Commentary

Re-evaluating endoscopy-associated infection risk estimates and their implications

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According to the Centers for Disease Control and Prevention (CDC), approximately 11 million gastrointestinal endoscopies are performed annually in the United States. The 2008 CDC/Healthcare Infection Control Practices Advisory Committee (HICPAC) Guideline for Disinfection and Sterilization in Healthcare Facilities states that contaminated endoscopes have been linked to more health care-associated infections than any other medical device. Paradoxically, several guideline-issuing organizations assert that the risk of endoscopy-associated infection (EAI) is only 1 in 1.8 million procedures.

Recent audits have documented widespread lapses in infection control involving medical equipment. Inspections of multiple facilities determined that certain endoscope equipment was not properly reprocessed for up to several years. Direct observation in a multisite study revealed that endoscopes were virtually never reprocessed in accordance with guidelines. The implications of these lapses are unknown because no epidemiologic studies have determined the risk of EAI associated with reprocessing quality.

Research was conducted to evaluate the origins and accuracy of the risk estimates after a single outbreak involved more cases of EAI than would be expected in 1 year nationwide. This article describes the methodology used to estimate risk and discusses the patient safety implications of relying on the statistics appearing in guidelines.

EVALUATING THE ORIGINS OF CURRENT EAI RISK ESTIMATES

How risk was calculated

The EAI risk estimate of “1 in 1.8 million procedures” first appeared in a 1993 Technology Assessment Position Paper by the American Society for Gastrointestinal Endoscopy (ASGE). ASGE authors calculated risk by dividing a subset of EAsIs (28) in the United States from 1988 to 1992 reported in 1 review article by an estimated number of gastrointestinal endoscopies performed during that time (40 million). This estimate is erroneous in part because of mathematical errors (28 cases in 40 million procedures represents a risk of 1 in 1.4 million procedures). There were also substantially more transmission events documented in the review than selected by the ASGE authors (145 rather than 28). When all 145 cases are used, the risk estimate is 1 in 276,000—a 6-fold increase over the stated risk.

In terms of the denominator for this calculation, there are large discrepancies in the reported number of procedures performed in the United States. For example, ASGE asserts that 34 million gastrointestinal endoscopies are done annually, compared with 20 million stated in the 2011 Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes. 11 million estimated using CDC data, and 5 million reported in the CDC/HICPAC Guideline. Recent government data suggest that 11 million to 22 million procedures are performed annually. Dividing minimal numbers of published case reports by high procedural volumes results in very low EAI risk estimates that are neither reliable nor representative of actual infection risk.

Problems inherent in relying on published case reports

Recently, ASGE cited a 2006 article that used the same methodology to estimate an EAI risk of 1 in 10 million procedures (35 EAsIs in 340 million procedures). Although the newer risk estimate suggests a considerable decrease in EAsIs since the first estimate was published in 1993, this method of estimating risk is highly prone to reporting bias. This estimate likely exemplifies decreasing numbers of published case reports rather than actual reduction in risk. As an analogy, if case reports published in peer-reviewed journals were used to determine risk of penicillin-resistant Staphylococcus aureus infection during the last decade, the risk would be almost zero. S. aureus was universally penicillin susceptible until the 1950s, when case reports of penicillin-resistant S. aureus were first published. By the 1970s, penicillin-resistant S. aureus was so prevalent that it was considered commonplace, and case reports were rarely published.
At present, there is no incentive for practitioners to report EAs or other adverse events. A recent study found that complications associated with outpatient endoscopy were rarely reported by physicians. The authors of the original review cited by ASGE stated that the cases included in their paper probably represented only a small fraction of actual EAs because reported incidents frequently involved large outbreaks or unusual clusters of cases, and most were due to bacterial infections that were easy to recognize and had brief incubation periods. Because of the substantial reporting bias, using published case reports to calculate EA risk is not methodologically sound.

REPROCESSING LAPSES AND ASSOCIATED OUTCOMES

Discordance between stated EAI risks and observed complications

Nearly all EAs have resulted from failure to adequately clean and disinfect endoscopes. Recent reports indicate reprocessing lapses are ongoing and widespread. Although outcomes of reprocessing lapses have been described on a case-by-case basis, to our knowledge no epidemiologic data exist. However, 3 recent studies have examined postendoscopy complications, with incidence rates ranging from 0.5% to 3.4%. Complications included fever, diarrhea, abdominal pain, and other signs and symptoms that may indicate infection. These findings suggest that the risk of EAI may be substantially higher than current estimates. Furthermore, it is reasonable to assume that the infection risk is greater when lapses occur than when there is rigorous adherence to reprocessing protocols. For example, contaminated duodenoscopes have been associated with outbreaks of multiple microorganisms, including Klebsiella pneumoniae carbapenemase-producing organisms, with multidrug-resistant organism (MDRO) attack rates ranging from 8% to 41% of exposed patients.

Improper focus on bloodborne virus transmission

When reprocessing lapses are documented, patients are often told there is little to no risk and no need for testing or follow-up. In rare instances when exposed patients are tested for infections, institutions typically choose to test only for viral infections, such as HIV and hepatitis B and C, which are unlikely to be transmitted by an endoscope. The focus on viral transmission is improper because these viruses are less prevalent in the population, and shorter survival times outside the body, and are easier to kill with standard disinfectants than bacterial pathogens, such as Clostridium difficile. Endoscopes are exposed to very high numbers of enteric microbes during each procedure, and Alfa et al found viable bacteria or fungi on 14% of patient-ready endoscopes.

Transmission and subsequent colonization with MDROs and other enteric pathogens through a fecally contaminated endoscope have not been assessed. Most MDROs become colonizers in the gastrointestinal tract before causing infection elsewhere in the body. As such, transmission and subsequent colonization are clinically unapparent but of high consequence. Because the gastrointestinal tract is a reservoir for pathogens, transmission of MDROs between patients through a contaminated endoscope is not only feasible but potentially quite common depending on the colonization status of prior endoscopy patients, the quality of reprocessing, and the degree of disruption of normal flora caused by pre-endoscopy bowel preparation. The frequency of MDRO colonization following endoscopy needs to be studied to accurately evaluate risk and reframe the clinical consequences of improperly reprocessed endoscopes.

CONCLUSION

Evidence indicates that current EAI risk estimates are inaccurate, outdated, based on flawed methodology, and can have profound effects on patients. These extremely low risk estimates are used to justify the lack of reporting, routine monitoring, patient notification, and laboratory testing following a lapse. In 1993, researchers recommended prospective studies involving both patient monitoring and laboratory cultures be conducted to evaluate the risk of transmitting infections via contaminated endoscopes. Today, there remains a need for epidemiologic studies to accurately estimate the risk of EAI and other complications. Prospective studies should involve observation of reprocessing practices, microbial testing, and outcomes assessment. The results could be used to develop criteria for patient notification and reporting of reprocessing lapses and assist decision makers in determining what actions to take when a lapse occurs.

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