Techniques and Innovations in Gastrointestinal Endoscopy 2021; 1–8

Optimizing the Decontamination and Reprocessing of Endoscopic Equipment

James Collins

Endoscopy Accreditation Nurse, Digestive Disease & Surgical Institute, Cleveland Clinic, Cleveland, Ohio

Abstract

Flexible Gastrointestinal Endoscopy is a commonly performed procedure about the globe as either a diagnostic or therapeutic tool in the treatment of GI Disease. In the United States, it has been estimated that over 20 million endoscopic procedures are performed annually. The reprocessing of an endoscope is an extremely detailed and multi-stepped process which is required after each procedure to render a contaminated instrument safe for reuse. Endoscopes are rather intricate instruments constructed with multiple long narrow internal channels with right angles. In addition to their complex construction, endoscopes must transverse an environment which bear high and diverse level of microbial population and organic matter. Due to this architectural structure, successful endoscope reprocessing is built upon a foundation of 9 primary steps which must be meticulously performed in concert with the Manufacturer's Instructions for Use as well as guidelines from professional organization to mitigate the potential of the transmission of Endoscope Associated Infections. The 9 pillars of effective endoscope reprocessing are: point of use precleaning, leakage testing, manual cleaning, rinse after cleaning, inspection, high level disinfection, liquid chemical sterilization or sterilization, rinse after high level disinfection or Liquid Cemical Sterilization, drying and storage. completing these steps each and every time an endoscope is processed is mission critical in the prevention of lapses and breaches in the reprocessing of endoscopes. Table 1 a well-trained and highly engaged reprocessing staff is also necessary to carry out these duties in accordance with strict institutional oversight of reprocessing protocols. While it is possible to gain insight into the general reprocessing practices throughout the nation through the use of surveys and interviews of endoscopists and nurses, due to the anonymity of these tools, it is often difficult to isolate specific facilities to gain a deeper appreciation of their practice unless the activities of these facilities has been published. Several topics and concepts related to opportunities to enhance reprocessing will be explored in this writing to evaluate and augment endoscope reprocessing with in the facility.

Keywords: Endoscope reprocessing; High level disinfection; Sterilization; Endoscope associated infection; Reprocessing opportunities.

Rigorous attention to the reprocessing of endoscopes is imperative to a facility's GI Endoscopy practice. In recent years, the improper reprocessing of endoscopes has been an escalating concern throughout healthcare and has generated substantial attention throughout the medical community as well as the media. A plethora of writings addressing endoscope reprocessing and Endoscope Associated Infections, EAIs are frequently published in today's professional and scientific journals. Even though gastrointestinal endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine, more health care acquired infections have been linked with the use of contaminated endoscopes than to any other medical device.[1] The Emergency Care Research Institute, known more commonly as ECRI, has published in their annual reports the potential risk of cross contamination and or patient infections due to improperly processed endoscopes and medical equipment. Ranking this concern as one of the top 10 safety matters in healthcare from 2013 to 2019.[2] The attention given to EAIs related to Multi-Drug Resistant Organisms, (MDRO) transmitted via the duodenoscope has also gathered many headlines. Governmental agencies have taken a keen interest into endoscope reprocessing practices throughout the nation. In May of 2015, the Food and Drug Administration (FDA) convened the Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee to seek expert scientific and clinical opinion related to the reprocessing of duodenoscopes based on available scientific information.[3] Historically, there has also been other findings from governmental agencies. The Centers for Disease Control and Prevention (CDC) piloted an infection control audit tool during the inspection of 68 Ambulatory Surgical Centers (ASC) in 4 states to assess compliance with recommended reprocessing practices in 2009. The CDC discovered a gap in the compliance and adherence to the recommended practices of endoscope reprocessing in 28% of these facilities.[4] Despite the large number of

Most current article

2590-0307

https://doi.org/10.1016/j.tige.2021.08.002

endoscopic procedures that are performed annually, documented data suggest that post endoscopic iatrogenic infections are rare. In GI endoscopy, the estimated rate of health care-associated infection is approximately 1 out of 1.8 million procedures. However, the true rate of transmission during endoscopy may go unrecognized because of technically inadequate surveillance, no surveillance at all, low frequency, or the absence of clinical symptoms (Table 1).

Breakdowns in reprocessing compromise patient safety. A breakdown in any of the reprocessing steps can compromise the integrity of the process, leading to an instrument related contamination risk. EAI remain a threat to the patients we serve. Effective endoscope reprocessing is structured upon a series of progressive steps. Each of these steps, holds a crucial purpose in the process (Table 2). The FDA requires device manufacturers to provide instructions for reprocessing their devices and to validate these reprocessing procedures. Facilities have raised concerns that some of these instructions are unclear, extremely complicated, and or lengthy in composition. Contributing to the potential of breaches occurring during reprocessing. In response to these pleas, the FDA has developed draft guidance to improve manufacturers' reprocessing instructions and is reviewing comments on the draft. While reprocessing steps are model specific, a general overview of reprocessing is outlined below. Always consult the MIFU for endoscope specific reprocessing protocols.

Opportunities for Innovation in the Reprocessing of Endoscopes

Centralization of Instrument Reprocessing

A concept of endoscope reprocessing which has gathered momentum recently has been the movement of facilities to centralize their practice of HLD within the institution. Centralization of reprocessing is when individual units elect to no longer manage and oversee the reprocessing of their instruments. Instead, the endoscopy unit as well as other departments with HLD needs, relies upon a “centralized” reprocessing unit within the facility to reprocess their instruments. The unit’s time and energies maybe more focused upon patient care activities.[5] The centralization process is driven with the primary goals of increasing reprocessing oversight and efficiency, increasing productivity through the deployment of a dedicated reprocessing team, promoting standardization of products utilized in reprocessing, reduction in the requirements for capital reprocessing equipment, and reducing the opportunity of reprocess variability. Due to the challenges from cleaning complex instruments such as endoscopes, centralization of the process assists to insure the right people with the correct equipment, proper education, training and skill level are dedicated to the task of HLD reprocessing.

Outsourcing Endoscope Reprocessing

In a somewhat similar fashion to a centralized approach to reprocessing, units may elect to eliminate the risks due to endoscope reprocessing through the outsourcing of this task. An outsourcing vendor is a third-party contractor which charges a negotiated fee to either high level disinfect or sterilize the facility’s instruments. As in the centralized model of reprocessing, many units are discovering that through the use of an outsourcing contractor, there is no longer a need to invest time, labor, and other resources into the reprocessing of instrument. Permitting caregivers to redirect their focus upon patient care activities. Outsourcing may be accomplished through 2 means. Facilities may select to have their instruments processed on site or to have the instruments transported off the premises to be processed. Extremely insightful contractual expectations must be placed into the contract to insure performance and quality parameters are maintained. Careful safety and damage prevention considerations are necessary when selecting to transport instruments off grounds. Advanced planning must also be performed to insure the proper number and model of endoscopes are on hand to meet routine and emergent patient needs. The quality of endoscope reprocessing within a centralized institutional sterile processing department with dedicated technicians should be compared with disinfection practices that are performed on the unit to insure a consistent approach to reprocessing within the facility.

Table 1. Endoscope Reprocessing Guidelines

Centers for Disease Control and Prevention	American Society for Gastrointestinal Endoscopy	Society of Gastroenterology Nurses and Associates	Association of perioperative Registered Nurses	Association for the Advancement of Medical Instrumentation
2017 “Essential Elements of a Reprocessing Program for Flexible Endoscopes” Recommendations of the Healthcare Infection Control Advisory Committee, HICPAC	2021 “Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes	2018 “Standards of Infection Prevention in Reprocessing of Flexible GI Endoscopes”	2016 “Guideline for Processing Flexible Endoscopes	2015 ST91 “Flexible and Semi-rigid endoscope reprocessing in healthcare facilities”

Table 2. Sequence of Reprocessing an Endoscope

Step	Purpose	When performed	Noted deficiencies
Precleaning cleaning	Aides in the prevention of the biofilm formation on the instrument	Performed at the site of the procedure immediately following the procedure	Often is omitted or incorrectly performed
Leak-test	Detects damage to the external surface and internal channels of the scope	In the decontamination room prior to manual cleaning	A leak may lead to inadequate disinfection and further damage of the endoscope
Manual cleaning	Composed of cleaning the both the exterior surface of the endoscope and internal channels and ports through brushing and flushing. Many be considered the most critical step in the process since remaining organic material on/in the endoscope will reduce the effectiveness of HLD or sterilization.	In the decontamination room prior to disinfection or sterilization	Multiple inconsistencies performed in accordance with the manufacturer's instructions for use. Improper concentration of detergent. Improper soaking duration. Incomplete brushing and flushing of channels.
Rinse after cleaning	To remove detergent solution used for manual cleaning.	Upon completion of manual cleaning.	Inadequate or omitted rinsing leaves residual detergent on/within endoscope and may interfere with HLD/Sterilization.
Visual inspection	Observe the instrument for damage and residual contamination. Facilities may also elect to conduct residual soil testing[24] and or Borescope examination.[25]	When rinsing of the endoscope post manual cleaning is performed.	Often omitted or incompletely performed. Damaged endoscopes may not be able to be effectively reprocessing, potentiating the risk of an EAI. Lack of use of a magnification device or performed in inadequate lighting.
High level disinfection (HLD) or sterilization	Remove microbial life to render the endoscope safe for patient use	Performed after the inspection of the endoscope	Not testing the disinfectant for Minimum Effective Concentration (MEC) Incorrect exposure time in disinfectant Incorrect temperature of disinfectant Use of incorrect adapters
Rinse	Removal residual disinfectant	When HLD is complete	Inadequate or omitted rinsing leaves residual disinfectant on /within endoscope
Dry	Remove all residual moisture from the surface and channels of the endoscope	After rinsing post HLD	Inadequate drying may lead to the retention of moisture within the channels of the endoscope leading to microbial growth
Storage	Prevent recontamination and protect the endoscope from damage	Upon drying the endoscope	Stored with removable components attached. Locks, breaks and stiffener engaged. Not hanging freely

Automated Endoscope Reprocessors/ Automated Endoscope Cleaners

Automated Endoscope Reprocessors (AER) more commonly referred to as "Scope Washers," greatly assist to facilitate the HLD of endoscopes. AERs standardize the reprocessing of endoscopes while reducing the exposure of caregivers to the harmful effects of the high-level disinfectants.[6] The most notable attribute of an AER is the elimination or reduction in the number of variables associated with reprocessing by the human factor of reprocessing. Although all endoscope reprocessing steps can be performed manually, automation of some of these steps has been shown to be advantageous with the occurrence of fewer reprocessing errors. Greatly reducing the well documented human factor errors in the reprocessing room.[7]

In addition to the standard AER, the FDA has labeled 2 endoscope reprocessors which also hold additional cleaning claims. With this labeling, the intensive and often problem prone manual cleaning steps of reprocessing are greatly modified with limited or no physical cleaning by brushing and flushing of the instrument's accessible channels.[8] One of these 2 units has been

labeled to replace the most critical manual cleaning on all flexible endoscopes, even the most challenging and difficult to manually clean duodenoscope.

Sterilization of Endoscopes

The recent outbreak of multidrug resistant organisms associated infections associated with Endoscopic Retrograde Cholangiopancreatography, (ERCP), which were traced to the use of duodenoscopes has rekindled discussions to move towards the sterilization of endoscopes from the norm of high level disinfection.[9] Considering endoscopes are extremely heat sensitive instruments and can be easily damaged and destroyed by the high temperatures utilized during steam sterilization, other sterilization modalities such as Ethylene Oxide (EtO) gas sterilization is often utilized. Ethylene Oxide sterilization is an effective modality for rendering heat sensitive instruments such as endoscopes sterile. However, Ethylene Oxide gas is a known carcinogen and highly toxic. It is volatile, costly, requires a long cycle time, and brings considerable health risks to your staff, patients, and community. Due to these characteristics, the process is also quite lengthy (14 hours in duration) to permit aeration of the endoscope to insure potentially harmful residual ethylene oxide and it's by products, ethylene chlorohydrin and ethylene glycol, have been removed from the instrument. On an economical view, there are barriers to the use of gas sterilization with Ethylene Oxide. It is a more expensive process than high level disinfection, the before mention long reprocessing time due to the prolong aeration process, potential toxicity, instrument degradation, and lack of wide spread availability.[10] While endoscope manufacturers lend guidance to the end user of the process of Ethylene Oxide sterilization of endoscopes, the FDA has not cleared this process.[11] Developments with sterilization technology and their use with endoscope have also advanced. A low temperature hydrogen peroxide–ozone sterilization unit has been labeled by the FDA to terminally sterilize the challenging minute and multichanneled flexible endoscopes such as colonoscopes, gastroscopes, and duodenoscopes without the present barriers of the Ethylene Oxide sterilization process.[11]

It must also be stressed that the use of sterilization does not negate or alleviate the requirement of reprocessing staff to meticulously manually clean the endoscope. As in high level disinfection, both the exterior surfaces and the inner channels of the endoscope must be free of debris for an effective processing cycle.

Re-crafted Endoscopes

The complexity of endoscopes, especially duodenoscopes, has been well noted as being a causative factor for the potential of lapses to occur in reprocessing. Unlike traditional endoscopes, duodenoscopes have a movable elevator mechanism at the tip of the endoscope. An engineering assessment conducted by the FDA and a growing body of literature, have identified design issues as the elevator mechanism, that renders the reprocessing of duodenoscopes more challenging than traditional instruments.[3] This elevator is an extremely complex, intricate, movable and recessed enhancement of the duodenoscope. It is however particularly prone to harboring bacteria and can be difficult to clean and disinfect before the instrument's subsequent uses. Creating the possibility of the instrument to be a vector for potential EAIs. In response to this challenging design of the elevator, developments in new models of duodenoscopes with disposable end caps have been introduced with the aim to simplify and facilitate manual cleaning and disinfection to mitigate the risk of EAIs. The first instrument labeled by the FDA of this new design was the Pentax ED34-i10T. Olympus introduced the TJF-Q190V and Fujifilm, the ED-580XT. Because of the noted challenges with the reprocessing of the traditional duodenoscope, along with the persistent high levels of contamination post reprocessing, the FDA recommended healthcare care facilities move away from using duodenoscopes with fixed endcaps to those duodenoscopes with disposable endcaps when they become available.[12] The use of disposable end cap duodenoscopes are designed to eliminate the particular challenges of manually cleaning the elevator mechanism by provide greater access for reprocessing personnel to decontaminate and HLD / sterilize the instrument.

Disposable Duodenoscope Sheath

Institutions may elect to use a single use disposable sheath to facilitate reprocessing of duodenoscopes. This device is placed upon the distal tip of the duodenoscope to act as a physical barrier with the aim in the prevention of bioburden from accumulating and soiling the elevator mechanism of the endoscope. After the procedure is complete, the sheath is to be left in place during the precleaning of the instrument to prevent contamination of the elevator assembly during this phase of reprocessing. It is to be noted the disposable duodenoscope sheath is not designed to replace or eliminate the manually cleaning and disinfection of the instrument. Their aim is simply to effectively reduce the contact contamination of the elevator assembly endoscope.[13]

Disposable Endoscopes

With the advancement of imaging technologies, disposable or single use endoscopes have been introduced into our endoscopy labs. The use of disposable endoscopes eliminates various risks that have been associated with re-useable instruments. This "one and done" nature of a disposable instrument is perhaps the primary talking point when discussions are held within facilities to onboard the technology. At the present time, the opportunity to employ the use of disposable duodenoscopes is a topic of many discussions within facilities. Though single use endoscopes will soon be available in other models in the very near future Disposable duodenoscopes are supplied in a sterile fashion, reducing the risk of patient cross contamination and exogenous endoscope associated infections.[14] While increasing the level of patient safety

within our practice is a paramount concern, we must remember the use of disposable instruments will not completely eliminate the threat of all ERCP related infections, as the risk for endogenous infections will remain. There are a number of additional fiscal characteristics of disposable instruments which foster the facilities interest in their utilization other than the principle benefit of eliminating reprocessing costs and improving patient safety. Costs which would be eliminated with the use of a disposal instrument are related to capital acquisition funds as the costs of maintaining an adequate endoscope inventory will no longer be a factor. Other budgetary expenditures which would foregone are endoscope surveillance and instrument repair costs. The conversations to introduce single use disposable endoscope into a practice echo in a very similar fashion the conversations held some 20 years ago when clinicians and administrators evaluated the potential risks and benefits from the introduction of disposable accessories into the practice.

In addition to increasing the safety of endoscopy to our patients through removing the threat of exogenous endoscope associated infections, disposable endoscopes should create a reduction of the number of endoscopes a unit will need to reprocesses to meet the daily needs of the facility.

It maybe theorized through the use of disposable endoscopes, a potential and significant reduction of the wastes generated from the reprocessing of instruments will be appreciated by decreasing the overall volume of consumable products utilized to reprocess endoscopes as highlighted in Table 3, to a simple collection / shipping container which will hold patient used endoscopes until the devices are transported off the premises for recycling, incineration and final disposal. There should also be a reduction in the exposure of reprocessing personnel to both biohazardous wastes and potentially harmful chemicals associated with reprocessing, creating a safer work environment Table 4.

Environmental Impact of Reprocessing

The environmental impact of hospital systems and healthcare providers is substantial. Many healthcare systems have developed innovative approaches to reduce their environmental impact. *Health Care Without Harm* is an international organization of healthcare providers that maintains a webpage which is dedicated to assisting organizations to reduce their carbon footprint and promote environmental health.[15] Upon a literature review, there is very little written that specifically addresses the waste stream created by the endoscopy unit let alone wastes generated through the reprocessing of endoscopes. Writings have been published addressing the disposal of endoscopic accessories and the segregation of trash generated by the endoscopy unit as regular or regulated medical wastes. (RMW) also known as infectious wastes. One paper by Deepak Agrawal, et al, revealed that most medical waste from endoscopy units is handled inappropriately due to the lack of comprehension of recommended disposal methods for endoscopic accessories. With the introduction of single use endoscopes, these conversations are beginning to generate more interest and a deeper appreciate of the waste streams created through reprocessing.[16]

Studies have been conducted to investigate the true economic impact to an endoscopy unit of the costs associated with the reprocessing of re-useable endoscopes. However, it has been rather difficult to truly assess both the economic and the environmental impact of reusable endoscopes. Ofstead provides an extremely comprehensive “glimpse” of both the economic and environmental impact of endoscope reprocessing. Analyzing the necessary personnel time and the required supplies to high level disinfect a single re-useable endoscope.[17] By reviewing the items consumed during endoscope reprocessing, it is possible for the facility to construct a model of the potential volume of refuse which will be generated and placed into the waste stream. In addition, the study revealed the great concern reprocessing personnel hold toward the large volume of waste generated with the reprocessing of a single endoscope (Table 3).

Water

Water is a crucial ingredient in the processing of endoscopes. The quality of the water utilized is critical to the ability to properly clean instruments. The overall goals of water treatment in medical device reprocessing is to prolong the life of medical instrumentation and, more importantly, to help promote patient safety through minimizing the risk of patient infection arising from contaminated medical devices.[18] Water used for reprocessing of endoscopes must meet the specifications outlined by the manufacturers’ instructions for the device and reprocessing equipment.[19] Appreciable volumes of water is consumed to perform precleaning, leakage testing, manual cleaning, and rinsing of the endoscope. While water quality differs among locations, MIFUs lend broad and general guidance to the water utilized in reprocessing. Use of either fresh, potable water or filtered and deionized water that has been processed filtered, deionized, or purified to improve its chemical and/or microbiological quality. Potable water by definition simply means the water is safe to drink or use for food preparation. Deionized water or also known as demineralized water, is a type of water in which all of its mineral ions such as sodium, iron, calcium, copper, chloride, and sulfate are removed. It also does not contain any chemicals or harmful toxins. Some national or professional guidelines recommend using sterile water for rinsing endoscopes.[20] If sterile water is not available, these guidelines recommend using potable tap water and flushing endoscope channels with alcohol. Consultation with the facility reprocessing/infection prevention committee when developing policies and procedures addressing endoscope reprocessing and the quality of the water to be utilized should always be taken.

Table 3. Estimated Materials Consumed to Reprocess an Endoscope With the Presumption 12 Endoscopes Daily for a Year

Item	Per endoscope	Daily	Weekly	Monthly	Annual
Reprocessing personnel					
Pair extended cuff glove	1	12	60	240	2880
Gown	1	12	60	240	2880
Face shield	1	1	5	20	240
Mask	1	1	5	20	240
Hair covering	1	1	5	20	240
Precleaning					
Precleaning kit Sponge/Wipe Plastic bowel	1	12	60	240	2880
Transport					
Container/Liner	1	12	60	240	480
Leak testing Manual cleaning					
Sponge/Wiper	1	12	60	240	480
Channel brush	1	12	60	240	480
Valve cylinder brush	1	12	60	240	480
Flushing tubing	1	1	5	20	240
Inspection					
Residual soil test	1	12	60	24	480
Post HLD drying					
Pair exam gloves	1	12	60	240	2880
Drying clothe	1	12	60	240	2880
Additional supplies					
Germicidal wipe transport container	1	12	60	240	2880
Germicidal wipe sink	1	12	60	240	2880

When calculating the amount of water which is utilized in the reprocessing of an endoscope, one may be quite surprised. While the reprocessing sinks to perform leak testing/manual cleaning and rinsing of the endoscope vary in size, one may expect 5 gallons of water to be consumed for each of these stages. AERs consume a considerable volume of water per cycle as well. For example, The Olympus OERPRO utilizes 24 gallons per cycle.[21] When these combined with the water utilized from leak testing/manual cleaning and rinsing of the endoscope, the total volume of water utilized to process a single endoscope is rather surprising at 30 gallons per instrument. Interesting enough, this volume is more than the average amount of water consumed for an individual during a normal shower.[22]

Table 4. Environmental Impact of Reprocessing Use of Disposable Devices

Decrease waste from disinfecting consumables
Greatly reduced water and energy costs
Eliminate staff exposure to potentially harmful toxic chemicals and biohazards
Less waste products to landfills
Less biohazard waste to incinerate leading to a decrease of greenhouse gases
Increased recycled of medical plastics

Establishing a Culture of Safety

Quality assurance in our healthcare facilities is dependent on promoting a culture of patient safety, where all members of the gastroenterology endoscopy team are

Table 5. Common Terminology

Terminology	Acronym
Manufacturer's Instructions for Use	MIFU
Endoscope associated infection	EAI
High level disinfection	HLD
Liquid chemical sterilization	LCS
Healthcare acquired infections	HAI
Multi-drug resistant organisms	MDRO
The Centers for Disease Control and Prevention	CDC
Ambulatory surgical centers	ASC
Automated endoscope reprocessor	AER
Automated endoscope cleaner	AEC
Endoscopic retrograde cholangiopancreatography	ERCP
Ethylene oxide	EtO
Regulated medical waste	RMW
National patient safety foundation	NPSF

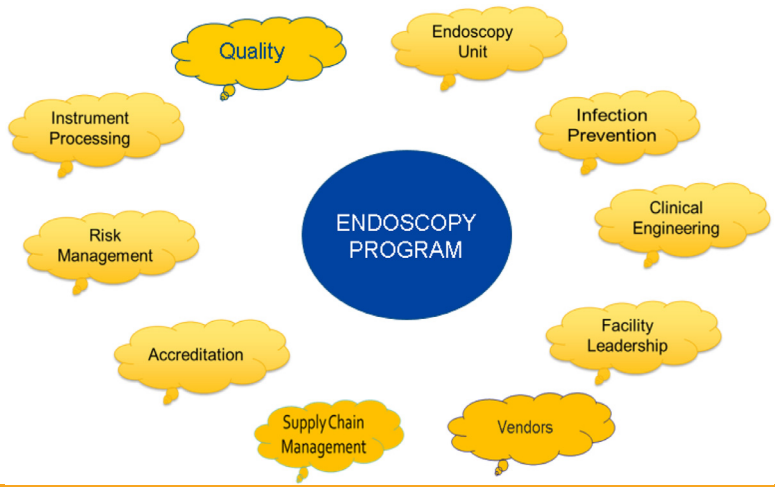

Figure 1. Reprocessing oversight committee membership.

engaged in infection prevention measures in the unit. Numerous studies reveal a strong link correlating a positive safety culture and improved patient safety within a healthcare organization. Yet many leaders continue to struggle to achieve such a culture in today's fast-paced and extremely complex healthcare environment.[23] The evidence is overwhelmingly convincing that the National Patient Safety Foundation (NPSF) cites leadership support for a safety culture as a significant component in the facility's quest for achieving patient safety (Tables 4 and 5).

Simply stated, a culture of safety is the combination of attitudes and behaviors focused upon patient safety that are conveyed to the caregiver not just when initially joining the healthcare facility, but is ongoing and demonstrated through the daily operation of the facility. The Joint Commission provides an enriched definition as; "A culture of safety is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization's commitment to quality and patient safety." In many components of our work life, there is a gradual process which takes place through which unacceptable practices become acceptable and the performance norm. Shortcuts taken in the reprocessing of endoscope is 1 example. As the deviant behavior is willing fully repeated without correction and without known catastrophic results. The behavior rapidly becomes the accepted norm for the worker and perhaps their peers and even for the organization. This phenomenon has been labeled as the "Normalization of Deviance." Leaders can assist their teams establish a strong culture that offers quality patient care in a transparent and safe environment. Building an institutional multi-disciplinary team with the specific goal of providing additional oversight and guidance of endoscope reprocessing may provide this safe environment with the opportunity to openly hold discussions concerning subjects such as compliance with regulatory mandates and accreditation expectations, literature review of reprocessing updates, appropriate space is provided for reprocessing with standardization of reprocessing protocols and equipment, scheduling of adequate reprocessing staff with sufficient time to complete reprocessing, with available continuing education and training of the reprocessing team (Figure 1).

In closing, the consequences from improperly performed reprocessing of endoscopes can be disastrous to our patients, clinicians, and the organization. Significantly placing patients are at risk of acquiring an infection. Exposing our clinicians to the biohazardous and toxic conditions in the reprocessing room and potentially damaging the reputation of the institution. Effective endoscope reprocessing is imperative and accomplished through the adherence of MIFUs, professional guidelines training and process oversight. Though endoscope reprocessing remains an extremely complex and tedious responsibility. Technology may assist in reducing the risk through improvements in the design of endoscopes, cleaning verification tests, microbial surveillance and terminal sterilization of endoscopes. However, through the use of disposable/single use endoscopes, the potential risks of an EAI should dramatically fall. The environmental impact from the utilization of these onetime use instruments will also be greatly diminished. Largely reducing the regulated and nonregulated waste stream created by the products consumed to reprocess endoscopes. As clinicians, administrators, support personnel and vendors, we must work together and actively strive to increase patient safety and reduce the risk of unnecessary harm to the patient

REFERENCES

1. Kenters N, Huijskens EGW, Meier C, et al. Infectious diseases linked to cross-contamination of flexible endoscopes. Endosc Int Open 2015;3(4):E259–65.
2. ECRI Institute. Top 10 health technology hazards list. Published annually. https://www.ecri.org. Accessed April, 2021.
3. Food and Drug Administration, FDA, Gastroenterology and urology devices panel of the medical devices

advisory committee; 2021. https://wayback.archive-it.org/7993/20170112002249/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/ucm445590.htm. Accessed April, 2021.

4. Schaefer MK, Jhung M, Dahl M, et al. Infection control assessment of ambulatory surgical centers. JAMA 2010;303:2273–9.
5. Seelan MT, Friend TH, Levine WC. Optimizing endoscope reprocessing resources via process flow queuing. Anal J Med Syst 2018;42:111.
6. Alfa MJ, DeGagne P, Olson N, et al. EVOTECH endoscope cleaner and reprocessor(ECR) simulated-use and clinical-use evaluation of cleaning efficacy. BMC Infect Dis 2010;10:200.
7. Ofstead CL, Wetzler HP, Snyder AK, et al. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. Gastroenterol Nurs 2010;33:304–11.
8. Alfa MJ, DeGagne P, Olson N, et al. Comparison of liquid chemical sterilization with peracetic acid and ethylene oxide sterilization for long narrow lumens. Am J Infect Control 1998;26:469–77.
9. Frias M, Tsai V, Moulton-Meissner H, et al. Notes from the Field: New Delhi Metallo-β-Lactamase-producing Escherichia coli associated with endoscopic retrograde cholangiopancreatography. Morb Mortal Wkly Rep [MMWR] 2014;62:1051.
10. Thacker Adarsh, Muthusamy V Raman, Sedarat Alireza, et al. Duodenoscope reprocessing practice patterns in U. S. endoscopy centers: a survey study. Gastrointest Endosc 2018;88:316–22. e2.
11. Molloy-Simard V, Lemyre Jean-Luc, Martel Karine, et al. Elevating the standard of endoscope processing: Terminal sterilization of duodenoscopes using a hydrogen peroxide–ozone sterilizer. Am J Infect Control 2019;47:243–50.
12. Food and Drug Administration, FDA, News Release: Recommends health care facilities and manufacturers begin transitioning to duodenoscopes with disposable components to reduce risk of patient infection 2019, https://www.fda.gov/news-events/press-announcements/fda-recommends-health-care-facilities-and-manufacturers-begin-transitioning-duodenoscopes-disposable.
13. Pasricha PJ, et al. Novel and effective disposable device that provides 2-way protection to the duodenoscope from microbial contamination. Gastrointest Endosc 2020;92: 199–208. https://doi.org/10.1016/j.gie.2020.03.001. Epub 2020 Mar 6.
14. Trindade AJ, et al. Single-use duodenoscopes and duodenoscopes with disposable end caps Practice Guideline. Gastrointest Endosc 2021;93:997–1005. https://doi.org/10.1016/j.gie.2020.12.033. Epub 2021 Mar 10. Accessed April, 2021.
15. Healthcare Without Harm, https://noharm-global.org/. 2021. Accessed April, 2021.
16. Agrwawal, D, Shoup, Valerie MBA; Montgomery, Amy RN, CGRN et al. Disposal of endoscopic accessories after use gastroenterological nursing, volume 40 2017
17. Ofstead, C et al. A Glimpse at the true cost of reprocessing endoscopes, https://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/portfolio-group/LithoVue/pdfs/Sterilization-Resource-Handout.pdf. Accessed April, 2021
18. Association for the advancement of medical instrumentation water for the reprocessing of medical devices technical information report TIR 34:2007. Accessed April, 2021.
19. Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee (HICPAC) essential elements of a reprocessing program for flexible endoscopes 2017 https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html. Accessed April, 2021
20. Day, Lukjohn, Muthusamy V. Raman, Collins James, et al. Multisociety guideline on reprocessing flexible GI endoscopes and accessories 2021
21. Olympus medical and surgical customer advisory letter OER-pro water consumption 2016. Accessed April, 2021.
22. Household Water Systems, https://www.householdwatersystems.com/how-much-water-does-a-shower-use/ 2021. Accessed April, 2021.
23. Sammer CE, James BR. Patient safety culture: the nursing unit leader's role. J Issues Nurs 2011;16:3. https://doi.org/10.3912/OJIN.Vol16No03Man03.
24. Visrodia KH, et al. The use of rapid indicators for the detection of organic residues on clinically used gastrointestinal endoscopes with and without visually apparent debris. Infect Control Hosp Epidemiol 2014;35:987–94. https://doi.org/10.1086/677148. Epub 2014 Jun 20. Accessed April, 2021.
25. Ofstead Cori, Wetzler Harry, Heymann Otis, et al. Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes: Results of visual inspections, biochemical markers, and microbial cultures. Am J Infect Control 2017;45(2):e26–33.

Correspondence
Address correspondence to: James Collins, BS, RN, CNOR, Endoscopy Accreditation Nurse, Digestive Disease & Surgical Institute, Cleveland Clinic, 9500 Euclid Avenue, Cleveland, Ohio 44195 e-mail: collinj@ccf.org

Conflicts of Interest
The authors disclose no conflicts.

Ethical statement
The study did not require the approval of an institutional review board.