

Heemstra, Sarah

From: Heemstra, Sarah
Sent: Tuesday, February 19, 2019 1:24 PM
To: Heemstra, Sarah
Subject: Infection Prevention Champions Program: Breaches - Part 1

Infection Prevention Champions Program



Dear Champion,

It has been estimated that over 20 million endoscopy procedures are performed each year in the United States (ASGE, 2011) which translates into a lot of reprocessed endoscopes. While the reported incidence of infection from endoscopy is considered low, there continue to be headline news stories linking patient infections to endoscopy which undermines patient confidence in our ability to keep them safe. It is essential that we prevent deviations from reprocessing standards, recognize reportable breaches and understand how to use the reporting process. Reprocessing breaches will be discussed in a two-part series of this letter discussing what constitutes a breach and steps needed to prevent them. The next letter (to be sent on 7/1/14) will discuss the reporting process and outline how to report a breach if one is identified.

The Multisociety guideline on reprocessing flexible gastrointestinal endoscopes (ASGE, 2011) states that every infection reported to have been transmitted by an endoscope has been linked to one of four reasons:

1. Failure to comply with cleaning and disinfection guidelines
2. Using unapproved chemicals for high level disinfection
3. Inadequate drying of the endoscope
4. Defective equipment

The FDA (2009) contend that processing errors include the use of improper accessories for endoscopy irrigation set-ups, improper reprocessing intervals for reusable endoscopy accessories, failure to discard single use accessories, and failure to follow the manufacturer's instructions for endoscope reprocessing.

Breaches are usually discovered incidentally, may last for several months or years before detection and may be serious enough to result in patient injury or infection (Dirlam Langlay, Ofstead, Mueller, Tosh, Baron, Wetzler, 2013). Our role in reprocessing is vitally important as a breach in any one of the reprocessing steps

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could place our patients at risk for infection and also affect our institutions reputation. Reprocessing failures draw unwelcome attention in the form of damaging headlines and undermine public confidence as evidenced by the following breaches:

- Between 2003 and 2009 failure to follow reprocessing guidelines resulted in notification of over 10,000 patients in several Veterans Affairs (VA) medical facilities (Dirlam Langlay, Ofstead, Mueller, et al., 2013)
- October 2011, Ottawa, Ontario - improper reprocessing of EGD and colon scopes resulted in notification of 6,800 patients (CBC News, 2011)
- July 2012, Bend, Oregon - Disinfection reprocessor malfunctioned after maintenance check eliminating the disinfection cycle and resulting in notification of 18 patients (Nogueras, 2012)
- July 2013, Kansas, MO - Auxiliary water channel not reprocessed resulting in contamination and risk for infection (Brunner, 2013)
- January-September 2013, Park Ridge, IL- 243 patients notified of CRE contamination of ERCP scopes (Placko, 2014)
- February 2015- The UCLA Health System notified 179 patients that they may be exposed to CRE during ERCP procedures. A total of seven patients were infection contributing to two deaths (UCLA, 2015).

The above notifications were made to hundreds of patients placed at risk for infection. However, if only one patient is exposed to infection due to reprocessing failures, it is one too many. Breaches can be prevented with training, education and strict adherence to the endoscope reprocessing steps. Refer to [SGNA's Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes \(2016\)](#). In addition, manufacturer guidelines for the endoscope, accessory equipment, reprocessor, and chemicals must be thoroughly reviewed and consistently followed. Accessory equipment should be reprocessed as recommended (high level disinfection vs. sterilization) and single-use devices should not be reused (refer to [Reuse of Single-Use Critical Medical Devices Position Statement \(2015\)](#)).

All staff are responsible for preventing breaches in the endoscopy suite. Like colon cancer, breaches are much easier to prevent than to address once the breach or problem has been discovered. The following FDA general recommendations are intended to prevent transmission of infections in processing endoscopes and accessories:

1. Establish a program for endoscope reprocessing which includes written procedures for monitoring compliance and maintaining competence
2. Train employees to set-up, clean, disinfect or sterilize, and store endoscopy equipment properly. Periodically retrain and assess competence (SGNA states at least annually and more often if needed) and stay up-to-date with the specific reprocessing needs of devices used
3. Read and follow manufacturer's instructions. Ensure that manufacturer's instructions are readily available for each endoscope and its accessories
4. Be sure staff members understand that the cleaning and disinfecting of endoscopes are two separate processes
5. Ensure that the automated endoscope reprocessor (AER) or sterilizer is compatible with the endoscope. Be sure that the instructions for

- endoscopes, AERs and germicides (high level disinfectant chemical) do not contradict one another
6. Be sure that endoscopes or accessories that contact sterile tissue are sterilized before each use, and that endoscopes that contact intact mucous membranes (e.g., the respiratory and gastrointestinal tracts) undergo at least high-level disinfection before each use
 7. Follow enhanced cleaning protocols for ERCP scopes as outlined by the manufacturer and CDC guidelines

We must be vigilant and intentional when it comes to endoscope reprocessing. Steps to prevent breaches include following manufacturer's guidelines for equipment and chemicals, training new staff, ongoing education, annual competencies in reprocessing, collaboration with the infection prevention/control department, and development of a culture of excellence which discourages short cuts and utilizes non-punitive reporting structures. Patient safety is everyone's responsibility and prevention of reprocessing breaches is paramount in ensuring a safe environment in the endoscopy suite.

Requirements should either be emailed to Champions@sgna.org or faxed to 312-673-6694 as due. The assignments for the next two weeks are as follows:

1. Continue to develop and implement infection prevention education for your peers (total of 120 minutes)
2. Seek for opportunities to educate yourself on infection prevention topics (total of 180 minutes).

These bi-monthly letters will be [archived](#) for you to access as needed. As always, SGNA is available for any questions or difficulties you may have.

Sincerely,
The SGNA Infection Prevention Work Group

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