Fall 2019

Reducing the Risks of Contaminated Flexible Endoscopes and Improving the Margin of Safety with the Reprocessing Process

Lisa Greenwell
lisagreenwell@comcast.net

Reducing the Risks of Contaminated Flexible Endoscopes and Improving the Margin of Safety with the Reprocessing Process

Lisa Greenwell

Murray State University

Abstract

Gastrointestinal (GI) endoscopy is a minimally invasive, medical procedure that is an important tool for the identification and treatment of disorders of the gastrointestinal tract. Contaminated flexible endoscopes pose a significant risk to patients. Endoscopy associated infections and outbreaks have been reported with multidrug resistant microorganisms. Inadequate endoscope reprocessing has been associated with infectious outbreaks, but some outbreaks have occurred despite strict adherence to established guidelines. To lessen the risk associated with endoscopy, it is imperative to identify problem areas within current reprocessing standards and develop, evaluate, and implement evidence-based solutions.

Keywords: flexible endoscope reprocessing, endoscope associated infections, contaminated endoscopes,

Table of Contents

LIST OF FIGURES

Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
ACG	American College of Gastroenterology
AER	Automatic endoscope Reprocessor
AORN	Association of perioperative Registered Nurses
APIC	Professionals in Infection Control and Epidemiology
ASG	Ambulatory Care Center
ATP	Adenosine triphosphate
BFF	Biofilm buildup
CDC	Centers for Disease Control and Prevention
CRE	Carbapenem-resistant Enterobacteriaceae
EGD	Esophagogastroduodenoscopy
ERCI	Emergency Care Research Institute
ERCP	Endoscopic retrograde cholangiopancreatography
FDA	Food and Drug Administration
HICPAC	Healthcare Infection Control Practices Advisory Committee
HLD	High-level disinfection
IAHCSMM	International Association of Healthcare Central Service Material Management
IFU	Manufacturer's Instructions for Use
JC	Joint Commission
MBEC	Minimum biofilm eradication concentration
MDRO	Multiple drug resistant organisms
SGNA	Society of Gastroenterology Nurses and Associates, Inc.
WGO	World Health Organization

Glossary of Terms

Antimicrobial agent: A drug or chemical that either kills or slows the growth of microbes.

Automated endoscope reprocessor: Is a machine designed to clean and disinfect endoscopes.

Bioburden: The number of microorganisms on a contaminated endoscope.

Biofilm: Collection of microorganisms than can attach to surfaces and each other to form colonies. This colony produces a protective gel that is difficult to penetrate with enzymatic cleaners and high-level disinfection.

Borescope: Is an optical device used for visual inspection of an endoscope's internal channels to check for moisture, damage, and organic material.

Cleaning: The process of removing bioburden from an endoscope.

Contamination: Refers to a flexible endoscope soiled by encountering microorganisms, bacteria, body fluids, and blood.

Cross contamination: Transmission of contaminates from one person to another via a flexible endoscope.

Decontamination: The process to remove or reduce microorganisms through reprocessing.

Disinfectant: A chemical that kills most pathogens but not spores.

Disinfection: Process to chemically destroy nearly all pathogenic microorganisms.

Endoscope-associated infection: An infection acquired from an endoscopic procedure. Can be an endogenous infection acquired by a patient's own microflora or bacteria. Or an exogenous infection acquired from a contaminated endoscope.

Forced air dying: The process of pushing low pressure instrument grade air through channels of an endoscope.

Inactivation: To stop or destroy microorganisms.

Instructions for use (IFU): Written instructions provided by the manufacturer of an endoscope to safely and effectively reprocess an endoscope.

High-level disinfectant: Is a chemical germicide used to disinfect contaminated endoscopes.

High-level disinfection: Refers to the process to eradicate all microorganisms except for low levels of bacteria spores.

Leak testing: Process to detect any damage to an endoscope which can cause fluid invasion.

Manual cleaning: Is the reprocessing step that includes cleaning the external surfaces of an endoscope and brushing the interior working channels with an enzymatic detergent solution.

Microbes: Microscopic organism, bacteria, fungi, protozoan, or parasite.

Microorganisms: An organism that can only be seen with the use of a microscope.

Pathogens: Microorganisms capable of causing disease such as bacteria, fungi, viruses, and protozoa.

Reprocessing: The validated process of rendering an endoscope safe and ready to reuse on another patient. The process includes all steps from pre-cleaning to storage.

Sterilization: Process which destroys all microorganisms including spores, bacteria, viruses, and fungi.

Turn over time: The total amount of time an endoscope is used on one patient and then needed for subsequent patients for another endoscopic procedure.

Introduction

Gastrointestinal flexible endoscopes are medical devices that play a vital role for the diagnosis, treatment, and surveillance for an extensive variety of health conditions and diseases. Approximately 75 million endoscopy procedures are performed in the United States annually (IData Research, 2018). Gastrointestinal endoscopies account for 68% or 51.5 million of the procedures performed annually (IData Research, 2018). Flexible endoscopes are re-usable, complex devices that present challenges to consistently reprocess and disinfect to use on subsequent patients. The United States Food and Drug Administration (FDA) defines reprocessing of flexible endoscopes as the process to render a contaminated endoscope ready for the next patient use (Society of Gastroenterology Nurses and Associates [SGNA], 2016). Reprocessing removes bioburden and contaminants through a validated cleaning process followed by high-level disinfection (HLD) or sterilization to inactive microorganisms (Klacik, 2018). The risk of endoscopy associated patient infections is much higher than the health care community once believed. There are more patient related infections associated with gastrointestinal flexible endoscopes than any other medical device (Griffiths & Dwyer, 2018). Multi-drug resistant outbreaks have been documented even with strict adherence to current guidelines for reprocessing flexible endoscopes. Cross-contamination of antibiotic-resistant drugs is becoming more prevalent in the United States (Beauclair, 2018).

Contaminated endoscopes generally result from inconsistencies or non-compliance with established reprocessing guidelines and is the leading cause for endoscope-acquired infections (Lind, 2018). Flexible endoscopes become highly contaminated during procedures and present significant challenges to reprocess consistently and effectively. During an endoscopy procedure, endoscopes are exposed to body fluids and potential contaminants on the internal and external

services of the device. These devices are reprocessed and used on multiple patients daily. The complex design of endoscopes enables these instruments to complete a wide range of diagnostic and therapeutic procedures but also presents significant challenges to reprocess these scopes for the next patient (Thornhill, Talapa, & Wallace, 2015). Endoscopes that are not effectively reprocessed can retain fluid or tissue from one patient and remain on the scope when used on subsequent patients. Any remaining fluid or tissue can lead to patient-to-patient transmission of infections.

Multiple studies site transmission of microorganisms by flexible endoscopes with multiple drug resistant organisms (MDROs) (Thornhill et al., 2015). The assumption that gastrointestinal endoscopy procedures have a very low risk of pathogen transmission is outdated and inaccurate. In 2013, endoscopy related infections gained media attention when two hospitals reported antibiotic resistant infections with patients who had endoscopic retrograde cholangiopancreatography (ERCP) procedures (Beauclair, 2018). Transmission of Carbapenem-resistant Enterobacteriaceae (CRE), was associated with the duodenoscopes used for ERCP procedures but all endoscopes carry risk of patient infection. The FDA reported in 2015, that two deaths occurred after contacting CRE during ERCP procedures (Beauclair, 2018). These outbreaks lead Senator Patty Murray, to launch an investigation into duodenoscope-linked infections. During the Senate Health, Education, Labor and Pensions Committee, lead by Senator Murray, an investigation discovered that 250 patients between 2012 and 2015 were affected with 25 different instances of antibiotic-resistant infections (Beauclair, 2018).

Since this time, the regulating agencies governing reprocessing guidelines have worked to revise the standards related to flexible endoscopes reprocessing. The American Journal of Infection Control published a study in 2017 which discovered that current techniques to

reprocess flexible endoscopes are inadequate to consistently produce patient-ready scopes despite rigorous reprocessing practices (Association for the Advancement of Medical Instrumentation [AAMI], 2017). In the wake of highly published endoscope associated multidrug-resistant organisms outbreaks, these agencies are focused on understanding the factors that influence transmission of microorganisms between endoscopes and patients and improving endoscope reprocessing standards.

There are many agencies that impact and govern endoscope reprocessing. These agencies include federal, state, and professional associations. Professional organizations develop both voluntary and regulation standards for the industry. Professional agencies develop reprocessing guidelines to improve the consistency of patient care and reduce the risk of endoscope related infections associated with contaminated endoscopes. Regulating or professional agencies include: Association for the Advancement of Medical Instrumentation (AAMI), Association of perioperative Registered Nurses (AORN), Society of Gastroenterology Nurses and Associates, Inc. (SGNA), along with the following government agencies Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA).

Flexible Endoscope Overview

Endoscopy procedures are minimally invasive and are considered nonsurgical procedures utilized to visualize internal structures in the body. Endoscopy offers a simple procedure with less discomfort and faster recovery times to diagnosis a wide range of gastrointestinal disorders as compared to invasive surgery. The three most common gastrointestinal procedures performed are esophagogastroduodenoscopy (EGD), which examines the esophagus, stomach, and the upper duodenum. Colonoscopy procedures which examines the rectum and colon. And, endoscopic retrograde cholangiopancreatography (ERCP), which examines the gallbladder, biliary system, pancreas, and liver.

A flexible endoscope is a long, thin tube attached to a light source and camera. This camera allows images to be relayed from the inside of the body to a video screen. Flexible endoscopes are inserted into the body through the mouth for endoscopy and ERCP procedures and the rectum for colonoscopy. In 2002, high-definition television (HDTV) was introduced and represented a significant advancement in medical technology (Beauclair, 2018). This technology allows images to be projected onto a TV screen. HDTV technology advanced physician's ability to make accurate diagnoses and treat Gastrointestinal disorders. In the process, technical advancements have created difficulties and challenges in reprocessing these complex endoscopes needed to accommodate for HDTV compatibility.

The Emergency Care Research Institute (ERCI) publishes an annual report called the Top 10 Patient Safety Concerns for Healthcare Organizations. This report identifies sources of danger or risks they feel should be given top priority for healthcare facilities to address in the upcoming year. In 2018, the ERCI's report labeled "failure to consistently and effectively reprocess flexible

endoscopes as #2 on the list", second only to cybersecurity (Scoping the problem, 2018). Endoscope reprocessing and patient safety has made this report since 2010 (Beauclair, 2018).

Rutala (2018) states, "If the margin of safety for flexible endoscopes is so small that perfection is required, then the design is too complex and the process is too unforgiving to be practical in a real-world setting" (Rutala, 2018). Challenges that the professional agencies that govern endoscope reprocessing have focused on since the beginning of multi-drug resistant outbreaks occurred with duodenoscopes in 2013. Since that time, all relevant agencies that govern endoscope processing, have updated the standards and guidelines for reprocessing these scopes (Prust, 2018).

Endoscope reprocessing is a challenging and difficult multi-step task process. (Hildebrand et al., 2010). Flexible endoscopes have long, narrow internal channels (3.5 ft in length and 1-3mm in diameter), right-angle turns, springs, valves, and rough or pitted surfaces (Pyrek, 2016). These characteristics along with the heavy contamination of microorganisms endoscopes encounter during a procedure make them very difficult to clean and reprocess. These technically advanced endoscopes are heat sensitive which cannot be sterilized with terminal steam sterilization. High level disinfection (HLD) is recognized by all governing agencies as the regulating standard for reprocessing flexible endoscopes (SGNA, 2016). HLD is defined as the chemical process that kills pathogenic microorganism but may not kill all microbial forms such as spores (Thornhill et al., 2015). As opposed to steam sterilization, HLD eradicates all microorganisms but may not eradicate all bacteria spores (SGNA, 2016). According to Thornhill et al. (2015) sterilization is defined as the process used to kill all microorganisms including bacteria spores and produces sterile devices (Thornhill et al., 2015).

Numerous studies suggest that current practices and standards to reprocess flexible endoscopes are not adequate to consistently and effectively produce patient ready endoscopes. To ensure patient safety and a greater margin of safety, agencies should work together to evaluate the causes of endoscope-related outbreaks and implement new strategies that will improve the safety margin associated with flexible endoscope reprocessing (Rutala & Weber, 2018). Standardized microbiological culturing of flexible endoscopes must be established as part of departmental quality assurance programs (Prust, 2017). As well as updating the Spaulding Classification System that categorizes reusable medical devices into three categories based on the devices intended use and the devices risk for infection.

Outbreaks associated with contaminated endoscopes gained national media attention when the FDA received 75 reports of CRE infection outbreaks that were linked to reprocessed duodenoscopes (AAMI, 2015). CRE is an important health concern because the treatment options are limited and are associated with high rates of mortality (Epstein, Hunter, & Arwady, 2014). The outbreaks involved 250 patients between 2012 and 2015 in Chicago, Pittsburg, Seattle, and Los Angeles (Pyrek, 2016). Recent outbreaks of antibiotic resistant micro-organisms have become an issue for endoscopy procedures worldwide. These outbreaks occurred with duodenoscopes despite strict adherence to the recommended reprocessing guidelines (Kenters et al., 2018).

To reduce the possibility of outbreaks due to contaminated endoscopes, it is imperative to identify problem areas with current reprocessing standards. According to the American Society of Gastrointestinal Nurses (2016), systematic reviews of endoscopy related infections indicated most reported outbreaks resulted from, non-compliance with existing guidelines (SGNA, 2016). Numerous studies have also concluded that lapses in essential reprocessing steps and storage of

endoscopes have contributed to infection outbreaks. However, outbreaks caused by CRE and other microorganisms have occurred despite strict adherence to established guidelines (Humphries & McDonnell, 2015).

A study by McCafferty et al. (2018) examined factors contributing to gastrointestinal related infections from 2008-2018. The authors concluded the study with a list of reprocessing errors which included: endoscopic design issues, endoscope damage, biofilm formation, lack of surveillance monitoring policies, and lapses in reprocessing (McCafferty, Aghahani, Abi-Hana, & Gosbell, 2018). Eighteen outbreaks were reviewed in the study which revealed that manual cleaning to prevent biofilm formation was inadequate in four outbreaks (McCafferty et al., 2018). Seven of the eighteen outbreaks occurred from biofilm formation with no apparent reprocessing lapses (McCafferty et al., 2018).

Multiple society and manufacturer recommendations emphasis that each step of the endoscope reprocessing procedure must be performed correctly (SGNA, 2016). Failure to strictly adhere to manufacturer instructions for use (IFU), standards, and guidelines increase the risk of infection (Lind, 2018A). When steps of the process are skipped or not performed correctly, cleaning errors occur. All endoscopes require a multiple step reprocessing process, some requiring over 100 steps in the process (Lind, 2018A). A study by Ofstead and Associates reported that most of the time one or more reprocessing steps were skipped or improperly completed and 45% of the time multiple steps were skipped (Lind, 2018A).

Microbiology Basics for Endoscope Reprocessing

Microbiology basics are vital for endoscope reprocessing personnel. Knowledge of microbiology enables professionals to understand how to identify and destroy pathogens before they lead to cross contamination of flexible endoscopes. Knowledge about microorganisms also helps promote a better understanding of how critical each step of the reprocessing process is to patient safety and prevention of cross contamination of endoscopes.

Endoscopy related infections occur in two ways, endogenously or exogenously (Puri, 2019). Endogenous infections are spread by a microorganism capable of causing disease (pathogen). In this type of infection, patients become infected with their own bacteria or microflora after an endoscopy procedure (Puri, 2019). Endogenous infections can occur when mucosal membranes are damaged or irritated during endoscopy procedures. This might occur if the flexible endoscope brushes up against the lining of the esophagus, stomach, or colon disrupting the mucosal lining. Bacteria present in the stomach useful for digestion of food can be harmful if it is spread to the esophagus. This type of bacteria is called symbiotic bacteria. A good bacterium helps a human body by its presence (International Association of Healthcare Central Service Material Management [IAHCSMM], 2017). Another example of an endogenous infection is pneumonia. Pneumonia results from aspiration of fluids into a patient's lungs during an endoscopy procedure. Endogenous infections are associated with complications from endoscopy procedures. This type of infection is not the result of contaminated endoscopes (Kovaleva, Peters, Mei, & Degener, 2013). Most endoscopy related infections are a result of endogenous infections (Kovaleva et al., 2013).

Exogenous infections are spread from bacteria entering a patient's body from the endoscopy unit. This type of infection is a direct result of foreign bacteria entering a patient's

body via an endoscope. Exogenous infections are transmitted from previous patients from contaminated flexible endoscopes (Puri, 2019). These are caused by pathogens that are not normally found in the body. They are less common than endogenous infections (Puri, 2019). Exogenous infections can be prevented. Exogenous infections are most commonly the result of human error, skipping reprocessing steps, inadequate standards for reprocessing, biofilm formation, improper reprocessing, and drying of endoscopes. However, recent outbreaks of endoscope-related exogenous infections have been documented when manufacturer's instructions and guidelines for reprocessing were strictly followed (Puri, 2019).

Pseudomonas aeruginosa pathogens are the most common type of exogenous infection associated with endoscopy-related procedures (Puri, 2019). Pseudomonas thrives in a moist environment and can form protective biofilms. Evidence from numerous studies, links most pseudomonas infection outbreaks to inadequate reprocessing of flexible endoscopes (Beauclair, 2018).

Bacteria are the smallest, independently living cells in existence (Alfa & Howie, 2009). They cannot be seen by the naked eye and are colorless. These small bacteria require stains or a microscope for visualization. During endoscopy procedures, endoscopes become contaminated with blood, body secretions, and bacteria (Kovaleva et al., 2013). These complex endoscopes are problematic to clean and reprocess between patients. When endoscopes are not properly reprocessed bacteria can form protective biofilms making the disinfectant solutions used to clean scopes less effective (Beauclair, 2018). Biofilms are a potential source of serious problems for flexible endoscopes and endoscopy departments (Boudarel, Mathias, Blaysat & Grediac, 2018).

Biofilm is a complex system of bacteria present on a surface which is housed in a three-dimensional extracellular matrix (Boudarel et al., 2018). Biofilm formation of flexible

endoscopes is a gradual process that begins with a preconditioning film of organic material deposited on the surface of an endoscope (Roberts, 2013). Colonizing bacteria continue attaching to this preconditioning film. During this stage, the preconditioning film and bacteria can be easily removed from an endoscope with cleaning and reprocessing because of their loose attachment (Roberts, 2013). If the biofilm is not removed during this stage, irreversible attachment begins. Bacteria will multiple and a mature biofilm can develop (Roberts, 2013). Once mature biofilm develops, they release colonizing cells which can form biofilms on other surfaces (Boudarel et al., 2018). To prevent biofilm development and colonization, it is imperative to promptly and properly reprocess endoscopes. Biofilms will continue to increase in both size and number of bacteria. The longer it takes for endoscope reprocessing to occur, the more difficult it becomes to completely remove the biofilm (IAHSCMM, 2017).

Biofilms offer bacteria protection against environmental, cleaning and disinfecting agents. (Boudarel et al., 2018). During the biofilm formation process, when bacteria attach to an endoscope, its grip strength increases, this can happen in as little as 12 minutes (IAHSCMM, 2017). Bacteria then send out messages for other bacteria to join the biofilm forming community (Roberts, 2013). These bacteria attach to each other in a way that fills the matrix between the bacteria (Roberts, 2013). In favorable conditions, wet and moist environments, some bacteria can double every 20 minutes as shown in Figure 1 below (IAHSCMM, 2017). Bacteria protected within biofilms have a high survival rate and are difficult to destroy. It has been clinically proven that bacteria found within a mature biofilm can be 10 to 1500 times more resistant to chemical disinfectant agents than that of the same bacteria not protected within a biofilm (IAHSCMM, 2017). Biofilms can be resistant to chemical agents and antibiotic exposure. Biofilms are found

everywhere and will colonize all surfaces which provide enough humidity, temperature, nutrients, and oxygen for microbial life (Roberts, 2013).

Time	# organisms
After HLD reprocessing	1
20 minutes	2
40 minutes	4
1 hour	8
2 hours	64
3 hours	512
4 hours	4,096
5 hours	32,768
6 hours	262,144
7 hours	2,097,153

Figure 1. How fast can bacteria multiple in favorable conditions, some bacteria can double every 20 minutes. Adapted from "Microbiology Basics for Endoscope Reprocessors,", 2017, *IAHCSMM Reprocessing Manual*, p. 38.

Biofilms are more resistant to inactivation using antimicrobial agents and antibiotics than free-standing bacteria (Roberts, 2013). Bacteria inside mature biofilms can be 1000 times more resistant to antibiotics than bacteria outside a biofilm (IAHSCMM, 2017). Antimicrobial agents and antibiotics must penetrate the biofilm matrix to reach the cells. Biofilm formation on flexible endoscopes can lead to serious infections. Biofilm inside or on the exterior surface of an endoscope is the result of organic material and moisture left on the scope from inadequate reprocessing (Roberts, 2013). Biofilm formation will readily occur on endoscopes if prompt

reprocessing guidelines are not strictly followed. The lumens and channels inside the endoscope create a perfect environment for biofilms to thrive and multiple.

Contaminated surfaces in the reprocessing and storages areas of endoscopy departments can contaminate a patient ready endoscope. Bacteria and or biofilms from work areas can then attach to patient ready scopes (Roberts, 2013). It is imperative to keep work surfaces disinfected and clean using proper disinfectants. Bacteria can live on a dry surface from 3 days to 30 months (IAHSCMM, 2017). Figure 2 below shows how long bacteria can survive on a dry surface. As well as careful handling of patient ready endoscopes and storage following strict adherence to the recommended standards.

Survival on dry surfaces

Pathogen	Survival on Dry Inanimate Surfaces
Acinetobacter sp.	3 days to 5 months
Clostridium difficile (spores)	5 months
Pseudomonas aeruginosa	6 hrs to 16 months; 5 weeks on dry floors
Staphylococcus aureus (including MRSA)	7 days to 7 months
Aspergillus (spores)	Months or longer
Coronavirus (e.g. SARS, GI infections, cold)	3-28 days
Influenza virus	1-2 days
Norovirus	Months or longer

Figure 2. Survival of bacteria on dry, non-living surfaces. Adapted from "Microbiology Basics for Endoscope Reprocessors," 2017, *IAHCSMM Reprocessing Manual*, p. 46.

Microbial growth within a mature biofilm is now recognized by governing agencies as the primary source of microbial growth on flexible endoscopes and work surfaces (Roberts, 2013). Progressive accumulation of organic material and or biofilm buildup (BFF) occurs with repeated cycles of endoscope reprocessing: drying, disinfectant exposure, and re-exposure to bacteria (Roberts, 2013). Flexible endoscopes are used repeatedly in one day. Repeated daily use over time can facilitate a BFF (Alfa & Howie, 2009). Inadequate reprocessing of endoscopes has been proven to decrease the effectiveness of HLD (Roberts, 2013). Alfa and Howie (2009) studied the effects of progressive accumulation of biofilm buildup on flexible endoscopes. Laboratory experiments were conducted using the Minimum Biofilm Eradication Concentration (MBEC) Assay method. According to Alfa and Howie (2009), MBEC Assay is a biofilm growth device that provides evaluation of testing conditions against microorganisms in their natural, biofilm state (Alf & Howie, 2009). During this study, biofilms were produced to mimic the biofilms than can grow and form on the internal channels of a flexible endoscope (Roberts, 2013). The study concluded the effectiveness of HLD can decrease if biofilms develop in the internal channels of an endoscope (Alfa & Howie, 2009). The results also indicated that HLD can kill microorganisms within a young biofilm but not a mature biofilm (Alfa & Howie, 2009).

Antibiotic resistant occurs when bacteria develop the ability to resist antibiotics used to destroy them. Infections caused by these bacteria are difficult to treat. Resistant bacteria can develop defense strategies that protect them from antibiotics. This process is called resistance mechanisms (Alfa & Howie, 2019). This occurs in several ways. Some bacteria such as gram-negative use their outer membrane to selectively keep certain antibiotics from entering this membrane. Pseudomonas aeruginosa resistant bacteria can use the pumps inside their cell walls to get rid of certain antibiotics (Boudarel et al., 2018). Klebsiella pneumoniae resistant bacteria

use enzymes to make antibiotics ineffective and break antibiotics down (Roberts, 2013). Staphylococcus aureus resistant bacteria have the ability to bypass the effects of antibiotics and change the antibiotic, so it becomes less effective (Boudarel, 2018). E Coli resistant bacteria can add a compound to the cell wall so that antibiotics cannot latch onto it (Roberts, 2013).

Antibiotic resistance is becoming a highly dangerous problem world-wide. This resistance threatens healthcare's ability to treat even common infectious diseases. According to the World Gastroenterology Organization (2018), if we do not find ways to control this problem, we are heading into a post-antibiotic era (World Gastroenterology Organization [WGO], 2018). An era where common infections and minor injuries can kill.

Drug resistant infection outbreaks have been documented with flexible endoscopes despite strict adherence to all reprocessing standards and guidelines. Cross contamination can lead to series even fatal consequences for patients. The best defense against antibiotic resistant bacteria is to prevent bacteria and biofilm from forming (Ofstead, Hopkins, Eiland, & Wetzler, 2018B). According to Ofstead et al. (2018), there are three different levels of disinfection to prevent bacteria and biofilm formation (Ofstead et al., 2018B):

1. Sterilization: Endoscopes are heat-sensitive and cannot be sterilized by steam. The following methods have been approved for flexible endoscopes:
    (a) EtO gas
    (b) Liquid chemical sterilization
2. High-Level Disinfection: HLD is the minimal requirement for reprocessing semi-critical endoscopes. HLD eliminates enough pathogens to prevent transmission of infection
3. Low-level disinfection: Cleaned with hospital disinfectant solution

Humphries and McDonnel (2015) state the FDA acknowledges that sterilization completely inactivates all microorganisms. HLD inactivates most microorganisms except for a small number of bacteria spores (Humphries & McDonnel, 2015). This process achieves a 4 to 6-log reduction of microorganisms (Humphries & McDonnel, 2015). Sterilization is required to produce a 12-log reduction of microorganisms including bacterial spores (Humphries & McDonnel, 2015). Gastrointestinal flexible endoscopes are heavily contaminated after procedures with a 10 7-10 log of microorganisms (Humphries, McDonnel, 2015). Cleaning of endoscopes results in a 2-6 log reduction in live bacteria. HLD results in a 4-6 log reduction (Humphries, McDonnel, 2015). The endoscope reprocessing process only results in a 6-12 log reduction of microbes (Humphries, McDonnel, 2015). The entire reprocessing process leaves a 4-log level of contamination on patient-ready endoscopes (Humphries, McDonnel, 2015). A 4-log level of contamination is the maximum level acceptable by the FDA (Prust, 2018). According to SGNA (2017), a small number of bacteria spores remaining on endoscopes after HLD is not harmful because the lungs and gastrointestinal tract are resistant to bacterial spores (SGNA, 2017). However, the lungs and gastrointestinal tract are not resistant to bacteria, mycobacteria, and viruses (SGNA, 2017). The margin of safety achieved by sterilization is two times that of HLD.

Microorganisms of concern for flexible endoscopes in a gastroenterology setting include: Clostridium difficile, Helicobacter pylori, Escherichia coli, Human immunodeficiency virus (HIV0), Hepatitis C virus, Hepatitis B virus, multidrug resistant M. tuberculosis, VRE, and MRSA which are susceptible to high level disinfectants (SGNA, 2017). Carbapenem resistant (CRE) endoscopy related infections and outbreaks have led to significant challenges to produce patient-ready scopes.

MRDOs are becoming increasingly problematic for all healthcare systems worldwide (WGO, 2019). MRDO microorganisms such as bacteria are becoming resistant to one or more antimicrobial agents. Some pathogens are resistant to only one agent, but many are resistant to most available antimicrobial agents. The pathogens that are resistant to most available antimicrobial agents include: Methicillin Resistant Staphylococcus aureus (MRSA), Vancomycin Resistant Enterococcus (VRE), Carbapenem Resistant Enterobacteriaceae (CRE), Escherichia coli, Klebsiella pneumoniae, and strains of S. aureus (WGO, 2019). These MRDOs are clinically relevant to Endoscopy Departments and reprocessing due to the limited options for treating patients with these infections (WGO, 2019).

During outbreaks of endoscopy related MDROs, patients may not have any symptoms of infection initially but will become symptomatic when bacteria begins colonizing (WGO, 2019). These patients may develop serious systemic infections weeks to months after their endoscopy procedure. The mortality rate of these infection can be as high as 40% (WGO, 2019).

Until recently, endoscopy associated infections were associated with lapses in reprocessing steps such as inadequate cleaning, improper drying, and cross-contamination between clean and dirty endoscopes. With recent outbreaks of CRE reported with no lapses in processing, governing agencies are working to improving guidelines to increase the margin of safety of endoscope reprocessing.

Common Causes of Endoscopy Infections and Outbreaks

Gastroenterology and the number of endoscopic procedures performed each year increases as both technology and procedural advancements occur. With this new technology, new challenges present in endoscope reprocessing and reducing the risk of endoscopy acquired infections. Meticulous reprocessing of flexible endoscopes is crucial to the prevention of cross contamination and infection control. Endoscopy governing agencies have developed evidence-based guidelines for reprocessing flexible endoscopes. Several themes were found to represent most of flexible endoscopy reprocessing failures. These include:

- Complex design
- Lapses in reprocessing steps and guidelines
    - Human error
- Endoscope damage
- Biofilm formation
- Inadequate manual cleaning
- Inadequate drying and storage
- Inadequate standards and guidelines

Endoscope reprocessing is a three-stage process. The first stage is pre-processing which includes cleaning the endoscope using an enzymatic cleaner and suctioning enzymatic cleaner into the endoscope's internal channels. This stage should be completed at bed side immediately following the procedure. The second stage is processing the endoscope by cleaning and rinsing the scope with enzymatic solutions followed by brushing of the internal channels of the scope. HLD with an automated endoscope reprocessed (AER) is the last step in the processing phase.

The third stage is post-processing which includes drying the endoscope's outer surface along with the scope's internal channels. This stage includes correct handling and storage of the endoscope after the scope has gone through the HLD cycle. Each stage has multiple steps which must be followed with strict adherence.

Endoscopy related infections have gained media attention because of the large number of potentially affected patients from endoscopy procedures. During these procedures endoscopes are contaminated with patient's native flora. This potentially contaminated flora must be removed to prevent cross-infection to the next patient. The reprocessing process to remove potential contaminants has been associated with a variable failure rate of 1.8% to 1.9% (McCafferty et al., 2018).

Outbreaks have been reported despite strict adherence to reprocessing guidelines and standards. Kola et al. reported an outbreak of carbapenemase-producing K. pneumoniae (CRKP) from one contaminated duodenoscope that infected five other patients (Ofstead, Heymann, Quick, Eiland, & Wetzler, 2018A). A reprocessing audit revealed no deviations from standard guidelines, but cultures on the scope were positive (Ofstead et al., 2018A). Humphries et al. reported an outbreak of multi-drug resistant Klebsiella pneumonia bacteremia and sepsis following an ERCP procedure in which two of the nine infected patients died (Humphries & McDonnell, 2015). Again, a review of the reprocessing process of the scope showed no deviations from standard guidelines. Qiu et al. (2019) report an outbreak where a duodenoscope from an infected patient contaminated two other patients with P. aeruginosa (Puri, 2019). Despite strict adherence to guidelines the scope remained positive for P. aeruginosa even after four rounds of reprocessing (Puri, 2019). The scope was removed from service and went thru EtO sterilization which rendered the scope negative for P. aeruginosa. Four months later, that same

scope tested positive for P. aeruginosa with biofilm formation in undamaged channels of the scope (Puri, 2019).

A study published by Ofstead et al. (2018A), tested 45 endoscopes from three different hospitals. The study found that 22 out of 45 endoscopes tested contained retained fluid from the reprocessing process in the internal channels (Ofstead et al., 2018A). Forty nine percent of the endoscopes tested were positive for microbial growth (Ofstead et al., 2018B). Two sites studied utilized alcohol flushes and vertical cabinets for endoscope storage. One site studied utilized the same practices and ten minutes of forced air drying. Despite the forced air drying, waterborne pathogens were still present in the scope's internal channels (Ofstead et al., 2018A). The study concluded inadequate and insufficient drying was the contributing factor for the retained fluid and contamination found in the endoscopes Ofstead et al. tested.

Complex Design of Flexible Endoscopes

The sophisticated, configuration and complex design of flexible endoscopes allows the devices to complete a wide range of diagnostic and therapeutic procedures but also presents significant challenges to reprocessing endoscopes for the next patient. Flexible endoscopes are the most complex device used in healthcare (Rutala & Weber, 2014). Many of these scopes contain 30 or more optical components and moveable parts that can be maneuvered around angles in the gastrointestinal tract. Endoscopes have long narrow internal channels (3.5ft, 1-3mm diameter), tight angle bends, springs, and valves. See Figure 3 below for diagram of an endoscope design. Due to their complex design, flexible endoscopes are difficult to clean and reprocess. This complex design allows microorganisms to accumulate in the internal channels during endoscopic procedures.

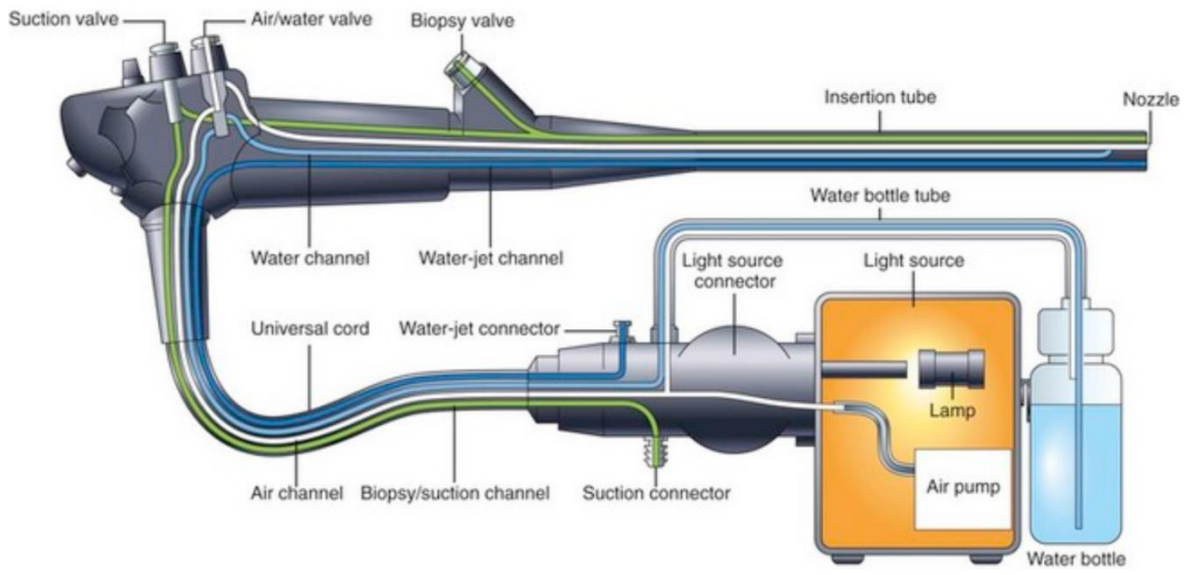

Figure 3. Diagram showing the complex design of the water, air, and suction channels of a flexible endoscope. Adapted from "How Endoscopes Work, Configuration of Air, Water, and Suction Systems," by D.E. Barlow, 2015, *Gastroenterology and Hepatology*, p. 30.

Flexible endoscopes have a control handle that allows physicians to flex the distal tip of the scope up and down and from side to side. The flexibility of endoscopes allows physicians to visualize structures and improve access during procedures. The fiber optics within endoscopes project light and objective lenses enable visualization. Channels within the endoscope provide air, water, suction, and a biopsy channel to insert instruments through. Figure 4 below illustrates the complex design of the components of a flexible endoscope. The distal tip of an endoscope shows the complexity of the design and all the channels present in the scope. Figure 5 illustrates the complexity of the distal tip design of a flexible endoscope.

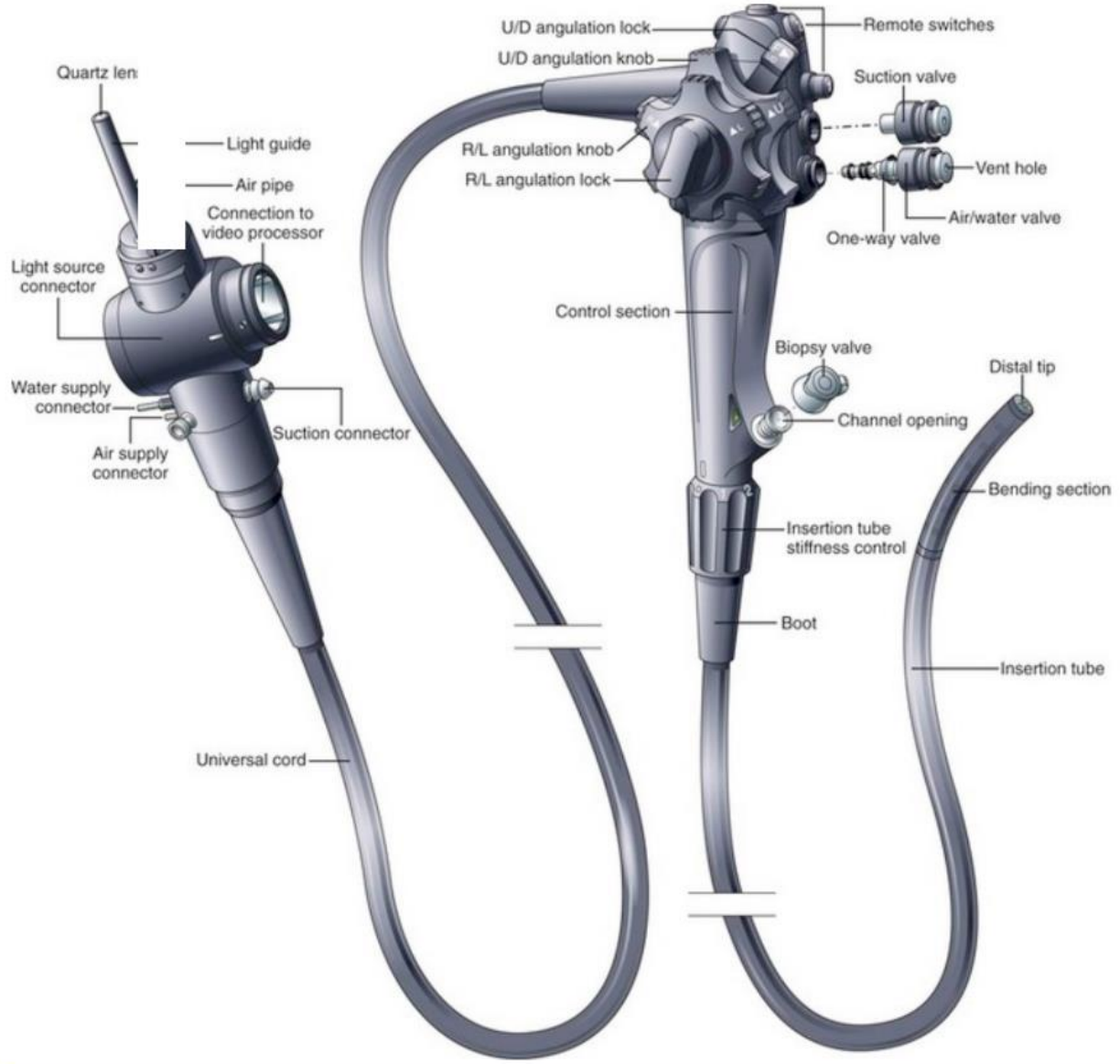

Figure 4. Illustration of the basic components and complex design of a flexible endoscope. Adapted from "How Endoscopes Work, Configuration of Air, Water, and Suction Systems," by D.E. Barlow, 2015, *Gastroenterology and Hepatology*, p. 25.

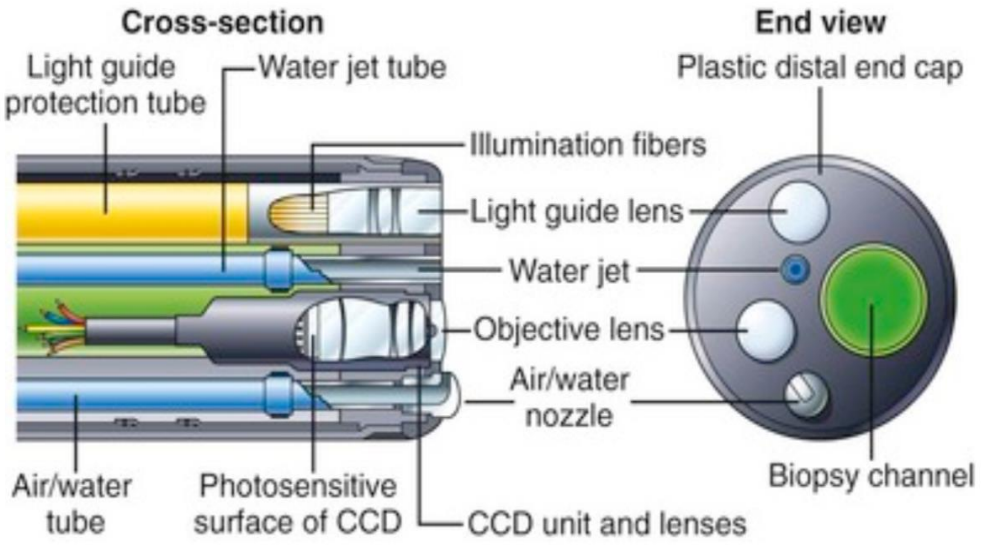

Figure 5. Cross section and end view of the complex design and the components of the distal tip of an endoscope. Adapted from "How Endoscopes Work, Configuration of Air, Water, and Suction Systems," by D.E. Barlow, 2015, *Gastroenterology and Hepatology*, p. 28.

Flexible endoscopes must be able to withstand rigorous manual cleaning and thousands of cycles of HLD. Endoscope design is not conductive for a device that has a high usage rate, subjected to strong manual cleaning, and HLD cycles multiple times a day (Pyrek, 2016). Because endoscopes are subjected to numerous cycles of manual cleaning and HLD daily, Pyrek concludes reprocessing may be creating a cycle of microbial growth, partial eradication of bacteria, and regrowth of bacteria in the internal channels of endoscopes (Kovaleva & Buss, 2011).

Flexible endoscopes are heat sensitive which eliminates the use of steam sterilizers as a method of sterilization. Flexible endoscopes do not tolerate high processing temperatures and cannot be autoclaved. Currently, endoscopes are only approved for HLD and low temperature

sterilization. HLD has become the standard of care recommended by agencies that govern reprocessing guidelines.

Flexible endoscopes are also very susceptible to damage at any point in their use cycle. The design incorporates delicate parts and fibro optics which can break or malfunction if the scope is handled wrong or with normal wear and tear with use (Pyrek, 2016). The distal tip contains both the lens for the endoscope and internal channels. Both are very vulnerable to scratches. Any scratch on the exterior or internal components of an endoscope may harbor bacteria. A study by Barkat et al. (2018), examined 68 endoscopes with a borescope to inspect for internal damage. The study found that scratches were present in the internal channels in 99% of the endoscopes examined (Visrodia, Peterson, 2018). Figure 6 identifies damage present on the distal end and internal channel of a flexible endoscope. These findings are important because they prove the impact of internal damage in promoting microbial growth and decreasing the efficiency of the reprocessing process (Visrodia, Peterson, 2018). This internal damage may go undetected without the use of visualization tools.

Figure 6. A: Damaged ends of colonoscope with visible scratches and cloudy lenses. B: Visible scratching present in the internal channel and brown staining. Adapted from "Glimpse at the True Cost of Reprocessing Endoscopes," Ofstead, C.L., Quick, M.R., Eiland, J.E., & Adams, S.J. (n.d.) *Communique*, p. 10.

In 2017, the American Journal of Infection Control performed a seven-month study on 20 gastroscopes at the University of Minnesota health System. All scopes used for the study were relatively new at the beginning of the study. This study found that 12 out of 20 scopes examined tested positive for bacteria growth even after reprocessed with strict adherence to current guidelines (Visrodia & Peterson, 2018). Seventeen of the scopes were pulled from use and returned to Olympus for repairs because of serious damage such as dents and scratches (Visrodia & Peterson, 2018). Organic material such as brown stains, debris, and residual fluid were found in the internal channels of the scopes (Visrodia & Peterson, 2018). The staining and buildup of biofilm indicated above in figure 6B, protects bacteria and other microbes from being removed properly with the reprocessing process.

Thaker et al. (2018) examined 59 patient-ready endoscopes with a borescope to determine if any of the scopes showed internal damage (Visrodia & Peterson, 2018). The most common observations were scratches (86%), channel shredding (59%), and channel debris (23%) (Visrodia & Peterson, 2018). They concluded that inner channel scratches, discoloration, and fluid/moisture retention are common with flexible endoscopes. Scratches and channel shredding will impede the HLD process making it less effective. This internal damage is not visible by the naked eye and can only be seen with direct visualization with a borescope.

The narrow, long lumens in the internal channels of an endoscope present the biggest challenge for reprocessing. These lumens make it very difficult if not impossible to clean. Reprocessing technicians are tasked with cleaning the internal channels with a brush that they cannot visualize. They are also tasked with drying the channels of flexible endoscopes which cannot been visualized. Any organic material left in the channel makes HLD less effective and

may lead to cross-contamination to the next patient. Any soil remaining on endoscopes will not be eradicated by HLD or sterilization (Lind, 2018C).

Noncompliance and Lapses in Reprocessing

There are no unimportant steps in flexible endoscope reprocessing. Every step of the cleaning process should be carried out meticulously with strict adherence to reprocessing guidelines. Effective cleaning is critical to ensure successful disinfection of flexible endoscopes. If any organic material is left on the instrument, disinfection may fail. Multiple peer-reviewed articles have reported breaches in reprocessing that have led to endoscopy related infections from improperly reprocessed endoscopes. Audits of healthcare facilities have proven widespread lapses in infection control and endoscope reprocessing (AAMI, 2015). Failure to comply with manufacturer's IFUs and established guidelines is the leading cause of numerous outbreaks of infection (AAMI, 2015).

Most cases of microbial transmission to patients with flexible endoscopes have resulted from noncompliance to reprocessing standards and guidelines (Rutala &Weber, 2014). According to SGNA (2017), reviews of endoscopy related infections have indicated that most of the documented outbreaks have resulted from non-compliance with existing reprocessing standards (SGNA, 2017). Noncompliance and lapses in reprocessing have been documented in various types of facilities and involved lapses in all the nine steps of reprocessing. Reprocessing lapses, noncompliance, and errors are a world-wide problem despite evidence-based standards by regulating agencies.

A Prospective Study on the Impact of Human Factors and Automation, a study by Ofstead, evaluated five healthcare facilities to observe how human factors affect endoscope reprocessing (Hildebrand et al., 2010). His study reported that two or more steps in reprocessing were skipped completely 44% of the time (Hildebrand, E., Branagham, R., Wu, Q., Garland, T., Taggart, H.,…Brown, V., 2010). Only 43% of endoscopes were brushed properly and only 45%

received forced air drying (Hildebrand et al., 2010). According to the article, the two most frequent steps skipped were brushing the internal channels of endoscopes and using forced air to dry the internal channels drying scopes with forced air (Hildebrand et al., 2010)). These steps are frequently skipped even though staff interviewed by Ofstead during the study acknowledged that brushing and drying are two of the most critical steps to prevent infections (Hildebrand, et al., 2010). Ofstead also reported that reprocessing personnel followed all steps 1.4% of the time, see Figure 7 (Hildebrand et al., 2010). During the study Ofstead also interviewed reprocessing staff to get a better understanding of why these steps and guidelines were not followed consistently. The staff shared the following reasons for skipping steps (Hildebrand et al., 2010):

1. Steps were difficult to complete
2. Posture required for reprocessing endoscopes caused pain and discomfort
3. Pressure to complete the reprocessing process quicker for faster turn over times
4. Exposure to HLD chemicals was irritating to their respiratory system

This study also examined the effectiveness of reprocessing staff with the manual cleaning step in reprocessing. The study found that the manual cleaning step worked for colonoscopes 99% of the time to achieve the benchmark for reducing microorganisms (Hildebrand et at., 2010). Only 48% of the gastroscopes reached the benchmark after the first round of manual cleaning (Hildebrand et al., 2010). And 11% never reached the benchmark even after repeating the manual cleaning step and two rounds of HLD in an AER (Hildebrand et al., 2010).

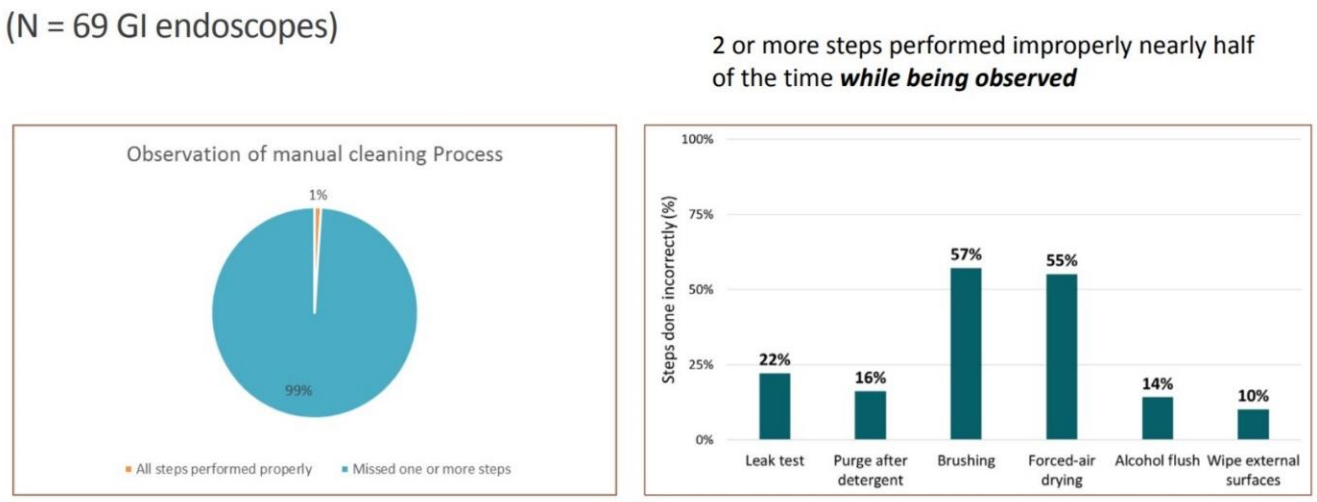

Figure 7. Observations from Ofstead and Associates, percentage of time reprocessing steps are skipped or performed incorrectly. Adapted from "Endoscope Reprocessing Methods: A Prospective Study on the Impact of Human Factors and Automation". 2010, *Gastroenterology Nursing*, 33(54), p. 3-10.

The International Association of Healthcare Central Service Material Management (IAHCSMM) asked its members about the biggest challenges they face during endoscope reprocessing (Ofstead, Hopkins, Eiland & Wetzler, 2018B). IAHCSMM developed a survey of 52 questions that could be completed in less than 20 minutes. In September 2018, IACHCSMM sent 17,315 members an invitation to participate in their survey. A total of 2,334 IAHCSMM members completed the survey. Members responded with the following occupational challenges (Ofstead et al., 2018B): lack of sufficient time allotted for endoscope reprocessing, inability to visualize internal lumens of endoscopes, reprocessing work areas where not set up correctly with the proper equipment, occupational health risks, and fear of being held responsible for infections (Ofstead, et al., 2018B).

Lack of sufficient time allotted to reprocess endoscopes is a reoccurring theme in all the literature I read. In this survey, members were asked how often they felt pressure to provide

quick turn over times and work quickly when reprocessing endoscopes. Of the 2,334 members who responded, 70% stated they felt pressure to work quickly and 17% reported skipping steps because of this pressure (Ofstead et al., 2018B). Forty percent of members reported they had been bullied or witnessed a co-worker being bullied for pressure to work quickly when reprocessing endoscopes (Ofstead et al., 2018B).

Seven hundred and twelve members stated that the inability to see inside the internal channels of endoscopes was a tremendous challenge and barrier to effective reprocessing (Ofstead et al., 2018B). Only 48% of members who responded, reported using cleaning verification tests and 50% reported using visual inspections for cleaning verifications (Ofstead et al., 2018B). Twenty-nine percent reported using both cleaning and visual verification tests (Ofstead et al., 2018B). Many members want changes such as: equipment to visually inspect the internal channels, better methods for cleaning verification tools, and mandates for testing all endoscopes before use (Ofstead et al., 2018B).

Members also responded to questions about challenges they experience when working with HLD. The most common problem reported was odor and poor ventilation in work areas (Ofstead et al., 2018B). Almost half, (47%) reported troublesome odors (Ofstead et al., 2018B). They also reported eye irritation and burns from working with HLD chemicals (Ofstead et al., 2018B). Members also reported pain associated with long periods of time spent leaning over sinks, repetitive bending, and standing for long periods of time. Of the members who reported pain during reprocessing: 41% experienced symptoms in the past month, 14% had consulted with a health professional, 9% stated pain interfered with the ability to do their job, and 7% missed work because of their symptoms (Ofstead et al., 2018B).

At the end of the survey in the comment section, over 1000 members responded with suggestions for improving the quality of endoscope reprocessing. The most common suggestions referred to enhancing education and training for reprocessing staff (Ofstead et al., 2018B). Another area which members suggested was improving working conditions for reprocessing staff. Members suggested the following improvements (Ofstead et al., 2018B): upgrade work areas to help backs and legs, better lighting over sinks, better ventilation, proper scheduling of procedures with consideration of the inventory of endoscopes available, and include reprocessing staff in the decision-making to make them a part of the team to find solutions.

Lind (2018C) suggests that personnel often skip the point of use cleaning directly following a procedure because of demands to turn rooms over quickly for the next procedure (Lind, 2018C). After a procedure is over staff are tempted to rush through steps, skipping steps or taking short cuts. Lind (2018C) emphasis staff should focus on the overall safety of patients rather than pressure from physicians and demands for a fast turn over between procedures (Lind, 2018C).

Leak testing of endoscopes is another step that is frequently skipped to save time (Lind, 2018B). Since endoscopes are susceptible to internal damage, leak testing must be performed each time they are reprocessed to detect damage to the interior and exterior of the endoscope. (SGNA, 2017). Noncompliance with the leak testing step can shorten the endoscope performance and increase infection risks to patients (Lind, 2018B). Even the smallest tear or hole in the internal channels can cause fluid invasion. Fluid invasion can lead to corrosion, damage to the scope, and a breeding ground for bacteria to grow (Lind, 2018B). Common errors or noncompliance to steps associated with leak testing include (Lind, 2018B):

1. Not following the manufacturer’s IFUs.

2. Failure to prepare the endoscope for submersion
3. Immersing the endoscope in water that contains chemical disinfectants
4. Not fully submerging the endoscope
5. Failure to angulate the distal tip
6. Failure to leak test for the required amount of time

Other factors that may influence reprocessing staff to skip steps include personal problems, mental or emotional problems, complacency or boredom, stress, and physical pain (IAHCSMM, 2017). Reprocessing technicians often work in small work areas with high workloads and pressure. During an average day, technicians may reprocess as many as 50 or more endoscopes. Reprocessing one endoscope requires an average of 76 minutes of hands-on-staff time, see figure 8 (Thornhill et al., 2015). Performing numerous repetitive steps and motions can lead to fatigue and errors (McCafferty et al., 2018). A study by Erasmus et al. (2018) showed failure to comply with good hand hygiene policies is also associated with high volume workloads and repetitive steps (ESGE, 2018).

Reprocessing step	Average time required* (minutes)
PPE changes and hand hygiene†	9.1
Bedside pre-cleaning	5.8
Transport to reprocessing room	5.5
Dry leak testing	2.1
Wet leak testing	5.5
Manual cleaning	17.3
Sinks and counter clean-up	6.0
Visual inspection	3.0
Performing cleaning verification tests	5.4
Re-cleaning & re-testing‡	4.5
Setting up AER§	4.0
Drying endoscope & accessories	7.3
Transport to storage	0.5
Total time and wages for reprocessing one endoscope	76 minutes

Figure 8. Total amount of staff time to complete the reprocessing process for one scope. Adapted from "Glimpse at the True Cost of Reprocessing Endoscopes," Ofstead, C.L., Quick, M.R., Eiland, J.E., & Adams, S.J. (n.d.) *Communique*.

Any deviation from the reprocessing guidelines can cause cross contamination or an increase in endoscopy acquired infections. Strict adherence to reprocessing guidelines is critical to provide quality care to patients undergoing endoscopy procedures. Investigations into reprocessing practices have identified lapses in guidelines with all steps of the reprocessing process.

There are many steps to achieve effective cleaning of a flexible endoscope. Each step is important and required as part of the cleaning process. Reprocessing steps are evidence-based guidelines validated by scope manufacturers and regulating agencies. Reprocessing steps are a complex process of sequential subtasks. (McCafferty et al., 2018).

Delayed Reprocessing

Delayed reprocessing of endoscopes is considered a non-compliance issue because reprocessing guidelines clearly define the timeframe for reprocessing contaminated endoscopes. Current endoscope reprocessing guidelines form all regulating agencies recommend reprocessing scopes immediately after use. Delayed reprocessing is defined by SGNA (2017) as an endoscope that is not reprocessed within an hour after use (SGNA, 2017). Delayed reprocessing usually occurs with emergency procedures after hours when the endoscope has been manually cleaned but left for further reprocessing until the next day (Choi & Cho, 2015). When endoscopes are not reprocessed within an hour, the risk of bacterial transmission and biofilm formation increases. Body fluids, native flora, and potentially infectious bacteria will dry on the exterior and interior channels. Biofilm may start to form and make reprocessing procedures less effective.

Delayed reprocessing increases the risk of transmission of infections and can also cause damage to the endoscope. Body fluids and bacteria allowed to dry on endoscopes are extremely difficult to remove with manual cleaning, disinfectant agents, and HLD cycles. Endoscope manufacturer's IFUs such as Olympus also mandate the maximum time delay which is allowed between pre-cleaning after the completion of a procedure and the start of the HLD cycle (Olympus Operation Manual, 2018). Studies have proven that patient infections have occurred when endoscope reprocessing is delayed past the recommended 60 minutes. After this time the risk of biofilm formation also increases. Reprocessing endoscopes within this period is critical to prevent bioburden and biofilm from hardening on the exterior and interior channels of an endoscope. Failure to strictly adhere to the maximum timeframe for reprocessing comprises patient care and can contribute to infection risks.

Insufficient Drying of Endoscopes

Any remaining moisture left on the exterior or the internal channels of an endoscope provides a breeding grown for bacteria. HLD does not destroy all microorganisms, even with strict adherence to all reprocessing steps. If any moisture remains on the endoscope after HLD, any bacteria remaining on the scope can multiple to a million colon-forming units in as quick as a few hours (SGNA, 2016). Drosnock (2019) states multiple studies have shown that endoscopes are not adequately dried before storage (Drosnock, 2019). One of the main causes of failures with the reprocessing process is improper or inadequate drying (Drosnock, 2019). These studies are advancing theories that drying is overlooked or even skipped during reprocessing.

Proper drying and storage of endoscopes is crucial to keep bacteria from forming on endoscopes. The possibility for bacterial regrowth after HLD is determined by the conditions of the interior channels of an endoscope during drying and storage (Kovaleva & Buss, 2011). Any moisture remaining in the interior channels of an endoscope during storage provides an opportunity for growth of bacteria such as Pseudomonas and Acinetobacter (Kovaleva & Buss, 2011). According to numerous studies, endoscopes stay bacteria-free during storage if proper drying techniques have been followed.

Ofstead and Associates conducted a study to evaluate issues related to processing flexible endoscopes. This study concluded that one of the steps commonly skipped during reprocessing is forced air drying and a 70% isopropyl alcohol flush after the HLD cycle (Drosnock, 2019). Additional studies by Ofstead and Associates discovered fluid remaining in the lumens of endoscope during borescope examination. They found fluid and moisture remaining in 19 out of 20 scopes that they inspected (Drosnock, 2019).

Inadequate Standards

The CDC estimates that patient risk for infections associated with endoscopy are rare, approximately 1 in 1.8 million procedures (AAMI, 2015). However, experts in the industry believe this estimate of patient risk for infection is underestimated according to recent reports of reprocessing lapses and documented exposures to contaminated endoscopes (AAMI, 2015). Multiple peer reviewed articles and documented studies report strict adherence to reprocessing guidelines does not ensure endoscopes are free from contamination especially when endoscope damage is present. Multiple recent studies reinforce the conclusion that current risks are outdated and underestimated. Beauclair (2018) states that prior to the past decades and outbreaks resulting from duodenoscopes in 2013-2015 it was rare to hear about endoscopy associated infections. (Beauclair, 2018). She concludes advancements in technology and endoscopy procedures have contributed to the increasing rate of infection. (Beauclair, 2018).

Director of North Carolina Statewide Program for Infection Control and Epidemiology, William Rutala, states the reason for endoscope related outbreaks is the margin of safety associated with reprocessing and HLD is minimal or nonexistent (Humphries & McDonnel, 2015). Humphries and McDonnel (2015) support the theory that guidelines are outdated and should be changed to update the Spaulding Classification from semi-critical to critical (Humphries & McDonnel, 2015). They base their theory on the fact that endoscopes are classified as semi-critical devices but become critical devices when used to treat GI bleeding, polypectomies, or to obtain a specimen sample (Humphries, McDonnel, 2015). In these instances, instrumentation penetrates mucosal lining warranting a critical classification (Humphries, McDonnel, 2015).

A study published by Wang et al. (2018) was performed to identify infection rates in colonoscopy and esophagogastroduodenoscopy performed in Ambulatory Care Centers (ASG) in six states in 2014 (Wang et al., 2018). The study was designed to estimate the rate of infection after colonoscopy and esophagogastroduodenoscopy procedures by tracking infection-related emergency department visits and unplanned in-patient admissions 7 and 30 days after procedures were performed. The study included 462,068 screening colonoscopies at 1157 ASCs and 914, 140 non-screening colonoscopies at 1202 ASCs. There were 873,138 esophagogastroduodenoscopy procedures performed at 1212 ASCs. They observed post-endoscopic infection rates that were over 100 times higher than the expected rates for the procedures patient severity and procedure complexity rating (Wang et al., 2018). The 7-day infection-related rate for unplanned visits for screening colonoscopies were 1.1 per 1000 procedures, 1.6 for non-screening colonoscopy, and 3.0 for esophagogastroduodenoscopy (Wang et al., 2018). The 30-day infection-related rate for unplanned visits was 2.9 for screening colonoscopy, 5.4 for non-screening colonoscopy, and 10.8 for esophagogastroduodenoscopy procedures (Wang et al., 2018). The infection rate that resulted in hospitalization was 61.8% for screening colonoscopy, 60.5% for non-screening colonoscopy, and 64.2% for esophagogastroduodenoscopy (Wang et al., 2018). Their findings suggest that post-endoscopic infections are occurring without being detected by existing surveillance systems and policies.

The study also concluded that the invasiveness of the procedure such as polyp removal did not alter the risk of infection after screening or non-screening procedures (Wang et al., 2018). The strongest predictor found during the study was procedure volume (Wang et al., 2018). ASCs with a higher-case volume had the higher rates of infections. ASCs with a lower-case volume had lower rates of infection.

The problems associated with recent outbreaks has been well documented and have been recognized for the past decade. These issues were typically associated with lapses in the reprocessing process, noncompliance, failure to dry endoscopes before storage, and endoscope damage. According to the WGO (2019), it is now possible to identify transmission and colonization of antibiotic resistant bacteria since CPE is now acting as a marker of transmission (WGO, 2019). The emergence of CPE markers has exposed flaws in the reprocessing system (Wang et al., 2019). Numerous recent studies have discovered that endoscope reprocessing standards do not consistently produce an effective level of margin of safety (WGO, 2019). Especially considering outbreaks in reprocessing have been documented with strict adherence to reprocessing guidelines and with no evidence of scope damage when inspected by the manufacturer (WGO, 2019).

The regulating agencies who oversee guidelines should elevate recommendations from the minimum requirements to best practices (Drosnock, 2019). Drosnock (2019) states that current reprocessing guidelines are inconsistent and lack detailed, specific drying recommendations (Drosnock, 2019). Drying is an essential element of the reprocessing process. Studies have concluded that a properly dried and stored scope will not produce bacterial growth. Any moisture remaining in the inner channels of an endoscope may promote growth of microorganisms and biofilm formation during storage.

The industry is aware of outdated assumptions that the alcohol flush and air purge cycle in an AER is inadequate to dry endoscopes (Drosnock, 2019). An issue and challenge that has presented itself in endoscope reprocessing for years. Multiple studies have indicated that endoscopes are not being adequately dried prior to storage. Drosnock (2019) contributes a portion of the increase in improperly dried scopes to the technical advancements which allow

visual inspections of the internal channels with a borescope to verify the drying process (Drosnock, 2019). Technology, such as the borescope, is uncovering microbial growth that until recently went undetected. The industry has recently learned that following the endoscope manufacturer's IFUs alone is not consistently producing dry scopes.

Although all the regulating agencies agree that endoscopes must be adequately dry, the standards and guidelines lack detailed information as to how to implement each stage of the drying process. The guidelines are vague and lack specific details. SGNA guidelines state after HLD scopes require an alcohol flush and forced air-drying with instrument-quality compressed air (Drosnock, 2019). AAMI ST91:2015 standards state drying followed HLD should be performed by flushing compressed air through all the endoscope channels (Drosnock, 2019). Both regulating agencies should clarify each process with additional instructions. Lack of clarity and specific instructions to implement these steps leads to confusion and inconsistencies within healthcare facilities.

SGNA Standards for Endoscope Reprocessing

Although professional organizations vary in recommended practices, they all agree on the nine steps of reprocessing. The steps of this reprocessing process below are part of a 31page manual which covers this nine-step process. According to SGNA(2016) standards, endoscope reprocessing steps include (SGNA, 2016):

(SGNA steps are recorded below word for word from the SGNA standards to emphasis the importance of each step and sub-step)

1. Precleaning

   Precleaning should be performed at the bedside directly after removing the insertion tube from the patient and before detaching the scope from the power source. Precleaning is performed to remove any blood, body fluids, and organic material to decrease the risk of bioburden and biofilm formation. Precleaning should be performed at point of use before bioburden has a chance to dry.

   a. Immediately after removing the insertion tube, wipe the insertion tube with a sponge or cloth freshly prepared with an enzymatic cleaner. Dispose of the cloth or sponge.
   b. The distal end of the scope should be place in the appropriate detergent solution. Suction a large volume of the enzymatic cleaner through the endoscope until clear, then suction air through the endoscope.
   c. Flush and manipulate the forcep elevator of duodenoscopes per the manufacturer's IFUs.
   d. Flush air and water channels per the manufacturer's IFUs.
   e. Detach the endoscope from the processor and suction.

f. Transport the soiled endoscope to the reprocessing area in a closed container labeled to indicate biohazardous contents. Containers must be large enough to prevent damage to the endoscope from coiling it too tightly.

2. Leak testing

Leak testing is the process to detect damage to the interior or exterior of the endoscope. Leak testing should be performed before immersing the endoscope in disinfectant detergents to protect the parts of the scope not designed for fluid exposure.

a. Remove all valves: suction, air and biopsy
b. Discard all parts that are disposable. All endoscopes must be completely disassembled so all surfaces may be cleaned.
c. Attach the leak tester and pressurize the endoscope before submerging it in clear water.
d. Do no add detergent to the water before or during the leak test because detergent will obscure bubbles leaking from the endoscope and may cause a leak to go undetected.
e. Completely submerge the pressurized scope. Flex the distal tip of the endoscope in all direction and look for bubbles. Press the freeze and release buttons on the control head of the endoscope while looking for bubbles. Check the insertion tube, distal bending section, and universal cord for bubbles coming from the internal channels of the endoscope.
f. Remove the endoscope from the sink, turn off the leak tester, disconnect the leak tester from the video cap. Continue with the next reprocessing step unless a leak is detected.

3. Manual Cleaning

Manual cleaning is performed to remove the microbial bioburden from the endoscope. Manual cleaning and brushing of internal channels are required even with the use of an AER.

a. Fill a sink with fresh filtered water and a low-foaming, neutral pH detergent approved for endoscopes.
b. Dilute the detergent according to the manufacturers IFUs. Clean water must be prepared for each endoscope.
c. Immerse the endoscope completely in the solution.
d. Wash the exterior of the endoscope by wiping and brushing the scope while completely submerged.
e. Use a small brush to clean inside and under the suction, air, and water values, biopsy opening.
f. Brush all the accessible endoscope channels, body of the scope, insertion tube, and umbilicus of the endoscope. All auxiliary channels must be brushed and flushed according to the manufacturer's IFUs.
g. If cleaning a duodenoscope additional steps are required in all steps of the reprocessing. Refer to the manufacturer's IFUs for additional instructions.
h. After passing the cleaning brush through the lumens, rinse the brush in the detergent to remove all visible debri before retracting it.
i. Continue brushing until there is no debris visible on the brush.
j. Flush all channels with detergent to remove debris.

4. Rinse after Manual Cleaning
    a. Thoroughly rinse the endoscope with clean water to remove debris and detergent.

b. Purge water from all channels using forced air. Dry the exterior of the endoscope with a soft lint-free cloth to prevent dilution of the HLD solution used in the next steps.

c. Rinsing may be done in the AER when this feature is provided.

5. Visual Inspection

Visual Inspections are a safety stop or time out to confirm that the scope is visually clean before proceeding to the next step.

a. Visually inspect the exterior surface for debris, cracks, corrosion, discoloration.

b. Visual inspections should include the use of magnification and adequate lighting.

c. Repeat manual cleaning steps if not clean.

d. Literature suggests confirming the efficiency of manual cleaning of the internal channels, a rapid monitor should be used prior to HLD. If the test is positive, repeat all manual cleaning steps.

6. High Level Disinfection

HLD is recognized as the standard for reprocessing flexible endoscopes by the Society of Gastroenterology Nurses and Associates (SGNA), American Society for Gastrointestinal Endoscopy (ASGE), the American College of Gastroenterology (ACG), the Association for Professionals in Infection Control and Epidemiology (APIC), The Centers for Disease Control and Prevention (CDC), and the Joint Commission (JC). Sterilization is indicated when the device is used as a critical medical device, or per hospital policy.

a. Test to assure the HLD is above the minimum effective concentration (MEC) required to kill or inactivate microorganisms. This test should be performed before each load per the manufacturer's IFUs. HLD solutions should be discarded if it fails

to meet the MEC requirements. Endoscopes should be purged with air and externally dried prior to HLD.

b. Reprocessing staff should have a good knowledge of the AER and the manufacturer's IFUs.

c. Place the endoscope in the AER per the manufacturer's IFUs and attach all channel adapters.

d. Set the machine for the appropriate time and temperature need per the disinfectants IFUs.

e. Start the AER and allow it to complete all cycles. If any cycles are interrupted the entire process must be restarted.

f. If the AER does not have a final alcohol rinse option, this step should be done manually followed by purging all the channels with air until dry.

7. Rinse After High Level Disinfection

a. Thoroughly rinse all surfaces, flush all channels, and removable parts with clean water according to the disinfectant and endoscope manufacturer's IFUs.

b. Fresh clean water should be used for each endoscope.

8. Drying

Drying is critical to achieve effective reprocessing for endoscopes. All channels and surface of the endoscope must be dried before storage to prevent microorganisms from surviving and multiplying. Endoscopes must be flushed with 70% to 90% isopropyl alcohol and dried with pressurized medical grade air.

a. Flush all channels with alcohol until the alcohol can be visualized exiting the opposite end of each channel.

b. Purge all channels with air:

    1. Use compressed medical grade air that has been filtered.

c. Remove all channel adapters.

d. Thoroughly rinse and dry all removable parts. Do not reattach any removable parts to the endoscope during storage.

9. Storage

Endoscopes should be stored in a clean, well-ventilated, dust-free area to keep the scope free of microbial contamination. An endoscope that is not completely dry must be reprocessed. Endoscopes should hang in a conventional or a drying cabinet, so they are not damaged by physical impact. Endoscopes should be stored in compliance with the endoscope and manufacture's IFUs.

a. Cabinets should be made of material that can be disinfected.

b. With conventional cabinets hang scopes in a vertical position to prevent moisture accumulation and microbial growth. Endoscopes should not touch each other.

c. With drying cabinets follow the manufacture's IFUs.

d. SGNA suggests a seven-day storage length time before the need to reprocess.

Solutions to Increase the Safety Margin of Endoscope Reprocessing

Movement Towards Standardized National Guidelines

Regulations and guidelines are published by multiple organizations that govern endoscope reprocessing to establish minimum levels of quality and safety (IAHSSMM, 2017). These organizations publish two types of standards that reprocessing staff must consider. The first is regulatory standards that provide a benchmark that is mandated from the governing organizations (IAHSSMM, 2017). Violation of regulatory standards may result in citations and legal penalties for healthcare facilities. The second one is voluntary standards. Voluntary standards provide guidelines or recommendations for techniques that have consistently shown to improve patient care (IAHSSMM, 2017). Voluntary standards are not subjected to citations or legal penalties and are considered optional practices.

Guidelines from the three main regulatory agencies: AORN, AAMI, and SGNA all agree on the main points of endoscope reprocessing. However, the guidelines from these agencies are inconsistent and lack clarity in many key areas. Lack of uniform, standardized guidelines further complicates an already complicated process. For instance, all three agencies state cleaning verification are recommendations. AORN states manual cleaning of flexible endoscopes should be verified using cleaning verification tests when new endoscopes are brought into facilities and at established periods by healthcare facilities such as: after each use, daily, or monthly (Prust, 2017). AAMI (2015) states that cleaning verification testing should occur at established time frames such as weekly or preferably daily (AAMI 2015). SGNA (2016) states if the test results for organic soil are positive, the endoscope should be re-cleaned before HLD (SGNA, 2016). There should be a standardized manual cleaning verification with specific intervals established by the guidelines rather than leaving the verification interval policies up to individual healthcare

facilities. Standardized regulatory standards should be implemented instead of voluntary standards to improve the margin of safety associated with endoscope reprocessing.

Another key element in regulating guidelines that lacks consistency and instruction is the recommended visual inspection for gross soil and damage on an endoscope. SGNA states "visual inspection should be its own step and considered a "a time out" or "safety stop" to verify that an endoscope is visually clean before proceeding to HLD" (Prust, 2017). AORN states lighted magnification should be used as a visual verification tool to inspect the exterior of an endoscope for cleanliness and damage (Prust, 2017). AORN also states that the internal channels of endoscopes may be inspected using a borescope to validate the cleaning process and check for damage present on the scope (SGNA, 2016). The key words that are of concern in the above guidelines are "should be" and "may be". These non-specific guidelines give individual facilities the freedom to choose how to implement these steps. None of these guidelines establishes detailed, specific instructions to carry out visual inspections.

AAMI ST91 2015, AORN 2016, and SGNA 2016 all recommend the use of rapid cleanliness indicators for verification of efficacy of the manual cleaning process (Prust, 2017). The microbial surveillance recommendations for endoscopes lack uniformity and defined frequency to culture endoscopes. Current microbial surveillance guidelines are (Prust, 2017):

- ESGE recommends a minimum every three months
- AORN 2016 and SGNA 2017 recommends conducting a risk assessment and may be considered in event of an outbreak
- AAMI 201 provides no guidance on the subject, TBA with new guidelines

Uniform standards and guidelines for sampling and microbiological culturing techniques are lacking uniformity and consistency.

Current standards and guidelines about specific drying recommendations for endoscopes are also inconsistent and vague. The agencies that govern reprocessing have recently learned that following the endoscope manufacturer's IFUs alone does not produce properly dried endoscopes (Drosnock, 2019). Studies have also proven that the air purge in an AER does not get endoscopes dried properly either (Prust, 2017). SGNA recommends the use of compressed air before storage but does not give specific information on the type of air to use or instructions to carry out the process (Drosnock, 2019). AORN recommendations contain more information about the drying step. AORN's guidelines on drying include the following: flush the endoscope with clean-filtered, instrument quality air to dry the internal channels of endoscopes, then dry the exterior of an endoscope before placing it in storage (Drosnock, 2019). AAMI ST91 recommendations state that all channels of an endoscope should be purged with filtered medical-grade air before storage to help prevent bacterial growth and development of biofilm (Drosnock, 2019). In 2018, the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) recommended that after HLD endoscopes should be flushed with an alcohol rinse followed by forced air drying to reduce microbial growth on stored endoscopes (Prust, 2016). The regulating agencies have failed to update their guidelines with detailed information about implemented the recommended drying steps to provide best practices and improve patient safety.

The length of time endoscopes should be dried with forced air to obtain complete dryness has not been established. A study by Alfa and Sitter was performed to evaluate the results of the drying process in AERs on the bacterial load in endoscopes (Muscarella & Nelson, 2016). The study found that moisture remained in the internal suction channel, even with strict adherence to the AER manufacturer's IFUs (Muscarella & Nelson, 2016). The next step of the experiment added ten minutes of drying time to the endoscopes by both purging the internal channels with

instrument air and adding ten minutes of drying time to the AER cycle. By applying an extra ten minutes with both methods, endoscopes were found to be completely dry (Muscarella & Nelson, 2016). Alfa and Sitter concluded that adding ten minutes of drying time to endoscope reprocessing prevented moisture and bacterial growth in the internal channels of endoscopes (Muscarella & Nelson, 2016).

Visual Inspections with a Borescope to Evaluate the Efficiency of Cleaning and Drying Steps

Borescope technology has existed for years. Endoscope repair facilities have used borescope technology to inspect endoscopes to diagnose and repair damage of internal channels and inspect for leaks (Visrodia, Peterson, 2018). Borescopes are like flexible endoscopes. A borescope is a small fiberoptic device inserted into the channels of an endoscope which allows visualization of inaccessible areas within the scope's internal channels (IAHSCMM, 2017). Some borescopes have cameras which provide still images or video of areas within endoscope lumens.

Healthcare facilities should implement defined policies for a comprehensive quality infection control program to monitor all aspects of the reprocessing process. Cleaning verification policies should include using a borescope to inspect the internal channels of endoscopes for any moisture, debri, or damage present on every scope after HLD. Visual inspections of the inside channels is crucial to prevent failures with the reprocessing process. These inspections confirm cleaning was effective, identify remaining residual material, and identify damage to the endoscope.

Current voluntary standards recommend but do not mandate regulatory standards for visual inspections using a borescope prior to the HLD cycle (Ofstead, et al., 2018B). Visual inspections should be mandated for every endoscope after every use. Ofstead et al. conducted a survey in conjunction with the Education Department of IAHSCMM. The objective of the survey was to learn what visual inspections members of IAHSCMM are currently using and to learn what challenges members encounter during endoscope reprocessing (Ofstead et al., 2018B). Of the members who responded to the survey only 14% reported using a borescope to perform

visual examinations of the internal channels of endoscopes (Ofstead et al., 2018B). Only 18% reported using a lighted magnifying glass to inspect the integrity of the exterior of an endoscope prior to HLD (Ofstead et al., 2018**).**

Visual inspections of the exterior and internal channels of an endoscope is a key quality check in every scopes manufacturer's IFUs although many do not specifically state it should be carried out with a borescope. Confirming an endoscope is clean is a necessary part of the reprocessing process before moving onto the HLD process. Confirming there is no damage to the endoscope is also a critical step of reprocessing to ensure it is safe for further use. All regulating agencies recommend at least periodic enhanced visual inspection of the internal channels of endoscopes to find damage and organic residue that would go unnoticed with the naked eye (Visrodia & Peterson, 2018).

However, these agencies do not specify the use of a borescope. AAMI ST 91, 2015 Guidelines for Flexible and Semi-Rigid Endoscope Reprocessing in Healthcare Facilities, Section 12, Quality Control 12.4.2 states that the cleaning verification of flexible endoscopes should include: " visual inspection combined with other verification methods (see section 12.3.40) that allow the assessment of both external surfaces and internal channels, testing of the cleaning efficacy of mechanical equipment, and monitoring key parameters" (AAMI,2015) These guidelines do not recommend use of a lighted magnifying glass to inspect the exterior of endoscopes or state the use of a borescope for visual verifications. The operations manual for Olympus Evis Exera III Gastointestinal Endoscope and Evis Exera III colonoscope IFU calls for inspection of both scopes including: the control section, connector boot, insertion tube, external surfaces, distal end, and the angulation mechanisms (Olympus Operation Manual, 2015). Every aspect of the exterior of the endoscope was discussed but there was no mention of visual

inspection using a lighted magnifying glass of borescope to complete the process. Inspections of the internal channel of an endoscope with a borescope can help detect issues with the reprocessing process before it becomes a threat to patients.

Time to Update the Spaulding Classification for Re-usable Medical Devices

According to Spanos (2019), the problem associated with endoscopy acquired infections and contaminated scopes will continue until the Spaulding Classification system is revised (Spanos, 2019). Now that we know contaminated endoscopes and infections are more common that once believed, the first step to prevent further contamination is to clarify the Spaulding Classification. Dr. Earl Spaulding developed a classification system for re-usable medical devices in 1968. This classification system defines how re-usable medical devices such as endoscopes should be disinfected based on their intended use. His classification system is widely used by the FDA, CDC, SGNA, AORN, and AAMI to categorize the level of disinfection or sterilization methods warranted for all reusable medical devices.

The Spaulding Classification system divides reusable medical devices into three categories based on their risk for patient infection. The lowest risk items are classified as non-critical such as blood pressure cuffs, stethoscopes, tourniquets, linens, and furniture. Non-critical reusable medical devices do not directly touch patients or encounter intact skin. These devices require cleaning by low-level disinfection. The next category is semi-critical devices which include bronchoscopes, endoscopes and respiratory equipment. Semi-critical devices encounter intact mucous membranes and require high-level disinfection. The third category is critical devices such as surgical instruments and cutting endoscopic accessories. Critical devices enter sterile tissue or the vascular system. These devices require sterilization.

According to Dr. Spaulding's Classification system, flexible endoscopes are considered semi-critical devices. Semi-critical reusable medical devices encounter intact mucous membranes but no do disrupt sterile tissue or of the vascular system. Many instruments used during endoscopy procedures to remove polyp and take tissue samples are classified according to

the Spaulding system as critical devices since they penetrate intact membranes, enter sterile tissue or the vascular system. However, the endoscope itself is classified as a semi-critical device. This creates a lack of consistency between the endoscope and the instruments used with these scopes.

Prust supports the theory that endoscopes should be reclassified as critical devices (Prust, 2018). Prust (2018) states "that even though endoscopes are considered semi-critical devices and states it should not be the name of a reusable medical device that outlines the potential risk for infection" (Prust, 2018). The risk of infection to the patient should be determined instead by the way the scope is used (Prust, 2018). Experts in the industry agree if an endoscope encounters the vascular system or disrupts mucosal lining it should be classified as a critical device requiring sterilization. Beauclair also supports reclassification of endoscopes. She states there is an urgent need for endoscopy reclassification from semi-critical to critical for reprocessing guidelines to keep up with modern technology and minimize outbreaks (Beauclair, 2018). Endoscopic procedures that perform biopsies, polypectomies, or intervene for gastrointestinal bleeding disrupt mucous membranes and should be sterilized to eliminate all possible microbial growth.

Rutala and Weber (2014) proposed a modification to the Spaulding Classification System to the FDA's Endoscope Devices Panel for all endoscopes to be considered critical devices which require sterilization (Rutala & Weber, 2014). His proposal included modifications for any complex reusable medical device that directly or secondarily disrupts sterile tissue or the vascular system such as endoscopes. According to Rutala and Weber (2014), these devices should be classified as a critical device (Rutala & Weber, 2014).

Need to Shift from High Level Disinfection to Sterilization

Since the margin of safety with the HLD process is low the FDA and AAMI have issued statements saying the HLD process does produce the same margin of safety linked with terminal sterilization (Thorn et al., 2015). The terminal sterilization process provides a margin of safety that is two times that of HLD (Thornhill et al., 2015). Endoscopes have more microbial contamination after use than any other health care instrument (Pyrek, 2016). According to Pyrek (2016), the contamination rate of endoscopes ranges from 10 million to 10 billion microorganisms (Pyrek, 2016). To produce patient ready endoscopes all 10 billion microorganisms must be removed by the reprocessing process. Manual cleaning and HLD removes 6-12 logs of microorganisms so as many as 10,000 organisms remain on an endoscope after reprocessing (Simard, Luc Lemyre, Martel, Catalone, 2018). Figure 9 illustrates the typical microbial load cycle of endoscopes.

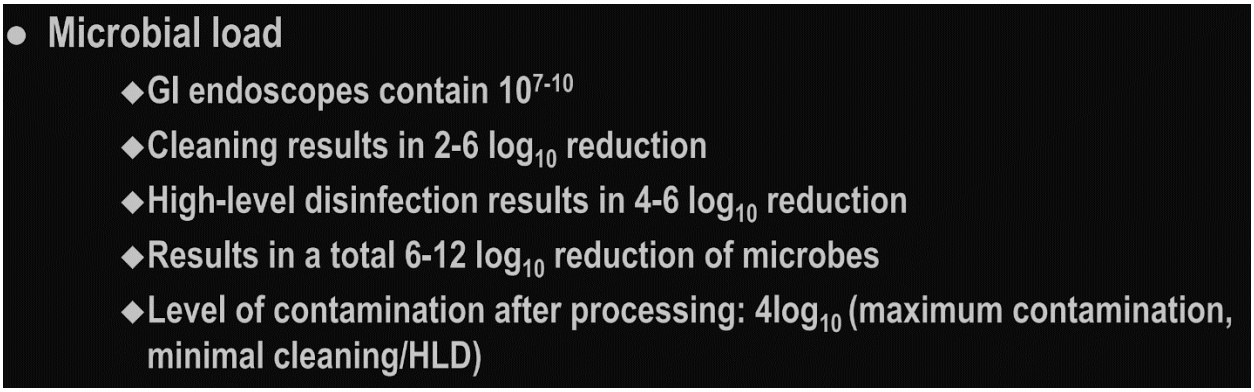

Figure 9. The microbial load of contaminated endoscopes throughout the reprocessing process. Adapted from, “Gastrointestinal Endoscopes: A Need to Shift from Disinfection to Sterilization.” By W.A. Rutala and D.J. Weber, 2014, *JAMA*, 312(14), p 1058.

The need to shift from HLD to sterilization of endoscopes is apparent with the documented studies of endoscopy related infections, inadequate control of steps associated with reprocessing, and the unreliable, inconsistent outcomes of HLD. Sterilization would eliminate human error, skipped steps, and biofilm formation. Sterilization would reduce the risks to patients and improve patient care by eradicating all bacteria and spores present on endoscopes.

On September 11, 2017 AAMI held a meeting with forty experts from the industry with governing organizations. These organizations included: IAHCSMM, SGNA, FDA, CDC, research groups, scope and AER manufacturers, and testing labs to discuss endoscopy associated infection outbreaks (Klacik, 2019). The experts present at the meeting agreed that endoscope reprocessing needs to move from HLD to sterilization (Klacik, 2019). This conclusion was based on evidence that some pathogens such as non-enveloped viruses have become resistant to HLD (Klacik, 2019). Non-enveloped viruses resistant to HLD include parvoviruses, enteroviruses, hepatitis A, and norovirus (Klacik, 2019). Bacteria resistant to HLD include mycobacteria, M tuberculosis, Mavium, Mabscessus, and Mchimera (Klacik, 2019). Sterilization can improve patient outcomes and produce effective, consistent reprocessing since sterilization produces twice the reduction in microbial contamination than HLD.

In AORN's 2019 Guidelines for Perioperative Practices, sterilization is being recommended for semi-critical devices (Klacik, 2019). Transitioning to sterilization would provide key benefits to the reprocessing process including eliminating biofilm formation, reducing human errors because it is a less complicated process than HLD, providing a greater margin of safety, eliminating storage requirements and hang time expirations. Terminal sterilization would eradicate all bacteria including spores from flexible endoscopes.

A study by Kovaleva and Buss (2011) was performed to mimic biofilm formation and regrowth of biofilm inside the internal channels of endoscopes. This study was conducted to test the effects of HLD on biofilm formation (Kovaleva & Buss, 2011). The invitro biofilm was subjected to all steps of the reprocessing process with and without drying. Their study revealed regrowth of all biofilms following a 48-hour incubation when the drying process was skipped (Kovaleva & Buss, 2011). No biofilm regrowth occurred after following recommended drying practices for five days (Kovaleva & Buss, 2011). The authors concluded that strict adherence to reprocessing steps and HLD may not consistently remove biofilm from the internal channels of an endoscope if effective drying is not performed (Kovaleva & Buss, 2011). Shifting from HLD to sterilization would eliminate reprocessing failures caused by improper drying techniques.

Multiple studies have shown that HLD does not consistently and reliably reduce the level of contamination on flexible endoscopes. One problem with HLD is that cleaning brushes, detergents and disinfectants may not penetrate the internal channels and hard-to-reach areas exposed to contaminants. Second rounds of manual cleaning and HLD have been shown to be unreliable to reach these areas of endoscopes. In addition to these factors, multiple studies have shown that reprocessing personnel often do not strictly adhere to current guidelines. Many studies indicate that all steps of the reprocessing process are rarely followed. Evidence shows that HLD provides little to no margin of safety, while sterilization has been proven to reduce microbial contamination.

The complexity of flexible endoscopes and the fact that they are highly contaminated during use, makes cleaning and disinfecting these devices very difficult. In theory, HLD should eliminate all microorganisms except spores, if all steps of the reprocessing process have been done properly. However, repeated studies have shown that even with strict adherence to

reprocessing guidelines, endoscopes remained contaminated after HLD. Outbreaks have occurred from inadequate cleaning, damaged scopes, flaws in design, and improper drying. In fact, the rate of endoscope contamination may be much higher than documented. Due to lack of standardized surveillance monitoring programs and long gaps between contamination and infection it is difficult to accurately estimate the true rate of endoscopy associated infections. According to Spanos (2019), analysis has shown that even when endoscopes are cleaned and disinfected according to guidelines, 30% or more scopes remain contaminated (Spanos, 2019).

To mitigate the risk and improve the margin of safety with HLD, many facilities have executed enhanced reprocessing techniques such as repeated HLD cycles. According to Rutala, research has shown that repeated HLD cycles does not reduce the level of contamination on endoscopes (Spanos, 2019). Repeated manual cleaning and HLD cycles of endoscopes has failed to eliminate bacteria and enhanced the opposite effect and promoted the resistance of bacteria (Boudarel et al., 2018). New clinical evidence supports some microorganisms have biocide resistance which can lead to infections due to disinfection failures (Boudarel et al., 2018). Multiple theories acknowledge that biofilm may have the capability to self-adapt with repeated HLD and alter its mechanical properties to resist the chemical process (Boudarel et al., 2018).

Terminal sterilization is a linear process. Sterilization is a predictable process for destroying microorganisms and can provide a probability calculation of surviving microorganisms after the sterilization process (Prust, 2018). This calculation is known as the sterility assurance level (SAL). Terminal sterilization provides a SAL of 10-6 which means there is a probability that only one microorganism in one million will survive (Prust, 2018). The terminal sterilization cycle time is determined by which biological indicator or a resistant spore is irradiated and then the cycle time is doubled for added assurance. (Prust, 2018). The safety

factor for sterilization or margin of safety is provided by the extra cycle time and predictability of the process. Sterilization is that predictable. Sterilization can also penetrate endoscopes long lumens and channels eliminating any remaining debris or moisture that HLD does not eradicate.

In May 2015, the FDA recommended the sterilization of duodenoscopes, but reprocessing guidelines have not changed for other types of endoscopes. The FDA mandated a similar shift from disinfection to sterilization in dental handpieces in 1992 even without the overwhelming documentation of contamination as with endoscopes (Spanos, 2019). In 2017, AAMI held an Endoscope Sterilization Stakeholders meeting. During this meeting, Rutala, Ofstead, and Alfa presented evidence supporting sterilization as a superior method to HLD for reprocessing endoscopes (Spanos, 2019). The stakeholders present at the meeting agreed that the move from HLD to sterilization of endoscopes needs to happen gradually (Spanos, 2019).

A study by Kola et al. followed documented cases of cross contamination of endoscopes with Extended Spectrum Beta-Lactamase-Producing Klebsiella pnemoniae (ESBL-KP) from patients from one endoscope (England, 2018). Kola et al. investigated the use of this scope and found that it was used on nine patients and received twelve rounds of HLD before it was identified as contaminated (England, 2018). The reprocessing of this scope was reviewed, and the investigation found no lapses in the reprocessing guidelines (England, 2018). Incidents like this clearly identify the need for sterilization to protect patients and improve the margin of safety with endoscope procedures.

To ensure patient safety it is imperative that reprocessing endoscopes move from HLD to sterilization. The professional organizations who govern endoscope reprocessing, device manufacturers, inpatient and outpatient centers should implement sterilization of endoscopes through standardized regulatory guidelines, research, and education. To reduce microbial

contamination and increase the margin of safety for patients regulatory agencies need to update current guidelines from HLD to sterilization.

Implement Standardized Quality Control Measurers and Cleaning Verifications

Comprehensive quality control policies and programs are essential for consistency and effective endoscope reprocessing programs. Early detection of contaminated endoscopes could prevent cross-transmission and infections with the use of microbiological monitoring. Currently, there are no regulatory standard protocols in place for microbiological surveillance monitoring for healthcare facilities, only voluntary standards. Most European countries have regulated standards regarding routine surveillance of endoscopes using the culturing method (Cattoir et al., 2017). The United States is falling behind European countries without clearly defined and accepted criteria for testing frequency, sampling technique, culture medium, and incubation conditions (Cattoir et al., 2017). All regulating agencies that govern reprocessing, SGNA, AORN, AMII, FDA, and the CDC recommend that healthcare facilities implement comprehensive quality control programs. According to the FDA Safety Commission Report from 2015, quality control monitoring policies should include detailed, written policies for monitoring adherence to reprocessing guidelines, documentation processes, and risk-quality monitoring (England, 2018). Along with implementing evidence based microbiological culturing programs to validate endoscope reprocessing (England, 2018). Effective control programs are needed to evaluate the implementation of all the reprocessing steps to detect failures with the manual cleaning process. Chemical cleaning verification tests to check for protein, hemoglobin, and carbohydrate as well as any organic residues present in the internal channels of the endoscope should be performed.

To decrease the possibility of endoscope-related infections and outbreaks, regulating agencies should include regulatory standardized and specific quality control guidelines. Currently, healthcare institutions are at their own discretion to implement these programs. There

is no gold standard or guideline specific instructions to determine when to perform cleaning verifications or which microbiological culture to use. Regulatory agencies should define the frequency of routine microbiological endoscope testing to trace and prevent contamination of endoscopes and infections in patients after endoscopic procedures.

It is standard practice is many countries to sample and culture endoscopes to monitor the adequacy of reprocessing and to identify endoscopes with persistent contamination despite multiple rounds of HLD. Currently, the United States regulatory guidelines for reprocessing and infection control do not define surveillance programs (Sampling and culturing, 2018). However, the three manufactures of duodenoscopes in the United States have established benchmark testing to validate the sampling and culturing protocol to evaluate the adequacy of reprocessing (Sampling and culturing, 2018). Regulatory agencies have not adopted the use of this protocol with all types of endoscopes except in states where sampling and culturing is required or regulated by state authorities (Sampling and culturing, 2018).

Microbiological surveillance involves sampling the internal channel and the distal end of an endoscope. These samples are cultured to identify any bacterial contamination remaining on the scope after reprocessing. Microbiological culturing can be performed routinely or periodically to test the efficiency of the reprocessing process and identify scopes with persistent contamination. Microbiological surveillance is necessary for quality control because it provides: quality markers for the assessment of the reprocessing program, training competency for staff, ensuring all steps in IFUs have been carried out, and assisting with internal investigation when infections are linked to reprocessing. Early detection of endoscope contamination is critical to prevent cross contamination and infection of patients.

The CDC has established baseline levels of acceptable microbes for endoscopes after reprocessing. Endoscopes are considered at an acceptable level if the current number of microbes present on an endoscope after reprocessing are > 10 CFU of low concern microbes (Patel & Kulkarni, 2016). Scopes which meet this criterion do not warrant further reprocessing. Any endoscope the is < 1 CFU warrants further intervention and reprocessing (Patel & Kulkarni, 2016). The CDC states any scope over this level should be reprocessed and taken out of service until it is proven to be free of high concern bacteria or reaches an acceptable level of low concern microbes (Patel & Kulkarni, 2016). If cultures of an endoscope are repeatedly positive for three rounds of culturing and reprocessing the scope should be quarantined and evaluated by the manufacturer (Patel & Kulkarni, 2016). Microbiological surveillance also provides feedback to identify any breaches in the reprocessing process.

Adenosine triphosphate (ATP) measurement is a useful tool used as an indicator of cleaning efficiency. It is a fast-microbiological monitoring tool for endoscopes where the volume of endoscopic procedures is high. ATP monitoring is capable of measuring levels of microorganisms and bioburden. ATP is an evidence-based process to validate an endoscope for the benchmark for cleanliness (Gedik, Gunay, Sahin, Sharifzade, 2018). According to AAMI, for endoscopes to be considered clean, the benchmark cannot exceed 6.4/ug/cm2 of protein, 4 log 10/cm2 of bioburden or 200 RLU of ATP can be present on a reprocessed scope (Thornhill et al., 2016).

ATP is a chemical that is found in all living organisms (Gedik et al., 2018). It is a simple testing method used to measure the amount of light that is emitted when the enzyme luciferase comes into contact with the ATP molecular (Gedik et al., 2018). ATPs real time feedback allows reprocessing staff to identify and correct cleaning issues before proceeding to the next step of the

reprocessing cycle. These quality control measures will provide information that can be documented and analyzed to identify threats and trends in all areas of the reprocessing process that need improvement. Routine testing would provide facilities with documentation for every endoscope in the event of patient infections occurring later associated with the use of one specific endoscope. ATP testing after reprocessing every endoscope will provide an equal standard of care for all patients and help reduce cross contamination of infection.

Education, Training, and Competency Verifications for all Endoscope Reprocessing Staff

Gastrointestinal endoscopy procedures and scopes have evolved into a highly specialized field. Consequently, endoscope reprocessing has become equally as specialized. Few areas of sterile processing of medical reusable devices have seen such rapid change as endoscope reprocessing. Reprocessing staff must have the knowledge and skills necessary to deal with this rapid evolving specialty. Ongoing training and continuing education are crucial to provide quality reprocessing programs. Training and education are imperative to ensure reprocessing staff have a good understanding of the importance of strict adherence to the reprocessing process. Endoscope reprocessing is a rapidly changing and challenging specialty. Reprocessing staff need adequate training in order to minimize risk of infections and provide quality patient care.

Unlike central sterile departments that reprocess surgical instruments and scopes, uncertified staff can work in endoscopy reprocessing departments (Williamson, 2017). Endoscope reprocessing certifications are currently encouraged but not mandated by the regulating agencies that govern endoscope reprocessing. Several agencies such as IAHCSMM and the Certification Board for Sterile Processing and Distribution (CBSPD) have recently developed certified reprocessing courses and exams. CBSPD launched their Flexible Endoscope Reprocessor Certification (CFER) in February 2008. IAHCSMM launched its Certified Endoscope Reprocessor (CER) certification in 2017 (Williamson, 2017). SGNA offers an Associates and Advanced Associates Programs to educate staff who work in procedure rooms and reprocessing areas of Gastrointestinal Departments (“Associates program,”. n.d.). This course does not provide a certification after competition of the program. These certification exams and programs are designed to demonstrate knowledge and skills necessary to perform all

steps of the reprocessing process. To provide a good understanding of the importance of microbiology basics related to endoscope reprocessing. As well as knowledge and understanding of the regulatory and voluntary standards that govern endoscope reprocessing. These exams cover knowledge in areas such as (Williamson, 2017):

- microbiology related to the importance of endoscope reprocessing
- endoscope design and structure
- reprocessing work area design and flow
- endoscope reprocessing steps and regulations
- proper endoscope handling for transport and storage
- required documentation of all reprocessed endoscopes, tracking, repair, and maintenance of all endoscopes
- human factors that impact endoscope reprocessing

The regulation agencies should mandate certification requirements for all reprocessing personnel in the regulatory standards for all facilities. There is a need to emphasis and focus on education and certifications for all staff who reprocess endoscopes. With the low margin of safety associated with endoscope reprocessing it is imperative to require reprocessing certifications for all staff.

Along with continued education for staff responsible for endoscope reprocessing, competency skills should be monitored by management. The competency of staff can mean the difference between providing quality care to patients or detrimental consequences for patients. Reprocessing staff must be competent in infection control measures to provide quality care to patients. Staff should consistently demonstrate strict adherence to all steps of the reprocessing through competency verifications performed during orientation, annually, and when new

equipment is introduced into the GI Departments (Herrin et al., 2016). All reprocessing staff must complete a comprehensive orientation and training program (Herrin et al., 2016). Management should conduct ongoing audits and visual observation of reprocessing staff to determine compliance with all reprocessing steps (AAMI, 2015). This process helps management determine both accurate compliance and identify any problem areas in the reprocessing process.

Conclusion

Millions of gastrointestinal procedures are performed annually. Gastrointestinal endoscopy plays an important role in the diagnosis, surveillance, and treatment of a wide variety of medical conditions. These endoscopic procedures and flexible endoscopes continue to evolve with technological advances. Minimally invasive, non-surgical procedures continue to replace traditional surgeries which once required large incisions. As gastrointestinal endoscopic procedures advance, so does the complexity and technology of the endoscopes needed to perform procedures. The complex design, and long narrow channels of flexible endoscopes present significant challenges to clean and reprocess for subsequent patient use. The risk of infection after endoscopy procedures remains unclear. Experts in the industry suggest that the risks associated with contaminated endoscopes are underestimated.

There are more patient associated infections and outbreaks linked to gastrointestinal flexible endoscopes than any other reusable medical device. Contaminated endoscopes and endoscopy acquired infections generally result from inconsistencies or non-compliance with established reprocessing guidelines. However, over the past decade infections and outbreaks have occurred despite strict adherence to evidence based regulatory guidelines. Reprocessing flexible endoscopes is a complicated, multi-task process that often fails to consistently produce patient-ready scopes. Barriers to consistently produce patient ready scopes include: complex design, non-compliance with reprocessing steps, endoscope damage, insufficient drying, and inadequate standards.

The reprocessing and high-level disinfection process is overly complex and does not ensure a consistent and effective margin of safety for patients. According to Ofstead and Associates (2018), “HLD is cutting the margin of safety so close, that everything has to be done

perfectly every time or the whole enterprise comes crashing down" (Ofstead et al., 2018). Current evidence and research suggests that current reprocessing regulatory standards and quality control policies are not adequate to ensure consistent and reliable results. To reduce the risks associated with contaminated endoscopes, it is imperative to identify problem areas with current reprocessing standards and improve the reprocessing process to increase the margin of safety.

+

References

Alfa, M., & Howie, R. (2009). Modeling microbial survival in buildup biofilm for complex medical devices. *BMC Infectious Diseases,* 9(1). doi:10.1186/1471-2334-9-56

American Society for Gastrointestinal Endoscopy. (2017). Quality indicators for gastrointestinal endoscopy units. doi:10.1016/j.vgie.2017.02.007

Association for the Advancement of Medical Instrumentation. (2015). ST91:2015 Flexible and semi-rigid processing in healthcare facilities.

Associates program & advanced associate program. (n.d.). Retrieved from https://www.sgna.org/Learn/Associated-Technicians

Beauclair, S. (2018). Nine years is enough! Conquering flexible scope reprocessing issues. *Healthcare Purchasing News,* May/June52-55.

Boudarel, H., Mathias, J.D., Blaysat, B., & Grediac, M. (2018). Towards standardized mechanical characterization of microbial biofilms: analysis and critical review. *Nature Partner Journals,* 4(17). doi:10.1038/s41522-018-0062-5

Flexible endoscope (GI scope) certification exam. (n.d.) Retrieved from https://www.cpspd.net/gi-scope/

Cattoir, L., Vanzieleghem, T., Florin, L., helleputte, T., Devos, M., Verhasselt, B.,…Roles, L. (2017). Surveillance of endoscopes: comparison of different sampling techniques. *Infection Control and Hospital Epidemiology,* 38(9), 1062-1069. doi:10.1017/jce.2017.115

Centers for Disease Control and Prevention. (2018). Duodenoscope surveillance sampling and culturing: reducing the risks of infection. Retrieved from https://www.cdc.gov/hai/organisms//cre/cre-duodenoscope-surveillance-protocol.html

Centers for Disease Control and Prevention. (2017). Essential elements of a reprocessing program for flexible endoscopes-recommendations of the healthcare infection control practices advisory committee. Retrieved from hhtps://www,cdc.gov/hicpac/recommendations/flexible-endoscope- reprocessing.html

Choi, H., Cho, Y. (2015). Endoscope reprocessing update on controversial issues. *Clinical Endoscopy*, 48(5), 356-360. doi:10.5946/ce.2015.48.5.356

Drosnock, M. A. (2019a). Cleaning verification for flexible endoscopes. *Process*, January-February 25-29.

Drosnock, M.A. (2019b). Drying of Flexible Endoscopes. *Process*, March-April, 29-32.

England, D. (2018). Implementing a comprehensive endoscope reprocessing program. *Infection Control Today.* Retrieved from https://www.infectioncontroltoday.com/sterile-processing/implementing-comprehensive-endoscope-reprocessing-program

Epstein, L., Arwandy, M.A., Tsai, V., & Stein, L. (2014). An outbreak of carbapenem resistant OXA-48 producing klebsiella pneumonia associated to duodenoscopy. *JAMA*, 312(14), 1447.

Gedik, H., Gunay, L., Sahin E.C., & Sharifzade, M. (2018). The importance of endoscope reprocessing with ATP-Bioluminescence tool. *Annuals of Medical and Health Sciences Research*, 8, 6-9. Retrieved from https://www.amhsr.org/articles/the-improvement-of-endoscope-reprocessing-with-atpbioluminescence-tool-4182.html

Griffiths, H., & Dwyer, L. (2018). What every endoscopist should know about decontamination. *Endoscopy Review*. doi:10.1136/fgastro-2018-101132.

Healthcare Infection Control Advisory Committee. (2017). Essential elements of reprocessing program for flexible endoscopes-the recommendations of the healthcare infection control practices advisory committee. Retrieved from https://cddc.gov/hicpac/pdf/flexible-endoscope-reprocessing.pdf

Herrin, A., Midolie, L., Bocian, S., Diskey, A., Friis, C., Herron-Rice, L.,…Selking, S. (2016). Standards of infection prevention in the gastroenterology setting, SGNA.

Hildebrand, E., Branagham, R., Wu, Q., Jolly, J., Garland, T., Taggart, H., …Brown, V. (2010). Exploring human factors in endoscope reprocessing. *Simplified Sterile Endoscopy,* doi: 10.1518/107118110X12829369606765

Humphries, R. M., & McDonnell G. (2015). Superbugs on duodenoscopes: the challenge of, cleaning and disinfection of reusable devices. *Journal of Clinical Microbiology,* 53(10), 3118-3125. doi:10.1128/JCM.01394-15

IData Research. (2018). 75 million endoscopies performed annually according to IData procedure analysis. Retrieved from https://idataresearch.com.

International Association of Healthcare Central Service Material Management. (2017). *Endoscope Reprocessing Manual* (1st ed). Chicago, IL.

Kenters, N., Tartai, E., Hopman, J., Rehab, H., Nago, M., Marimuthu, K., …Voss, A. (2018). Worldwide practices on flexible endoscope reprocessing. *Antimicrobial Resistance and Infection Control,* doi:10.1186/s13756-018-0446-6

Klacik, S. (2019). Transitioning from high-level disinfection to sterilization for semi-critical devices. *Process*, May/June, 41-46.

Kovaleva, J.B., & Buss, A. (2011). Usefulness of bacteriological monitoring of endoscope Reprocessing. *Therapeutic Gastrointestinal Endoscopy,* doi:10:5772/23447

Kovaleva, J.B., Peters F.T., Mei, H.C., & Degener, J.E. (2013). Transmission of infection by GI endoscopy and bronchoscopy. *Clinical Microbial Review*, 26(2), 231-254. doi: 10.1128/ CMR.00085-12

Lind, N., (2018a) Dangers of dirty scopes. *Communique*, July/August 21-24.

Lind, N., (2018b). Leak testing. *Communique*, November/December, 25-28.

Lind, N., (2018c). The importance of point-of-use cleaning and handling. *Communique*, September/October, 23-26.

McCafferty, C.E., Aghahani, M.J., Abi-Hana, D., & Gosbell, I.B. (2018). Update on GI endoscopy-associated infections and contamination factors. *Annuals of Clinical Antimicrobials*, 17(36), doi:10.11861S12941-081-0289-2

Microbiologic assessment of flexible-gastrointestinal endoscope reprocessing using a pump-assisted sampling technique: an investigation involving endoscopy units in Tianjin, China. (2018). *American Journal of Infection Control*, 46, 43-48. doi: 10.1016/j.ajic.2018.04.216

Muscarella, L.F., & Nelson, B.D. (2016). Inconsistencies in endoscope-reprocessing and infection control guidelines: the importance of endoscope drying. *American Journal of Gastroenterology*, 101(9), 2147-2154.

Ofstead, C., Heymann, O.L., Quick, M.R., Eiland, J.E., & Wetzler, H.P. (2018). Residual moisture and waterborne pathogens inside flexible endoscopes: evidence from a multisite study of endoscope drying effectiveness. *American Journal of Infection Control*, 46(6), 689-696. doi:10.10161/j.ajic.2018.03.002

Ofstead, C., Hopkins, K., Eiland, J., & Wetzler, H. (2018). Endoscope reprocessing current practices and challenges in the field. *Process*, July/August.

Ofstead, C., Wetzler, H., & Snyder, A. (2010). Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. *Gastroenterology Nursing*, 33(54), 3-10. doi:10.1097/SGA.06013e3181e9431a

Ofstead, C.L., Quick, M.R. Eiland, J.E., & Adams, S.D. (n.d.). Glimpse at the true cost of Reprocessing endoscopes. Communique. Retrieved from https://www.bostonscientific .com/content/dam/bostonscientific/uro-wh/portfolio-group/LithoVue/pdfs/Sterilization-Resource-Handout.pdf

Olympus Operation Manual, (2018). Instructions for evis exera III gastrointestinal videoscope and colonovideoscope. *3.3 Inspection of the videoscope, 30-37.*

Outbreaks, investigations and evidence for flexible endoscope reprocessing-overcoming the challenges. (2017). *Hong Kong Hospital Authority*. Retrieved from: https://icidportal.ha.org.hk/Home/File?path=/Training%20Calendar/113/Lecture%206_OutbreaksforEndo%20HKHAIPFinal.Nov2017.pdf

Patel, A., & Kulkarni, J.K., (2016). Retrieved from https://hmark.com/becker_december 2016.pdf

Peterson, B., Cohen, J., Hambrick, R., Buttar, N., Greenwald, D., Buscaglia, J., …Eisen, G. (2017). Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update. *Gastrointestinal Endoscopy*, 85(2), 282-294. doi:10.1016/j.gie.2016.10.002

Prust J. (2017). Improving the standard of care of flexible endoscope reprocessing. *NJHCSA*. Retrieved from: https://www.njcl.is/images/Janet_Prust-sept-standard _of_care_flex_Endo_2018.pdf

Prust, J. (2018). Sterilization of flexible endoscopes: does current evidence support a change. *Healthcare Purchasing News*, 36-41.

Pyrek, K.M., (2016). Hospital, industry and government wrestle with approaches to address scope- related outbreaks. Infection Control Today. Retrieved from https://www.infection controltoday.com/sterile-processing/hospitals-industry-and-government-wrestle

Pyrek, K.M. (2017). Ineffectiveness of reprocessing techniques sustains focus: need for improved quality control resources. *Infection Control Today*. Retrieved from https:// www.infectioncontroltoday.com/sterile-processing/ineffectiveness-reprocessing- -techniques-sustains-focus-need-improved-quality

Puri, P. (2019). Hospital infection control endoscopy. *Infectious Disease Advisory*. Retrieved from https://infectiousdiseaseadvisor.com/home/decision-support-in-medicine-hospital-infection-control-endoscopy

Rauwers, A.W., Voor in't holt, A.F., Buijs, J.G., de Groot, W., Hansen, B.E., Bruno, M.J., & Vos, M.C. (2018). High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. *GUT*, 67(9), 1637-1645. doi:10.1136/gutjnl-2017-315082

Roberts, C. (2013). The role of biofilms in reprocessing medical devices. *American Journal of Infection Control*, 41(5), 77-80. doi:10.1016/j.ajic.2012.12.008

Rutala, W. (2014a). Endoscope reprocessing: challenges NDM-producing E-coli associated ERCP. *JAMA*, 312, 1447-1455.

Rutala, W.A., & Weber, D.J. (2014b). Gastrointestinal endoscopes: a need to shift from disinfection to sterilization. *JAMA*, 312(14), 1045-1406. doi: 10.1001/jama.2014.12559

Rutala, W.A., & Weber, D.J. (2016). Reprocessing semi critical items: current issues and new Technologies. *American Journal of Infection Control*, 2(44), 53-62. doi:10.1016/j.ajic.

2015.12.029

Saliou, P., Le Bars, H, Hery-Arnaud, G., & Payan, C. Evaluation of current cleaning and disinfection procedures of GI endoscopes. *Gastrointestinal Endoscopy*, 84(6). doi: 10.10161/j.gie.2016.06.041

Scoping the problem, endoscopy-related associated infections. (2018). *The Lancet Gastroenterology and Hepatology*, 3(7), 445. doi:10.1016/S2468-1253(18)30168-7

SGNA. (2016). Standards of infection prevention in reprocessing flexible gastrointestinal endoscopes.

Simard, V.M., Lemyre, J.L., Martel, K., & Catalone, B.J. (2018). Elevating the standard of endoscope processing: terminal sterilization of duodenoscopes using hydrogen peroxide-ozone sterilizer. *American Journal of Infection Control*, 1-8. doi:10.1016/j.ajic. 2018.09.009

Spanos, S. (2019). As the MDRO threat mounts, its time to update the Spaulding classification. *ICT Infection Control Today*. Retrieved from https://www.infectioncontroltoday.com/ Sterile-processing/mrdo-threat-mounts-it-s-time-update-spaulding-classification

Spees, T., Alfa, M., Cowen, A., Jones, D., Vickery, K., Griffith, … Le Mair, A. (2019). Endoscope disinfection update a guide to reprocessing. *World Gastroenterology Organization Global Guidelines*, Retrieved from hhtps://www.spg.pt/wp-content/ Uploads/2019/07/endoscope-disinfection-english-2019.pdf.

Study shows endoscope reprocessing practices often insufficient. (2017). *American Journal of Infection*. Retrieved from https://www.aami.org

Thornhill, G. (2016). Measuring the efficacy of manual endoscope cleaning sterile processing. *Healthcare Purchasing News*. Retrieved from https://hpnonline.com/sterile-

Processing/article/13000131/measuring-the-efficacy-of-manual-endocope-cleaning

Thornhill, T., Talapa, L., & Wallace, C. (2015). An approach to improving the quality and consistency of flexible GI endoscope reprocessing. Retrieved from https://multimedia.3m.com/mws/media/1086141O/improving-the-quality-of-flexible-gi-endoscope-reprocessing.pdf

Visrodia, K., Peterson, B.T. (2018). Borescope examination: is there value in visual assessment of endoscope channels. *Gastrointestinal Endoscopy*, 88(4), 620-623, doi: 10.1016/j.gie.2018.07.005

Wang, P., Xu, T., Ngamruengphong, S., Makary, M., Kalloo, A., & Hutfless, S. (2018). Rates of Infection after colonoscopy and esophagogastroduodenoscopy in ambulatory surgery in the USA. *GUT*, 67, 1626-1636. doi:10.1136/gutjnl-2017-315082

When it comes to endoscope reprocessing, every step matters-one weak link can put entire practices-and patients-at risk, experts say. (2019). *Gastroenterology and Endoscopy News*. Retrieved from https://gastroendonenews.con/In-the-News/Article/03-19/When-it-comes-to-endoscope-Reprocessing-Every-Step-Matters/54356

Williamson, J.E., (2017). IAHCSMM now accepting applications for new endoscope Certification program pilot exam. *Healthcare Purchasing News*. Retrieved from https://hpnonline.com/sterile-processing/article/13000907/iahcsmm-now-accepting-applications-for-new-certification-program-pilot-exam/

World Gastroenterology Organization Global Guidelines. (2019). Endoscope disinfection update: a guide to resource-sensitive reprocessing. Retrieved from: a guide to resource-sensitive reprocessing