provider. If neither of those, then whom do they benefit?

The fact of the matter is that our healthcare delivery system simply can no longer afford the luxury of using some things once and then throwing them away. That having been said, rather than a requiem and wake for the reuse of SUDs in hospitals as Dr. Favero suggested, perhaps the requiem and wake should be held for what appears to be the unjustified FDA reprocessing regulations.

REFERENCES

1. Favero MS. Requiem for reuse of single-use devices in US hospitals. *Infect Control Hosp Epidemiol* 2001;22:539-541.
2. Food and Drug Administration. Reusing medical devices: ensuring safety the second time around. *FDA Consumer Magazine* 2000; 34:7.
3. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health. *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.* Rockville, MD: U.S. Department of Health and Human Services; 2000.
4. GAO report sheds light on reuse. *Materials Management in Healthcare* 2000;9:9.
5. Money crunch: one-third of U.S. hospitals face financial ruin. *Health Facilities Management* 2000;13:8.
6. Shields T. British appear to reprocess fewer SUDs than U.S. *Healthcare Purchasing News* 2002;26:24.

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The author declines to reply.

Leading a Horse to Water: Are Crucial Lessons in Endoscopy and Outbreak Investigations Being Learned?

To the Editor:

In 1999, the Centers for Disease Control and Prevention (CDC) reported an outbreak of *Pseudomonas aerguinosa* that occurred in 1998 in a hospital in Flushing, New York.[1] This outbreak, referred to as cluster 3, was investigated by officials from the New York State Department of Health, the CDC, and the Food and Drug Administration (FDA). Eighteen infections and 1 death were reported.[1,2] This cluster 3 outbreak was discussed in greater detail by Sorin et al.[2] and Weber et al.[3] in the July 2001 issue of *Infection Control and Hospital Epidemiology*. Sorin et al.[2] agreed with the CDC that improper connection of both Olympus (Olympus America, Inc., Melville, NY) and Pentax (Pentax Precision Instrument Corp., Orangeburg, NY) bronchoscopes to a specific automated endoscope reprocessor (AER) model was primarily responsible for this *P. aeruginosa* outbreak. The editorial by Weber et al.[3] discussed in part lessons that may have been learned from this and other outbreak investigations.

Several questions and unresolved issues remain after reviewing these two articles. If, as Sorin et al.[2] concluded, this cluster 3 outbreak was due at least in part to hospital personnel improperly connecting bronchoscopes to the AER, what does this reprocessing mishap portend for gastrointestinal endoscopes? Because they are more difficult to clean and have many more internal and complex channels and connectors, gastrointestinal endoscopes would then seem to be even more susceptible to improper connection to an AER, and therefore to patient infection, than bronchoscopes, the simplest flexible endoscopes to reprocess. If true, the implications of Sorin et al.'s conclusion are far-reaching and clinically significant.

In short, Sorin et al. concluded that, due to "faulty connections" of the AER to the bronchoscope, "inadequate" flow of the AER's peracetic acid sterilant through the bronchoscope's instrument channel resulted in "incomplete sterilization," which contributed to, if not caused, the cluster 3 outbreak.[2] Although their conclusion may have merit, the authors did not publish the flow and pressure data necessary to support it. Moreover, although faulty connections between any AER and endoscope can no doubt raise serious infection control concerns, the authors' conclusion requires that the bronchoscopes remained contaminated with *P. aeruginosa* despite being repeatedly (1) precleaned manually with a brush and detergent solution (the authors noted that the bronchoscope's suction valve was also thoroughly cleaned); (2) completely immersed in a liquid sterilant (although possibly being connected improperly to the AER); (3) rinsed with 70% alcohol followed by purging with forced air; and (4) hung vertically to dry in a dedicated storage cabinet. Although this conclusion is plausible, human error is unlikely to have been solely responsible. Reports have demonstrated for years that *P. aeruginosa* infection is rare when the endoscope's channels are thoroughly dried using 70% alcohol.[4,5] These reports suggest that some other factors possibly unrelated to connecting the bronchoscope to the AER may have contributed to this cluster 3 outbreak.[5]

The well-recognized contribution of the environment to *P. aeruginosa* outbreaks raises several questions. What was the source of the *P. aeruginosa*? To what extent might the environment have contributed to this outbreak? During the investigations of the cluster 3 outbreak,[1,2] was the filtered rinse water (0.2 μm rated) sampled microbiologically? And if so, was it immediately tested for *P. aeruginosa*? In general, epidemiologic investigations of similar types of outbreaks routinely sample the environment[6] and relevant water sites to identify the outbreak's source. Indeed, several reports have linked contaminated water supplies to nosocomial infections.[7-9] One report linked contaminated filtered rinse water to an outbreak following gastrointestinal endoscopy.[9]

It is unclear whether Sorin et al. or the CDC's investigators sampled the filtered rinse water microbiologically for *P. aeruginosa*, as these data were not published.[1,2] Sampling the AER and its filtered rinse water, among other sites, is crucial to investigating and identifying the source of this cluster 3 (or any other) outbreak. In one scenario, if the filtered rinse water was not sampled, then it cannot be ruled out as a possible source of the cluster 3 outbreak. As a consequence, the conclusion that improper connection of the AER to bronchoscopes was primarily to blame for the *P. aeruginosa* outbreak may be incomplete.[5]

In another scenario, as pointed out previously by Muscarella,[5] if the filtered rinse water, which by the AER's design contacts the endoscope *after* chemical immersion, was sampled and found to be contaminated with *P. aeruginosa*, then the bronchoscope could have been recontaminated by the rinse water prior to bronchoscopy and the outbreak might

have occurred even if the bronchoscope had been properly connected to the AER. The clinical significance of this scenario warrants underscoring the importance of sampling the filtered rinse water and publishing the results.

Despite the prior publication of a relevant article by Muscarella that discussed this cluster 3 outbreak,[5] neither Sorin et al.[2] nor Weber et al.[3] referenced this article or discussed the possibility that the AER's filtered rinse water could potentially have been a source of the cluster 3 outbreak. Nevertheless, Sorin et al.[2] lend credence to Muscarella's[5] suggestion that, based on the data presented in the CDC report,[1] the filtered rinse water (or another environmental site) could have been a source of the cluster 3 outbreak. Sorin et al.[2] acknowledged that *P. aeruginosa* is an environmental microorganism and patient-to-patient transmission of this waterborne, gram-negative microorganism was not identified during their investigation (nor was the source of the outbreak identified). Without having identified an index patient or a route for disease transmission, the potential exists for the environment to be a source of the outbreak.

Noteworthy, Sorin et al.[2] and Weber et al.[3] describe an AER labeled for endoscope "sterilization" at times as a device that achieves instead endoscope "disinfection." Although the infection rates associated with sterilization and disinfection of flexible (and rigid) endoscopes are reported to be clinically indistinguishable,[10] the view that this specific AER model is both a sterilizer and a disinfector can be confusing, particularly to operating room and endoscopy personnel. Whether Sorin et al. and Weber et al. are suggesting that this AER achieves disinfection despite its label's sterilization claim—a suggestion that may have been intended and valid[11]—is unclear. Of concern, an AER labeled for sterilization dissuades (if not prevents, per standard aseptic protocol) users from terminally rinsing the endoscope's channels with 70% alcohol,[4] an agent that facilitates drying but is generally unsterile. As a result, such a label claim may paradoxically increase the risk of patient infection.[11] On the other hand, AERs labeled for disinfection routinely and universally recommend this drying step, because it is vital to the prevention of bacterial colonization and patient infection.[4,5,11-13]

In accordance with Muscarella's suggestion that the environment may have played a role in the cluster 3 outbreak,[5] the FDA appears to have recently considered the rinse water as a possible contributor to patient infection. On April 23, 2001, the FDA wrote a letter to an AER manufacturer that read, in part, "We [the FDA have] concerns pertaining to continued reports of patient infections . . . associated with [a specific AER model]. Review of the various reports submitted to [the] FDA indicates that the infections are usually caused by waterborne organisms. The association of [your AER] with patient infections usually caused by waterborne organisms leads us to question the ability of [your AER] to provide a sterile water rinse (using a 0.2 micron filter). . . ." This cluster 3 outbreak and several other unpublished reports of injuries linked to *P. aeruginosa*, bronchoscopy, and an AER may have contributed to the writing of this letter. The extent to which this letter affects the label claims and applications of future AERs that use a liquid chemical sterilant for reprocessing endoscopes is unclear.

Several important lessons and considerations can be learned from this cluster 3 outbreak investigation. Investigations of *P. aeruginosa* and other gram-negative bacteria (and mycobacteria) outbreaks associated with endoscope reprocessing should always include sampling the rinse water. Irrespective of an AER's claim, the FDA is encouraged to label all current models to require that the endoscope's channels be rinsed with 70% alcohol (to facilitate drying) followed by forced-air drying to prevent patient infection.[4-6,9,11-13] Bacterial colonization during overnight storage has been linked to patient infection and death.[7,9,12] To be clear, no cases of patient infection have been reported when the endoscope was precleaned, disinfected, dried, and properly stored in accordance with published guidelines.[14]

Further, the FDA is encouraged to consider whether the application of liquid chemical sterilants for the "sterilization" of instruments, particularly in the operating room setting, may be contrary to accepted standards.[11] Claims that the process may instead be "100% sporicidal" may be more appropriate. Future research to demonstrate the specific claims and effectiveness of all types of AERs is recommended, as is the suggestion not to use interchangeably the terms "sterilization" and "disinfection" to describe the effectiveness of a specific AER or other process. Also recommended is monitoring the rinse water used during endoscope reprocessing to ensure it is not contaminated with gram-negative bacteria or mycobacteria.[15,16] The final water rinse's quality is part and parcel of an AER's claim. If the rinse water is not monitored to confirm that it is at least bacteria free, then the AER's claim arguably cannot be supported. Finally, more frequent training of personnel on how to connect AERs properly to each channel of different endoscope models is clearly warranted.[1,2]

REFERENCES

1. Centers for Disease Control and Prevention (CDC). Bronchoscopy-related infections and pseudoinfections: New York, 1996 and 1998. *MMWR* 1999;48:557-560.
2. Sorin M, Segal-Maurer S, Mariano N, et al. Nosocomial transmission of imipenem-resistant *Pseudomonas aeruginosa* following bronchoscopy associated with improper connection to the STERIS SYSTEM 1 processor. *Infect Control Hosp Epidemiol* 2001;22:409-413.
3. Weber DJ, Rutala WA. Lessons from outbreaks associated with bronchoscopy. *Infect Control Hosp Epidemiol* 2001;22:403-408.
4. Muscarella LF. Current instrument reprocessing practices: results of a national survey. *Gastroenterol Nurs* 2001;24:253-260.
5. Muscarella LF. Déjà vu . . . all over again? The importance of instrument drying. *Infect Control Hosp Epidemiol* 2000;21:628-629.
6. Kressel AB, Kidd F. Pseudo-outbreak of *Mycobacterium chelonae* and *Methylobacterium mesophilicum* caused by contamination of an automated endoscopy washer. *Infect Control Hosp Epidemiol* 2001;22:414-418.
7. Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Intern Med* 1993;118:117-128.
8. Rutala WA, Weber DJ. Water as a reservoir of nosocomial pathogens. *Infect Control Hosp Epidemiol* 1997;18:609-616.
9. Streulens MJ, Rost F, Deplano A, et al. *Pseudomonas aeruginosa* and Enterobacteriaceae bacteremia after biliary endoscopy: an outbreak investigation using DNA macrorestriction analysis. *Am J Med* 1993;95:489-498.
10. Muscarella LF. High-level disinfection or "sterilization" of endoscopes? *Infect Control Hosp Epidemiol* 1996;17:183-187.
11. Muscarella LF. Anticipated reliability of liquid chemical sterilants. *Am J Infect Control* 1998;26:155-156.
12. Allen JI, Allen MO, Olson MM, et al. *Pseudomonas* infection of the biliary system resulting from use of a contaminated endoscope. *Gastroenterology* 1987;92:759-763.

13. Muscarella LF. Disinfecting endoscopes immediately before the first patient of the day. *AORN J* 2001;73:1159-1163.
14. Muscarella LF. Automatic flexible endoscope reprocessors. *Gastrointest Endosc Clin N Am* 2000;10:245-257.
15. Muscarella LF. Limited surveillance in the endoscopic setting: has its time arrived? *Am J Infect Control* 2002;30:66-67.
16. Muscarella LF. Application of environmental sampling to flexible endoscope reprocessing: the importance of monitoring the rinse water. *Infect Control Hosp Epidemiol* 2002; 23:285-289.

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The authors reply.

In reading Dr. Muscarella's comments, we identified several points for response, corrections, or both. We did not report 18 patient infections, but rather 18 patients with imipenem-resistant *Pseudomonas aeruginosa* (IRPA) isolates from bronchoscopic lavage specimens. Only 3 of 18 had clinical and radiographic evidence of infection requiring specific anti-*Pseudomonas* therapy. One of 3 patients died 9 days following bronchoscopy.[1]

In the "Microbiology" and "Environmental Cultures" sections, we reported that multiple cultures from the water supply (including rinse water) and multiple STERIS (STERIS Corp., Mentor, OH) sites were negative for IRPA.[1] Foremost, Dr. Muscarella fails to recognize an important infection control principle regarding antibiotic-resistant *P. aeruginosa*. It is widely recognized that such antibiotic-resistant organisms are not found in the general water supply (and thus distinguished from the usual *P. aeruginosa* found in tap water). IRPA is an organism exclusively associated with the presence of nosocomial infection or colonization.[2] There are numerous reports in the literature of *P. aeruginosa* in the water supply leading to contamination or infection.[1] These are all antibiotic-susceptible strains. The author needs to substantiate scientifically his implication that IRPA may be found in the general water supply.

Flow studies were not performed. We based our conclusions on finding faulty connections for bronchoscopes to the STERIS automatic endoscope reprocessor; finding a nosocomial organism in bronchoscopic lavage specimens of noninfected outpatients; and finding that IRPA was not present in bronchoscopic lavage specimens prior to institution of STERIS or following correction of faulty connections. We did not change manual processing of our bronchoscopes or alcohol flush following the automatic endoscope reprocessor and could not explain the outbreak on this basis.

Although we have read Dr. Muscarella's publications, we limited our reference list in the interest of brevity. We apologize if we appeared to have overlooked Dr. Muscarella in not citing more than one of his articles.

Finally, we cannot comment on U.S. Food and Drug Administration (FDA) product labeling based on only our experience. Subsequent to our outbreak, we continue to use STERIS automatic endoscope reprocessors without further incident. We continue to perform frequent microbiologic surveillance of all of our bronchoscopes and have found no recurrence of processing failure. Our endoscopy personnel are vigilant when dealing with connection devices and all new personnel receive extensive education. We continue to adhere to recommendations of the FDA and the Centers for Disease Control and Prevention by following endoscope manufacturer instructions, resolving conflicts between endoscope manufacturer and automatic endoscope reprocessor recommendations, and providing intensive education to all involved in using the automatic endoscope reprocessor.[3,4]

REFERENCES

1. Sorin M, Segal-Maurer S, Mariano N, Urban C, Combest A, Rahal JJ. Nosocomial transmission of imipenem-resistant *Pseudomonas aeruginosa* following bronchoscopy associated with improper connection to the STERIS SYSTEM 1 processor. *Infect Control Hosp Epidemiol* 2001;22:409-413.
2. Harris DA, Smith D, Johnson JA, Bradham DD, Roghmann MC. Risk factors for imipenem-resistant *Pseudomonas aeruginosa* among hospitalized patients. *Clin Infect Dis* 2002;34:340-345.
3. Centers for Disease Control and Prevention. Bronchoscopy-related infections and pseudo-infections: New York, 1996 and 1998. *MMWR* 1999;48:557-560.
4. Feigal DW Jr, Hughes JM. *Infections From Endoscopes Inadequately Reprocessed by an Automated Endoscope Reprocessing System.* FDA and CDC Public Health Advisory. Washington, DC: Department of Health and Human Services; September 10, 1999. Available at www.fda.gov/cdrh/safety/endoreprocess.pdf.

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