One of the Top 10 Health Technology Hazards - Cross Contamination from Flexible Endoscopes

By Georgette A. Samaritan, R.N., B.S.N., Senior Risk Management Consultant

The Case

Patient cross-contamination from improperly reprocessed flexible endoscopes continues to affect large groups of patients. Endoscope reprocessing problems may be detrimental to a facility’s reputation, create anxiety when patients are told they may have been exposed to a contaminated endoscope, and at worst, may lead to life-threatening infections. Such incidents are almost always associated with either failure to follow established cleaning and disinfection/sterilization guidelines and instructions, or with the use of damaged or malfunctioning equipment. The ECRI Institute lists cross-contamination from flexible endoscopes as one of the top 10 health technology hazards for 2012.

Incident #1

The policyholder’s disinfecting machine malfunctioned, necessitating the staff manually clean and soak the endoscopes over a three-day period. Five patients out of the 40 scoped during that three-day period returned two days post-procedure with complaints of diarrhea, fever, chills and bloody stools.
During the investigation, it was discovered that the staff had not followed the manufacturer’s (manual) disinfection protocol. Since logs were not maintained and timers were not used, the exact time the scopes were in the solution could not be determined. So the possibility of cross-infecting the exposed group of patients with bacteria, viruses and/or hepatitis remained a probability. All of the exposed patients were notified, returned to the surgical center for baseline laboratory testing, and returned again for follow-up labs in six months. One of the patients tested positive for hepatitis C antibodies during the baseline testing period. Another patient filed a lawsuit against the center, claiming that the center’s negligence caused his wife and him a great deal of emotional harm. The patient reportedly has not tested positive for any infections in connection with the incident. However, he is reportedly seeking to have his lawsuit granted class-action status.

Incident #2

The case involved a man in his 30’s who underwent facial surgery including an endoscopic brow lift, chin implant and neck lift. The patient alleged that he developed a post-operative mycobacterium infection from a contaminated endoscope. He was treated with IV antibiotics for a number of weeks and sustained facial scarring. Experts opined:

- The endoscope was used at almost all the points of infection. There was no infection in areas where the endoscope was not used, which indicated that the surgeon used a contaminated instrument.
- The endoscope had a biofilm of contamination between the lumen and protective sheath covering the endoscope, which resulted from improper cleaning, disinfection and/or sterilization of the endoscope.
- The biofilm would have survived autoclaving because of its location within the endoscope’s internal mechanisms.
- Although the timing of the infection did not suggest an operative date inoculation, it did not rule it out either.

In addition, the surgeon’s equipment disinfection logs were not well-maintained, and the staff member performing instrument cleaning and disinfection for the office had not been technically trained.

Risk Management Commentary

1. Try to avoid purchasing devices that are extremely complicated or that call for equipment or supplies you are not currently using.
2. Ensure that specific reprocessing protocols exist for each flexible endoscope model in your facility’s inventory. Refer to the device’s user manual and consult the endoscope manufacturer to identify any unique requirements.
3. Periodically review protocols to ensure that they are clear, comprehensive, and reflect current workflow and chemical processing.
4. Ensure that the steps outlined in your protocols are sufficiently detailed - from pre-cleaning of equipment at the treatment site to safe and aseptic transport of equipment back to the treatment site for subsequent use.
5. If your facility reprocesses endoscopic equipment using a reprocessing unit, ensure that:
   - Endoscopes and related equipment in your facility’s inventory are compatible with the reprocessor and its disinfecting/sterilizing agent.
   - The appropriate channel adapters are available to connect the endoscope to the reprocessor, and staff are familiar with the correct endoscope/connector combinations, have access to information on the correct combinations and know where this information is located if there are any questions.
   - Staff are familiar with and adhere to appropriate reprocessor maintenance schedules, including the periodic replacement of particulate and bacterial filters.
   - Documented protocols are readily available to staff, that staff are trained to understand and follow them and receive refresher training at periodic intervals.
   - Monitor adherence to protocols. Be alert to the possible need for revisions to protocols and training when a new endoscope model is added to your inventory.
The information provided in this resource does not constitute legal, medical or any other professional advice, nor does it establish a standard of care. This resource has been created as an aid to you in your practice. The ultimate decision on how to use the information provided rests solely with you, the PolicyOwner.

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