubt, endoscopic shuffling raises a number of medical, legal, and ethical issues and questions. Whether endoscopic shuffling, like the reuse of disposable (single-use) devices, is yet another medical practice that potentially jeopardizes patient safety for the sake of reducing costs is unclear.

Recommendations: The following recommendations are provided as guidance to GI endoscopy units considering endoscopic shuffling, the merits and safety of which are questioned. These recommendations are to be reviewed in the context of this and last month's issue of this newsletter.

1. Endoscopic shuffling is not recommended, unless documentation and data are available that indicate it is likely to improve the clinical outcome and optimize patient care.

A. Endoscopic shuffling can jeopardize patient safety.^{4,9}

(a) Performing push enteroscopy using, for example, a colonoscope may result in reduced diagnostic yields and misdiagnosis.

(b) Although it may not be required, consider patient disclosure or obtaining informed consent before performing endoscopic shuffling (or another practice whose safety and effectiveness may be in doubt).

B. Endoscopic shuffling is not consistent with the GI endoscope's labeling and intended uses.^{4,8,9}

(a) Use of a colonoscope to perform push enteroscopy or another *upper* GI procedure, for example, is inconsistent with the labeling of the colonoscope, which is intended "to provide optical visualization of, and therapeutic access to, the *lower* gastrointestinal tract."⁸

C. Endoscopic shuffling may pose a conflict of interest.

(a) Because the primary reason for endoscopic shuffling is reportedly to compensate for limited endoscope availability⁹—not necessarily to improve or optimize patient care—this practice is associated with the potential for a conflict of interest.

D. Endoscopic shuffling may introduce different and inconsistent standards of patient care.

(a) *Consider this scenario:* Two patients undergo push enteroscopy to evaluate their proximal small bowels for cancer. A push enteroscope is used on the first patient, while on the second patient a colonoscope is used. Two different standards of care may exist, because, compared to the first patient, the second patient's diagnostic yield may be reduced—due to the use of a shorter colonoscope whose access into, and visualization of, the small bowel is limited—increasing the risk of misdiagnosis and failure to identify sites of pathology that might have been detected using a longer push enteroscope.^{1,2,4}

E. In addition, the interchangeable use of a GI endoscope to perform both upper and lower GI procedures—either in sequence on the same patient or on different patients at different times—raises infection control and hygienic concerns and is at odds with the patient's expectations.

(a) Failure to properly reprocess the GI endoscope after each use could result in disease transmission via the fecal-oral route.

(b) Endoscopic shuffling is at odds with the understanding of the patient, who would not expect a GI endoscope, used previously on a patient to perform (per-rectally) colonoscopy, to be introduced per-orally and used to perform an upper GI endoscopic procedure, such as push enteroscopy.

(c) Use of a GI endoscope to perform in sequence on the same patient during the same sitting both an upper and lower GI procedure, without reprocessing the GI

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endoscope between the two procedures, is a variation of endoscopic shuffling that, additionally, is contraindicated by published endoscope reprocessing guidelines and the manufacturer's reprocessing instructions.¹⁰⁻¹⁷

2. Purchase a sufficient number of appropriate types and models of both upper and lower GI endoscopes to accommodate patient demand and avoid endoscopic shuffling.^{4,9}

- A. Purchase of a push enteroscope, for example, is recommended if a GI endoscopy unit intends to perform push enteroscopy.
- B. Perform each GI endoscopic procedure using the specific type and model of GI endoscope labeled and intended for the procedure.
- C. If the type and model of GI endoscope indicated for a specific procedure is not available, consider referring the patient to another GI endoscopy unit that has the GI endoscope in inventory and available for use.
- D. A request for more funding to purchase additional upper and lower GI endoscopes as required to meet patient demand may be necessary.

3. Under some circumstances, endoscopic shuffling may be acceptable, provided data are available that indicate it is likely to improve the clinical outcome and optimize patient care.

- A. Push enteroscope has been reported to improve the clinical outcome and, for example, prevent incomplete or unsuccessful colonoscopy.⁵⁻⁷
- B. Retain on file the studies, reports, and published data that support the safety, effectiveness, and clinical benefit of the off-label application of endoscopic shuffling.
- C. Dedicate and clearly mark, or label, any GI endoscope subject to endoscopic shuffling.
 - (a) Marking, for example, a colonoscope exclusively for use during push enteroscopy, instead of using the colonoscope interchangeably during both upper and lower GI procedures, eliminates the risk of fecal-oral disease transmission.
- D. Ensure endoscopic shuffling is performed with care and caution and only by GI endoscopists trained in the use of a lower or upper GI endoscope in the upper or lower GI tract, respectively.

4. As with all types of reusable instruments, reprocess upper and lower GI endoscopes in strict accordance with both published guidelines and their respective manufacturers' reprocessing instructions.¹⁰⁻¹⁷

- A. Clean, high-level disinfect (and water rinse), and dry GI endoscopes after each endoscopic procedure (not after each patient sitting, during which time more than one GI endoscopic procedure may be performed using the same

endoscope; refer to section 1.E.c, above).

- B. The endoscope ordinarily does not require reprocessing upon its removal from storage and immediately prior to its first use of the day.¹⁸
 - (a) Only under a limited number of circumstances would reprocessing the endoscope before the first patient of the day be indicated.¹⁸ (Refer to the June, 2000, issue of this newsletter.)
- C. Consider asking patients not to ingest foods containing Olestra, or a similar type of dietary fat substitute, or to take "fat-blocking" drugs such as orlistat (Xenical), several days prior to scheduled lower GI endoscopy.
 - (a) Consider using detergents that have been shown during simulated in-use studies to facilitate removal of all types of patient debris, including fats and Olestra and other dietary fat substitutes, from all of the GI endoscope's surfaces, including its valves, during cleaning and endoscope reprocessing. *The End* • LFM

Critique of a FDA-CDC health advisory

Lessons taught in a recent series of articles published in this newsletter in 2005 question the conclusion of a FDA-CDC public health advisory that discusses endoscope reprocessing.²⁰ These lessons can be applied to, and used to identify the mode of transmission of, most true and pseudo outbreaks linked to bronchoscopes.

A FDA-CDC public health advisory entitled "Infections from endoscopes inadequately reprocessed by an automated endoscope reprocessing system" provides several recommendations to prevent true and pseudo infections associated with bronchoscopes improperly reprocessed using automated endoscope reprocessors or an automated system.²⁰ For example, this health advisory recommends that health-care staff members compare, and resolve any conflicting instructions between, the reprocessing instructions provided by the manufacturers of both the endoscope and the automated endoscope reprocessor or system.²⁰ In addition to bronchoscopes, this advisory's recommendations apply to gastrointestinal (GI) endoscopes, ear-nose-and-throat ("ENT") endoscopes, and other types of flexible endoscopes.

The purpose for the issuance of this FDA-CDC health advisory was to publicize specific reprocessing breaches that reportedly were responsible for three clusters of respiratory specimens contaminated with *Mycobacterium tuberculosis*, *M. avium-intracellulare* (MAI), and imipenem-resistant *Pseudomonas aeruginosa* (IRPA), respectively.²⁰⁻²² All three of these clusters were associated with the use of a specific automated system labeled to "sterilize" bronchoscopes, and, according to this health advisory, were a result of apparent

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“patient-to-patient transmission.”²⁰ The investigation of each of these three clusters was summarized in a report referenced by this advisory and previously published by the CDC in *Morbidity and Mortality Weekly Report (MMWR)*.²¹

- The first of these three clusters, referred to in this *MMWR* as *cluster 1*, describes five patients whose respiratory specimens were contaminated with *M. tuberculosis*. Only one of these five patients displayed clinical evidence of tuberculosis. The respiratory specimens of these five patients were collected using three bronchoscopes that were reprocessed using an automated system (whose manufacturer assisted in the investigation).²¹

- The second cluster, referred to in this *MMWR* as *cluster 2*, describes seven patients whose respiratory specimens were contaminated with MAI.²¹ None of the patients displayed clinical evidence of infection of MAI. The respiratory specimens of these seven patients were collected using one bronchoscope that was reprocessed using the same automated system associated with *cluster 1*.

- The third cluster, referred to in this *MMWR* as *cluster 3*, describes 18 patients whose respiratory specimens were contaminated with IRPA.²¹ Three of these 18 patients displayed clinical symptoms of IRPA infection following bronchoscopy. One month earlier, the medical facility changed its reprocessing procedure and began reprocessing bronchoscopes using the same automated system associated with *clusters 1* and *2*. An article that provides a more detailed discussion of this incident than reported in this *MMWR* was published by infectious disease physicians in an infection control journal.²² Ruling out the possibility of the environment as a source of *cluster 3*'s IRPA, these physicians conclude, in agreement with the FDA-CDC advisory,²⁰ that this cluster's mode of transmission was patient-to-patient.^{24,25}

A series of five articles that discusses contaminated respiratory specimens associated with true and pseudo outbreaks was published last year in this newsletter (*refer to the January through October 2005 issues*). This series focuses on the modes of transmission associated with gram-negative bacteria, such as *P. aeruginosa*, and both atypical and tuberculo-cidal mycobacteria. The lessons taught in this series of articles were studied and applied to this FDA-CDC health advisory (and to the physicians' conclusion), to evaluate the validity of its claim that the mode of transmission associated with each of these three clusters was patient-to-patient.²⁰

The results of this study refute this health advisory's conclusion and suggest not only that both *clusters 1* and *2* were pseudo outbreaks, but that *cluster 3* was a true and pseudo outbreak, the sources of which may have been the environment in addition to, or in lieu of, an index patient. First, *cluster 1* describes four patients not displaying symptoms of tuberculosis, suggesting that this incident is a pseudo outbreak of *M. tuberculosis*—not, as the health advisory suggests, a true outbreak of *M. tuberculosis* due to patient-to-patient transmission. As reported in the *MMWR*, environmental contamination occurring in the microbiology laboratory may have been responsible for *cluster 1*.²¹

Second, none of *cluster 2*'s seven patients displayed clinical evidence of MAI infection. Moreover, as thoroughly discussed last year in several of this newsletter's articles, reports of patient-to-patient transmission of atypical mycobacteria, including MAI, via a bronchoscope are lacking. This finding leads to the conclusion that *cluster 2* most likely describes a pseudo outbreak of MAI caused by environmental contamination of the respiratory specimens—not, as the health advisory suggests, a true outbreak of MAI due to patient-to-patient transmission.²¹ If *cluster 2* were to describe a true outbreak of MAI due to patient-to-patient transmission via a contaminated bronchoscope, it would be one of the very few cases reported in the medical literature.

And, third, the FDA-CDC health advisory's conclusion that the mode of transmission of *cluster 3* was (exclusively) patient-to-patient is questioned for a number of reasons. First, as reported by physicians investigating this outbreak,²² *cluster 3* describes both a true and pseudo outbreak of IRPA, indicating that at least some of the respiratory specimens were contaminated by the environment and not due to cross-infection. Second, these physicians published that neither an index patient nor “patient-to-patient transmission” of IRPA was identified, notwithstanding the advisory's conclusion about *cluster 3*. And, finally, IRPA is a gram-negative bacterium that, like MAI (*cluster 2*), is opportunistic and has been cultured in the environment.²³⁻²⁵ Therefore, the possibility exists not only that the environment was a source of both *cluster 3*'s true and pseudo outbreaks, but that the mode of transmission of *cluster 3*'s true outbreak was environment-to-patient, not patient-to-patient. • LFM *The End*

References for the 2 articles in this series are available at: <http://www.myendosite.com/refs010206.htm>

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability.* Respectfully, the Publisher: *Lawrence F. Muscarella, Ph.D.* Please direct all correspondence to:

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