

# The Q-Net™ Monthly

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## What's News

### ~ Happy Holidays ~

This month's double issue discusses *endoscopic shuffling*, defined as the use of a *lower* GI endoscope to perform an *upper* GI procedure (or, the use of an *upper* GI endoscope to perform a *lower* GI procedure). **This is one of the first articles that discusses this topic.** Next month's newsletter, which is the second in a series of two articles, provides recommendations to health care facilities considering this practice.

## Editor-in-Chief

All of the articles published in this newsletter are written by: **Lawrence F Muscarella, PhD, Chief, Infection Control at Custom Ultrasonics, Inc. Ivyland, PA**

## What is 'Q-Net'?

**Q**-Net is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

The mail 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" and Push Enteroscopy

### Question

***"Our GI endoscopy unit sometimes uses a colonoscope to perform push enteroscopy and examine the small bowel. After completion of this upper GI procedure, the colonoscope may be used a second time in sequence on the same patient to perform colonoscopy, without reprocessing the colonoscope between the two procedures. Are there any infection control concerns associated with this practice?"***

This article discusses **endoscopic shuffling**, defined as the use of a *lower* GI endoscope to perform an *upper* GI procedure (or, vice versa).

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**Answer and Background:** For patients suffering from gastrointestinal (GI) disorders including obscure bleeding, GI endoscopists may perform a number of different procedures including "EGD" (or esophagogastroduodenoscopy) and colonoscopy. During

the former, a gastroscope is typically used to examine and treat disorders of the *upper* GI tract, specifically the esophagus and stomach. Colonoscopy, on the other hand, typically uses a colonoscope to examine and treat disorders of the *lower* GI tract, specifically the colon.

Patients on whom EGD and colonoscopy fail to identify and diagnose the cause of obscure bleeding or another GI disorder may be indicated for *push enteroscopy* – a procedure that pushes, or advances, a long, narrow flexible GI endoscope, known as a push enteroscope, into the *upper* GI tract to examine and evaluate the proximal (first one third) section of the small bowel. The Olympus SIF-100 and Pentax VSB-3430 are examples of push enteroscopes. Primarily because of its greater depth of advancement, push enteroscopy may improve diagnostic yields and identify sites of pathology not detected during EGD.<sup>1,2</sup>

**Endoscopic shuffling:** Prior to the development of the push enteroscope, adult and pediatric colonoscopes were used, if imperfectly, to perform push enteroscopy. The use of a *lower* GI endoscope to perform an *upper* GI procedure (or, the use of an *upper* GI endoscope to perform a *lower* GI procedure) is defined in this article as *endoscopic shuffling*.

Despite the introduction of push enteroscopes on to the U.S. market, some GI endoscopy units may continue today

Type of endoscope	Working length (approximate; cm)	Insertion tube diameter (approximate; mm)	Cost (approximate; U.S. \$)
"push" enteroscope	220	11	\$35,000
adult colonoscope	170	13	\$25,000
pediatric colonoscope	130	11	\$25,000
gastroscope for EGD	105	9	\$24,000
endoscope for ERCP	125	11	\$30,000
sigmoidoscope	70	13	\$15,000

**Table 1:** Characteristics of different types of gastrointestinal (GI) endoscopes. The working length of the endoscope is important to its advancement into the GI tract.

to use a colonoscope to perform push enteroscopy. GI endoscopy units that rarely perform push enteroscopy may be unable to justify the purchase of a push enteroscope. These GI endoscopy units, as well as those that frequently perform push enteroscopy but for which purchase of a dedicated push enteroscope is infeasible due to inadequate funding, may instead perform push enteroscopy using a colonoscope, which, although not designed for push enteroscopy, is less expensive and readily available in virtually every GI endoscopy unit.<sup>3,4</sup> Whereas colonoscopes are used frequently, typically cost-effective, and sell for \$25,000 or less, push enteroscopes may not be cost-effective, may be infrequently used and not in inventory, and are significantly more expensive, selling for approximately \$35,000 (Table 1).

Moreover, the operation, design (and appearance), and some of the functions of colonoscopes (and EGD endoscopes) are similar to push enteroscopes, providing for some GI endoscopy units the rationale to use a colonoscope to perform push enteroscopy. Most models of colonoscopes and push enteroscopes feature a working channel, air and water channels, and an auxiliary water jet channel. The use of a colonoscope to perform push enteroscopy may also afford the GI endoscopist the convenient opportunity, depending on the patient's clinical symptoms, to use the colonoscope a second time on the same patient to perform in sequence colonoscopy.

The use of an EGD endoscope (or gastroscope) to perform colonoscopy is another example of endoscopic shuffling (Table 2). Whereas some GI endoscopy units may dedicate and mark, or label, a colonoscope or EGD endoscope exclusively for push enteroscopy or colonoscopy, respectively, others may more commonly use a GI endoscope interchangeably to perform *both* upper and lower GI procedures, depending on patient demand and endoscope availability. Endoscopic shuffling may not only be convenient, cost-effective, and provide health care that might otherwise not be possible, but, in some instances, this practice may improve clinical outcomes. As a third example of endoscopic shuffling (Table 2), a push enteroscope, which is thinner, longer, and more flexible than a colonoscope (Table 1), may be used to more easily traverse an angulated colon or fixed sigmoid loop, improve the clinical outcome, and prevent incomplete or

unsuccessful colonoscopy.<sup>5-7</sup>

But endoscopic shuffling is not without its limitations and the potential for adverse patient outcomes. Although endoscopic shuffling may be used to avoid incomplete colonoscopy, the use of a colonoscope to perform push enteroscopy may limit access to, and visualization of, the proximal small bowel, reducing the endoscope's advancement and, possibly, the diagnostic yield,

compared to a push enteroscope.<sup>4</sup> A reduction in diagnostic yield is problematic, because it can jeopardize patient health by increasing the risk of misdiagnosis and "false-negative" results (i.e., failure to detect and identify diseased tissues).

**A variation of endoscopic shuffling:** As a variation of endoscopic shuffling, some GI endoscopy units may use the same GI endoscope to perform in sequence and on the same patient *both* an upper and lower GI procedure. For example, depending on the patient's clinical symptoms and the GI endoscopy unit's endoscope inventory and availability, a colonoscope may be used twice on the same patient to perform push enteroscopy followed by colonoscopy. Similarly, an EGD endoscope may be used to perform gastroscopy followed by colonoscopy during the same patient sitting. In these examples (each of which has been anecdotally reported), the GI endoscope is not reprocessed between the two GI procedures (i.e., after completion of the upper GI procedure and before beginning the lower GI procedure).

Some GI endoscopy units may not oppose (and may even favor) this variation of endoscopic shuffling, because, in addition to its convenience, this practice saves time, reduces costs (e.g., two GI endoscopic procedures are performed during one patient sitting, and the endoscope is not reprocessed between the two GI procedures), and increases patient throughput. (Whether the physician is reimbursed for one or two GI procedures is unclear.) Instead of scheduling two different times to perform on a patient an upper and a lower GI procedure—each with its own required preparations and associated costs—using two different types of GI endoscopes (i.e., an upper and a lower GI endoscope), one GI endoscope is used

- Use of a **colonoscope** (a *lower* GI endoscope) to perform **push enteroscopy** (an *upper* GI procedure)
- Use of an **EGD endoscope** (an *upper* GI endoscope) to perform **colonoscopy** (a *lower* GI procedure)
- Use of a **push enteroscope** (an *upper* GI endoscope) to perform **colonoscopy** (a *lower* GI procedure)

**Table 2.** Examples of endoscopic shuffling.

to perform in sequence and on the same patient both an upper and lower GI procedure, without reprocessing the GI endoscope between the two procedures (*refer to this article's question on page 21*). While arguably efficient and cost-effective, this practice raises a number of economic, legal, medical, and ethical questions and concerns vis-à-vis the endoscope's labeling and intended uses, infection control, and patient expectations.

**Labeling, intended uses:** *Endoscopic shuffling* uses a medical device that, while not necessarily posing a risk of patient injury, is inconsistent with its manufacturer's labeling and intended uses. For instance, the labeling of a colonoscope states that its intended use is "to provide optical visualization of, and therapeutic access to, the lower gastrointestinal tract."<sup>8</sup> The colonoscope's labeling and its intended use, therefore, contraindicate endoscopic shuffling and the use of a colonoscope to perform push enteroscopy or another upper GI endoscopic procedure. Colonoscopes are manufactured in accordance with a specific set of design parameters for their safe and effective passage through the colon. These parameters include the insertion tube's working length, diameter, stiffness, and angle of view. Push enteroscopes are manufactured in accordance with a unique and different set of design parameters for their safe and effective passage through the upper GI tract and proximal small bowel, the anatomy of which has twists and turns, tissues, and dimensions that may be quite different from those encountered in the colon.

A GI endoscopist may, of course, use discretion and practice endoscopic shuffling or otherwise use an endoscope in a manner that is not necessarily consistent with its manufacturer's labeling and intended uses. But, while endoscopic shuffling may under certain circumstances be considered safe, this practice is not necessarily without legal risk, and, under some clinical conditions, it can yield reduced diagnostic yields increasing the risk of misdiagnosis and patient injury.<sup>4</sup> Legitimate questions about the appropriateness of endoscopic shuffling might understandably arise, and its practice questioned and closely and legally scrutinized, were, for instance, a patient's cancerous jejunum (proximal section of the small bowel) not detected and misdiagnosed as a result of using a shorter colonoscope whose visualization of the jejunum is limited and reduced, compared to a push enteroscope;<sup>4</sup> or, a patient's esophagus perforated, or torn, with associated bacterial infection, due to the use of a wider and less flexible colonoscope, compared to a push enteroscope.

The "off-label" use of a medical device is considered appropriate and medically sound provided, among other considerations, the application provides optimal patient care. The driving force behind endoscopic shuffling, however, may be as much to improve clinical outcomes as to reduce health care costs, improve efficiency, increase patient throughput, and compensate for limited endoscope availability. According to the *American Gastroenterological Association (AGA)*, "use of a long push enteroscope specifically designed to examine the small bowel may have advantages over per-oral use of a

standard or pediatric colonoscope and that the 'deciding factor,' or primary consideration, for using a colonoscope instead of a push enteroscope is equipment availability."<sup>9</sup> Under circumstances in which a limited inventory of endoscopes or a reduction in expenses – not necessarily clinical benefit and improved patient care – is the deciding or primary factor that dictates medical practice and influences the type of GI endoscope that may (or may not) be used during a specific procedure, endoscopic shuffling may pose a conflict of interest and arguably be unsound and unethical, if not also legally tenuous. As a consequence, when practicing endoscopic shuffling, prior informed consent or disclosure to the patient of this practice's potential shortcomings and risks may be necessary.

**Infection control, hygiene:** In addition to having potential legal and ethical implications, endoscopic shuffling can raise infection control and hygienic concerns. For instance, performing "per-oral" (or, introduction into and through the upper GI tract via the oral cavity) push enteroscopy on a patient using a colonoscope that had been used previously on patients to perform "per-rectal" (or, introduction into and through the colon via the rectum) colonoscopy would seem to be, at the very least, a violation of hygienic standards. Whether the use of a colonoscope to perform both upper and lower GI procedures poses a risk of patient-to-patient disease transmission depends in large part on the effectiveness of the reprocessing procedure. Failure to properly reprocess the colonoscope after each procedure could result in this unconventional, if unseemly, practice transmitting bacteria from one patient's colon to another patient's oral cavity.

Moreover, Olestra<sup>®</sup>, a fat-based dietary substitute that has been anecdotally reported to coat the colon's lining and, in turn, the endoscope's insertion tube during colonoscopy, can be formidable to remove during reprocessing. (Some detergents claim to be chemically formulated to facilitate removal of Olestra from the endoscope's surfaces. Dawn<sup>®</sup> dishwashing detergent has been suggested to facilitate removal of Olestra from the endoscope during cleaning). There is understandable concern that GI endoscopes, contaminated and coated with Olestra not removed during cleaning and used to perform both upper and lower GI procedures, could transmit embedded and shielded bacteria and other types of microorganisms and viruses from one patient's colon to another patient's oral cavity, resulting in nosocomial infection. (Infection control and hygienic concerns would not apply to GI endoscopy units that perform endoscopic shuffling but that, instead of interchangeably using upper and lower GI endoscopes, mark or label, for example, a colonoscope or EGD endoscope exclusively for push enteroscopy or colonoscopy, respectively.)

**Patient expectations, the standard of care:** Although endoscopic shuffling is inconsistent with the labeling of GI endoscopes,<sup>8</sup> it is unclear whether this practice warrants disclosure to the patient. Some reports indicate that endoscopic shuffling—specifically, the use of a push enteroscope to perform colonoscopy—may improve clinical outcomes.<sup>5-7</sup> Other

reports indicate, however, that endoscopic shuffling—specifically, the use of a colonoscope to perform push enteroscopy—may increase the risk of false-negative results, misdiagnosis, and patient injury.<sup>4</sup> Nevertheless, whether endoscopic shuffling requires patient disclosure, due to real or perceived safety risks, seems less important than to clarify the patient's presumptions, understandings, and expectations. In general, patients undergoing GI endoscopy presume and trust that their GI endoscopist will provide optimal health care and will not compromise diagnostic yield. Implicit to this presumption is the patient's understanding that a GI endoscope labeled and intended for use, for example, in the lower GI tract would not be used to perform upper GI endoscopy. Patients certainly would not expect a colonoscope, used previously to perform colonoscopy, to be introduced into their oral cavity to perform push enteroscopy.

Assurances by a GI endoscopy unit that a colonoscope to be used for push enteroscopy was properly reprocessed after previous colonoscopy would not likely allay patients' concerns about fecal-oral disease transmission. Moreover, patients indicated for push enteroscopy might expect that if a GI endoscopy unit did not have access to a push enteroscope, the patients would be referred to, or offered the opportunity to seek treatment at, another GI endoscopy unit with a push enteroscope available and in inventory. It seems fair, if necessary, to ask whether two patients, both being evaluated for potential cancer of the proximal small bowel, receive the same standard of care if one of the patients undergoes push enteroscopy using a push enteroscope while, due to limited "equipment availability,"<sup>9</sup> a second patient instead undergoes push enteroscopy using a (shorter) colonoscope (Table 1). No doubt, this scenario appears to present a double standard of patient care, because reports suggest that for the second patient the potential exists for a reduced diagnostic yield, a compromised clinical outcome, and misdiagnosis.<sup>4</sup>

**Published reprocessing guidelines:** Although few, if any, directly address endoscopic shuffling, most endoscope-reprocessing and infection-control guidelines would appear to contraindicate using a GI endoscope to perform in sequence and on the same patient *both* an upper and lower GI procedure, without reprocessing the endoscope between the two procedures. Specifically, published guidelines, which are used to establish the standard of care and include a set endorsed by the *American Society for Gastrointestinal Endoscopy* (ASGE), recommend reprocessing the endoscope after completion of *each* procedure or use (*not* after each patient sitting, during which time more than one GI endoscopic procedure may be performed in sequence).<sup>10-12</sup> The reprocessing instructions, operator's manuals, and labeling supplied by the manufacturers of GI endoscopes provide similar recommendations, requiring that the endoscope be reprocessed after *each* procedure or use.<sup>13-16</sup> Compliance with these guidelines and manufacturers' instructions would presumably require that the GI endoscope be thoroughly reprocessed after completion of the first GI procedure, a requirement that is impractical due to the


prohibitive time required to reprocess an endoscope.

**Conclusion:** The merits and safety of endoscopic shuffling are questioned. Unless an improved clinical outcome can be expected, this practice is not recommended. The use of an upper, or lower, GI endoscope to perform a lower, or upper, GI procedure, respectively, violates the endoscope's labeling and intended use and, under some circumstances, may reduce diagnostic yield, increasing the risk of misdiagnosis and patient injury. Moreover, the interchangeable use of a GI endoscope to perform both upper and lower GI procedures, depending on patient demand and equipment availability, violates, at the very least, hygienic standards, if not the principles of infection control, posing a potential risk of fecal-oral disease transmission via an improperly reprocessed endoscope. No doubt, endoscopic shuffling is at odds with the patient's presumptions, understandings, and expectations and may pose a double standard of patient care dilemma.

Finally, the use of a GI endoscope to perform both an upper and lower GI procedure in sequence and on the same patient, without reprocessing the endoscope between the two procedures, is inconsistent with endoscope-reprocessing guidelines and manufacturers' instructions, which recommend reprocessing the endoscope after *each* procedure or use. Not to be overlooked, however, is the responsibility of the GI endoscopist to optimize patient care and diagnose and treat diseases of the upper and lower GI tracts using whichever "tools," or models of GI endoscopes, are available. • **LFM**  
☞ **To be continued ... Recommendations for health care facilities considering the practice of 'endoscopic shuffling' are provided next month.**

This article's references are available at:  
<http://www.myendosite.com/refs111205.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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