Advanced Sterilization Products

Infection & Contamination Challenges in Endoscopic Reprocessing

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Background

Effective reprocessing of endoscopes is essential for infection prevention in healthcare, particularly for procedures involving the gastrointestinal and respiratory tracts. Due to their intricate design and frequent reuse, endoscopes present unique cleaning and disinfection challenges, making effective sterilization both critical and complex. This review consolidates current research on endoscope sterilization methods, addresses associated challenges, and explores ongoing innovations aimed at enhancing patient safety.

The risk of infection transmission from improperly reprocessed endoscopes, particularly complex devices like duodenoscopes used in endoscopic retrograde cholangiopancreatography (ECRP) procedures, has been underscored by past outbreaks. These incidents have exposed vulnerabilities in current reprocessing practices and spurred efforts to improve guidelines, technologies, and training to protect patients.

Endoscope reprocessing typically involves multiple steps, including pre-cleaning, manual cleaning, high-level disinfection, drying, and storage. Each step requires strict adherences to protocols, as any deviation can compromise the effectiveness of the process. However, maintaining this level of precision can be resource-intensive, particularly in high-volume healthcare settings with limited staffing.

This review consolidates the latest research on endoscope reprocessing methods and highlights ongoing advancements. It addresses persistent challenges such as biofilm formation, compatibility with delicate device components, and compliance with regulatory standards. By examining these issues and evaluating the potential of emerging technologies, this review provides a comprehensive understanding of strategies to improve endoscope reprocessing and enhance patient safety.

Disinfection & Sterilization of Endoscopic Equipment

Disinfection vs. Sterilization

Sterilization, disinfection, and cleaning are essential processes in infection control, each serving a specific role in ensuring medical device safety. Sterilization involves the complete destruction of all microbial life, while disinfection focuses on eliminating most pathogenic microorganisms, although it does not eradicate bacterial spores.

Confusion often arises between these terms, with "disinfection" sometimes mistakenly labeled as "sterilization" in healthcare settings, potentially leading to misunderstandings about the level of microbial elimination achieved.[1]

Understanding the distinctions between sterilization, disinfection, and cleaning is vital, as each step—beginning with effective soil removal—plays a critical role in achieving reliable disinfection or sterilization outcomes. For a list of common terms and their definitions related to endoscope reprocessing, please see Appendix A.

Microbes vary significantly in their resistance to cleaning, disinfection, and sterilization, creating a hierarchy of difficulty when attempting to eliminate them.[2] See Appendix B (as well as Reprocessing Modalities Diagram) for more information.

At the lower end of the spectrum are enveloped viruses and vegetative bacteria, which are relatively easy to eliminate through basic cleaning or low-level disinfection. Moving up the scale, non-enveloped viruses, mycobacteria, and fungal spores require more robust measures, such as intermediate-level disinfection. **At the top of the hierarchy are bacterial spores, which are highly resistant to most disinfection processes and require sterilization methods**, such as autoclaving, ethylene oxide gas, or vaporized hydrogen peroxide (including hydrogen peroxide gas plasma), to ensure complete eradication.

Reprocessing Modalities [1, 2]

Most Difficult to Kill ↑

Organism	Sterilization	High-Level Disinfection (HLD)
Bacterial Spores	✓	X
Mycobacteria	✓	✓
Fungi	✓	✓
Vegetative Bacteria	✓	✓
Enveloped Viruses	✓	✓

↑ Less Difficult to Kill

Effective cleaning is foundational to all these processes, as residual soil and biofilms can shield microbes and hinder the efficacy of disinfectants and sterilants. Understanding this hierarchy is critical to selecting the appropriate level of microbial control for specific healthcare settings and devices.[2]

The Spaulding Classification

The *Centers for Disease Control Guideline for Disinfection & Sterilization* emphasize "a rational" approach to sterilization and disinfection of hospital equipment. This framework, introduced by E.H. Spaulding in 1956, categorizes equipment based on the risk of infection into three levels (See Appendix C).[1,2]

This classification, grounded in Spaulding's perception of "risk of infection," has remained a cornerstone in infection prevention and is widely applied in both Infection Prevention and Central Sterile Processing Departments.[1,2] While Spaulding's logical approach has endured, advancements in understanding healthcare-associated infections (HAIs) have introduced additional considerations. Everyday patient-care items, such as thermometers, ultrasound probes, and stethoscopes, can serve as reservoirs for pathogens, with documented links to infectious outbreaks.[1] This highlights the critical need for proper disinfection practices.[3]

Critical Items: Those with the highest infection risk—come into contact with sterile tissue, including the vascular system. These items, typically supplied in sterile packaging, include implants, cardiac and urinary catheters, arthroscopes, laparoscopes, and ultrasound probes used in sterile environments.

Semi-Critical Items: Those that encounter mucous membranes or non-intact skin.[1] Examples include airway equipment and endocavitary probes. The CDC Guidelines state "**these medical devices should be free of all microorganisms,**" though a small number of bacterial spores may be present.[1,2] Historically, these instruments were rinsed with nonsterile water. However, tap water can harbor organisms such as nontuberculous mycobacteria, Legionella, and Pseudomonas, which can contaminate endoscopes during rinsing and potentially lead to patient infections. Forced-air drying plays a crucial role in reducing contamination, particularly by biofilm-forming species like *Pseudomonas*, which thrive on moist environmental surfaces.[1]

Noncritical Items: Those that encounter intact skin but not broken skin or mucous membranes. "The sterility of items coming into contact with intact skin is 'not critical' in the prevention of infection."[1]

Originally intended as a simple, practical guide for clinical practice, the Spaulding Classification is not an absolute framework. Over the past 50 years, significant advancements and trends have prompted a re-evaluation of its relevance to modern healthcare practices.[4] When the classification was first introduced, complex endoscopic procedures were not yet widespread.

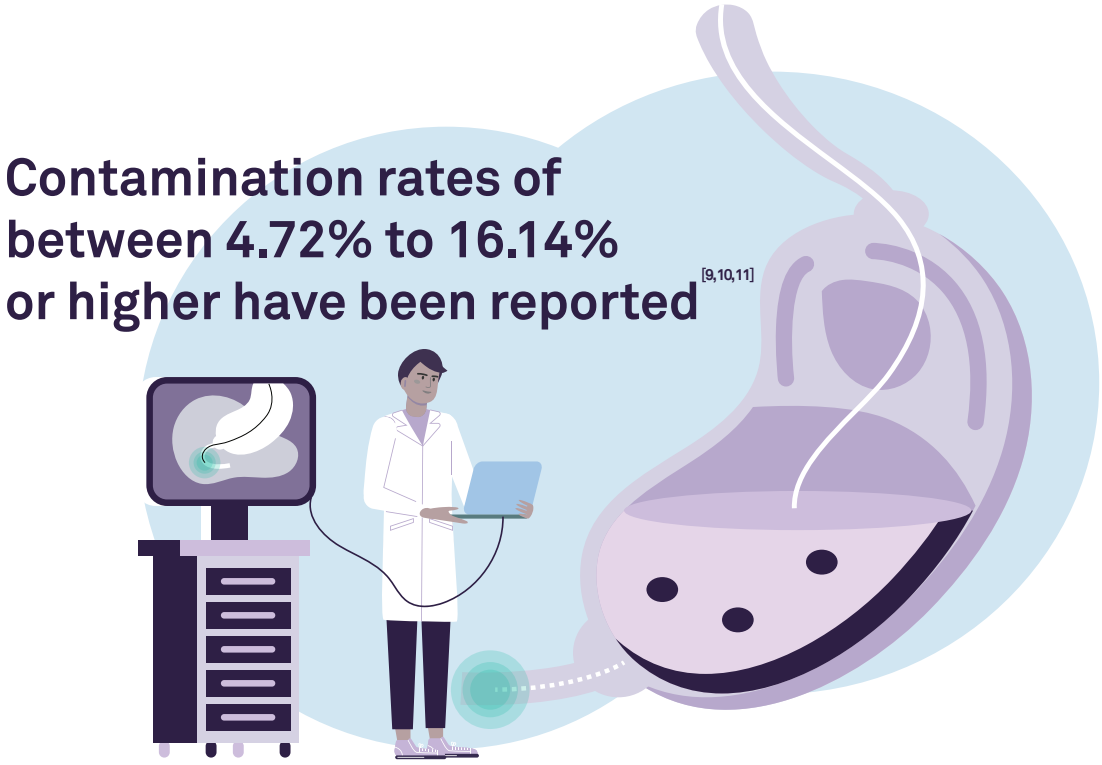
Today, while there is broad consensus that surgical instruments passing through mucous membranes should be considered critical items requiring sterilization or single use, opinions vary on whether endoscopes should also be classified as critical. Despite this debate, the adoption of reprocessing methods that enhance patient safety should not be delayed, as classifying endoscopes as critical devices could drive progress in infection prevention.[5]

For example, the rise of multidrug-resistant organisms (MDROs) and high-concern organisms has amplified the risks of procedure-related infections, especially in vulnerable patient populations.[6] Additionally, advancements in endoscopic technology have blurred the boundaries between "semi-critical" and "critical" devices. As more sophisticated therapeutic instruments and endoscopy-driven procedures are introduced, the need for updated classification criteria becomes increasingly apparent.

Importance of Medical Endoscope Reprocessing

Failures in the reprocessing of flexible endoscopes remain a leading patient safety concern, primarily due to the complexity and multiple steps involved in the procedure.[6,7] Annually, approximately 23.5 million gastrointestinal endoscopies are performed, each involving direct contact between medical devices and a patient's sterile tissue or mucous membranes.[8]

While some aspects of endoscope reprocessing have been automated to reduce operator error, vigilant monitoring of manual procedures is essential to prevent lapses.[6] Despite adherence to high-level disinfection (HLD) protocols, infections associated with contaminated endoscopes continue to be reported.[6] Recent publications have reported a contamination rate ranging from 4.72% to 16.14%.[9–11] Similarly, a prospective, multicenter, post-market study by Okamoto et al. revealed a concerning 5.3% contamination rate of high-concern organisms in duodenoscopes that had undergone reprocessing procedures.[6]



In response to these issues, the U.S. Food and Drug Administration (FDA) mandated post-market surveillance studies in 2015, requiring major duodenoscope manufacturers to assess real-world reprocessing practices and document contamination rates under standardized conditions. **Endoscopes continue to be the most frequently implicated reusable medical devices in healthcare-associated infections, yet the actual infection rate is likely underestimated due to incomplete surveillance, underreporting, asymptomatic cases, and delayed infection onset.**[12]

Endoscope Reprocessing Challenges and The Margin of Safety

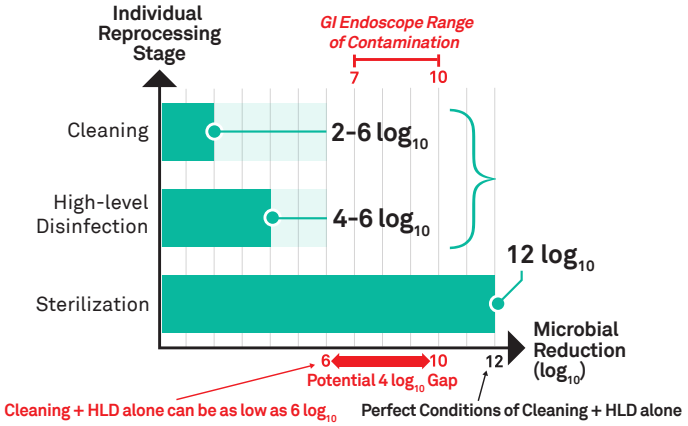
Achieving effective sterilization or disinfection depends on multiple factors, typically requiring comprehensive quality control measures and strict adherence to documented protocols throughout the entire process. Factors that include "real world" conditions are the microbial load, the presence of biofilms, the presence of inorganic material such as hard water salts, and the presence of dried serum. All these "real world" factors decrease the margin of safety of instrument reprocessing. Furthermore, increasingly complex manufacturer instructions for use present educational challenges and add significant burdens to sterilization and disinfection protocols. Regional requirements vary, but **high-level disinfection should eliminate at least one million (10^6 or 6 $\log_{10}$) reductions of mycobacterial cells on a contaminated device.**[4] This depends on ideal cleaning and HLD conditions.

The challenges of reprocessing have intensified as minimally invasive instruments become more complex, potentially leading to higher microbial burdens and more difficult soil removal. Multiple reprocessing studies have reported double-digit rates of microbial growth on endoscopes.[13] The complexity of these devices—characterized by numerous channels, crevices, and potential defects—creates areas where contaminants can accumulate.[14] The literature demonstrates a wide variation in reprocessing practices and educational procedures.[4] Publications cite several factors related to the effectiveness of reprocessing:[15,16]

Endoscopes encounter extremely high levels of microbes when used in the gastrointestinal (GI) tract, particularly in the colon, where microbial density can be as high as 1 trillion colony-forming units (CFU) per milliliter. Research indicates that GI endoscopes can retain millions to billions (10^7-10^{10} CFU) of microorganisms within their internal channels after use. [17,18]

The reprocessing process involves three essential steps to reduce microbial contamination:

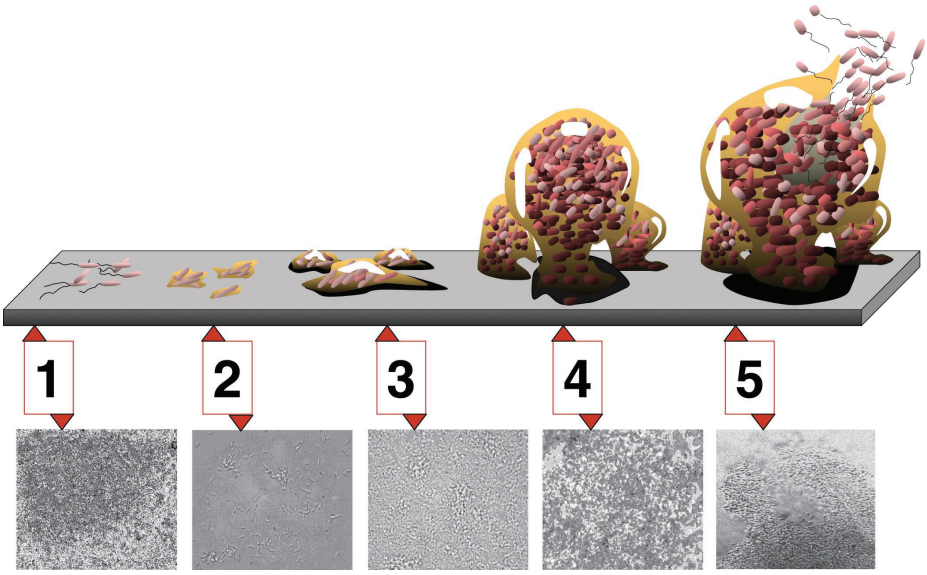
- **Cleaning:** When cleaning and HLD are not ideal, effectiveness can be as low as 6-$\log_{10}$ reduction of microorganisms. This is not effective if there is between 10^7 and 10^{10} organisms.[17]
- **High-Level Disinfection (HLD):** Further reduces microbes by 10,000 to 1 million times (4-6 $\log_{10}$ reduction).
- **Sterilization:** Achieves a 12 $\log_{10}$ or greater reduction, effectively eliminating all microbes, including spores, providing the highest margin of safety. This process ensures that the device is completely free from viable microorganisms, offering a significant advantage over cleaning and HLD alone.



The enormous variability of Cleaning & HLD creates important contamination risk for organisms of concern

This highlights the gap between HLD and sterilization. While HLD is effective in reducing a significant portion of microorganisms, it does not achieve the same level of microbial eradication as sterilization. Given endoscopes' high microbial burden, HLD alone may leave behind microbes if the steps leading up to HLD are not executed according to the manufacturer's specified instructions. In contrast, sterilization provides a significantly higher margin of safety, reinforcing the need for improved reprocessing practices.[1,17]

Biofilms



Five stages of biofilm development

(1) Initial attachment, (2) Irreversible attachment, (3) Maturation I, (4) Maturation II, and (5) Dispersion. Each stage of development in the diagram is paired with a photomicrograph of a developing P. aeruginosa biofilm. All photomicrographs are shown to the same scale.[19]

Biofilm is a complex aggregation of microorganisms, primarily bacteria, which adhere to surfaces and are embedded in a self-produced matrix of extracellular polymeric substances (EPS). This matrix enhances bacterial adhesion to surfaces and between cells, making biofilm formation common in clinical settings like contact lenses, central venous catheters, and urinary catheters.[20,21] Recent studies have confirmed the presence of biofilms in the inner channels of gastrointestinal endoscopes.[22]

> Bacteria within biofilms can be up to 1,000 times more resistant to chemical disinfectants compared to free-floating (planktonic) bacteria.[21]

Biofilms serve as reservoirs for pathogenic bacteria, which can detach, revert to their planktonic state, and potentially contaminate patients. Additionally, biofilms may release endotoxins that can enter a patient's circulation through damaged mucosa, possibly leading to systemic disorders.[21] Research indicates that if the channels of endoscopes are not thoroughly cleaned before disinfection, complete decontamination may not be achieved.[23] Therefore, identifying effective cleaning agents capable of disrupting and removing biofilms on gastrointestinal endoscopes is critical for enhancing anti-biofilm efficacy under current reprocessing conditions.

Biofilm plays a major role in bacterial persistence within endoscope channels. Biofilms have been found in endoscope channels despite following recommended cleaning and disinfection protocols. Studies have shown that biofilm can accumulate in endoscope channels within 30-60 days of use and reprocessing, especially in air/water channels.[24] There is also growing evidence that biofilms may resist high-level disinfectants.[24] For example, a recent outbreak linked to a carbapenem-resistant enterobacteriaceae (CRE) strain* showed weak resistance to peracetic acid in its planktonic state but strong resistance when in biofilm form.[24] Due to this, it has become a major concern for patient safety because these biofilms can harbor bacteria and thus lead to infection.[24]

*Carbapenem is a class of powerful antibiotics often considered a last-resort option.

The reprocessing of endoscopes is a complex and critical process that directly impacts patient safety.

Outbreaks and Contamination of Endoscopic Equipment

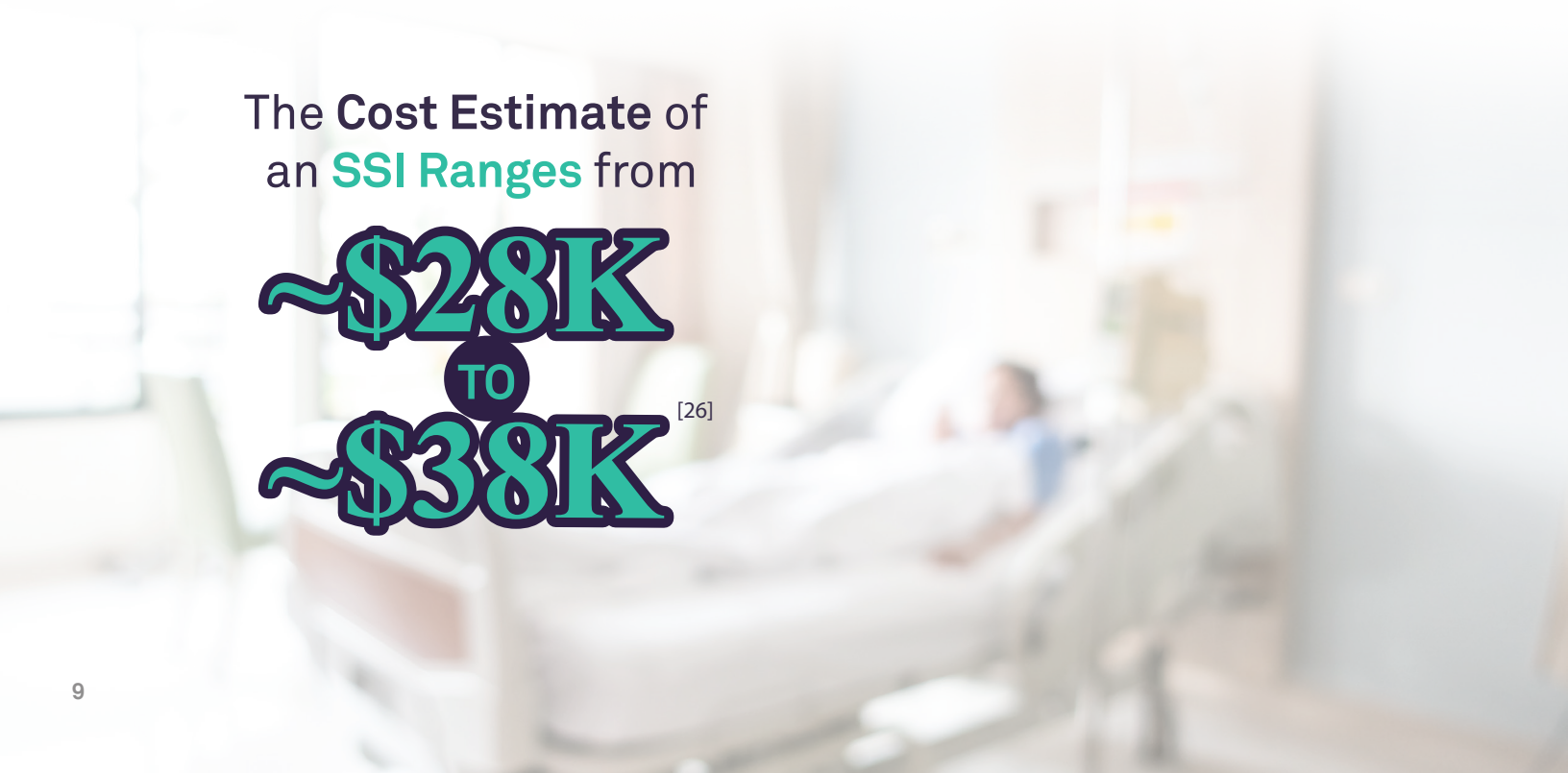
Types of Healthcare-Associated Infections (HAIs):

- One in 31 hospital admissions is at risk for an HAI[25]
- HAIs fit into 4 general categories as classified by the CDC:[17,25]
    - Surgical Site Infections (SSI)
    - Catheter-Associated Urinary Tract Infections (CAUTI)
    - Ventilator-Associated Pneumonia (VAP)
    - Central-Line-Associated Bloodstream Infections (CLABSI)

Additional notable HAIs include:

- *Clostridioides difficile*-associated diarrhea, caused by a spore-forming organism in the gastrointestinal tract.
- Methicillin-resistant *Staphylococcus aureus* (MRSA), often linked to skin structure infections.

The cost estimate of an SSI ranges from $28,219 to $38,202, while CLABSI-related bloodstream infections can cost between $48,108 to $68,983.[26]



Duodenoscopy

Ofstead et al. note that multiple studies and regulatory investigations have examined methods for providing "pathogen-free" instruments in endoscopy.[27] Estimates of contamination rates and infection outbreaks associated with duodenoscopes vary widely, highlighting inconsistencies in reprocessing outcomes.[27] Additionally, the methodologies used for reprocessing differ significantly and often have critical limitations.[27] A study by Loor showed that patients who underwent Endoscopic retrograde cholangiopancreatography (ERCP) had more than double the post-procedure infection rate (4.1% vs. 1.8%) with more resistant pathogens (1.1% vs. 0.2%) compared to patients who did not undergo ERCP.[27] Many of these were pathogens of high-concern.[14,27]

Frequently, outbreaks involve multidrug-resistant organisms (MDROs), sometimes referred to as "superbugs." Despite receiving the attention from the press, regulatory bodies, and industry, outbreaks continue to occur, and the true incidence may be more widespread.

In fact, underreporting may be due to additional limitations:[27]

- Failure to detect asymptomatic colonization
- Long lag time between the procedure and infection manifestation
- Disseminated infection occurring away from the procedure site
- Assumptions that the infection came from the patient's own gut

Of course, some infection may have originated from the patient's own gut flora.

IN THE REAL WORLD: Several high-profile outbreaks prior to the COVID-19 pandemic prompted regulatory scrutiny from the U.S. Food and Drug Administration and congressional oversight. U.S. Senator Patty Murray played a key role in investigating these incidents, which ultimately led to a U.S. Congressional report highlighting concerns about duodenoscope-associated infections and the need for improved reprocessing protocols.[28]

One of the challenges for duodenoscope reprocessing is the presence of a complex elevator mechanism at the distal tip. This elevator mechanism allows the endoscopist to steer guidewires into the pancreatic duct and biliary tree. The complexity of the elevator may allow for the harboring of infectious organisms even after the cleaning process.

Challenges in Duodenoscope Reprocessing:

- The complex elevator mechanism at the distal tip, essential for guiding instruments, is particularly challenging to clean thoroughly.
- Manufacturers have introduced disposable distal endcaps to simplify cleaning, which has shown improvements in contamination rates.[29]

Concerns over patient-to-patient transmission of infection resulted in manufacturers of endoscopes implementing changes to duodenoscope design. One of these changes was the introduction of a disposable distal endcap, making cleaning the complex elevator mechanism easier. Studies have shown an improvement in contamination rates.[29]

It is important to note that the distal elevator area is not the only area of an endoscope that may be contaminated.

Endoscopic Retrograde Cholangiopancreatography (ERCP) High Risk Clinical Populations

ERCP is now frequently performed in high-risk patient populations, including individuals who are elderly, immunocompromised, or have complex medical conditions such as chronic liver disease, pancreatitis, or biliary obstructions. Subsequently:

- Patients undergoing ERCP often have a weakened immune response and may be more susceptible to infection.
- Due to the complex design of duodenoscopes, infected patients can transfer pathogens, including multidrug-resistant organisms (MDROs), to the device during ERCP, increasing contamination risks and potential transmission to future patients if reprocessing is inadequate.

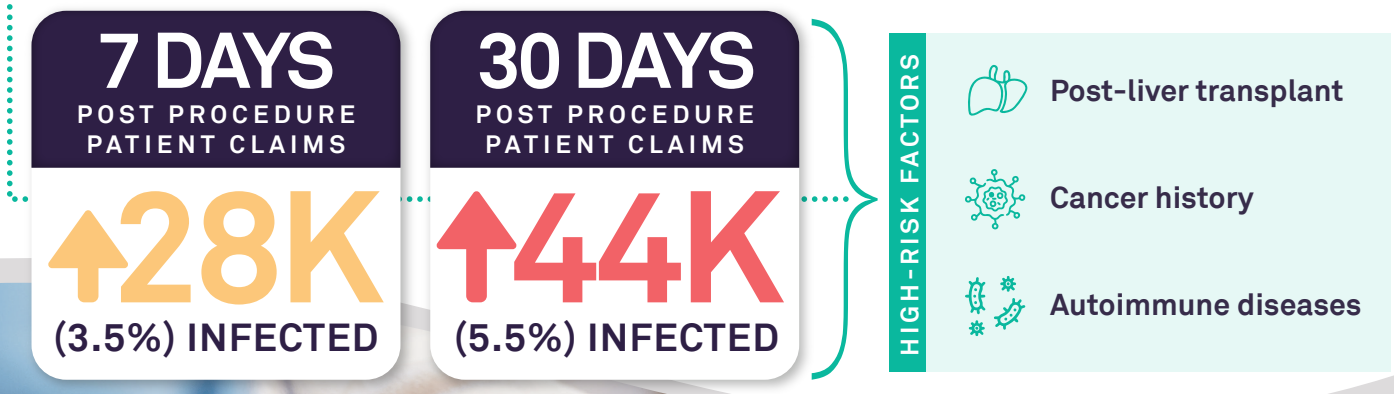
A retrospective cohort analysis of ERCP data examined over 800,000 US Medicare Fee-For-Service claims (2015-2021) and over 16,000 all-payer data (2017) looking at 7 and 30-day post-procedure infection, hospitalization and pancreatitis rates. The study found that approximately 3.5% were infected after 7 days and 5.5% after 30 days (see graphic below).[30] Risk factors identified in this study include those with chronic conditions including being post-liver transplantation, a history of cancer and autoimmune disease.

While single-use devices are sometimes employed when a patient's infection status is known—such as cases involving MDROs, Hepatitis B or C, or HIV—**a patient's infectious status may not be known ahead of time.** Additionally, hospital protocols do not generally require the use of "sterile" endoscopes for immunocompromised patients, despite their increased vulnerability to infection.

The Spaulding classification was originally designed as a general guideline and did not account for MDROs, high-risk patients, or complex devices. Therefore, while endoscopy devices have traditionally been categorized as "semi-critical", the nature of the patient population and the elevated risk of infection transmission should place duodenoscopes in Spaulding's "critical" category–requiring sterilization.[31]

Often, liver transplant patients require duodenoscopy/endoscopic retrograde cholangiopancreatography (ERCP) for biliary complications.[32] In a single-center trial, 97% of patients required therapeutic intervention for their biliary disease.[32] Within this transplant cohort, the infection rate was 16.1%.[32]

Post ERCP infection, hospitalization and pancreatitis rates:[30]



Bronchoscopy Outbreaks

While at least 25 outbreaks of multidrug-resistant organism from duodenoscopy have been reported internationally, bronchoscopy has had at least 130 reported outbreaks.[4] The actual numbers are potentially higher as these may be underrecognized, underdiagnosed, and/or underreported. There are 500,000 U.S. bronchoscopies performed each year. The CDC has conducted 15 separate investigations of bronchoscope outbreaks, with a vast range of organisms, including those that can be considered MDRO species.[33]

Bronchoscopy Contamination

Ofstead et al. published a study demonstrating an alarmingly high rate of contamination of bronchoscopes after cleaning (100%) and a 58% rate after processing. The study suggests that pathogen transmission is an issue despite guideline adherence.[15] The comprehensive multi-site study indicated important contamination challenges, including damaged endoscopes and improper use and maintenance of automated endoscope reprocessing (AER) equipment.

Urology Contamination and Outbreaks

Advancements in endoscopy have had significant application in urology. Flexible ureteroscopy is an important modality for treating renal and ureteral stones. Effective reprocessing of urological scopes is underpinned by close adherence to the manufacturer's Instructions for Use (IFU) and meticulous adherence to cleaning protocols. This has been the subject of a Food and Drug Administration (FDA) letter to healthcare providers.[16] Outbreaks have included *Pseudomonas aeruginosa* as well as Gram-positive cocci.[16]

Advocating for Endoscope Sterilization

The Healthcare Sterile Processing Association (HSPA) Endoscope Reprocessing Manual highlights the growing consensus among experts and regulatory bodies regarding the need to elevate endoscope reprocessing standards.[34] This shift is driven by increasing concerns over healthcare-associated infections, particularly those linked to inadequately reprocessed endoscopes. By transitioning from HLD to sterilization for certain devices, healthcare facilities can significantly enhance patient safety. Sterilization offers a higher level of assurance, eliminating all microbial life, including bacterial spores, which can be resistant to HLD (see Appendix B). While this transition may require additional investments in equipment and training, the potential benefits in terms of reduced infection rates and improved patient outcomes make it a worthwhile consideration.

Environmental Sustainability Considerations in Endoscopy

Single-use endoscopes have been promoted to entirely prevent cross-contamination and eliminate the complexities associated with reprocessing reusable endoscopes. However, the widespread adoption of single-use endoscopes has been met with challenges related to cost and environmental impact.[35] One key factor to consider is the break-even cost of single-use devices (SUDs), which also involve added supply chain logistics and storage expenses.[35]

SUDs also have environmental impact:

- They have a higher carbon footprint: 10.9 kg CO_2 vs. 4.7 kg for reusable gastroscopes. This is equivalent to a 28 km (17.5 mile) car drive.[36]
- They have an additional 40% creation of disposable medical waste.[37]

To meet physicians' needs, single-use duodenoscopes must closely match the maneuverability, flexibility, and image quality of reusable scopes, as these factors are essential for procedural effectiveness.[38]

The environmental impact of disposable endoscopes, resulting from increased medical waste, raises concerns that warrant further evaluation—particularly considering the healthcare sector's commitment to sustainability.

Since the materials used in the construction of reusable endoscopes are not compatible with the heat of steam sterilization, low-temperature methods of sterilization are essential to prevent endoscope damage and degradation. Ethylene oxide (EtO) sterilization has been widely used for sterilizing medical devices and is now being considered for endoscopes as well. This method is highly effective, capable of eliminating all microbial life, including spores. However, its practical use for endoscope reprocessing is constrained by lengthy cycle times and the need for extensive aeration to remove residual toxic gas.

Conclusion

The reprocessing of endoscopes is a complex and critical process that directly impacts patient safety. While significant advancements have been made in recent years, challenges persist, particularly in achieving complete microbial elimination and preventing biofilm formation. The rise of multidrug-resistant organisms (MDROs) further underscores the importance of rigorous reprocessing protocols.

The Spaulding classification system, while useful, may need to be revisited to better categorize endoscopes, especially those used in complex procedures like ERCP. The increasing complexity of endoscopic devices and the potential for biofilm formation highlight the need for innovative cleaning and disinfection techniques.

Shifting from high-level disinfection to sterilization for certain devices, particularly those used in high-risk procedures where mucosal surfaces may be compromised, is a promising approach to enhance patient safety. However, this requires careful consideration of the device's material compatibility and the sterilization method's effectiveness.

Future research should focus on developing more effective cleaning agents, improving biofilm removal techniques, and evaluating the efficacy of newer sterilization technologies such as hydrogen peroxide gas plasma. Furthermore, standardized reprocessing protocols, rigorous quality control measures, and ongoing surveillance are essential to minimize the risk of healthcare-associated infections especially where there is a risk of MDRO transmission.

By addressing these challenges and implementing evidence-based practices, healthcare facilities can significantly reduce the risk of endoscope-related infections and improve patient outcomes.

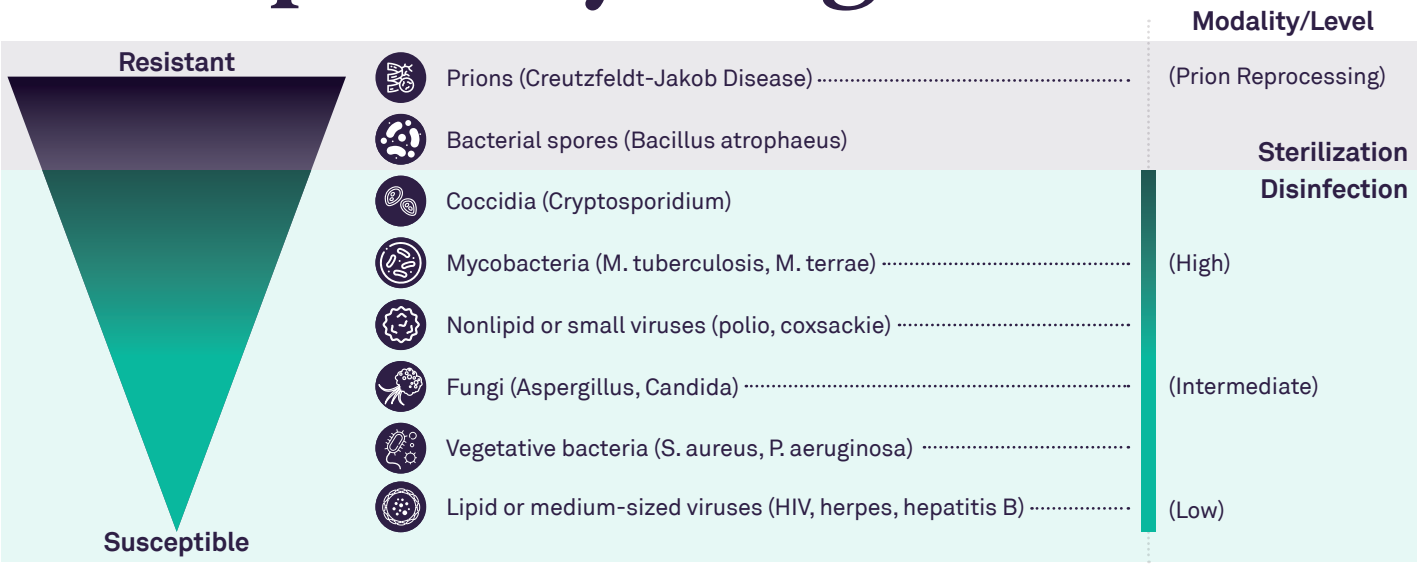
Appendix A:

Glossary of Helpful Definitions[1,6,39,40]

- **Automated endoscope reprocessor (AER):** A machine that automates the cleaning and disinfection of endoscopes.
- **Biofilm:** A complex aggregation of microorganisms, primarily bacteria, which adhere to surfaces and are embedded in a self-produced matrix of extracellular polymeric substances (EPS).
- **Cleaning:** The removal of visible soil and microbial contaminants. Water, detergent and enzymatic products may all be used. Cleaning is essential to the overall high-level disinfection or sterilization process.
- **Colony-forming unit (CFU):** A unit of measurement used to estimate the number of viable (living) bacterial or fungal cells in a culture.
- **Critical Items:** Have the highest potential for creating risk of infection because they encounter sterile tissue including the vascular system. Historically, these are sold in sterile packaging and include implants, cardiac and urinary catheters, arthroscopes and laparoscopes and ultrasound probes used in sterile tissue.
- **Disinfection:** A process that eliminates many or all pathogenic microorganisms on inanimate objects except for spores.
- **Duodenoscope:** A specialized endoscope used to view and perform procedures on the duodenum (the first part of the small intestine) and pancreatic and bile ducts.
- **Endoscope Reprocessing:** The multi-step process of cleaning, disinfecting, and drying an endoscope after each use to prevent transmission of infection to the next patient.
- **Endoscopic retrograde cholangiopancreatography (ERCP):** A minimally invasive procedure that uses a duodenoscope to diagnose and treat problems in the bile ducts and pancreatic duct.
- **Endoscopy:** A medical procedure that uses a thin, flexible tube with a light and camera at the end to examine the inside of the body.
- **Ethylene Oxide (EtO):** A low-temperature sterilization method commonly used for sterilizing heat-sensitive medical devices.
- **Exogenous infection:** An infection that arises from an external source, such as a contaminated medical device.
- **Hydrogen Peroxide Gas Plasma (HPGP):** A low-temperature sterilization method that uses a combination of hydrogen peroxide gas and plasma to kill microorganisms. This method is effective for sterilizing heat-sensitive medical devices and is considered a safer alternative to other low-temperature sterilization methods.
- **High-Level Disinfection (HLD):** A disinfection process that eliminates most pathogenic microorganisms, but not all spores, on inanimate objects.
- **High-concern organisms:** Microorganisms that are considered to be more likely to cause patient infection than low-to-moderate concern organisms.
- **Liquid Chemical Sterilization (LCS):** A method of sterilization that uses a liquid chemical solution to kill microorganisms.
- **Low-Level Disinfection:** Destroys most bacteria and some viruses especially enveloped viruses.
- **Low-to-moderate concern (LMC) organisms:** Microorganisms that are considered to be less likely to cause patient infection than high-concern organisms.
- **Margin of Safety:** The difference between the level of microbial contamination on a medical device and the level at which infection is likely to occur.
- **Multidrug-Resistant Organisms (MDROs):** Bacteria that are resistant to two or more classes of antibiotics.
- **Semicritical Items:** Those that encounter mucous membranes or non-intact skin.
- **Spaulding Classification:** A three-category methodology for classifying medical devices based on their risk of infection transmission. The categories are critical, semicritical, and noncritical.
- **Sterilization:** The destruction or complete elimination of all forms of microbial life.

Appendix B:

Susceptibility Diagram[1,2]



This schema allows an approach to ranking resistance to disinfection and sterilization based on cellular structure. Of note, Prions are proteinaceous infectious material that do not contain nucleic acid (i.e. deoxyribonucleic acid or ribonucleic acid).[2] Destruction of spores requires sterilization.

Appendix C:

Spaulding Classification[1]

The Spaulding Classification System divides medical devices into three categories based on the intended use of the device and the degree of risk of patient infection.

CATEGORY	DESCRIPTION	EXAMPLES	CLASS OF DISINFECTION
Non-critical	Device that only contact intact skin	▸ Blood pressure cuff ▸ Crutches ▸ Other patient care equipment	Since the risk of infection is low, these surfaces are disinfected with low- or intermediate-level disinfectants (e.g., phenolic, iodophor, alcohol, chlorine).
Semi-critical	Device that contact intact mucous membranes or nonintact skin of the patient	▸ Endotracheal tube ▸ Non-invasive endoscope ▸ Cystoscopes ▸ Anesthesia breathing tubes	Minimally requires high-level disinfection with FDA-cleared chemical disinfectants such as glutaraldehyde, hydrogen peroxide, *ortho*-phthalaldehyde, and peracetic acid.
Critical	Device that are introduced directly into the bloodstream or sterile areas of the body	▸ Needles ▸ Surgical instruments ▸ Cardiac catheters ▸ Implants (e.g., heart valves)	Since the risk of infection is very high, these devices must be sterilized before each use.

References

[1] Rutala, W. A., & Weber, D. J. (2019). Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. In J. E. Bennett, R. Dolin, & M. J. Blaser (Eds.), Principles and Practice of Infectious Diseases: Vol. Volume 2 (9th ed., pp. 3294-3309.e4). Elsevier. https://doi.org/10.1016/b978-1-4557-4801-3.00301-5

[2] Rutala, W., Weber, D., & (HICPAC), H. I. C. P. A. C. (2008). Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (CDC_2008). CDC. https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

[3] Kanamori, H., Rutala, W. A., & Weber, D. J. (2017). The Role of Patient Care Items as a Fomite in Healthcare-Associated Outbreaks and Infection Prevention. Clinical Infectious Diseases, 65(8), 1412–1419. https://doi.org/10.1093/cid/cix462

[4] Rowan, N. J., Kremer, T., & McDonnell, G. (2023). A review of Spaulding's classification system for effective cleaning, disinfection and sterilization of reusable medical devices: Viewed through a modern-day lens that will inform and enable future sustainability. Science of The Total Environment, 878, 162976. https://doi.org/10.1016/j.scitotenv.2023.162976

[5] WFHSS. (2024). FLEXIBLE ENDOSCOPY REPROCESSING - PRINCIPLES. https://guidelines.wfhss.com/frontpage/flexible-endoscopy/

[6] Okamoto, N., Sczaniecka, A., Hirano, M., Benedict, M., Baba, S., Horino, Y., Takenouchi, M., Morizane, Y., Yana, I., Segan, R., Pineau, L., & Alfa, M. J. (2022). A prospective, multicenter, clinical study of duodenoscope contamination after reprocessing. Infection Control & Hospital Epidemiology, 43(12), 1901–1909. https://doi.org/10.1017/ice.2021.525

[7] Casini, B., Tuvo, B., Marciano, E., Magro, G. D., Gemignani, G., Luchini, G., Cristina, M. L., Costa, A. L., Arzilli, G., Totaro, M., Baggiani, A., & Privitera, G. (2021). Improving the Reprocessing Quality of Flexible Thermolabile Endoscopes: How to Learn from Mistakes. International Journal of Environmental Research and Public Health, 18(5), 2482. https://doi.org/10.3390/ijerph18052482

[8] Peery, A. F., Murphy, C. C., Anderson, C., Jensen, E. T., Deutsch-Link, S., Egberg, M. D., Lund, J. L., Subramaniam, D., Dellon, E. S., Sperber, A. D., Palsson, O. S., Pate, V., Baron, T. H., Moon, A. M., Shaheen, N. J., & Sandler, R. S. (2025). Burden and Cost of Gastrointestinal, Liver, and Pancreatic Diseases in the United States: Update 2024. Gastroenterology. https://doi.org/10.1053/j.gastro.2024.12.029

[9] Larsen, S., Russell, R. V., Ockert, L. K., Spanos, S., Travis, H. S., Ehlers, L. H., & Mærkedahl, A. (2020). Rate and impact of duodenoscope contamination: A systematic review and meta-analysis. EClinicalMedicine, 25, 100451. https://doi.org/10.1016/j.eclinm.2020.100451

[10] Ploeg, K. van der, Vos, M. C., Erler, N. S., Bulkmans, A. J. C., Mason-Slingerland, B. C. G. C., Severin, J. A., & Bruno, M. J. (2024). Impact of duodenoscope reprocessing factors on duodenoscope contamination: a retrospective observational study. The Journal of Hospital Infection, 154, 88–94. https://doi.org/10.1016/j.jhin.2024.09.018

[11] Ayres, A. M., Wozniak, J., O'Neil, J., Stewart, K., Leger, J. St., Pasculle, A. W., Lewis, C., McGrath, K., Slivka, A., & Snyder, G. M. (2023). Endoscopic retrograde cholangiopancreatography and endoscopic ultrasound endoscope reprocessing: Variables impacting contamination risk. Infection Control & Hospital Epidemiology, 44(9), 1485–1489. https://doi.org/10.1017/ice.2022.319

[12] TJC. (2023). The Joint Commission Guide to Reprocessing Reusable Medical Devices (S. Garcia-Houchins & R. N. Olmsted, Eds.). Joint Commission Resources.

[13] Ofstead, C. L., Hopkins, K. M., Buro, B. L., Eiland, J. E., & Wetzler, H. P. (2020). Challenges in achieving effective high-level disinfection in endoscope reprocessing. American Journal of Infection Control, 48(3), 309–315. https://doi.org/10.1016/j.ajic.2019.09.013

[14] Ofstead, C. L., Wetzler, H. P., Eiland, J. E., Heymann, O. L., Held, S. B., & Shaw, M. J. (2016). Assessing residual contamination and damage inside flexible endoscopes over time. American Journal of Infection Control, 44(12), 1675–1677. https://doi.org/10.1016/j.ajic.2016.06.029

[15] Ofstead, C. L., Quick, M. R., Wetzler, H. P., Eiland, J. E., Heymann, O. L., Sonetti, D. A., & Ferguson, J. S. (2018). Effectiveness of Reprocessing for Flexible Bronchoscopes and Endobronchial Ultrasound Bronchoscopes. Chest, 154(5), 1024–1034. https://doi.org/10.1016/j.chest.2018.04.045

[16] Ofstead, C. L., Hopkins, K. M., Smart, A. G., Eiland, J. E., Wetzler, H. P., & Bechis, S. K. (2022). Reprocessing Effectiveness for Flexible Ureteroscopes: A Critical Look at the Evidence. Urology, 164, 25–32. https://doi.org/10.1016/j.urology.2022.01.033

[17] Rutala, W. A., Donskey, C. J., & Weber, D. J. (2023). Disinfection and sterilization: New technologies. American Journal of Infection Control, 51(11), A13–A21. https://doi.org/10.1016/j.ajic.2023.01.004

[18] Rutala, W. A., & Weber, D. J. (2023). Reprocessing semicritical items: An overview and an update on the shift from HLD to sterilization for endoscopes. American Journal of Infection Control, 51(11), A96–A106. https://doi.org/10.1016/j.ajic.2023.01.002

[19] Monroe, D. (2007). Looking for Chinks in the Armor of Bacterial Biofilms. PLoS Biology, 5(11), e307. https://doi.org/10.1371/journal.pbio.0050307

[20] Roilides, E., Simitsopoulou, M., Katragkou, A., & Walsh, T. J. (2015). How Biofilms Evade Host Defenses. Microbiology Spectrum, 3(3), 10.1128/microbiolspec.mb-0012–2014. https://doi.org/10.1128/microbiolspec.mb-0012-2014

[21] Fang, Y., Shen, Z., Li, L., Cao, Y., Gu, L.-Y., Gu, Q., Zhong, X.-Q., Yu, C.-H., & Li, Y.-M. (2010). A study of the efficacy of bacterial biofilm cleanout for gastrointestinal endoscopes. World Journal of Gastroenterology, 16(8), 1019–1024. https://doi.org/10.3748/wjg.v16.i8.1019

[22] Neves, M. S., Silva, M. G. da, Ventura, G. M., Côrtes, P. B., Duarte, R. S., & Souza, H. S. de. (2016). Effectiveness of current disinfection procedures against biofilm on contaminated GI endoscopes. Gastrointestinal Endoscopy, 83(5), 944–953. https://doi.org/10.1016/j.gie.2015.09.016

[23] Pajkos, A., Vickery, K., & Cossart, Y. (2004). Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination? Journal of Hospital Infection, 58(3), 224–229. https://doi. org/10.1016/j.jhin.2004.06.023

[24] Moshkanbaryans, L., Shah, V., Tan, L. Y., Jones, M. P., Vickery, K., Alfa, M., & Burdach, J. (2024). Comparison of two endoscope channel cleaning approaches to remove cyclic build-up biofilm. The Journal of Hospital Infection, 150, 91–95. https://doi.org/10.1016/j.jhin.2024.05.014

[25] CDC. (2024). Current HAI Progress Report. https://www.cdc.gov/healthcare-associated-infections/php/data/progress-report.html

[26] Bysshe, T., Gao, Y., Heaney-Huls, K., Hockenberry, J., Hovey, L., Laffan, A. M., Lee, S., Murphy, D. J., & Watts, E. (2017). Estimating the Additional Hospital Inpatient Cost and Mortality Associated With Selected Hospital-Acquired Conditions (Agency for Healthcare Research and Quality). AHRQ.

[27] Ofstead, C., Buro, B., Hopkins, K., Eiland, J., Wetzler, H., & Lichtenstein, D. (2020). Duodenoscope-associated infection prevention: A call for evidence-based decision making. Endoscopy International Open, 08(12), E1769–E1781. https://doi.org/10.1055/a-1264-7173

[28] Murray, P. (2016). Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients (pp. 1–301).

[29] Forbes, N., Elmunzer, B. J., Allain, T., Parkins, M. D., Sheth, P. M., Waddell, B. J., Du, K., Douchant, K., Oladipo, O., Saleem, A., Cartwright, S., Chau, M., Howarth, M., McKay, J., Nashad, T., Ruan, Y., Bishay, K., Gonzalez-Moreno, E., Meng, Z. W., … Heitman, S. J. (2023). Effect of Disposable Elevator Cap Duodenoscopes on Persistent Microbial Contamination and Technical Performance of Endoscopic Retrograde Cholangiopancreatography. JAMA Internal Medicine, 183(3), 191–200. https://doi.org/10.1001/jamainternmed.2022.6394

[30] Hutfless, S., Shiratori, Y., Chu, D., Liu, S., & Kalloo, A. (2022). Risk factors for infections after endoscopic retrograde cholangiopancreatography (ERCP): a retrospective cohort analysis of US Medicare Fee-For-Service claims, 2015–2021. BMJ Open, 12(9), e065077. https://doi.org/10.1136/bmjopen-2022-065077

[31] Chang, W.-K., Peng, C.-L., Chen, Y.-W., Sun, C.-K., Chen, C.-C., Liu, T.-C., Chu, Y.-Y., Tsai, I.-F., Chung, C.-S., Lin, H.-F., Hsu, F.-Y., Tai, W.-C., Lee, H.-C., Yen, H.-H., Wang, E.-M., Chen, S.-H., Chu, C.-H., Chen, M.-J., Lu, C.-L., & Chiu, C.-T. (2024). Recommendations and guidelines for endoscope reprocessing: Current position statement of digestive endoscopic society of Taiwan. Journal of Microbiology, Immunology and Infection, 57(2), 211–224. https://doi.org/10.1016/j.jmii.2023.12.001

[32] Kühl, N., Vollenberg, R., Meier, J. A., Ullerich, H., Schulz, M. S., Rennebaum, F., Laleman, W., Froböse, N. J., Praktiknjo, M., Peiffer, K., Fischer, J., Trebicka, J., Gu, W., & Tepasse, P.-R. (2024). Risk Factors for Infectious Complications following Endoscopic Retrograde Cholangiopancreatography in Liver Transplant Patients: A Single-Center Study. Journal of Clinical Medicine, 13(5), 1438. https://doi.org/10.3390/jcm13051438

[33] Chhabria, M. S., Maldonado, F., & Mehta, A. C. (2023). Infection control in the bronchoscopy suite: effective reprocessing and disinfection of reusable bronchoscopes. Current Opinion in Pulmonary Medicine, 29(1), 21–28. https://doi.org/10.1097/mcp.0000000000000925

[34] HSPA. (2022). Endoscope Reprocessing Manual Workbook (By HSPA).

[35] Kwakman, J. A., Poley, M. J., Vos, M. C., & Bruno, M. J. (2023). Single-use duodenoscopes compared with reusable duodenoscopes in patients carrying multidrug-resistant microorganisms: a break-even cost analysis. Endoscopy International Open, 11(6), E571–E580. https://doi.org/10.1055/a-2064-9721

[36] Pioche, M., Pohl, H., Neves, J. A. C., Laporte, A., Mochet, M., Rivory, J., Grau, R., Jacques, J., Grinberg, D., Boube, M., Baddeley, R., Cottinet, P.-J., Schaefer, M., Santiago, E. R. de, Berger, A., Vienne, A., Kaassis, M., Lacroute, J., Grau, R., & Biscay, M. (2024). Environmental impact of single-use versus reusable gastroscopes. Gut, 73(11), 1816–1822. https://doi.org/10.1136/gutjnl-2024-332293

[37] Namburar, S., Renteln, D. von, Damianos, J., Bradish, L., Barrett, J., Aguilera-Fish, A., Cushman-Roisin, B., & Pohl, H. (2022). Estimating the environmental impact of disposable endoscopic equipment and endoscopes. Gut, 71(7), 1326–1331. https://doi.org/10.1136/gutjnl-2021-324729

[38] Yano, T. (2023). Impact and potential use of disposable single‐use endoscopes. Digestive Endoscopy, 35(7), 866–868. https://doi.org/10.1111/den.14596

[39] Rutala, W. A., & Weber, D. J. (2016). Disinfection and Sterilization in Health Care Facilities: An Overview and Current Issues. Infectious Disease Clinics of North America, 30(3), 609–637. https://www.sciencedirect.com/science/article/pii/S0891552016300228?via%3Dihub

[40] FDA. (2017, December 12). Liquid Chemical Sterilization _ FDA. Liquid Chemical Sterilization. https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/liquid-chemical-sterilization

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