Reprocessing Lapses Highlight Urgency

The Financial and Legal Risks of Faulty Reprocessing

More healthcare-associated outbreaks are linked to contaminated endoscopes than to any other medical device, causing federal agencies and accreditation entities to increase scrutiny on GI endoscopy reprocessing.

New studies reveal a disturbing lack of adherence to established reprocessing protocols, and two lawsuits expose potential legal ramifications. Whether these lawsuits represent a new trend remains to be seen, but an examination of the potential cost of a reprocessing lapse shows that many millions of dollars are at stake.

New Lawsuits Expose Potential for Damages

In June 2012, a whistleblower lawsuit was filed against the owners of a surgery center alleging reprocessing failure exposed patients to hepatitis C. The plaintiff in the lawsuit also alleges that it was common practice by the defendant to reuse single-use biopsy forceps and single-use cleaning brushes to save money. This is one of the first lawsuits to involve a specific practice that led to a reprocessing breach and may encourage more reporting of breaches and unsafe practices.

In July 2012, despite the fact that no patients contracted a disease as a result of their exposure, a Pennsylvania jury found a community hospital was negligent in failing to properly clean and sterilize colonoscopes used on more than 225 patients in 2004 and 2005. The ruling allows for individual jury trials to determine if damages should be awarded to patients for their “pain and suffering, inconvenience and ‘loss of life’s pleasures.’”

Penny Wise, Pound Foolish

GI facilities that fail to comply with the established society guidelines on reprocessing often blame the cost of single-use cleaning supplies. However, that could be a false economy once the risks from inadequate cleaning and disinfection of endoscopes are considered.

The cost of a breach begins with patient notification and testing ($70.58 to $76.63 per patient) and includes reporting the adverse event to state and federal agencies (estimated at $25,000-75,000). Add to that legal costs and settlement or verdict costs - which are not covered by malpractice insurance - plus the loss of volume and market share that result from negative publicity, and the total cost per incident begins at $1.8 million on the low side, rising to $20 million for a breach with a large number of affected patients.

Focus on Standardization to Achieve Compliance

With an emphasis on standardizing reprocessing procedures to ensure adherence and eliminate potential variables, many organizations have discovered that providing their endoscopy units with GI compliance kits delivers the right tools at the right time, thereby facilitating compliance.

Compared with the cost of an infectious outbreak, or paying overtime for skilled medical staff to manage supplies and turn rooms over, GI compliance kits are not only cost effective, but are rapidly becoming the clinical gold standard for endoscopy procedures.

This article is excerpted from the white paper, Reprocessing Lapses Highlight Urgency: The Financial and Legal Risks of Faulty Reprocessing. For a copy, go to www.endochoice.com/compliance.

1 Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, Centers for Disease Control and Prevention
2 http://documents.latimes.com/whistleblower-lawsuit-vs-1-800-get-thin