For IC Practitioners, OR, Endoscopy and Reprocessing Staff, Risk Managers, et al.

The Q-Net™ Monthly

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What's News

Q-Net would like to welcome several of its newest subscribers who include health care practitioners in Australia, Ecuador, Israel and Mexico.

Visit this newsletter's website for discussions in endoscopy, infection control, and instrument reprocessing. Past issues of *The Q-Net™ Monthly* can be downloaded at*:* **www.myendosite.com**. This website offers a powerful search engine that retrieves past issues of this newsletter that address a specific term or topic.

Editor-in-Chief

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What is 'Q-Net'?

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

Q-Net's main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and 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.

Dear *Los Angeles Times,*

*The following **editorial** responds to a recently published newspaper article that suggests colonoscopy poses a significant risk of infection.*

~ Editorial ~

Background: In its February 13, 2003, issue, the *Los Angeles Times* published an article that discussed the risk of disease transmission during colonoscopy,[1] a procedure that uses a colonoscope to exam and treat diseases of the colon (and rectum). Colonoscopes are long and narrow flexible fiber-optic or video endoscopes that feature several internal channels used, among other functions, to suction patient debris and to wash the colon's mucosa as required to enhance examination and visualization.

Additionally, colonoscopes and most other types of flexible endoscopes, such as bronchoscopes and gastroscopes, feature an internal instrument channel through which a biopsy forceps (or other accessory) can be passed to sample and remove for analysis a patient's potentially abnormal or diseased tissue.

What appears to have prompted the publication of this *Los Angeles Times* article was in part the issuance of a letter of concern written by the California Department of Health Services (CDHS) to over 1000 general acute care hospitals.[1-3] This letter, dated January 8, 2003, discusses the importance of properly cleaning and disinfecting flexible endoscopes after each use.[2] This letter also recommends that hospital administrative staff — in addition to developing and implementing policies and procedures to ensure that the facility's endoscope reprocessing practices are in accordance with the manufacturer's instructions — monitor the cleaning and (high-level) disinfection of endoscopes as part of the facility's quality assurance program.

The CDHS promptly issued this letter after it received reports from two hospitals that observed patient debris leaking from a colonoscope just prior to its use on a patient.[3] Reprocessing staff at these two hospitals apparently were unaware that certain models of colonoscopes feature an "auxiliary water" (or "forward water jet") channel that requires cleaning and disinfection. As a result, this channel, which had become contaminated during routine use, remained contaminated after reprocessing, posing a potential risk of disease transmission.[1-3]

Out of concern for the potential risk of cross-infection associated with improperly reprocessed endoscopes, these two hospitals contacted more than 3000 patients who had undergone colonoscopy and were deemed at risk.[1,3] These patients were advised to be evaluated to determine whether they might have been infected during colonoscopy with a potential pathogen, such as the hepatitis C virus (HCV). As of the May, 27,2003,

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none of these "at risk" patients had reported an infection[4] (a finding that ostensibly suggests the risk of disease transmission during colonoscopy is very low, the *Los Angeles Times* article's reporting notwithstanding).

Also concerned about patient safety at these two and other hospitals, an endoscope manufacturer mailed a safety notice, dated February 10, 2003, to an additional 2200 hospitals in the United States to remind users that, although rarely linked to cross-infection, a colonoscope can transmit disease if all of its channels, ports and connectors are not properly reprocessed after each use.[1,5] Emphasis in this manufacturer's safety notice was placed on the importance of cleaning and disinfecting *all* of the colonoscope's channels — including the auxiliary water jet channel of specific colonoscope models — even if the channel is not used during the procedure.[5]

Questionable reporting: Several salient issues were discussed in this *Los Angeles Times* article, including the importance of endoscope reprocessing to the prevention of cross-infection, and of colonoscopy as a crucial screening tool for colon cancer,[1] the second-leading cause of cancer-related deaths in the U.S.[6] Although tens of thousands of patients die each year in the U.S. from colon cancer, this disease has a high cure rate if detected early during a procedure such as colonoscopy.[7] Reports suggest that as many as 15 million procedures that use a flexible endoscope are performed each year in the U.S.[1,8] Of this number, it is estimated that approximately 10 million are gastrointestinal (GI) endoscopic procedures,[8] with 4.4 million being colonoscopy.[9]

➨ *Because colonoscopy is used so frequently to screen and treat patients for colorectal cancer and other bowel diseases, risks and complications associated with this procedure would have significant and far-reaching public health implications and consequences.*

Despite discussing the importance of endoscope reprocessing and colonoscopy, this *Los Angeles Times* article unfortunately presented a perspective arguably intended less to educate a concerned and vulnerable public than to incite its readership's understandable fear of disease. Some aspects of its reporting were questionable and not based on fact. For instance, this newspaper article discusses a recent case in which several patients who underwent GI endoscopy at a clinic in Brooklyn (NY) were infected with the HCV.[1,10] Although acknowledging that health officials "suspect" that the reuse of contaminated needles was responsible for this HCV outbreak, this *Los Angeles Times* article reported that "others say the clinic's failure to sterilize biopsy forceps or properly clean the scopes was the (sic) more likely the cause of the outbreak."[1]

This statement is confusing and misleading: Last year, in February (2002), a year before the publication of this *Los Angeles Times* article, the New York City Department of Health (NYCDH) concluded that "the endoscopy itself was not the source of the transmission" of the HCV.[11] As reported by *Newsday* in an article dated July 3, 2002, the NYCDH concluded last year that this HCV outbreak was a result of the violation of aseptic technique by the clinic's anesthesiologist — specifically, the reuse of needles and the contamination of multi-dose medicine vials with HCV during the administration of intravenous medications as had been required for patient comfort and sedation.[11,12] Further, there are no published reports in the medical literature that indicate anything other than the reuse of contaminated needles or another violation of aseptic technique was likely the cause of this HCV outbreak. Who these "others" are that reportedly claim a contaminated GI endoscope or biopsy forceps was more likely responsible for this outbreak is unclear and was not disclosed in the article.

Presumably as a consequence of this Brooklyn clinic's HCV outbreak and the questionable suggestion by "others" that its likely cause was improperly reprocessed endoscopes or biopsy forceps, this *Los Angeles Times* article reported that New York legislators had decided to study whether toughening the state's "disinfectant standards for endoscopes" might be warranted.[1] In truth, these legislators' sudden and piqued interest with the state's current standards for endoscope reprocessing probably has little if anything to do with this clinic's HCV outbreak. More likely the impetus for debate among these legislators is the publication of emotionally-laced newspaper and magazine articles intended to rouse hysteria (rather than allay fear),[1,13-15] as well as a conspicuous marketing effort to promote the application of various sterilization technologies to flexible endoscopy, notwithstanding the lack of data demonstrating not only that a flexible endoscope can be reliably sterilized using any method, but also that high-level disinfection poses an infection risk.[15,16]

Second, this *Los Angeles Times* article discusses an isolated and anecdotal report about a patient who claims to have been infected by a colonoscope contaminated with the human papilloma virus (HPV), an otherwise sexually-transmitted contagion.[1] Discussion of this case in this newspaper's article is inexplicable and suspect, since a review of the medical literature demonstrates that there are no published reports that document either this specific patient's case or any other case of the transmission of HPV during colonoscopy or any other GI endoscopic procedure.

With respect to other viruses of clinical concern, during the past ten years only a few reports document the likely transmission of HCV via a contaminated GI endoscope,[17-20] and none was reported in the U.S. Whereas transmission of the hepatitis B virus (HBV) during GI endoscopy is rarely reported,[11,21] there are no reports that document infection of a patient with the feared HIV during GI endoscopy. This very low number of cases of transmission of these viruses suggests the risk of being infected by a GI endoscope contaminated with HBV, HCV, HIV, or HPV is extremely remote. The risk of infection by a contaminated GI endoscope has been

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reported to be one in 1.8 million.[1,8,17] A recent study indicates that this risk is approximately one in 3 million.[11]

Although the risk of infection during GI endoscopy is very low, it can be reduced even further, and the transmission of all pathogens including HCV prevented, by ensuring that endoscopes are reprocessed in strict accordance with the manufacturer's recommendations and published guidelines.[11,17,22-25]

➨ *Every documented case of patient infection linked to a contaminated endoscope reports as its cause a breach in endoscope reprocessing protocol, such as: inadequate cleaning, improper disinfection, or insufficient drying of the endoscope; a defective or recalled device; or failure to sterilize the biopsy forceps.*[22,23]

Data indicate that published endoscope reprocessing standards and guidelines are adequate, effective and prevent the transmission of all pathogenic microorganisms and viruses that may be encountered in the endoscopic setting.[11,16,17,25-30]

Moreover, during the past few years, the majority of the published reports that document disease transmission during flexible endoscopy has been linked to contaminated bronchoscopes — not colonoscopes or other GI endoscopes as the *Los Angeles Times* article implies by its sheer focused attention. And several of these published reports identify bronchoscopes contaminated with *Pseudomonas aeruginosa* and other waterborne bacteria as the cause of the infections and outbreaks. Transmission of these exogenous microorganisms during flexible endoscopy often indicates — not inadequate cleaning or improper disinfection — but rather re-contamination of the endoscope during rinsing (after chemical immersion) with water that contains bacteria, followed by insufficient drying of the endoscope's channels *(refer to the October-November and December 2002 issues of this newsletter).*[31-42] Failure to thoroughly dry the endoscope after reprocessing using a liquid chemical sterilant can result in disease transmission.[43]

Approximately 500,000 bronchoscopies are performed each year in the U.S.[8,31] This number (the denominator) is a small percentage (11%) of the number of colonoscopies performed (i.e., 4.4 million). Because more cases of infections (the numerator) linked to contaminated bronchoscopes have been reported during the past several years than infections linked to contaminated GI endoscopes,[11,31-40] it would appear that the risk of infection associated with bronchoscopy may be significantly higher than GI endoscopy.

Several factors may contribute to this not-too-surprising finding. First, the lower respiratory tract is ordinarily pristine, and the introduction of bacteria inimical to its health and general condition. In contrast, the GI tract in its normal and healthy state is contaminated with large numbers of many different varieties and species of innocuous bacteria, known as bacterial flora. Introduction of bacteria into the GI tract may therefore not always result in infection. Second, a large percentage of bronchoscopic procedures is performed on hospitalized and critically ill patients. Because the immune systems of these patients are often severely compromised, introduction of even a small number of bacteria can have catastrophic consequences. GI endoscopy, on the other hand, is routinely performed on an out-patient basis to screen otherwise healthy patients whose intact immune systems are well-equipped to combat and destroy invading microbes.

➨ *By not providing its readers with a meaningful and clinically significant exposé that could have focused on recent investigations and reports of nosocomial outbreaks caused by contaminated bronchoscopes,*[33,36-38] *this* Los Angeles Times *article missed its mark, choosing instead to center its misdirected crosshairs on colonoscopes and other GI endoscopes, despite these instruments being very rarely linked to disease transmission.*[11]

(Failing again to capitalize on an important opportunity fraught with significant public health implications and lessons, this *Los Angeles Times* article makes no reference to a 1999 report, documented in the Food and Drug Administration's MAUDE database and investigated by the CDHS, that describes a *P aeruginosa* outbreak that resulted in multiple patient injuries and four patient deaths.[36,37] This outbreak, remarkably similar to two other outbreaks reported in Flushing, NY,[33] and Pittsburgh, PA,[38] was linked to inadequately dried bronchoscopes contaminated with *P aeruginosa* after automated reprocessing. And, ironically, this outbreak occurred at a hospital located in Los Angeles, CA, this newspaper's hometown.[36] Although it involved multiple injuries and deaths, neither the Centers for Disease Control and Prevention (CDC) nor the FDA investigated, reported on, or publicly discussed this Los Angeles hospital's outbreak.)

Third, although it correctly stated that as a result of identifying a bacterial outbreak last year a hospital in Baltimore (MD) warned several hundred patients who had undergone bronchoscopy of their potential exposure to *P aeruginosa*,[39,40] this *Los Angeles Times* article implies that this outbreak (and the other outbreaks it discussed) was, among other causes, a result of inherent problems with the current designs of bronchoscopes and other flexible endoscopes. According to this newspaper article, an endoscope manufacturer reportedly has been aware of these design problems for years but has refused to fix any of them, choosing instead "to bury its head in the sand."[1] In truth, the *P aeruginosa* outbreak at this Baltimore hospital was caused — not by an ignored inherent limitation in the design of flexible endoscopes — but by an incidental and unanticipated flaw in the manufacturing of the biopsy port channel housing of several bronchoscope models that were subsequently recalled.[39,40]

In addition, there are no published data to suggest that: (1) current endoscope reprocessing guidelines are inadequate;[42] (2) high-level disinfection poses an infection risk in endoscopy;[16] or (3) this *P aeruginosa* outbreak in Baltimore

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(or any of the newspaper article's other reported outbreaks) was, as implied by the *Los Angeles Times*, a consequence of health care staff who, while keeping from the public a "dirty little secret" and employing a "McDonald's-style" mentality simply "to serve more clients," knowingly and intentionally provide inferior patient care.[1]

And, finally, this *Los Angeles Times* article reports that there are some current endoscopes on the U.S. market that feature internal channels that "cannot be disinfected" or presumably cleaned.[1] It is unclear the specific endoscope models or types to which this article is referring. Discussions with two leading endoscope manufacturers indicate that there are no endoscope models currently on the market that contain internal channels that can become contaminated with patient debris during a procedure, but that cannot be adequately cleaned and disinfected using a detergent and a liquid chemical sterilant (or high-level disinfectant).

Summary and conclusions: Although at times belied by this *Los Angeles Times* article's focus on reports of disease transmission during colonoscopy, only thirty-five cases of likely or possible infection caused by a contaminated GI endoscope have been reported over the last ten years, despite approximately 10 million GI endoscopic procedures being performed each year.[8,11,15,17] Of these thirty-five reported cases of infection following GI endoscopy, disease transmission was suspected or confirmed during colonoscopy in only five cases,[11] yielding a risk of approximately one infection for every 9 million colonoscopies. To be sure, the benefits to public health gained by undergoing colonoscopy for the screening and early detection of potentially malignant tissues far outweigh this very low risk of infection, a conclusion that could have been but was not adequately reported or conveyed in this *Los Angeles Times* article.

Moreover, whereas only five cases of infection suspected or confirmed to be caused by contaminated colonoscopes were reported over the last decade, during this same period of time a significantly higher number of cases of nosocomial infection and colonization likely or possibly due to contaminated bronchoscopes was reported,[8,31-40] a finding that suggests bronchoscopy may pose a significantly higher risk of infection than colonoscopy and other GI endoscopic procedures. The reported higher number of infections following bronchoscopy compared to colonoscopy is even more significant when it is realized that the number of bronchoscopies performed per year (500,000 in the U.S.) is but a small percentage (11%) of the number of colonoscopies performed per year (4,400,000 in the U.S.).

As a result of this finding, newspaper articles and other media reports that discuss the risk of infections associated with flexible endoscopes might serve the public better, and both more effectively and earnestly, if each were to focus attention, not on infections potentially related to colonoscopy, but rather on infections linked to contaminated bronchoscopes, which appear to be more frequently reported. It is also recommended that these media reports discuss the importance of simple and inexpensive precautionary measures — such as terminally drying the endoscope's internal channels using a 70% alcohol rinse followed by forced air — whose effectiveness to the prevention of the transmission of bacteria during endoscopy is well documented .[11,41]

Important to note, each reported case of disease transmission during bronchoscopy and GI endoscopy identified as its cause a breach in established instrument reprocessing guidelines and recommended practices.[11,18-21] Published endoscope reprocessing guidelines for years have been shown to prevent disease transmission during flexible endoscopy,[11,42,43] provided reprocessing staff strictly adhere to the guidelines' recommended steps, which include cleaning, high-level disinfection, and drying of the endoscope after each use. Finally, although an otherwise reputable news source, the *Los Angeles Times* was remiss in its failure to disclose that at least one of the researchers interviewed for its article and presented as an objective contributor has been financially associated with sterilization technologies discussed in the article.[13,44]

To be continued next month ...

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, PhD.* Please direct all correspondence to:

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The references to this article are available at:
http://www.myendosite.com/refs05603.htm

Next month's issue of this newsletter will provide several infection control recommendations. These recommendations, which are applicable to both bronchoscopy and GI endoscopy, are presented in the context of this double issue's discussion.