

## Reprocessing failure

*This is one of a series of statements discussing the use of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) prepared this text. In preparing this guideline, a search of the medical literature was performed by PubMed, supplemented by accessing the "related articles" feature of PubMed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice. The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence (Table 1).<sup>1</sup>*

*This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient's condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines.*

The risk of transmission of infection during GI endoscopy is estimated at 1 case per 1.8 million procedures.<sup>2</sup> The ASGE published a national multisociety guideline in 2003 for the cleaning and high-level disinfection of GI endoscopes.<sup>3</sup> There are no reported cases of transmission of infection when these guidelines have been followed. In the absence of defective equipment, the reported cases of transmission of infection appear to have resulted from

failure to adhere to currently accepted guidelines for the high-level disinfection of endoscopes.

Where breaches in high-level disinfection protocols have occurred, the risk of transmission of bacterial and viral infections is increased, although this will vary with the severity of the reprocessing failure and the prevalence of these infections in the given population. These reprocessing failures have most often been discovered incidentally, usually after a number of patients have undergone endoscopy with potentially contaminated instruments. Although a failure to appropriately reprocess endoscopic instruments is not acceptable, it is important to realize that even when reprocessing is incomplete, transmission of infection is not inevitable. This is due to the efficacy of the gut immune system and the fact that the improperly processed endoscopes may not be contaminated with pathogenic organisms.

In instances where a breach in the disinfection protocol has been determined to pose a negligible patient risk, affected institutions have had to weigh the ethical issues of patients' right to know against the possibility of causing unnecessary patient distress in a situation where the risk of infection may be very small. There is also the concern that adverse publicity associated with the reporting of a reprocessing outbreak might lead patients to avoid potentially life-saving endoscopic procedures because of an unwarranted fear of infection. This in turn could have deleterious health consequences for the community at large because many significant life- and health-threatening conditions may remain undiagnosed and untreated.

When patients are notified of a reprocessing breach, they are usually advised to have some form of serologic evaluation for blood-borne pathogens. A confounding factor is that, although around 1.6% of the U.S. population has been infected with the hepatitis C virus, only 5% to 50% of infected individuals are aware of their infection.<sup>4,5</sup> Thus, in the setting of a reprocessing failure in which baseline serologic studies for blood-borne pathogens are performed on a large population of individuals, there is a significant chance of uncovering preexisting but previously undiagnosed cases of chronic viral infection. These patients may erroneously conclude that they were infected as a result of the reprocessing breach. Transmission can be attributed to the endoscopic procedure with a greater certainty when an exposed patient who has negative serology results at initial testing demonstrates subsequent seroconversion.

**TABLE 1. Grades of recommendation\***

| Grade of recommendation | Clarity of benefit | Methodologic strength/supporting evidence  | Implications  |
|-------------------------|--------------------|--|---|
| 1A                      | Clear              | Randomized trials without important limitations  | Strong recommendation; can be applied to most clinical settings   |
| 1B                      | Clear              | Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws) | Strong recommendation; likely to apply to most practice settings  |
| 1C +                    | Clear              | Overwhelming evidence from observational studies   | Strong recommendation; can apply to most practice settings in most situations   |
| 1C                      | Clear              | Observational studies  | Intermediate-strength recommendation; may change when stronger evidence is available                                    |
| 2A                      | Unclear            | Randomized trials without important limitations  | Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values |
| 2B                      | Unclear            | Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws) | Weak recommendation; alternative approaches may be better under some circumstances                                      |
| 2C                      | Unclear            | Observational studies  | Very weak recommendation; alternative approaches likely to be better under some circumstances                           |
| 3                       | Unclear            | Expert opinion only  | Weak recommendation; likely to change as data become available  |

*Adapted from* Guyatt G, Sinclair J, Cook D, et al. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, editors. *Users' guides to the medical literature*. Chicago: AMA Press; 2002. pp. 599-608.

The ASGE recognizes that the risk of transmission of infection through endoscopy is extremely low and also recognizes the difficulties that institutions face with the previously mentioned ethical issues. However, the ASGE believes that institutions have an ethical obligation to inform affected patients in a timely manner when a significant breach in reprocessing is discovered. Prompt notification allows patients to take precautions to minimize the risk of transmitting infection to others and allows for early serologic testing. This may help distinguish chronic infections from those potentially acquired at the time of endoscopy and to permit earlier initiation of treatment for newly acquired infections.

### **RECOMMENDATIONS (LEVEL OF EVIDENCE GRADE 3 FOR ALL)**

1. When a breach of the high-level disinfection protocol is discovered, it should be reported to the institution's designated infection control personnel, local/state public health agencies, the Food and Drug Administration, the Centers for Disease Control and Prevention, and the manufacturers of the involved equipment.
2. Patients at risk should be notified directly of the breach in a timely manner and of the estimated risk of infection. Successful notification or attempts at notification should be documented.
3. Early serologic testing is imperative to distinguish prior infection(s) from those potentially acquired as a result of the breach in the high-level disinfection protocol. In cases where testing is delayed, it may be difficult to exclude the endoscopic procedure as a potential source of the infection.
4. A toll-free helpline should be established to provide information to all patients at risk.
5. Patients should be advised against donating blood and tissue products and engaging in sexual contact without barrier protection until all serologic testing is complete.
6. Personal counseling should be offered to all patients. The risk of infection should be discussed and placed in context to minimize patient anxiety. In addition, the possibility that the patient might previously have a chronic viral infection should be discussed, along with the role of testing in distinguishing preexisting from newly acquired infections.
7. Patients should be asked whether they developed new symptoms suggestive of transmission of enteric bacteria or viruses after the endoscopic procedure. Prior vaccination history for hepatitis A and B should be documented. If patients have undergone prior hepatitis B vaccination, postvaccination titers should be documented if they were measured. An attempt should be made to identify risk factors for hepatitis B, hepatitis C, and HIV. If patients have previously undergone testing for these infections, the results should be documented.

8. Baseline serologic testing for hepatitis B, hepatitis C, and HIV should be performed. Patients should be informed about their baseline serology results in a timely manner.
9. Repeat testing, which may include serology and RNA tests, should be performed in all cases. The timing and the choice of tests will be influenced by the period of time that has elapsed between patient exposure and initial testing, by the presence or absence of patient symptoms, and by the advice of the institution's infectious diseases specialist. Institutions may consider obtaining follow-up testing at 6 weeks, 3 months, and 6 months post procedure. In some situations, additional follow-up testing may be advisable at 1 year post exposure.

## REFERENCES

1. Guyatt G, Sinclair J, Cook D, et al. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, editors. *Users' guides to the medical literature*. Chicago: AMA Press; 2002. pp. 599-608.
2. Kimmey MB, Burnett DA, Carr-Locke DL, et al. Transmission of infection by gastrointestinal endoscopy. *Gastrointest Endosc* 1993;36:885-8.
3. Nelson DB, Jarvis WR, Rutala WA, et al. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointest Endosc* 2003;58:1-8.
4. Alter MJ, Kruszon-Moran D, Nainan OV, et al. The prevalence of hepatitis C virus infection in the United States, 1988 through 1994. *N Engl J Med* 1999;341:556-62.
5. Armstrong GL, Wasley A, Simard EP, et al. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. *Ann Intern Med* 2006;144:705-14.

---

Prepared by:  
STANDARDS OF PRACTICE COMMITTEE

Subhas Banerjee, MD  
Douglas B. Nelson, MD  
Jason A. Dominitz, MD, MHS  
Steven O. Ikenberry, MD  
Michelle A. Anderson, MD  
Brooks D. Cash, MD  
Seng-lan Gan, MD  
M. Edwyn Harrison III, MD  
Bo Shen, MD

Todd H. Baron, MD, Chair  
Trina Van Guilder, RN, SGNA Representative  
Kenneth K. Lee, MD, NAPSGHAN Representative

This document is a product of the Standards of Practice Committee. This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

---