REVIEW

Best practices for flexible endoscope high-level disinfection – an integrative review

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ABSTRACT

Background: Flexible endoscopes have a complicated design which includes several small lumen channels intended to facilitate the flow of fluids, tissue, and tools through the length of the device. This complex design leads to reprocessing challenges for high-level disinfection (HLD) to ensure endoscopes are free from contaminants that could lead to hospital-acquired infections. The aim of this project was to identify optimal strategies and obstacles for each stage of flexible endoscope HLD through an integrative review with the goal of achieving reprocessing excellence.

Methods: A literature search was conducted using PubMed/Medline and CINAHL databases. A total of 32 articles and six guidelines were included in the review.

Results: Ten elements with best-practice recommendations of flexible endoscope HLD have been identified. The HLD elements that received the most literature support include quality assurance/process monitoring and manual cleaning/decontamination. Several barriers to the adequate performance of HLD elements were also identified.

Conclusion: This integrative review applied varying levels of rigour to identify and synthesize best practices for the following HLD elements: point-of-use treatment, transport, leak testing, manual cleaning/decontamination, visual inspection, manual or automated HLD, rinsing/drying, storage/hang time, record keeping, and quality assurance/process monitoring.

KEYWORDS

High-level disinfection, flexible endoscopes, best practices

INTRODUCTION

Every year, more than 20 million diagnostic and therapeutic operations make use of flexible endoscopes. To accommodate this need, flexible endoscopes may need to undergo numerous daily reprocessing cycles per device (Rahman *et al.*, 2019). Flexible endoscopes have a complicated design which includes several small lumen channels intended to facilitate the flow of fluids, tissue, and tools through the length of the device (ESGE, 2018). Improper high-level disinfection (HLD) or reprocessing of endoscopes leads to an elevated risk of patients being exposed to potentially life-threatening infections (Kovaleva *et al.*, 2013; DiazGranados *et al.*, 2009). These infections can include hepatitis C, human immunodeficiency virus, and multidrug-resistant organisms

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(MDRO) infections. Hospital-acquired infections, such as those transmitted by contaminated endoscopes cost roughly CAN$2 billion yearly, and may result in an average of hospitalizations of up to 25 days, and costs ranging from CAN$2,265 to more than CAN$18,000 per patient (Hassan *et al.*, 2010; Pan-Canadian Action Plan on Antimicrobial Resistance, 2023; The Canadian Patient Safety Institute, n.d.; Public Health Agency of Canada, 2017).

High institutional costs and the criticality of patient safety justifies the importance of the 10 elements of HLD, each requiring meticulous attention to guarantee the safety of endoscopes for patient procedures (Association for the Advancement of Medical Instrumentation, 2021, Public Health Agency of Canada, 2011). The 10 elements of HLD (point-of-use treatment, transport, leak testing, manual cleaning/decontamination, visual inspection, manual or automated HLD, rinsing/drying, storage/hang time, record keeping, and quality assurance/process monitoring) depict the complex steps in endoscope reprocessing.

Endoscope reprocessing failures are often attributed to human errors occurring during the reprocessing steps of flexible endoscopes both in manual and automated processes (Benowitz *et al.*, 2020; Oftead *et al.*, 2010). Adherence to endoscope instructions for use (IFU) is key to overcoming the human factors associated with endoscope reprocessing issues. IFUs offer validated guidelines for properly managing and upkeeping equipment that is tailored to each individual endoscope and its related accessories. In order to ensure that safety standards are met during the HLD process, it is necessary for reprocessing workers to adhere to the convergence of literature best practices, guidelines, and IFUs as requirements (Ofstead *et al.*, 2020). An integrated literature review such as the current study is, therefore, necessary to compile best practices from literature and guidelines to address the barriers associated with the reprocessing of endoscopes. This project aims to identify optimal strategies and obstacles for each stage of flexible endoscope HLD through an integrative review, with the goal of achieving reprocessing excellence.

METHODS

Search strategy and study selection

The databases PubMed/MEDLINE® and CINHAL® (Cumulative Index to Nursing and Allied Health Literature) were used for a literature search. One hundred fifty-two articles were found using the keywords *endoscope, flexible endoscope, high-level disinfection, and HLD* with 26 duplicates removed. Utilizing the Boolean connective *"and"* the search was made more precise. *Human and English limitations were applied*. The authors conducted identification, screening, exclusion, and extraction without restricting date ranges due to the scarcity of literature. This resulted in literature spanning 16 years.

Inclusion and exclusion criteria

Out of the 152 articles found in the literature search, exclusion criteria were applied during the identification phase to remove duplicates manually (n=2) and using software duplicate identification (n=24). Two reviewers screened each study during the title and abstract screening. A third reviewer adjudicated disagreements between reviewers. During title and abstract screening, studies were excluded that focused on sterilization of endoscopes (n=13), HLD product evaluation (n=20), and those that did not inform HLD best practices (n=40). Studies were assessed by receiving full-text reviews to further evaluate for inclusion. Two reviewers assessed each full-text article. Articles were excluded if they were the wrong study design (n=2), translation unavailable (n=3), library request unavailable (n=3), focused on HLD product evaluation (n=4), summarized versions of professional guidelines older than current editions (n=4), and does not inform HLD best practices (n=5). A third reviewer adjudicated disagreements between reviewers. Ten professional organizations or international government guidelines and recommendations were utilized in synthesizing the literature and identifying HLD best practices. Guidelines included the Public Health Agency of Canada (PHAC, 2011), Centers for Disease Control and Prevention (HICPAC and CDC, 2018), The Gastroenterological Society of Australia (GSA, 2021), The European Society of Gastrointestinal Endoscopy (ESGE, 2018), The National Health Service (NHS, 2016), the Association for the Advancement of Medical Instrumentation (AAMI, 2021), (Behm and Robinson, 2020), the Society of Gastroenterology Nurses and Associates (SGNA, 2023), the American Society for Gastrointestinal Endoscopy (ASGE, 2021), and the Association of Perioperative Registered Nurses (AORN, 2023).

Quality Assessment and Data Extraction

Fifty-three full-text articles were appraised utilizing a Rapid Critical Appraisal (RCA) checklist inclusive of conflict of interest, test validity, population focus, result outcomes, and risk of bias (Melnyk and Fineout-Overholt, 2019). Each article's study category utilized the applicable RCA, including the *RCA for Systematic Reviews and Meta-Analysis of Clinical Interventions, RCA for Randomized Clinical Trials, RCA for Quasi-experimental Studies, RCA for Randomized Cohort Studies, RCA for Descriptive Studies, RCA for Qualitative Evidence, RCA for Evidence-Based Practice Implementation or Quality Improvement Projects, RCA for Case Studies, RCA for Literature Review, RCA for Evidence-Based Guidelines* (Melnyk and Fineout-Overholt, 2019). After evaluation with the RCA checklist, 32 articles were included in the data extraction. Data extraction and quality assessment were completed using Covidence literature review software (Covidence, 2023). Data extraction included general information, characteristics of the studies, evaluation of the HLD elements addressed, identification of HLD element best practices, and identification of HLD element barriers to implementation. Each article received data extraction from two different reviewers and a final assessment from a third reviewer. Literature appraisal, quality, and synthesis can be found in Appendix A (see online edition). The PRISMA for this literature search can be found in Figure 1.

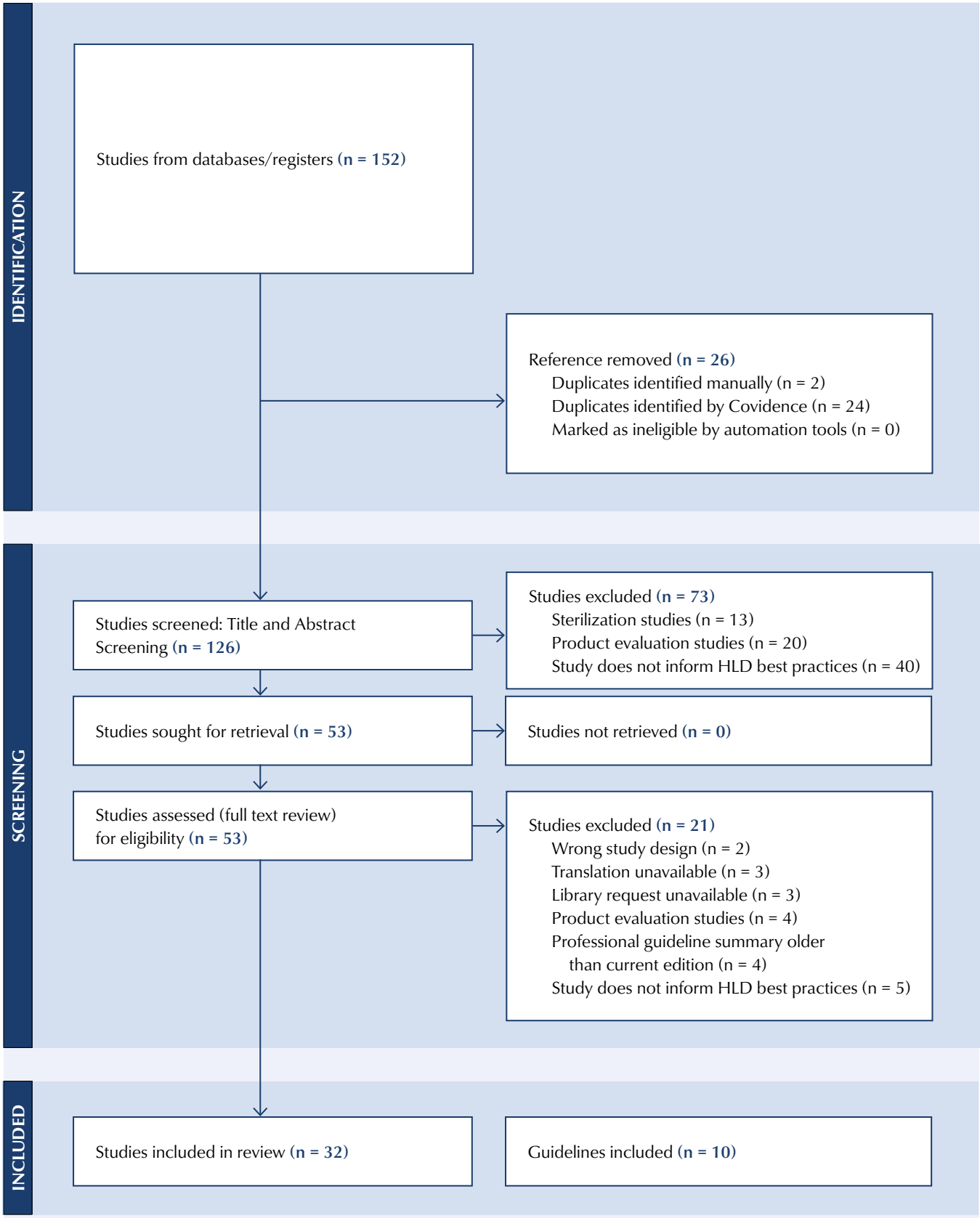

FIGURE 1: PRISMA flow diagram showing summary of the systematic review on the best practices for flexible endoscope high-level disinfection

TABLE 1: Barriers to HLD Best Practices	
Barriers to HLD	References
Point-of-use treatment	
The timeliness of POU cleaning is to be less than 1 hour, ideally immediately after the procedure to prevent the development of robust biofilms.	Roberts, 2013; Pynnonen & Whelan, 2019; Montero *et al.*, 2023; Devereaux, *et al.*, 2019; Chhabria *et al.*, 2023; Akinbobola *et al.*, 2017; Schmelzer *et al.*, 2015; GSA, 2021; PHAC, 2011.
Endoscopes can be difficult to achieve effective POU cleaning due to complex designs, narrow channels, and mechanisms.	Rahman *et al.*, 2019; Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Ofstead, *et al.*, 2016; Muscarella, 2014; Devereaux, *et al.*, 2019; Chhabria *et al.*, 2023; El-Sokkary *et al.*, 2017; Ofstead *et al.*, 2010; Mehta & Muscarella, 2020.
Transport	
Lack of enclosed containers or transport carts with impermeable properties, leak-proof surfaces on their sides and bottom, puncture resistance, and sufficient capacity to accommodate individual endoscopes without requiring excessive coiling of the insertion or light guide tubes.	Statham & Willging, 2010; SGNA, 2023.
Leak testing	
If leak testing is not performed, breaches in the structure of the endoscope can go undetected, harbouring microorganisms and putting patients at risk.	Kovaleva *et al.*, 2013; Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Chhabria *et al.*, 2023; Ofstead *et al.*, 2020; Mehta & Muscarella, 2020; GSA, 2021; PHAC, 2011.
Knowledge deficit can lead to staff incorrectly performing leak tests (i.e., leak testing in enzymatic solution instead of clear water).	El-Sokkary *et al.*, 2017; Ofstead et al., 2010.
Manual cleaning/decontamination	
Due to the complexity of the endoscope, laborious physical procedures, and lengthy manufacturer instructions for use, manual cleaning, and disinfection is a process that is prone to error and employee injury.	Benowitz *et al.*, 2020; Roberts, 2013; Pynnonen & Whelan, 2019; Muscarella, 2014; Devereaux, *et al.*, 2019; Schmelzer *et al.*, 2015; El-Sokkary *et al.*, 2017; Statham & Willging, 2010; Ofstead *et al.*, 2010; Ofstead *et al.*, 2010; Washburn & Pietsch, 2018; Ofstead *et al.*, 2015; Sethi *et al.*, 2015; GSA, 2021; PHAC, 2011.
Biofilms pose the most significant risk to adequate manual cleaning/decontamination.	Rahman *et al.*, 2019; Benowitz *et al.*, 2020; Roberts, 2013; Ofstead *et al.*, 2017; Chhabria *et al.*, 2023; Akinbobola *et al.*, 2017; Schmelzer *et al.*, 2015; Gonzalez *et al.*, 2019; El-Sokkary *et al.*, 2017; Statham & Willging, 2010; Ofstead *et al.*, 2010; Ofstead *et al.*, 2015.
Visual inspection	
Although current recommendations urge focusing more on visual inspections, limited strategies for carrying out visual examinations or evaluating results are needed.	Ofstead *et al.*, 2017; Devereaux, *et al.*, 2019; AAMI, 2021; AORN, 2023.
Damaged components of a device not detected by visual inspection pose an infection risk.	Rahman *et al.*, 2019; DiazGranados *et al.*, 2009; Chhabria *et al.*, 2023.
Manual HLD	
Compliance with manual reprocessing is much lower than compliance with automated reprocessing.	Pynnonen & Whelan, 2019; Devereaux, *et al.*, 2019; Chhabria *et al.*, 2023; Ofstead *et al.*, 2010; Ofstead *et al.*, 2020; Sethi *et al.*, 2015; AAMI, 2021; ESGE, 2018.

Training deficiencies, highly complex endoscopes, and manufacturer IFUs make manual reprocessing challenging to perform correctly.	Benowitz *et al.*, 2020; Ofstead *et al.*, 2020; Patel & Jain, 2020; PHAC, 2011; ESGE, 2018.
HLD solutions need to be manually checked for temperature, concentration, and expiration before each HLD cycle because they are susceptible to falling below the manufacturer's suggested levels.	Benowitz *et al.*, 2020; Roberts, 2013; Pynnonen & Whelan, 2019; Ofstead, *et al.*, 2016; Schmelzer *et al.*, 2015; Ofstead *et al.*, 2020; AAMI, 2021; ESGE, 2018.
HLD solutions require careful handling to avoid employee exposure and injury.	Pynnonen & Whelan, 2019; Ofstead *et al.*, 2010; AAMI, 2021; PHAC, 2011; ESGE, 2018.
Automated HLD	
Automated HLDs are not available for or compatible with all medical devices that require reprocessing.	AAMI, 2021.
Extensive attention to IFU details is needed to run automated HLD properly.	Benowitz *et al.*, 2020; Muscarella, 2014; Ofstead *et al.*, 2020; Ofstead *et al.*, 2015; AAMI, 2021 AAMI, 2021; Mehta & Muscarella, 2020; AORN, 2023.
A deficit exists in reprocessing staff-automated HLD training and education.	Ofstead *et al.*, 2020; Ofstead *et al.*, 2015; Mehta & Muscarella, 2020.
Poor water-quality monitoring with automated HLD results in outbreaks.	Kovaleva *et al.*, 2013; Benowitz *et al.*, 2020; Montero *et al.*, 2023; Patel & Jain, 2020; Gavalda *et al.*, 2015; AORN, 2023; GSA, 2021; ESGE, 2018.
Rinsing/drying	
Lack of a drying procedure with or without alcohol flushing is associated with endoscope contamination.	Kovaleva *et al.*, 2013; Roberts, 2013; Ofstead, *et al.*, 2016; Devereaux *et al.*, 2019; Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; El-Sokkary *et al.*, 2017; Ofstead *et al.*, 2020; Pasternak & Taylor, 2023; GSA, 2021; PHAC, 2011.
Rinsing with contaminated water is associated with endoscope-related outbreaks.	Benowitz *et al.*, 2020; Roberts, 2013; Ofstead *et al.*, 2017; Ofstead, *et al.*, 2016; Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; El-Sokkary *et al.*, 2017; Ofstead *et al.*, 2020; GSA, 2021.
Storage/hang-time	
No hang-time consensus among professional organizations and regulatory bodies.	Pynnonen & Whelan, 2019; Chhabria et al., 2023; Schmelzer *et al.*, 2015; Hansen, 2016; Garcia & Oliveira, 2022; Behm & Robinson, 2020; HICPAC & CDC, 2018; Mehta & Muscarella, 2020; Troutner *et al.*, 2020; Pasternak & Taylor, 2023; ESGE, 2018.
Limited studies to support evidence of safe time without microbial growth.	Kovaleva *et al.*, 2013; Pynnonen & Whelan, 2019; Schmelzer *et al.*, 2015; Mallette *et al.*, 2018; El-Sokkary *et al.*, 2017; Hansen, 2016; Garcia & Oliveira, 2022; ESGE, 2018.
Quality assurance/process monitoring	
Microbial surveillance is costly.	Kovaleva *et al.*, 2013; El-Sokkary *et al.*, 2017; Garcia & Oliveira, 2022; Gavalda *et al.*, 2015; Higa *et al.*, 2016; Legemate *et al.*, 2019.
Endoscope damage can be challenging to visualize.	Kovaleva *et al.*, 2013; Benowitz *et al.*, 2020; Ofstead *et al.*, 2017; Mehta & Muscarella, 2020; Higa *et al.*, 2016.
Endoscopes under surveillance require quarantining; this requires an increased endoscope inventory.	Chhabria *et al.*, 2023; Garcia & Oliveira, 2022; Higa *et al.*, 2016.

RESULTS

Point-of-use treatment

Point-of-use (POU) treatment is the first stage of endoscope reprocessing. It occurs throughout and immediately after procedures, and keeps the scope clean and free of debris according to 19/42 (45%) of studies and guidelines (Rahman *et al.*, 2019, Benowitz *et al.*, 2020), Roberts, 2013, Pynnonen and Whelan, 2019, Ofstead *et al.*, 2017, Ofstead, *et al.*, 2016), Muscarella, L., 2014, Montero *et al.*, 2023, Devereaux, *et al.*, 2019, Chhabria *et al.*, 2023, Schmelzer *et al.*, 2015, Washburn and Pietsch, 2018, AAMI, 2021, SGNA, 2023, ASGE, 2021, Mehta and Muscarella, 2020, GSA, 202, PHAC, 201, ESGE, 2018). Eleven out of 42 (26%) of the studies and guidelines described this element of HLD using the following phrases: POU treatment, Pre-cleaning, and POU Cleaning. POU treatment during the procedure and immediately following completion aims to help avoid biofilm formation by removing bioburden (Rahman *et al.*, 2019, Benowitz *et al.*, 2020, Roberts, 2013, Pynnonen and Whelan, 2019, Montero *et al.*, 2023, Akinbobola *et al.*, 2017, Schmelzer *et al.*, 2015, Washburn and Pietsch, 2018, AAMI, 2021, ASGE, 2021, ESGE, 2018). Wiping the endoscope's exterior, suctioning the POU solution through all of the endoscope's channels until clear, and preparing the endoscope for transport following the IFU are all critical steps in POU (Rahman *et al.*, 2019, Roberts, 2013, Pynnonen and Whelan, 2019, Ofstead *et al.*, 2017, Ofstead, *et al.*, 2016, Muscarella, L., 2014, Devereaux, *et al.*, 2019, Chhabria *et al.*, 2023, Schmelzer *et al.*, 2015, Mallette *et al.*, 2018, Gonzalez *et al.*, 2019, El-Sokkary *et al.*, 2017, AAMI, 2021, ASGE, 2021, ESGE, 2018). The usage of lint-free cloths (Devereaux, *et al.*, 2019, Chhabria *et al.*, 2023, Mallette *et al.*, 2018, AAMI, 2021), single-use sponges soaked in detergent (Ofstead, *et al.*, 2016, Chhabria *et al.*, 2023, AAMI, 2021), and detergent or enzymatic detergent (Pynnonen and Whelan, 2019, Ofstead *et al.*, 2017, Ofstead, *et al.*, 2016, Chhabria *et al.*, 2023, Gonzalez *et al.*, 2019, El-Sokkary *et al.*, 2017, GSA, 2021, PHAC, 2011, ESGE, 2018) are among the products recommended for POU.

Transport

Endoscope transport was identified as a critical element of HLD best practices in 11 of 42 (26%) studies and guidelines (Rahman *et al.*, 2019; Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Devereaux, *et al.*, 2019; Akinbobola *et al.*, 2017; Schmelzer *et al.*, 2015; Gonzalez *et al.*, 2019; Statham & Willging, 2010; AAMI, 2021; PHAC, 2011; ESGE, 2018). Endoscopes should be kept moist during transport to prevent drying that could result in biofilm formation (Roberts, 2013; AAMI, 2021). Endoscopes should be transported to a designated disinfection area for reprocessing within1 hour to begin manual cleaning (Roberts, 2013; Pynnonen & Whelan, 2019; Chhabria et al., 2023; Akinbobola et al., 2017; Gonzalez *et al.*, 2019; Statham & Willging, 2010; ASGE, 2021). Transport containers with contaminated devices must be labelled with biohazard markings to safely identify the contents of the container (Pynnonen & Whelan, 2019; Chhabria *et al.*, 2023; AAMI, 2021; SGNA, 2023; ASGE, 2021; PHAC, 2011). Endoscopes are transported in specialized, individualized containers which are rigid and equipped with leak-proof lids. They ensure the scope is securely housed without excessive coiling during transportation, while also maintaining a clean environment and preventing contamination. (Pynnonen & Whelan, 2019; Statham & Willging, 2010; AAMI, 2021; GSA, 2021; ESGE, 2018). Transport containers must adhere to facility-approved intermediate-level disinfection standards, or must be marked as disposable (Pynnonen & Whelan, 2019; AAMI, 2021).

Leak testing

In 19 of 42 (45%) studies and guidelines, it is found that, before decontamination**,** leak testing determines if the integrity of an endoscope has been compromised (Rahman *et al.*, 2019; DiazGranados *et al.*, 2009; Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Muscarella, 2014; Devereaux, *et al.*, 2019; Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; El-Sokkary *et al.*, 2017; Hansen, 2016; Statham & Willging, 2010; Ofstead *et al.*, 2010; Ofstead *et al.*, 2020; Patel & Jain, 2020; AAMI, 2021; Mehta & Muscarella, 2020; GSA, 2021; PHAC, 2011; ESGE, 2018). Endoscope damage introduces the risk of water, bioburden, and chemical contamination, compromising internal structures (Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Schmelzer *et al.*, 2015; El-Sokkary *et al.*, 2017; Patel & Jain, 2020; ESGE, 2018). Endoscope contamination and damage expose subsequent patients to infectious pathogens and hazardous chemicals (Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Chhabria *et al.*, 2023; El-Sokkary *et al.*, 2017; Mehta & Muscarella, 2020). If a leak is found, the endoscope must be removed from service and sent to the manufacturer for repair (Pynnonen & Whelan, 2019; Chhabria *et al.*, 2023).

Manual cleaning/decontamination

Manual cleaning removes bioburden contaminants and biofilms that could complicate an HLD procedure according to 15 of 42 (35%) studies and guidelines. (Rahman *et al.*, 2019; Kovaleva *et al.*, 2013; Benowitz *et al.*, 2020; Roberts, 2013; Pynnonen & Whelan, 2019; Montero et al., 2023; Devereaux, *et al.*, 2019; Akinbobola *et al.*, 2017; Schmelzer *et al.*, 2015; Gonzalez *et al.*, 2019; Statham & Willging, 2010; Washburn & Pietsch, 2018; Ofstead *et al.*, 2015; GSA, 2021; ESGE, 2018). Unfortunately, this crucial element of HLD exhibits the highest rates of non-compliance and is often prone to errors. This is largely due to the demanding nature of the required tasks, such as hand cleaning, scrubbing, and flushing, which can be labour-intensive and susceptible to human error. (Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Schmelzer *et al.*, 2015; Mallette *et al.*, 2018; Gonzalez *et al.*, 2019; El-Sokkary *et al.*, 2017; Statham & Willging, 2010; Ofstead *et al.*, 2010; Ofstead *et al.*, 2015; Sethi *et al.*, 2015; AAMI, 2021; SGNA, 2023; ASGE, 2021; NHS, 2016). Unless otherwise specified by the endoscope IFU, manual cleaning should begin within 60 minutes of transport from the procedure, with the interval between POU and the

start of manual cleaning being recorded (Devereaux et al., 2019; AAMI, 2021; SGNA, 2023; ASGE, 2021; GSA, 2021). Endoscope cleaning starts with soaking in an enzymatic or detergent solution in accordance with the concentration mixing and temperature parameters of the IFU (Pynnonen & Whelan, 2019; Montero *et al.*, 2023; Schmelzer *et al.*, 2015; Gonzalez *et al.*, 2019; AAMI, 2021; SGNA, 2023; ASGE, 2021). In addition, endoscope cleaning should be performed under the solution's surface to avoid aerosolization, along with brushing all channels, lumens, ports, and external surfaces with specific specialty brushes for elevator channels and ultrasonic mechanisms. (Rahman *et al.*, 2019; Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Ofstead, *et al.*, 2016; Muscarella, 2014; Schmelzer *et al.*, 2015; Mallette *et al.*, 2018; El-Sokkary *et al.*, 2017; Sethi *et al.*, 2015; AAMI, 2021; SGNA, 2023; ASGE, 2021; Higa *et al.*, 2016; GSA, 2021; PHAC, 2011; ESGE, 2018). After brushing, it is necessary to flush and rinse every surface and channel with an approved cleaning solution; repeating this process until the endoscope is entirely free of debris and the flushing solution is visually clean (Benowitz *et al.*, 2020; Roberts, 2013; Pynnonen & Whelan, 2019; Ofstead *et al.*, 2017; Devereaux, *et al.*, 2019; Chhabria *et al.*, 2023; Akinbobola *et al.*, 2017; Schmelzer *et al.*, 2015; Mallette *et al.*, 2018; El-Sokkary *et al.*, 2017; Ofstead *et al.*, 2010; Ofstead *et al.*, 2015; SGNA, 2023). When utilized in accordance with the IFU, the flushing procedure can be automated using the approved accessories and devices (Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Schmelzer *et al.*, 2015; El-Sokkary *et al.*, 2017; Ofstead *et al.*, 2010; Ofstead *et al.*, 2015; AAMI, 2021; SGNA, 2023). Inspect the endoscope for visible contaminants, and continue cleaning if necessary (Roberts, 2013; Pynnonen & Whelan, 2019; AAMI, 2021; SGNA, 2023). The endoscope must be dried using an instrument or filtered air before the HLD reprocessing to prevent the dilution of HLD solutions (Benowitz *et al.*, 2020; Roberts, 2013; Pynnonen & Whelan, 2019; El-Sokkary *et al.*, 2017; AAMI, 2021; SGNA, 2023).

Visual inspection

Endoscope-related infections may result from debris in the endoscope's components and from the endoscope's undetected deterioration (DiazGranados *et al.*, 2009; Benowitz *et al.*, 2020). Meticulous visual inspection identifies lingering residue or indications of inadequate cleaning as found in 8/42 (19%) studies and guidelines (Rahman *et al.*, 2019; Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Muscarella, 2014; Chhabria et al., 2023; SGNA, 2023; Mehta & Muscarella, 2020; PHAC, 2011). Several resources are available to assist with visual inspection. For example, video borescopes examine channels for endoscope structural changes, including discoloration, scratches, and the presence of moisture, residue, and other contaminants (Benowitz *et al.*, 2020; Ofstead *et al.*, 2017; Devereaux, *et al.*, 2019; ASGE, 2021; Garcia & Oliveira, 2022; Mehta & Muscarella, 2020). Additionally, damage and persistent debris may be visible with bright magnification (Benowitz *et al.*, 2020; Devereaux, *et al.*, 2019; GSA, 2021).

Manual HLD

Best practices for manual HLD include checking the HLD solution temperature with calibrated thermometers, verifying the minimum effective concentration of the HLD solution and its expiration, and safe handling of the solutions to avoid unnecessary exposure to the chemicals (Benowitz *et al.*, 2020; Roberts, 2013; Pynnonen & Whelan, 2019; Muscarella, 2014; Schmelzer *et al.*, 2015; AAMI, 2021; SGNA, 2023; ASGE, 2021).

Automated HLD

Automated endoscope reprocessors (AERs) are correlated with better adherence to the cleaning method due to reduced potential for human errors in processing (Devereaux, *et al.*, 2019; Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; Ofstead *et al.*, 2010; Garcia & Oliveira, 2022; GSA, 2021). During this endoscope processing, AERs monitor every step, limit contamination, and avoid personnel interacting with chemicals or contaminated equipment (Rahman *et al.*, 2019; Kovaleva *et al.*, 2013; Schmelzer *et al.*, 2015; ASGE, 2021). In Australia, use of AERs is mandated (GSA, 2021). In Canada, manual cleaning/decontamination is required prior to AER use (PHAC, 2011). When using an AER, there are a few requirements to ensure that it is operating as intended, has been validated for the efficient reprocessing of each type of endoscope in stock, has been serviced and maintained as required, and that its internal surfaces and components are routinely self-disinfected as directed by its manufacturer (Muscarella, 2014; SGNA, 2023; ASGE, 2021; ESGE, 2018). Subsequently, if these requirements are not adhered to, patients can suffer from potential adverse associated outcomes. For example, contaminated water in the AER or internal component damage has been shown to lead to infectious outbreaks (Kovaleva *et al.*, 2013; DiazGranados *et al.*, 2009; Benowitz *et al.*, 2020; GSA, 2021).

Rinsing/drying

In 16 out of 42 studies and guidelines (38%), it's recommended that after HLD, rinsing and drying of endoscopes are essential. This process is necessary to eliminate any lingering residual chemicals and moisture from both the inner channels and exterior surfaces (Kovaleva *et al.*, 2013; Benowitz *et al.*, 2020; Roberts, 2013; Pynnonen & Whelan, 2019; Muscarella, 2014; Devereaux, *et al.*, 2019; Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; Mallette *et al.*, 2018; El-Sokkary *et al.*, 2017; AAMI, 2021; SGNA, 2023; ASGE, 2021; Garcia & Oliveira, 2022; Gavalda *et al.*, 2015; Mehta & Muscarella, 2020). The final rinse prevents subsequent patients and providers from being exposed to harmful chemicals (Kovaleva *et al.*, 2013; Pynnonen & Whelan, 2019; Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; Statham & Willging, 2010). Rinse water should have undergone reverse osmosis (Mallette *et al.*, 2018), be sterile (Kovaleva *et al.*, 2013; Muscarella, 2014; Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; El-Sokkary *et al.*, 2017; ESGE, 2018; Statham & Willging, 2010), or be filtered (Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; Statham & Willging, 2010) to aid in the prevention of endoscopy-associated infections.

After the final rinse, intraluminal forced air will aid the drying process (Rahman *et al.*, 2019; Kovaleva *et al.*, 2013; Roberts, 2013; Pynnonen & Whelan, 2019; Muscarella, 2014; Montero *et al.*, 2023; Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; El-Sokkary *et al.*, 2017; SGNA, 2023; GSA, 2021). If not adequately dried, residual moisture can allow surviving microorganisms to be replicated and regressed (Kovaleva *et al.*, 2013; Pynnonen & Whelan, 2019; Ofstead, *et al.*, 2016; Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; Gavalda *et al.*, 2015; Pasternak & Taylor, 2023). Additionally, a solution consisting of 70-90% ethyl alcohol or isopropyl alcohol can be utilized for flushing endoscopes. (Rahman *et al.*, 2019; Kovaleva *et al.*, 2013; Roberts, 2013; Pynnonen & Whelan, 2019; Muscarella, 2014; Schmelzer *et al.*, 2015; El-Sokkary *et al.*, 2017; SGNA, 2023; ASGE, 2021; Gavalda *et al.*, 2015; Mehta & Muscarella, 2020; PHAC, 2011). However, some concern remains regarding alcohol's protein-fixing properties. There is a potential for biofilm formation due to the buildup of protein residue on the inner channels (Ofstead *et al.*, 2017; Schmelzer *et al.*, 2015; ASGE, 2021; Garcia & Oliveira, 2022; ESGE, 2018). For this reason, some practices only utilize forced air drying.

Storage/hang time

Evidence-based decisions must occur when executing the storage or hang time for flexible endoscopes as this crucial element in reprocessing can affect patient outcomes according to 12/42 (28%) studies and guidelines (Rahman *et al.*, 2019; Kovaleva *et al.*, 2013; Benowitz *et al.*, 2020; Pynnonen & Whelan, 2019; Chhabria *et al.*, 2023; Schmelzer *et al.*, 2015; Hansen, 2016; Statham & Willging, 2010; Patel & Jain, 2020; AAMI, 2021; Mehta & Muscarella, 2020; Troutner *et al.*, 2020). Variables in this element include the storage environment, space/containers, ventilation, maximum allowable hang time, and strict adherence to all reprocessing steps leading to storage. Many healthcare organizations and agencies find common positions in recommended practices for endoscope storage, such as free vertical hanging in closed, dust-free and ventilated cabinets (Rahman *et al.*, 2019; Kovaleva *et al.*, 2013; Benowitz *et al.*, 2020; Roberts, 2013; Pynnonen & Whelan, 2019; Schmelzer *et al.*, 2015; Hansen, 2016; SGNA, 2023; ASGE, 2021; Behm & Robinson, 2020; Pasternak & Taylor, 2023; ESGE, 2018). However, the maximum allowable hang time remains at the forefront of unresolved recommended practices across the healthcare system (Pynnonen & Whelan, 2019; Schmelzer *et al.*, 2015; Hansen, 2016; ASGE, 2021; Garcia & Oliveira, 2022; Behm & Robinson, 2020; HICPAC & CDC, 2018; Mehta & Muscarella, 2020). Comprehensive literature reviews have examined recommended hang times, ranging from the commonly cited five to seven days (Schmelzer *et al.*, 2015; SGNA, 2023; Troutner *et al.*, 2020; GSA, 2021; PHAC, 2011), 14 days (AORN, 2023), up to 21 days (Rahman *et al.*, 2019; Schmelzer *et al.*, 2015; Mallette *et al.*, 2018), and some studies testing recommended storage days reaching 56 (Schmelzer *et al.*, 2015; Hansen, 2016; ASGE, 2021; Behm & Robinson, 2020).

Record keeping

Eight of 42 (19%) studies and guidelines discussed the importance of record keeping (Benowitz *et al.*, 2020; Devereaux, *et al.*, 2019; Chhabria *et al.*, 2023; Gavalda *et al.*, 2015; Mehta & Muscarella, 2020; Troutner *et al.*, 2020; GSA, 2021; ESGE, 2018). HLD records should include manufacturer-recommended preventative maintenance for endoscopes and their processing equipment and service details for lifecycle introduction and retirement (AAMI, 2021; HICPAC & CDC, 2018; GSA, 2021; ESGE, 2018). Completing preventive maintenance is critical. For example, a study found that every endoscope inspected by the manufacturer had a defect requiring maintenance (Ofstead *et al.*, 2017). Reprocessing records should include the lot control identifier, device identifier, patients exposed to the endoscope, the date and time of exposure, the processing equipment used, cycle number if automated, and the person(s) who processed it (Benowitz *et al.*, 2020; Montero *et al.*, 2023; Chhabria *et al.*, 2023; AAMI, 2021; Mehta & Muscarella, 2020; GSA, 2021; ESGE, 2018). Reprocessing centers should also maintain records of compliance, such as temperatures, pH results, chemical concentrations, and quality assurance tests (Benowitz *et al.*, 2020; Devereaux, *et al.*, 2019; AAMI, 2021; Gavalda *et al.*, 2015; HICPAC & CDC, 2018). Technology, such as real-time locating systems, can automatically identify and track the locations of endoscopes in a healthcare facility. This technology can be leveraged to improve endoscope storage record-keeping, and optimize endoscope rotation to avoid endoscope expiration and subsequent reprocessing (Troutner *et al.*, 2020). Subsequently, improved HLD record-keeping enhanced compliance with facility hang-time, and showed potential for significant cost savings (Troutner *et al.*, 2020).

Quality assurance/process monitoring

Quality control and assurance are critical in ensuring effective high-level disinfection of flexible endoscopes as highlighted in 23 of 42 (54%) studies and guidelines (Rahman *et al.*, 2019; Kovaleva *et al.*, 2013; DiazGranados *et al.*, 2009; Benowitz *et al.*, 2020; Ofstead *et al.*, 2017; Ofstead, *et al.*, 2016; Muscarella, L., 2014; Devereaux, *et al.*, 2019; Akinbobola *et al.*, 2017; Schmelzer *et al.*, 2015; Gonzalez *et al.*, 2019; El-Sokkary *et al.*, 2017; Washburn & Pietsch, 2018; Ofstead *et al.*, 2015; Sethi *et al.*, 2015; AAMI, 2021; ASGE, 2021; Garcia & Oliveira, 2022; Gavalda *et al.*, 2015; Mehta & Muscarella, 2020; Higa *et al.*, 2016; Legemate *et al.*, 2019; Pasternak & Taylor, 2023). Best practices identified included visual inspection of the endoscope, performing cleaning verification tests, and using microbial surveillance and logging results. An example of cleaning verification involves the protein testing for adenosine triphosphate (ATP) of high-risk or complex endoscopes following manual cleaning (Ofstead *et al.*, 2017; El-Sokkary *et al.*, 2017; Washburn & Pietsch, 2018; Ofstead *et al.*, 2015; Sethi *et al.*, 2015; ASGE, 2021; Legemate *et al.*, 2019). Cleaning verification points should include at minimum, the suction/biopsy channels and elevator mechanisms/channels, if applicable.

However, ATP testing is not sensitive enough to differentiate between human secretions and pathogenic organisms. In response, microbial surveillance following manual and automated HLD can monitor for the presence of specific microorganisms (Rahman *et al.*, 2019; DiazGranados *et al.*, 2009; Benowitz *et al.*, 2020; Ofstead *et al.*, 2015; Gavalda *et al.*, 2015; Legemate *et al.*, 2019). Pre-assembled toolkits enhance the efficiency and practicality of surveillance sampling (Ofstead, *et al.*, 2016). Sampling methodologies, such as flush-only versus flush-brush-flush sampling, can influence microbial detection (Pynnonen & Whelan, 2019).

DISCUSSION

While conducting the literature review, it is evident that all 10 elements of HLD are supported by substantial evidence. However, it is worth noting that certain elements have received more robust support than others. The highest quantity of articles (23; 54%) support quality assurance/process monitoring, POU treatment (19; 45%), and leak testing (19; 45%). Among the elements of HLD, record keeping (8; 19%), transport (11; 26%), and visual inspection (8; 19%) have the fewest articles endorsing best practices. Randomized controlled trials (RCTs) and systematic reviews/meta-analyses of RCTs (evidence types I and II) are examples of evidence missing from the literature review. Seven articles support the two forms of evidence: V (systematic review or meta-synthesis of descriptive or qualitative studies) and III (controlled trial without randomization). Six articles support each of the three forms of evidence: IV (case-control and cohort study), VI (descriptive or qualitative study, clinical practice guideline, literature review, QI, or EBP project), and VII (expert opinion).

HLD calls for a multidimensional strategy that assigns correct tasks at each stage of this complex operation. Implementing this strategy is imperative for minimizing the risk of patient exposure and ensuring the safe handling of flexible endoscopes and their components, thus preventing any potential damage. For example, medical professionals must execute elements of HLD necessary to correctly store, handle, and reprocess flexible endoscopes and test their functionality while maintaining proper records. Furthermore, most flexible endoscopes are reprocessed with an AER, but can also be reprocessed via manual cleaning when an AER is unavailable. Automation does not eliminate critical manual cleaning steps such as POU, quality assurance, and testing before transport and placement into the AER (Statham & Willging, 2010). The education and training of endoscope-reprocessing professionals enable proficient handling and execution of these actions required to achieve HLD.

Unfortunately, HLD failures occur because of non-adherence to education and training, guidelines, facility policies, and standards by not following the IFU. In a study evaluating the HLD process, it was found that 98.6% of manually cleaned endoscopes had missed certain elements, while automated cleaning resulted in the omission of elements in 24.6% of observations (Ofstead *et al.*, 2010). The omission of steps and improper handling of flexible scopes, contrary to the IFU resulted from either non-compliance by handlers, or failures in quality control evaluations of the AERs (Ofstead *et al.*, 2020). This is a multitudinous risk healthcare facilities accept if they fail to implement effective quality assurance measures, critical thinking assessments of handlers, and enforcement of policy adherence. Table 1 further describes HLD best-practices barriers identified in the literature.

Some barriers to HLD can be addressed using automated reprocessing devices and AERs. These devices are used to improve efficiency and standardize the process to achieve the HLD of endoscopes, but require manual tasks to be completed before the machine's use. Challenges with AERs include quality control measures to evaluate safety and failing results before the disinfectant's lifetime expectancy. Subsequently, AERs will require early changing of HLD fluids, contributing to an increased workload for staff. Contaminated or failed AERs heighten the risk of patient infection by increasing bioburden exposure.

Implications for practice

Leadership support

Due to the potential exposure of contaminants, each element of endoscope HLD reprocessing is treated as critically required. These elements include POU, transport, leak testing, manual cleaning/rinsing, HLD, drying/storage, quality assurance, and record keeping. Furthermore, these elements consist of more than 65 actions to reprocess an endoscope reliably, leaving no safety net if one of these elements is forgotten, missed, or performed inaccurately. To recommend a mitigation strategy, sterile processing staff, management, and facility leadership must be involved in developing and implementing a robust program which encourages continuous education and training, quality assessment, and administration management.

Staff training

The outcome of continuous education and training, quality assessment, and administration management is a highly reliable and safe program that minimizes the risk of infection. An education and training program includes a competency assessment of current HLD practices. Establishing a "champion" who is educated and highly specialized in HLD enables the training and verification of incoming and current staff in building and sustaining the HLD program. Verifying initial competency performance allows individuals to showcase their highly specialized skills in HLD. Skill mastery in this technique hinges on the ability to apply acquired knowledge and seamlessly translate it into effective performance. Upon hire, assess POU, transport, leak testing, manual cleaning, visual inspection, HLD, drying, storage, quality assurance, and record-keeping competencies. Additionally, assess the occurrence of updates to the IFUs and facility policy. Checklists can be used to document staff's competencies for the specific endoscope at the facility. Maintaining staff competencies on file is a source of documentation during surveys for accreditation. Increasing employee knowledge and competency assessments can ultimately contribute to adherence surveys and infection control compliance.

Continuous Process Improvement

Implementing a quality assessment through a gap analysis and an assurance tool can lead to positive patient outcomes by identifying staff adherence to essential steps in endoscope reprocessing. Establishing an interdisciplinary quality assessment team of management personnel, reprocessing experts, infection preventionists, and endoscope-handling staff is crucial for developing corrective measures and evaluating target achievement and sustainability (AAMI, 2021). Healthcare organizations should conduct regular gap analyses guided by their policies before adopting new endoscopes, updating IFUs, or implementing changes in national and professional guidelines (Behm & Robinson, 2020). Management, in collaboration with infection prevention, should explore the use of quality assessment tools to evaluate the effectiveness of cleaning procedures. ATP, protein, and hemoglobin tests offer valuable insights into assessing the cleaning efficacy of surgical instruments. Such strategies enable rapid assessment of compliance with reprocessing standards. Lastly, administrative facility management must ensure an effective and safe HLD program for endoscope processing. A multidisciplinary team including infection prevention, nurses, technologists, and external subject matter experts, should develop policies supported by government and professional organizations' standards and recommendations on staff requirements, endoscope use, and reprocessing according to the IFUs (HICPAC & CDC, 2018). HLD programs must ensure that they are transparent and have the full support of all levels of leadership to succeed.

LIMITATIONS

This integrative review was limited by its broad scope in addressing 10 elements of HLD. A greater understanding of best practices and barriers related to each HLD element can be uncovered with a dedicated investigation into each element. For example, the HLD element storage/hang time features multiple reviews investigating best practices to support the safe storage of endoscopes (Schmelzer *et al.*, 2015; Hansen, 2016). Additionally, the literature has robustly investigated the benefits of automated reprocessing steps and the value of culture surveillance initiatives (Ofstead *et al.*, 2010; Ofstead *et al.*, 2015; Ofstead *et al.*, 2016). The flexible endoscope reprocessing community could benefit from similar investigations supporting POU, transport, leak testing, visual inspection, and record keeping. Additionally, a more focused literature review could facilitate a high-level approach, such as a systematic review or meta-analysis. In addition to focused HLD studies, research should explore broader program elements such as recalls, traceability, reprocessing methods, risk assessments, quality control, and policy development. (NHS, 2016).

CONCLUSION

Evidence-based practice for processing endoscopes is continuously evolving, and a proactive approach to building an HLD program is a necessity. Continuous education and training, quality assessment, and administration management should be implemented where endoscope reprocessing occurs. Incorporating these three recommendations into an HLD program provides an outline for facilities, managers, and staff to achieve a reliable and safe program. Healthcare organizations can proactively devise strategies to address the reprocessing process' strengths and weaknesses through education on best practices and barriers to reprocessing flexible endoscopes. This must be a top priority for our professional community, the safety of our patients and staff depend on it.

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