A Call to Sterilize Endoscopes

Jeff Wiser

Despite being cleaned properly and reprocessed according to manufacturers’ instructions for use (IFUs) and in compliance with reprocessing guidelines, multiple types of flexible endoscopes have been linked to outbreaks and infections. These incidents have received considerable attention in the mainstream news and journal articles, as well as garnered the attention of professional organizations.¹

The current research indicates that up to 58% of processed/ready-for-patient-use endoscopes harbor microbes.² Although endoscope technology has advanced and the clinical uses for these devices has expanded, endoscope reprocessing has not kept pace. The convergence of endoscope complexity, endoscope usage, endoscope damage, and multidrug-resistant organisms can place patients at risk for infection. Several outbreaks were halted by moving from high-level disinfection (HLD) to terminal sterilization (through the addition ethylene oxide [EO] sterilization), thereby supporting the need for endoscope sterilization.³

Endoscope Complexity

Initially, flexible endoscopes were used primarily for diagnostic procedures. The first flexible endoscopes housed rolls of film in the distal end, along with a lens and light source.⁴ A picture was taken, and the roll of film for the picture was advanced. Although the picture quality was inconsistent, these endoscopes contributed to the early detection of stomach cancer.

The development of fiberoptics ushered in the next advances in endoscope technology. These endoscopes now had fiberoptic cables embedded with an ocular eyepiece, allowing physicians to visualize the gastric lining in real time. This change greatly enhanced the clinical use of endoscopes. Soon, cameras were able to be attached to the eyepiece, allowing clinicians to keep a permanent record.

These early endoscopes were sealed devices used for observation only. Because they did not cross membrane barriers or enter sterile tissue, they were considered semicritical devices. As a result, HLD became the accepted reprocessing procedure.

Endoscope Usage

Endoscope technology continued to advance, with new features opening up a wide variety of uses to physicians. Videoscopes included built-in cameras that generated images on a large screen, and various ports were added. The number of uses and types of endoscope accessories expanded greatly, with many being used in surgical procedures crossing membrane barriers and entering sterile tissue. In addition to observation, therapeutic accessories could be passed down the length of the endoscope lumen.

The uses for endoscopes have expanded to the point that therapeutic colonoscopies outnumber the cases of diagnostic-screening-only colonoscopies.⁵

HLD

Because flexible endoscopes are collectively designated as semicritical devices, they routinely undergo HLD. HLD is designed to kill $10^6$ vegetative bacteria but not all bacterial spores. Given the bacterial load reported on flexible endoscopes, the 6-log reduction delivered by HLD may not be sufficiently rigorous.

In 2016, Rutala and Weber⁶ reported that flexible endoscopes can become contaminated with as much as $10^{10}$ bacteria. If cleaning can remove up to $10^4$ bacteria and HLD another $10^4$ bacteria, then $10^{10}$ bacteria will be removed. However, no margin for safety exists in this scenario. The endoscope must be in good condition, and the cleaning/HLD processes must have peak performance to eliminate all vegetative bacteria on the endoscope.

Of important note, however, HLD is not designed to kill all bacterial spores. Even at peak performance, some bacterial spores could remain on the endoscope. In addition, at minimum performance, the cleaning step would remove $10^2$ bacteria and HLD would kill another $10^4$ bacteria. In this scenario of

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minimum effectiveness, up to $10^4$ bacteria could remain on the endoscope after reprocessing.

**Endoscope Drying**
While endoscope cleaning and HLD processes are fairly standardized, endoscope drying is more varied and continues to be an issue. Reports have indicated that residual moisture can be found in roughly half of fully reprocessed, ready-for-patient-use flexible endoscopes.

Improper drying can permit microbes to multiply and build biofilms in the residual moisture inside the endoscope.

**Endoscope Damage**
In addition to having a high microbial load, flexible endoscopes are fragile and can be damaged easily. Ofstead et al. reported that endoscopes can become damaged in as little as two months.

In another article, based on observations made in three large healthcare facilities, Ofstead et al. reported that bronchoscopes continued to be used despite a high percentage of the devices being damaged and contaminated with microbes. The investigators also reported that damaged endoscopes were in use in every facility they observed. Examples of external endoscope damage included scratches, damaged insertion tubes, and damaged distal ends, while internal damage included lumen scratches, dented channels, and filamentous debris in the lumens. In addition, red, white, and brown residue was found on the external endoscope surfaces, while fluid and discoloration were observed internally.

As is commonly known in the industry, areas of endoscope damage can be difficult to clean and can harbor microbes. Ofstead et al. reported that 58% of the endoscopes had positive cultures. All of these positive cultures were found after the endoscopes had been fully reprocessed, including HLD.

Similar findings have been found on other types of flexible endoscopes, including ureteroscopes and duodenoscopes.

**Increased Findings**
The Joint Commission (TJC) published an article stating that lapses in sterilization or HLD were a growing concern. TJC infection control standard IC.02.02.01 requires organizations to reduce the risk of infections associated with medical equipment, devices, and supplies. The accreditation body reported that facilities’ rates of noncompliance in reducing the risk of infections has been increasing rather than decreasing. Despite reprocessing staff doing their best to follow manufacturers’ IFUs and reprocessing guidelines, 20.8% of hospitals were observed to be noncompliant in 2009, with the percentage increasing to 60% by 2016 (Table 1).

TJC reported that from 2013 to 2016, “immediate threat to life (ITL) declarations directly related to improperly sterilized or HLD equipment increased significantly.” The article further reported that among noncomplying organizations, some stated a mistaken belief that the risk of passing pathogens to the patient was low or nonexistent. Lack of training, no access or knowledge of evidence-based guidelines, processes not being followed properly, and lack of leadership also were reported as reasons for the high rates of noncompliance.

**Endoscope Reclassification**
The current Spaulding classification for devices is as follows:
- **Noncritical items** are those that come in contact with intact skin but not mucous membranes. Low-level disinfection is required for these items.
- **Semicritical items** are those that come in contact with mucous membranes or nonintact skin. At a minimum, these items require HLD.

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*Table 1. Annual percentage of Joint Commission–accredited hospitals with noncompliant findings linked to infection control standard IC.02.02.01, which requires organizations to reduce the risk of infections associated with medical equipment, devices, and supplies. Source: reference 10.*
Critical items are those that come in contact with sterile tissue or blood. These items require sterilization. Confusion exists regarding the application of the Spaulding classification to endoscopes. For example, in some cases, endoscopes are listed as both critical and semicritical devices. This implies that the reprocessing facility has a choice regarding the level of disinfection and can choose either HLD or sterilization. Departments that are under pressure to save costs and turn around scopes quickly often will choose HLD.

A device’s intended use should be used to determine its classification. Endoscope technology has advanced from observational devices to being used in complex, minimally invasive surgical procedures in which the endoscope or endoscope accessories cross the membrane barrier into sterile tissue. Because of this, experts are starting to recommend that the Spaulding classification be updated so that endoscopes are considered critical devices.

To better align with clinical use, Rutala and Weber suggested that the critical device classification be reworded to “objects which directly or secondarily (i.e., via a mucous membrane, such as a duodenoscope, cystoscope, or bronchoscope) enter normally sterile tissue or the vascular system or through which blood flows should be sterile.”

Endoscope Sterilization

The evidence is clear that residual bioburden puts patients at greater risk when endoscopes are not sterilized. Patients are at risk when multiple risk factors converge. In others words, when you combine high microbial load, endoscope complexity, endoscope damage, and endoscope residual moisture, the result is increased risk.

Endoscope sterilization is becoming more common as a risk mitigation approach and has helped halt several endoscope-related outbreaks. In one case, the source of an endoscope-related carbapenem-resistant Enterobacteriaceae (CRE) outbreak was investigated in a northeastern Illinois hospital. The outbreak, which occurred from January through December 2013, included 39 patients. The endoscope underwent HLD...
at least 28 times but infections continued. The contamination persisted even though the duodenoscope reprocessing was followed in accordance to the manufacturer’s IFU and current guidelines. After the hospital changed its reprocessing procedure from automated HLD with OPA (ortho-phthalaldehyde) to gas sterilization with EO, no additional case patients were identified.

At another facility, from May to November 2013, three patients were identified as having a clinical infection related to an identical strain of CRE. The three infected patients were found to have undergone a procedure with the same duodenoscope in May 2013. This finding initiated a review of endoscope reprocessing procedures and a review of all patients who underwent a procedure with the potentially contaminated endoscope. The review of the disinfection procedure revealed that all standard recommendations and guidelines with regard to endoscope reprocessing were followed. After EO sterilization of all duodenoscopes was added to reprocessing, no additional cases of CRE infection were diagnosed.

Rubin and Murthy\textsuperscript{14} reviewed CRE outbreaks (from 2013 to 2015) in Europe and the United States related to duodenoscope use. They indicated that although historical outbreaks had been related to improper cleaning and reprocessing, the outbreaks during the period of study occurred in spite of strict adherence to current reprocessing guidelines. “Outbreaks were halted with enhanced cleaning and surveillance measures or by adopting gas sterilization methods,” the authors reported. Their findings also indicated that:

- Even when duodenoscopes are properly reprocessed using HLD and following the manufacturer’s IFU and current guidelines, outbreaks occur.
- Established cleaning methods that include HLD may not clean endoscopes enough to prevent cross-contamination infections.
- Sterilization of duodenoscopes may be required to increase the level of patient safety by decreasing the risk of residual contamination.

In light of several endoscope-related CRE outbreaks, the effectiveness of EO gas sterilization for duodenoscopes was assessed.\textsuperscript{15} During a seven-month period, the study site sterilized its six duodenoscopes 645 times for 589 ERCP (endoscopic retrograde cholangiopancreatography) procedures. The investigators concluded that HLD may not be sufficient to protect patients and that adding EO sterilization and culture monitoring reduced contamination and eliminated infections at the facility. The authors stated: “The addition of EO sterilization and frequent monitoring with cultures reduced duodenoscope contamination and eliminated clinical infections.”

Healthcare facilities and systems that do not currently possess the capability for EO sterilization can either use an out-of-house sterilization facility or bring the technology in-house. Bringing an EO sterilizer in-house would include meeting installation and site-planning requirements, such as those related to space, utilities, and venting.

EO abatement is required in several states and promotes good sustainability. For facilities not familiar with this process, a concern of occupational exposure to EO often exists. During the past two decades, multiple new regulations targeting work practices and environmental impact have been passed that make currently available EO systems safe to use. Healthcare facilities need to be aware of the installation and operation requirements of the sterilizer while following Occupational Safety and Health Administration and Environmental Protection Agency regulations. For example, to reduce staff exposure to partially aerated loads, chamber aeration became required in 2008.

**Sterilization Benefits**

Published reports of infections associated with contaminated endoscopes continue to emerge. Widespread recognition exists of the complexity and difficulty in effectively reprocessing flexible endoscopes with HLD, as evidenced by updates to multiple guidelines and mandated validation updates to manufacturers by the Food and Drug Administration.
manufacturers by the Food and Drug Administration. Terminal sterilization addresses the key limitations of HLD. As an overkill process, sterilization can better accommodate variations in reprocessing (e.g., brushing variation, water contamination). Endoscopes are easily damaged, the damaged areas can harbor biofilms, and damage increases the difficulty of cleaning. Sterilized endoscopes are dry and terminally packaged at the end of the process, without repeated periodic reprocessing needed for endoscopes that undergo HLD. Sterilization processes are closely monitored with physical monitors, biological indicators, and chemical indicators. Because the endoscopes would be terminally packaged and dry, they could be stored in any orientation permitted by the manufacturer in sterile storage.

Although endoscope technology has advanced and clinical uses for endoscopes have expanded, endoscope reprocessing guidance has not kept pace. With so many challenges to endoscope reprocessing, sterilization of endoscopes is recommended.

References