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Evaluation of Flexible Endoscope Reprocessing Training and Education Programs

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Abstract

Project Site: Uniformed Services University of the Health Sciences, Bethesda, MD

Project Title: Evaluation of Flexible Endoscope Reprocessing Training and Education Programs

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Background or Problem/Issue: The High-Level Disinfection (HLD) reprocessing of flexible endoscopes is a high-risk, high-volume process. Literature supports a lack of standardized training and education leads to variability in clinical practice, which has resulted in Healthcare Associated Infections (HAI's) and in some cases even death.

Clinical Question or Purpose: Will performing an evaluation of existing flexible endoscope reprocessing training and education programs (FERTEPs) compared to evidence-based practice guidelines result in the identification of a comprehensive program that could be implemented across the Defense Health Agency (DHA)?

Project Design: The Centers for Disease Control and Prevention's (CDC's) framework for program evaluation was utilized as a procedural guide to evaluate five HLD FERTEPs over six months.

Analysis of Results: HLD FERTEPs graded using an audit checklist. 80% of HLD FERTEPs did not include visual inspection of endoscopes for damage in the precleaning phase of their training and education material. Only 40% of HLD FERTEPs provided training and education on cleaning and brushing the elevator and recesses surrounding it on duodenoscopes. A 39% variance noted between the top and bottom HLD FERTEPs concerning use of evidence-based rationales to support training and education content. HLD FERTEPs averaged 63% for training and education delivery platform training element fulfillment.

Organizational Impact/Implications for Practice: Implementation of a standardized HLD FERTEP by the DHA is projected to impact 424,944 patients and 700 reprocessing personnel while preventing 8,799 HAI's and saving the enterprise \$84,991,600.00 dollars annually.

Organizational Impact: By decreasing variability in clinical practice and improving clinical competencies through consistent delivery of knowledge, DHA would achieve MHS's Quadruple Aim goals of improved military readiness, provision of better care and promotion of better health while lowering health care costs.

Running Head: FERTEP PROPOSAL

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Keywords: evidence-based endoscope reprocessing guidelines, endoscope reprocessing programs, clinical learning theories, best practices for clinical education, educational delivery modalities, and clinical competencies in endoscope reprocessing

Reprocessing flexible endoscopes is a complex high risk, high volume process involving many intricate steps that occurs approximately 20 million times a year in the United States (Association for the Advancement of Medical Instrumentation [AAMI], 2015; Association of periOperative Registered Nurses [AORN], 2018; American Society for Gastrointestinal Endoscopy [ASGE], 2016). The proper cleaning of flexible endoscopes is made especially difficult related to unique design features such as small lumens, multiple internal channels, and hard to access device surfaces (Food and Drug Administration [FDA], 2015a; FDA, 2018; Kenters, Huijshens, Meiere, & Voss, 2015). Missing or omitting one step in the endoscope reprocessing cycle can place patients at an increased risk of contracting diseases like Hepatitis C and Human Immunodeficiency Virus (HIV), as well as, infections from microorganisms such as *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Salmonella enteritidis*, and Multiple Drug Resistant Organisms (MDROs) like *Carbapenem resistant enterobacteriaceae* (CRE) (Kenters et al., 2015; Kovaleva, Peters, van der Mei, & Degener, 2013; McCafferty et al., 2018; Mitchell, 2018; Wang, Ngamruengphong, Makary, Kalloo, & Hutfless, 2018). The magnitude of patients being harmed by contaminated endoscopes can be further underscored when looking at the MDRO CRE, which has a mortality rate of up to 40% for patients who become infected following an endoscopic procedure (Eisler, 2015). New research presented in the journal *Gut*, showed that the risk of contracting an infection from an endoscopic procedure has increased from 1:1,000,000 to 1:3000. This risk increases to 45-59:1000 for patients who've had a recent admission to the hospital (Wang et al., 2018). Despite all the advances in endoscope reprocessing technology, more patients undergoing endoscopic procedures are being exposed to harmful pathogens than at any time in the past (Calderwood, 2018).

A key factor identified in the literature affecting flexible endoscope reprocessing failures is the lack of consistency or standardization of the guidelines detailing the best evidence-based practices for flexible endoscope reprocessing (World Health Organization [WHO], 2016; Kenters et al., 2018). A review of published endoscope reprocessing guidelines from Association for the Advancement of Medical Instrumentation, Association of periOperative Registered Nurses, Centers for Disease Control and Prevention, and Society of Gastroenterology Nurses and Associates, revealed the existence of variances in content depth, clarity, and overall comprehensiveness to guide the process of high-level disinfection (HLD)(AAMI, 2015; AORN, 2018; Centers for Disease Control and Prevention [CDC], 2017a; Society of Gastroenterology Nurses and Associates [SGNA], 2016). The existence of these variances makes it imperative to consult multiple guideline sources to ensure comprehensive guidance to support each phase of the HLD process. Having an inclusive HLD guideline will aid in standardizing processes and address patient safety concerns related to improperly reprocessing flexible endoscopes (Emergency Care Research Institute [ECRI], 2018). The most comprehensive and complete set of reference guidelines currently available can be found in the *ANSI/AAMI ST91: Flexible and Semi-Flexible Endoscope Reprocessing in Health Care Facilities* manual, which is a compilation of various guidelines put forth by professional organizations (AAMI, 2015). These guidelines serve as the foundation for evidence-based endoscope reprocessing practices.

Recent findings from The Joint Commission (TJC) highlight the need for healthcare organizations to implement standardized endoscope reprocessing educational programs to address the fact that personnel do not have the necessary training or knowledge to access guidelines when needed to correctly sterilize/high-level disinfect equipment (TJC, 2017). A review of the literature revealed a multitude of endoscope reprocessing training and education

programs offered either online or in-person; however, these programs vary in course curriculum, objectives, and outcome goals (Medivators, 2019; Olympus University, 2019; Steris University, 2019). Currently, there are no standardized evidence-based FERTEPs being utilized by federal or civilian organizations to support endoscope reprocessing. Each program differs on what endoscope guidelines were consulted when formulating their training and education curriculum. These variances place patients at risk of harm due to inadequate or incomplete reprocessing guidance (WHO, 2016).

The Defense Health Agency (DHA) has not been immune to problems stemming from failures in endoscope reprocessing. In 2014, the Department of Defense (DoD) performed a review of the entire DHA, prompted by public outcry related to a series of adverse patient outcomes looking at patient safety, access to care, and quality of care issues. One of the recommendations from the review was for the transformation of DHA into a high reliability organization that promotes quality, safety and continuous process improvement (DoD, 2014), and allows the enterprise to achieve MHS's Quadruple Aim goals of increased military readiness, provision of better care and promotion better health to lower health care costs (Reardon, 2013). Therefore, identification and eventual implementation of a standardized evidence-based FERTEP for use in the DHA can have a positive influence on improving the quality of care delivered, patient safety standards, and continued process improvements related to the performance of HLD.

Significance of the Problem

Infections Related to Contaminated Endoscopes

The Office of Disease Prevention and Health Promotion (ODPHP) defines Healthcare Associated Infections (HAI's) as infections patient's contract when receiving medical or surgical

care (ODPHP, 2014, p.1). HAI's can be caused by bacterial, viral, or fungal pathogens (e.g., MDRO's, HIV, and Hepatitis C) (Custodio, 2016). Contaminated endoscopes are a known causative element associated with HAI's (Malette, Pieroni, & Dhalla, 2018) and are responsible for more patients contracting HAI's than all other medical devices (Oh & Kim, 2015).

Approximately one in every twenty-five hospitalized patients acquires an HAI during the course of their admission (ODPHP, 2014, p.1). HAI's acquired from contaminated endoscopes are a serious patient safety hazard that do not seem to be getting better despite increased surveillance vigilance.

There has been a dramatic increase in reported patient exposures to Blood Borne Pathogens (BBP's) related to contaminated endoscopes being used during endoscopic procedures. In 2009, the Department of Veterans Affairs Office of Inspector General (VAOIG) had to notify over ten thousand patients about their potential exposure to virulent pathogens from improperly reprocessed flexible endoscopes. Patient exposures to BBP's have not only occurred in hospital settings but have also taken place in outpatient endoscopy clinics. An example of outpatient BBP exposures related to endoscope reprocessing failures was detailed in a 2015 retrospective cohort study involving almost 7000 patients who underwent an endoscopic procedure at one clinic. This facility was inspected in May of 2011 and was noted to have reprocessing deficiencies dating back to 2002. The endoscope reprocessing deficiency findings necessitated that all the nearly 7000 patients who had undergone an endoscopic procedure during the dates in question had to be notified of their potential exposure and offered testing and treatment for active infections (Willmore et al., 2015). These findings show that a failure to properly adhere to reprocessing guidelines exponentially increases patient's exposure to BBP's.

The federal government has also been closely monitoring adverse events associated with contaminated endoscopes for some time. In 2015, the FDA reported data from medical device reports (MDRs) collected from 1997 to 2015. During this time frame, the FDA received a total of 433 reports on incidents of adverse events to include patient infection, device contamination, or patient exposure (Pyrek, 2015). The increased number of MDRO outbreaks and patient exposures related to improperly reprocessed endoscopes also prompted the CDC, in 2015, to issue a safety alert stating that facilities that reprocessed endoscopes need to strictly adhere to recommended reprocessing practices. The CDC also recommended that facilities should follow the endoscope manufacturers (MFGs) instructions for use (IFUs) concerning endoscope reprocessing and contact the endoscope MFG regarding any questions or concerns related to the process (CDC, 2015a). By consistently following MFG's IFU's and evidence-based practice guidelines, like AAMI, personnel can use the collective expertise of healthcare professionals and industry experts to safely and effectively apply comprehensive endoscope reprocessing knowledge to enhance patient safety (AAMI, 2015).

The pervasiveness of HAI's caused by improperly processed endoscopes is not isolated to the United States but can be seen in pandemic proportions affecting the global healthcare delivery system. In 2016, the World Health Organization published a report which stated that hundreds of millions of patients around the world acquired HAI's annually, many of which stemmed from the improper reprocessing of medical devices and equipment. In response to the growing dangers of HAI's associated with contaminated endoscopes, in 2015, the CDC issued a national health alert concerning the increased number of adverse events associated with improper reprocessed endoscopes and recommended all personnel who reprocess medical devices should receive adequate training with competency evaluations (CDC, 2015b). Also, in 2015, TJC

created the HLD and Sterilization Boosterpak as a reference to provide healthcare professionals with a guide to address breaches in practice and noncompliance issues related to HLD of semi-critical devices (TJC, 2015).

In 2017, as a result of the continuation of the HAI crisis from contaminated endoscopes, the CDC asked for help from the Healthcare Infection Control Practices Advisory Committee (HICPAC) seeking “guidance on ways to improve facility-level training and ensuring competency for reprocessing endoscopes” (CDC, 2018, p.1). In response to this request from the CDC, HICPAC created a document detailing the essential elements that should be included in a reprocessing program for flexible endoscopes. The intent was for this tool to be used by healthcare professionals when formulating new or updating existing reprocessing programs to better align with evidence-based practice standards (CDC, 2018).

The DHA’s response to the CDC’s national health alert related to contaminated endoscopes was to disseminate procedural instructions for the creation of a comprehensive infection prevention and control program (ICP) and establish training standards and core competencies related to infection prevention to promote high quality, safe healthcare (DHA, 2017). Multiple recent breaches of HLD endoscope reprocessing practices had been directly linked to HAIs occurring within DHA (Bean, 2017). As a result, DHA directed leadership at all MTFs to conduct HLD program evaluations to determine adherence with evidence-based endoscope reprocessing guidelines (DHA, 2017).

Not only are patients at risk of exposure to BBP's when having an endoscopic procedure performed but there have been at least thirty-five deaths in the United States directly linked to contaminated endoscopes since 2013 (Terhune, 2018). In 2016, TJC issued multiple immediate threat to life citations to healthcare facilities for noncompliance with infection control standard

IC.02.02.01 that “requires organizations to reduce the risk of infections associated with medical devices” (TJC, 2017, p.1). Of these threat to life citations issued, 74% were determined to be directly related to the improper sterilization or HLD of medical instrumentation and equipment (TJC, 2017, p.1). Preventing HAI’s related to clinical practice in medical facilities is, and has been for years, one of TJC top patient safety goals (TJC, 2018). Standardizing FERTEPs to mirror best practices within an organization will improve patient safety and have an overall impact on the quality of healthcare delivered.

HLD Endoscopic Reprocessing

HLD endoscope reprocessing consists of ten separate sequential phases that need to be thoroughly completed in order to verify these devices are safe and ready for patient use (CDC, 2018). These phases consist of precleaning at the point of use (POU), transporting, leak testing, cleaning, rinsing, inspecting for cleanliness, disinfection/HLD and monitoring, rinsing, drying and alcohol flush, and storage (AAMI, 2015). Omission or failure to properly complete even one of the elements within any of the reprocessing phases will increase patient’s risk of contracting an HAI (Kenters et al., 2015). There are multiple professional organizations that publish HLD endoscope reprocessing guidelines to include but not limited to AAMI, AORN, CDC, and SGNA. The ten phases of the HLD processes are discussed in each of the different organizations published HLD reprocessing guidelines with variations noted pertaining to the amount of detail provided for the completion of each phase (Society for Healthcare Epidemiology of America [SHEA,2018]. To further guide the process, endoscope MFGs provide specific IFU’s on how to properly reprocess their endoscopes that must be followed and utilized along with the published HLD endoscope reprocessing guidelines to ensure these phases are completed properly (CDC,

2018). The HLD endoscope reprocessing phases are listed in Table 1 below along with the corresponding recommended practices supporting each phase.

Table 1. *Phases of HLD Reprocessing and Recommended Practices*

Phases	Recommended Practices
Precleaning (Point of Use)	Perform immediately in the OR or treatment room after procedure is completed to prevent biofilm formation. Wipe down the exterior of endoscope using fresh solution with a wet low-linting or non-linting sponge or cloth. Flush all channels with cleaning solution, water, and air. Visually inspect for damage (AAMI, 2015).
Transporting	Contaminated endoscopes should be transported to the reprocessing room as soon as possible after use. Should be kept wet and transported in a closed container marked biohazard (AORN, 2018).
Leak Testing	Tested by machine or manually to ensure integrity of the endoscope. Damaged endoscopes must not be used on patients. Leak testing should be done before manual cleaning (CDC, 2018).
Manual Cleaning	Should occur as soon as possible after leak testing to prevent the formation of biofilm. Includes endoscopes exterior, valves, detachable parts, channels, and elevators if present (AAMI, 2015).
Manual Rinsing	After manual cleaning, rinse endoscope, removable components, and any accessories with copious amounts of potable water to remove any debris and cleaning solution. Follow MFGs IFUs regarding amount of water and psi to flush channels to prevent damaging the endoscope (AAMI, 2015).
Inspection	Upon completion of manual rinsing, inspect endoscope for cleanliness, missing parts, damage, and function (AORN, 2018).
HLD	HLD can be performed manually by soaking endoscopes in a basin or tub filled with HLD solution or in an automated endoscope reprocessing machine (AER). HLD solutions can be used repeatedly until they fall below their minimally recommended concentration (MRC) as verified by testing (AAMI, 2015).
Rinsing	Regardless if endoscopes are reprocessed manually or using an AER, endoscopes will be rinsed thoroughly with water to remove any HLD chemical residues (AAMI, 2015).
Drying	Exterior surfaces should be dried with a lint-free cloth or sponge. All endoscope channels should be flushed with alcohol and purged with instrument air to ensure drying and prevent bacterial growth (AAMI, 2015).
Storage	Hang endoscope in a way to prevent damage or coiling (vertically suspend). No detachable parts left on endoscope while in storage. All valves dried and lubricated. Tag on endoscope to identify that the scope has been reprocessed and is ready for use (AAMI, 2015).

Critical Phases of HLD Endoscope Reprocessing

Deficiencies in completing the critical phases of flexible endoscope reprocessing, precleaning and manual cleaning, to remove or prevent adherence of biofilms to endoscopes can have catastrophic consequences for patients undergoing endoscopic procedures. A 2018 study by Jamal et al., looking at biofilm formation and associated infections, found that 65% of all microbial infections are directly linked to biofilms. The severity of HAI's associated with exposure to contaminated endoscopes has seen a steady increase in recent years with outbreaks of the MDRO CRE resulting in numerous patient deaths at multiple health care facilities across the country (Eisler, 2015). Therefore, the prevention of pathogenic HAI's associated with bacterial biofilm formation and retained residual organic material must be addressed to ensure patients are receiving safe care founded on evidence-based practice guidelines. According to Decristo et al., a key factor to decreasing a patients' exposure to harmful pathogens and decrease endoscope contamination rates is by having reprocessing personnel perform the critical phases of endoscope reprocessing (e.g., precleaning and manual cleaning) on every device after every use (Decristo et al., 2018).

Moreover, if residual organic material is not promptly removed during the critical phases of endoscope reprocessing, precleaning and manual cleaning, biofilms may form (Jamal et al., 2018). Biofilms are microscopic slimy film layers of bacteria that adhere to surfaces of living and nonliving material (e.g., endoscopes). Biofilm formation can begin to occur as soon as 20-30 minutes from the time of initial contact of bacteria with an endoscope (Roberts, 2013). Once established, biofilms are exceedingly difficult or impossible to remove from endoscopes even if all phases of reprocessing are completed. This fact was underscored in a 2016 study published in *Gastrointestinal Endoscopy* by Neves et al., which found that viable virulent microorganisms

were detected using confocal microscopy in biofilm layers noted to be present on 5 out of 27 endoscopes studied, despite strict adherence to and completion of all phases of endoscope reprocessing.

Inadequacies or failures to complete all required endoscope reprocessing phases were highlighted in a 2010 prospective observational study conducted by Ofstead, Wetzler, Snyder, & Horton. The results from the study showed that personnel responsible for endoscope reprocessing only completed all required reprocessing phases 1% of the time, meaning 99% of the time, 1 or more reprocessing phases were skipped or done incorrectly. With that being said, the consensus amongst organizations governing the reprocessing of flexible endoscopes, CDC, SGNA, AAMI, and AORN, all concur that the cleaning phase, consisting of precleaning at the point of use and manual cleaning after the completion of leak testing, are the most critical phases of endoscope reprocessing. Proper completion of these two critical phases in the disinfection process allows for the removal of residual organic material (e.g., fat, blood, and proteins) from endoscopes that would otherwise impede the efficacy of the HLD and sterilization process (CDC, 2018).

Spaulding Classification System

The Spaulding Classification is used to guide the process to determine what level of disinfection is appropriate for reprocessing surgical instruments and medical devices (CDC, 2015a). The system is delineated into categories related to the potential risk of infection a reprocessed item might pose to a patient undergoing a medical or surgical procedure (CDC, 2016). The Spaulding Classification system categories are listed below in Table 2 along with the corresponding locations, level of reprocessing required, and pathogens eliminated.

Table 2. *Spaulding Classification System Categories*

Category	Location	Level of Reprocessing	Pathogens
Critical	Enters normally sterile body tissues	Sterilization	Deactivates all biological agents: bacteria, fungi, viruses, spores, and prions (CDC, 2016).
Semi-critical	Contacts mucous membranes	Sterilization or HLD using a sterilant	Kills vegetative microorganisms and inactivates viruses, but not bacterial spores (AORN, 2018).
Non-critical	Contacts intact mucous membranes	Low to medium disinfection using a hospital disinfectant	<p>Low-level disinfection: kills most vegetative bacteria except <i>Mycobacterium tuberculosis</i>, most fungi, and inactivates some viruses.</p> <p>Medium-level disinfection kills vegetative bacteria including <i>Mycobacterium tuberculosis</i>, all fungi, and inactivates viruses (AORN, 2018).</p>

Endoscopes: Comparison of Flexible Endoscope Reprocessing Methods

The risk of iatrogenic transmission of infections related to contaminated endoscopes continues to be an ongoing problem that poses a significant health hazard to patient safety (Molloy-Simard, Lemyre, Martel, & Catalone, 2019). Endoscopes, which are considered semi-critical medical devices according to the Spaulding Classification system, can be reprocessed using several different reprocessing methods (CDC, 2015a). For optimal terminal sterilization results, the FDA currently recommends that all semi-critical and critical medical devices should be sterilized but at a minimum high-level disinfected prior to patient use (FDA, 2019). Terminal sterilization has been acknowledged as one of the essential solutions to enhance endoscope reprocessing outcomes. It provides a significant margin of safety while decreasing a patients' risk of contracting an infection from contact with a contaminated endoscope compared to HLD

(Molloy-Simard, Lemyre, Martel, & Catalone, 2019). Unfortunately, these devices are very complex in their design and construction, making them easily susceptible to damage from heat if reprocessed using the steam sterilization method (Sabnis, Bhattu, & Vijaykumar, 2014).

Alternate endoscope reprocessing methods are listed in Table 3 (Healthcare Purchasing News, 2018) and arranged according to lowest to highest level of sterility achieved.

Table 3. *Flexible Endoscopes Reprocessing Methods*

High-Level Disinfection	Liquid Chemical Sterilization	Low-Temperature Terminal Sterilization
Kills mycobacterium and less resistant organisms, but not all spores	Kills all organisms, including spores	Kills all organisms, including spores
Various test organisms used for validation	Kills all organisms, including spores	Specific spore type defined in standards used for validation
Designed to kill up to 1 million (6 log reduction) of mycobacterium 1,000,000	Designed to kill up to 1 million (6 log reduction) of mycobacterium including spores	Designed to kill up to 1 billion (12 log reduction) of the most resistant spores
Performed with manual soak Method or automated endoscope reprocessor	Performed in automated liquid chemical sterilant reprocessing system	Performed in a sterilizer
Provides a wet, high-level disinfected item	Provides a wet, liquid sterilized item to be used immediately. If stored, must be reprocessed before use	Provides a sterile, packaged item that maintains sterile barrier until used or packaging is compromised
Effectiveness dependent on effective cleaning and complete drying of device prior to storage	Effectiveness dependent on effective cleaning. Device wet when used on patient. Complete drying required prior to storage as an HLD device	Effectiveness dependent on effective cleaning and complete drying of device prior to packaging.

Lack of Comprehensive Flexible Endoscope Reprocessing Guidelines

The need for standardized, comprehensive endoscope reprocessing guidelines is a consistent theme echoed throughout the literature (CDC, 2018; VAOIG, 2009; Kenters et al., 2018; MHS, 2014). According to WHO, significant gaps in medical device reprocessing knowledge still exists globally in healthcare facilities and “procedures to clean and

decontaminate these devices are inadequate and not standardized” (WHO, 2016, p.12). This lack of knowledge related to endoscope reprocessing guidance or standardization of the HLD process, places patients at undue risk of harm (Pyrek, 2017).

The importance of standardized endoscope reprocessing guidelines was further addressed in a 2018 position statement published by the European Society of Gastrointestinal Endoscopy (ESGE) in collaboration with the European Society of Gastroenterology Nurses and Associates (ESGENA) that stated, “all endoscopes should be reprocessed with a uniform, standardized reprocessing procedure” (Bielenhoff et al., 2018, p. 5). The strategy of following only one set of guidelines may prove to be inadequate to ensure proper reprocessing of medical devices due to differences in MFG’s IFU’s, variety of device designs, and variances in the different reprocessing recommended practices put forth by professional organizations (Petersen et al., 2017). A review of an article written by Oh and Kim (2015) published in the journal *Clinical Endoscopy*, supports the need for the formation of comprehensive standardized guidelines since “different organizational guidelines for reprocessing GI endoscopes are similar, but they include subtle differences” (p. 367). These differences in reprocessing guidelines can be seen in critical reprocessing phases (e.g., precleaning and manual cleaning) that leaves a patient vulnerable to infection (AORN, 2018).

As early as 2009, the VA conducted unannounced inspections at 42 of its facilities related to reports of failures in endoscope reprocessing compliance. From the results of these inspections, a report was generated describing deficiencies in the practices of reprocessing endoscopes across the VA enterprise. A major conclusion derived from this report was that “reprocessing of endoscopes requires a standardized, monitored approach to ensure that these instruments are safe for use in patient care” (VAOIG, 2009, p. I). This systemic noncompliance

with reprocessing guidelines at the VA resulted in increased risk of patient exposure to infectious diseases (VAOIG, 2009).

Lack of Standardized Flexible Endoscope Reprocessing Education

Deficiencies or inadequate training and education have been shown to be a major contributing factor in endoscope reprocessing failures. In 2015, Kenters, Huskins, Meier, and Voss conducted a review of 32 studies looking at the link between cross-contamination of flexible endoscopes with infectious diseases and reported “that lack of education is one of the reasons flexible endoscope reprocessing guidelines are not strictly followed” (p. E263). From 2005-2012, Dirlam-Langlay et al., analyzed peer-reviewed and non-peer reviewed literature in North America and identified major lapses in all phases of endoscope reprocessing that have exposed patients to potential contamination. The key root cause of reprocessing breaches was directly linked to inadequate training and education. A specific recommendation put forth from this review was for national improvements in endoscope reprocessing training and education to include competency testing that can be measured (Dirlam-Langlay et al., 2013). These knowledge gaps are not isolated only to the United States but also exist globally between published international flexible endoscope reprocessing guidelines and actual clinical endoscopy reprocessing practices (WHO, 2016). Therefore, regardless of the setting where endoscopic procedures are performed, these variances in training and education are placing patients in harm’s way.

The international community has also identified the need for standardized training and education programs to address the endoscope reprocessing crisis. An electronic survey was conducted by the International Society for Antimicrobials and Chemotherapy (ISAC) which

looked at the worldwide practices in flexible endoscope reprocessing (Kenter et al., 2018). Out of 165 responses from healthcare facilities in thirty-nine different countries, approximately fifty percent of the survey respondents recognized there is a lack of education in support of the HLD process and routine training and education programs need to be developed to improve patient safety (Kenters et al., 2018). When the respondents were queried about the level of reprocessing training and education personnel received, they reported that 15-33% of their endoscope reprocessing staff were not trained to perform this task. The review concluded by saying that “a standardized education and training programme with competency assessment is essential to prevent reprocessing lapses and improve patient safety” (Kenters et al., p. 1) and supports the need for a comprehensive and standardized training and education program on endoscope reprocessing.

Flexible Endoscope Reprocessing Issues in the DHA

Issues plaguing endoscope reprocessing on a national and global level (e.g., increased risks of infection, no comprehensive guidelines, and lack of standardized training and education) have also affected the DHA. In 2014, fueled by public demand originating from reports of substandard care provided to beneficiaries, DoD ordered a ninety-day review of the entire military health system. HLD practices were one of many elements included in the review. The recommendations from this review to DHA were to “continue to develop common standards and processes to improve outcomes across the enterprise” (DoD, 2014, p. 8). In regard to HLD practices, implementation of standardized evidence-based endoscope reprocessing guidelines by DHA would limit process variability, promote continuous process improvement throughout the enterprise, and improve patient safety. This strategy supports the MHS’s Quadruple Aim goals

and moves the enterprise towards becoming a high reliability organization related to HLD practices.

Within the past five years of the issuance of these recommendations, incidences related to breaches in HLD practices have unnecessarily exposed patients to harmful or even fatal pathogens. An example of one such lapse was reported at the Air Force Academy (10th Medical Group), where 267 patients were potentially exposed to HIV and Hepatitis related to reprocessing personnel failing to follow proper HLD standards of practice (Roeder, 2016). Another incident involving failure to adhere to evidence-based reprocessing standards occurred in 2018 at General Leonard Wood Army Community Hospital (GLWACH). A total of 135 patients had to be notified about their potential exposure to contaminated surgical equipment and medical devices related to personnel performing improper cleaning practices and failure to follow reprocessing guidelines (Bean, 2018). Clinical Practice Guidelines supporting HLD practices are only recommendations; however, they are foundational elements to support safe, quality care. According to the CDC, leadership engagement and oversight are critical to ensure adherence to professional standards of practice and guidelines. Regarding HLD, this oversight and support are vital to the success or failure of any reprocessing program for flexible endoscopes (CDC, 2018).

Summary

The general public, as well as healthcare professionals, have become ever more cognizant of endoscope reprocessing breaches that have resulted in increased patient exposures to BBP's and infections (Molloy-Simard, Lemyre, Martel, & Catalone, 2019). Scores of patients have died as a direct result from contracting an infection obtained from exposure to contaminated endoscopes (Terhune, 2018). This healthcare crisis is not just local or national in origin but can

be seen at the global level as well (WHO, 2016). Contributing factors to this problem centers around the absence of a comprehensive set of reprocessing guidelines (AAMI, 2015; AORN, 2018), as well as, inadequacies in standardization of training and education (Kenters, et al., 2015). These factors inadvertently place patients at risk of exposure to infection (Petersen et al., 2017). Since the MHS report was released in 2015, actions were taken across the DHA to standardize common practices and processes (DoD, 2014). However, variability in HLD practices continue to be seen across the enterprise which hinders DHA's ability to become a High Reliability Organization and meet the MHS's Quadruple Aim goals. These breaches in practice have resulted in the steady erosion of the communities' confidence in the provision of high quality, safe healthcare to all beneficiaries across the DHA enterprise (Roeder, 2016). Moreover, these breaches have a negative impact on the mission readiness capabilities of military personnel, thus adversely affecting mission success (Harvey, 2019).

Therefore, the purpose of this project is to promote the formation of a high reliability health system within the DHA related to HLD. This will be accomplished through the identification of the most robust and comprehensive flexible endoscope reprocessing training and education program for implementation. This project will also aid in meeting the MHS's Quadruple Aim goals of improved military readiness, provision of better care and promotion of better health in order to lower health costs (Reardon, 2013).

Clinical Question

This project will conduct a current-state evaluation of available HLD flexible endoscope reprocessing training and education programs to determine the viability of one program as the future standardized training and education platform for endoscope reprocessing within the DHA. The clinical question is: Will performing an evaluation of existing flexible endoscope

reprocessing training and education programs (FERTEPs) compared to evidence-based practice guidelines result in the identification of a comprehensive program that could be implemented across the Defense Health Agency (DHA)?

Focus Areas

The focus areas for this Doctor of Nursing Practice (DNP) project will be as follows:

1. Identify available flexible endoscope reprocessing training and education programs (FERTEPs).
2. Develop an evidence-based audit checklist based on professional, federal, and regulatory guidelines/standards for reprocessing flexible endoscopes to perform program evaluations of FERTEPs that align with national recommended reprocessing guidelines.
3. Perform a gap analysis between FERTEPs related to fulfillment of evidence-based recommended practice training content, use of evidence-based recommended practice rationales to support training content, and program specific educational delivery platforms utilized to deliver training content.
4. Identify the most comprehensive flexible endoscope reprocessing training and education program to be recommended across the Defense Health Agency.

Project Long and Short-Term Goals

The short-term goal for this project is to identify and recommend the most suitable HLD FERTEP for the unique setting of military health. The long-term goal of this project will be the implementation of the identified FERTEP throughout the DHA.

Relevance to Military Nursing

Military nurses are unique in that they care for active duty service members, their families, and veterans from all branches of the armed services who undergo flexible endoscopic procedures at MTFs, clinics, and in the austere deployed environment. The DHA does not currently have a standard training and education platform in place to teach endoscope reprocessing to personnel assigned these duties as part of their job description. Therefore, even with the increased awareness of patients being exposed to contaminated endoscopes, breaches in clinical practice guidelines for flexible endoscope reprocessing continue to plague military health across the DHA system.

Maintaining mission readiness is the military's top priority. If soldiers or their families are harmed or incapacitated by contaminated endoscopes, this adversely affects a service-member's ability to perform his or her assigned duties. The second and third order effects stemming from such an incident can negatively impact servicemember's unit cohesion, mission outcomes, and overall success or failure of a given mission (Harvey, 2019).

Knowing about an ongoing threat to patient safety, demands an actionable intervention be performed. The perioperative Clinical Nurse Specialist (CNS) as a consultant, nursing leader, clinical Subject Matter Expert (SME), evidence-based scholar, and educator, make them the ideal professional to lead change across the DHA enterprise to improve practice related to endoscope reprocessing. As advocates for patient safety, nursing must stand up and speak out to ensure flexible endoscope reprocessing practices follow evidence-based recommended practice guidelines. Standardizing the flexible endoscope reprocessing training and education platform supports the DHA's goal of becoming a high reliability organization focused on improving patient safety, quality, and continuous process improvement, as well as the goals of the MHS's

Quadruple Aim of improved military readiness, provision of better care and promotion of better health in order to lower health costs.

Organizing Framework

The CDC's Framework for Program Evaluation was used as the organizing framework in support of this project (CDC, 1999). This framework was first presented in a Morbidity and Mortality Weekly Report (MMWR) published by the CDC in 1999 and "continues to serve as the backbone of the CDC evaluation process" (Kidder & Chappel, 2018, p. 356). This framework provided a comprehensive way to summarize and organize essential elements for program evaluations. It involved an integrated evaluation approach consisting of six phases: engaging stakeholders, describing the program, focusing the evaluation design, gathering credible evidence, justifying conclusions, and ensuring use and sharing lessons learned (CDC, 1999). Performing an evaluation on FERTEPs curriculum will provide guidance to the DHA and military education departments on current best practices that could be utilized by all Sterile Processing Departments (SPDs) and clinics that perform HLD. The CDC framework for program evaluation steps are listed in *Figure 1*.

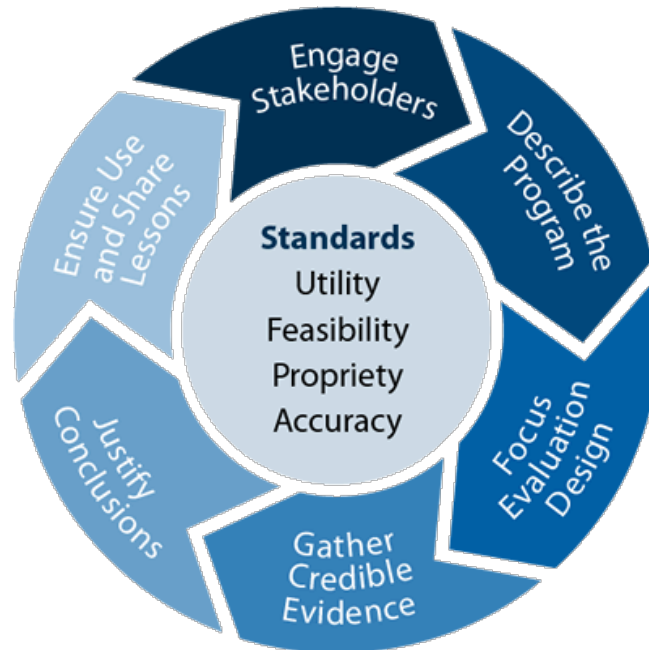


Figure 1. A Framework for Program Evaluation. From “Program Performance and Evaluation” by the CDC, 2017b, Retrieved from <https://www.cdc.gov/eval/framework/index.htm>

Project Design

General Approach

This project performed a current-state evaluation of available HLD FERTEPs to determine if one program met criteria to be recommended as a standardized training and education platform for endoscope reprocessing in the DHA. The CDC’s framework for program evaluation served as a procedural guide in the performance of a systematic program evaluation and comparison of selected FERPs. Available literature on flexible endoscope reprocessing standards and best practices for education were reviewed and synthesized in order to create an evidence-based program evaluation checklist. The checklist was used to quantitatively score, and grade selected educational programs to determine the most comprehensive for recommendation to be implemented across the DHA.

Project Setting

This project consisted of evaluating flexible endoscope reprocessing training and education programs. The identified courses were offered either entirely online or in-person. For this project to be successful, evaluator access to selected FERTEPs was key. Some of the programs were offered at no cost, while other organizations charged a fee to attend their online or in-person course. Grants were investigated as an option to negate the cost of gaining access to the FERTEPs but were not pursued due to project completion timeline restrictions. Furthermore, some of the programs were sponsored by the manufacturers of flexible endoscopes and reprocessing equipment, only highlighting their products, which could pose a potential conflict of interest.

To narrow the selection of courses to be evaluated, inclusion criteria was established. To be considered for evaluation, programs had to be in English, offered in the United States, and accessible to the evaluator. Exclusion criteria eliminated programs that were not in English, not accessible to the evaluator, required any type of work-experience in reprocessing endoscopes in order to access the program, and were not feasible based on cost. A web-based search was conducted which identified a total of nine FERTEPs from industry and academia (see Table 4).

Table 4. *Identified Flexible Endoscope Reprocessing Programs*

Program Sponsor	Platform	Cost	Location	Program Name
Steris University	E-learning	No charge	Online	Endoscope Reprocessing 101
Olympus University	Face to Face	\$175.00	Pittsburgh, PA	Flexible Endoscope Reprocessing Course
Medivators	Face to Face	No charge	Uniformed Services	Reprocessing Excellence

Program Sponsor	Platform	Cost	Location	Program Name
			University of the Health Sciences	
International Association of Healthcare Central Services Material Management (IAHCSMM)	Self-study (Reprocessing Manual)	\$120.00 for manual	Online	IAHCSMM Endoscope Reprocessing Manual
Certification Board for Sterile Processing and Distribution (CBSPD)	E-learning	\$325.00 (\$25.00/module x13) and \$25.00 for final exam	Online	Reprocessing of Flexible Endoscopes
Pentax Medical	Face to Face	No charge. Will come to facility if have contract and use Pentax scopes	Sponsoring Healthcare Facility	Reprocessing of GI Endoscopes
Florida Institute of Sterile Processing	Face to Face	\$1050.00. Classes once weekly x 2 hours x 4 weeks	Miami, FL	Flexible Endoscope Course
Altamont Healthcare	Face to Face	\$2400.00. Classes twice weekly x 3 hours x 5 weeks	Stockton, CA	Endoscope Reprocessing Certification
Martinson College	E-learning	\$999.00. Take at own pace. Once complete all tests with 80% pass rate, receive certificate of completion	Online	Endoscopy/GI Scope Technician Certification

After applying the exclusion criteria to the identified FERTEPs, the following programs were eliminated as viable candidates for this project related to accessibility (e.g., no

manufacturer contract, not locally available) and/or feasibility (e.g., cost prohibitive, time commitment) issues:

1. Pentax Medical
2. Florida Institute of Sterile Processing
3. Altamont Healthcare
4. Martinson College

Conversely, upon applying the inclusion criteria to the identified FERTEPs, the following programs were chosen for evaluation:

1. Steris University
2. Olympus University
3. Medivators
4. IAHCMM
5. CBSPD

Procedural Steps

Implementation of this project commenced after obtaining a letter of Institutional Review Board/Performance Improvement (IRB/PI) determination from USUHS Office of Research. The procedural steps for this project were grouped within the six phases of the CDC Framework for Program Evaluation as outlined below.

I. CDC Program Evaluation Procedural Phase 1: Engage stakeholders

A. Identified stakeholders:

1. Office of the Surgeons General.
2. Perioperative Nursing Consultants of the Surgeons Generals of the Armed Forces.

3. SMEs in HLD (Infection Preventionists, Industry Experts, Manufacturers, and End Users of HLD).
 4. Program administrators of FERTEPs.
- B. Engaged stakeholders to verify flexible endoscope reprocessing deficiencies within the DHA and civilian sector to include:
1. Absence or presence of flexible endoscope reprocessing programs at local, DHA, or national level.
 2. Programs that do exist, do they align with recommended practice guidelines?
 3. Identified the existence of flexible endoscopes being improperly processed whereby contaminated scopes have been used in procedures which have resulted in HAIs and/or sentinel events.
- C. Identified professional, federal, and regulatory guidelines/standards for flexible endoscope reprocessing.
- D. Identified available educational FERTEPs for the purpose of evaluation.
1. Engaged stakeholders to identify flexible endoscope reprocessing programs that are currently being utilized at the local and national level.
 2. Performed a literature search using multiple search engines (i.e., Cinahl, PubMed, Google, and Google Scholar) to identify additional FERPs.

II. CDC Program Evaluation Procedural Phase 2: Describe the Program

- A. Established inclusion and exclusion criteria to identify viable programs.

- B. Applied the identified inclusion and exclusion criteria to select FERTEPs to be evaluated.
- C. Performed a literature review to develop an evidence-based audit checklist to evaluate educational content of flexible endoscope reprocessing programs that was based on professional, federal, and regulatory guidelines/standards.
- D. Performed a literature review to develop an evidence-based audit checklist to identify best practices in educational delivery modalities to achieve clinical competence.

III. CDC Program Evaluation Procedural Phase 3: Focusing the Evaluation

Design

- A. Created a data collection worksheet (raw data input into Excel worksheet) that was used to evaluate each FERTEP. After each program was evaluated, collected data was collated into one all-inclusive document for purposes of gap analysis.
- B. Created a template to represent the synthesis of the data for each FERTEP evaluated in a PowerPoint presentation.
- C. Established timelines for completion of each FERTEP evaluation.

IV. CDC Program Evaluation Procedural Phase 4: Gathering Credible Evidence

- A. Performed a comprehensive evaluation on the selected flexible endoscopic reprocessing programs using the audit checklist.
- B. Conducted a gap analysis between FERTEPs related to educational content, alignment with established recommended practice guidelines, and educational delivery platform.

1. Identified variances in programs.
2. Identified areas that need improvement and provided evidence-based recommendations.

V. CDC Program Evaluation Procedural Phase 5: Justify Conclusions

- A. Identified the most comprehensive flexible endoscope reprocessing program for recommendation to be implemented across the DHA.

VI. CDC Program Evaluation Procedural Phase 6: Ensuring Use and Sharing Lessons Learned

- A. Disseminated lessons learned/evidence-based recommendations to stakeholders:
 1. Office of the Surgeons General
 - i. Written report/EXSUM
 - ii. Oral with PowerPoint presentation
 2. Perioperative Nursing Consultants of the Surgeons Generals of the Armed Forces
 - i. Written report/EXSUM
 - ii. Oral with PowerPoint presentation
 3. SMEs in HLD (Infection Preventionists, Industry Experts, Manufactures, and End Users of HLD)
 - i. Written report/EXSUM
 4. Program administrators of educational FERPs
 - i. Written report/EXSUM
- B. Presented project results at the following venues:

1. TriService Nursing Research Program
2. AORN Global Surgical Conference and Expo
3. USUHS Research Week
4. Publication in peer reviewed journal

HIPAA Concerns

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191 was established to protect Personal Identifiable Information (PII). Under HIPAA privacy rule sections 45 Code of Federal Regulations (CFR) 164.502(d), and 164.514(a)-(c), private data may be used or disclosed for research if approved by an Institutional Review Board (IRB) or Privacy Board (Department of Health and Human Services (HHS), 2003). This is an EBP project with potential opportunity for implementation across the DHA. There was no interaction with human subjects during this flexible endoscope reprocessing program evaluation project. PII was not accessed or utilized to complete this project. From an ethical standpoint, the integrity of intellectual property gathered from the evaluated programs was protected as well as data gathered, presented, and disseminated during this project.

Project Results

The programs included in this project were evaluated using an integrated systematic approach based on the CDC Framework for Program Evaluations. This DNP project was initiated as a result of noted variances in High-Level Disinfection flexible endoscope reprocessing training and education within the DHA enterprise with the end goal of identifying the most comprehensive and robust HLD FERTEP for recommendation to be implemented across the DHA. Programs were assessed according to fulfillment of evidence-based recommended practice training content, use of evidence-based recommended practice rationales

to support training content, and program specific educational delivery platforms utilized to deliver training content.

A total of five FERTEPs were evaluated utilizing an evidence-based audit checklist created from existing federal, professional, and regulatory guidelines/standards. Two of these programs, Steris and CBSPD, were conducted as web-based e-learning educational offerings, while two other programs, Medivators and Olympus, were conducted in face to face settings. The IAHCMM program on the other hand, was a self-paced/self-directed didactic training manual covering how to perform HLD on flexible endoscopes. HLD FERTEP evaluations were conducted over a six-month period beginning in July of 2019 and concluding in December of that same year.

HLD FERTEPs were assessed according to 17 identified evidence-based categories of training content related to the process of reprocessing flexible endoscopes, which is comprised of 171 individual training elements (See appendix A). Fulfillment of each evidence-based recommended practice training element was scored using a binary scale (e.g., yes or no) with totals being calculated and converted into overall training element fulfillment percentages. A 100% attainment threshold for fulfillment of all evidence-based recommended practice training elements in the 17 individual training categories was established in order for that area of training content to be considered successfully fulfilled.

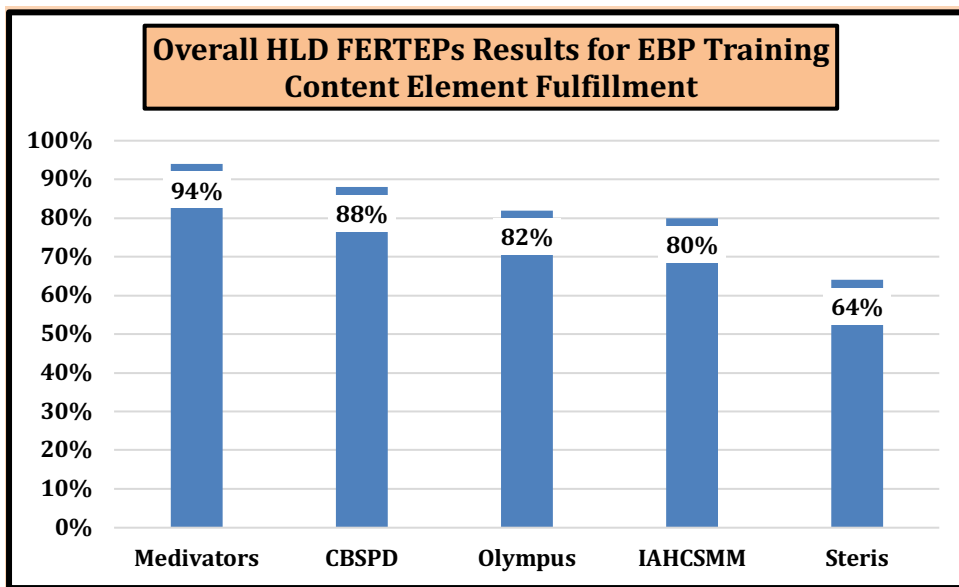
Overall HLD FERTEPs Results for Evidence-Based Recommended Practice Training Content Element Fulfilment

Inadequacies or deficiencies in flexible endoscope reprocessing education and training content have been directly linked to reprocessing failures (Kenters, Huijshens, Meier, & Voss, 2015). These avoidable lapses in endoscope reprocessing training expose patients to

unnecessary risks (Dirlam Langlay et al., 2013). Out of the five FERPS evaluated in this project, the Medivators program achieved the highest score of 94% of evidence-based recommended practice element fulfillment while the Steris program achieved the lowest score, fulfilling only 64% of the training elements. Overall element fulfillment scores for each evaluated HLD FERTEPS can be seen in Table 5.

Table 5. *Overall HLD FERTEPs Results for Evidence-Based Recommended Practice Training Content Element Fulfillment*

Medivators HLD FERTEPS Results for Evidence-Based Recommended Practice Training Content Element Fulfillment



The Medivators HLD FERTEP was the top performing program evaluated, containing 161/171 of the identified evidence-based recommended practice training content elements for an overall fulfillment percentage of 94%. Medivators met the 100% training content element fulfillment threshold in 10/17 training categories. However, two training categories, mechanical leak testing via automated endoscope reprocessor and mechanical automated endoscope reprocessing, scored below 80% of training content element fulfillment, fulfilling only 33% and

75% of these noted training elements. Looking at the critical phases of endoscope reprocessing, precleaning and manual cleaning, Medivators scored 92% and 95% respectively for training content element fulfillment in regard to these training categories. Recorded in Table 6 are the overall Medivators HLD FERTEP results for evidence-based recommended practice training content element fulfillment percentages.

Table 6. *Medivators HLD FERTEP Results for Evidence-Based Recommended Practice Training Content Element Fulfillment*

Training Categories	Elements Met	Percent Met
General Knowledge	17/17	100%
Endoscope Inspection	8/8	100%
<i>Precleaning/POU</i>	<i>11/12</i>	92%
Transport	3/3	100%
Leak Test Manual (Dry)	11/11	100%
Leak Test Manual (Wet)	16/17	94%
Mechanical Leak Test (AER)	1/3	33%
Leak Test Failure	3/3	100%
<i>Manual Cleaning</i>	19/20	95%
Manual Rinse	6/6	100%
Manual Liquid HLD	10/10	100%
Manual Rinse	3/3	100%
Manual Dry	7/7	100%
Mechanical AER	9/12	75%
Storage	15/16	94%
Reprocessing Cycle	16/17	94%
Quality Control	6/6	100%
Totals:	161/171	94%

CBSPD HLD FERTEP Results for Evidence-Based Recommended Practice Training

Content Element Fulfillment

The CBSPD program was the second highest scoring HLD FERTEP evaluated regarding training content fulfillment, having 151/171 of the predetermined training elements which equated to an overall evidence-based recommended practice training content fulfillment score of 88%. CBSPD attained the 100% training content element fulfillment threshold in 8/17 training

categories while failing to score above 80% in the following categories: mechanical leak testing via automated endoscope reprocessor (33%), manual liquid HLD (70%), mechanical automated endoscope reprocessing (58%), and storage (69%). Regarding the critical phases of endoscope reprocessing, precleaning and manual cleaning, the CBSPD program scored 92% and 100% for training content element fulfillment in these training categories. Displayed in Table 7 are CBSPD HLD FERTEP results for individual evidence-based recommended practice training elements that were met as well as overall training content element fulfillment percentages.

Table 7. *CBSPD HLD FERTEP Results for Evidence-Based Recommended Practice Training Content Element Fulfillment*

Training Categories	Elements Met	Percent Met
General Knowledge	15/17	88%
Endoscope Inspection	8/8	100%
<i>Precleaning/POU</i>	11/12	92%
Transport	3/3	100%
Leak Test Manual (Dry)	11/11	100%
Leak Test Manual (Wet)	17/17	100%
Mechanical Leak Test (AER)	1/3	33%
Leak Test Failure	3/3	100%
<i>Manual Cleaning</i>	20/20	100%
Manual Rinse	6/6	100%
Manual Liquid HLD	7/10	70%
Manual Rinse	3/3	100%
Manual Dry	6/7	86%
Mechanical AER	7/12	58%
Storage	11/16	69%
Reprocessing Cycle	16/17	94%
Quality Control	6/6	100%
Totals:	151	88%

Olympus HLD FERTEP Results for Evidence-Based Recommended Practice Training Content Element Fulfillment

The third highest scoring HLD FERTEP evaluated for this project in relation to training content fulfillment was the Olympus program, fulfilling 140/171 of the predetermined

evidence-based recommended practice training content elements for an overall fulfillment score of 82%. Additionally, the Olympus program met the 100% training content element fulfillment threshold in 6/17 evaluated categories but conversely failed to score greater than 80% in the following training areas: general knowledge (71%), transport (67%), mechanical leak test via automated endoscope reprocessor (0%), manual rinse (67%), manual liquid HLD (30%), manual dry (57%), mechanical 67%), and storage (38%). Upon evaluation of the critical phases of endoscope reprocessing, precleaning and manual cleaning, the Olympus program was found to have met 92% and 100% of the training content elements for these training categories respectively. Listed in Table 8 are the overall results for the Olympus HLD FERP concerning fulfillment of individual training category elements and associated fulfillment percentages.

Table 8. *Olympus HLD FERTEP Results for Evidence-Based Recommended Practice Training Content Element Fulfillment*

Training Categories	Elements Met	Percent Met
General Knowledge	12/17	71%
Endoscope Inspection	8/8	100%
<i>Precleaning/POU</i>	12/12	100%
Transport	2/3	67%
Leak Test Manual (Dry)	11/11	100%
Leak Test Manual (Wet)	17/17	100%
Mechanical Leak Test (AER)	0/3	0%
Leak Test Failure	3/3	100%
<i>Manual Cleaning</i>	19/20	95%
Manual Rinse	4/6	67%
Manual Liquid HLD	3/10	30%
Manual Rinse	3/3	100%
Manual Dry	4/7	57%
Mechanical AER	8/12	67%
Storage	6/16	38%
Reprocessing Cycle	16/17	94%
Quality Control	5/6	83%
Totals:	140/171	82%

IAHCSMM HLD FERTEP Results for Evidence-Based Recommended Practice Training

Content Element Fulfillment

The IAHCSMM program was the fourth highest scoring HLD FERTEP evaluated for this project, possessing 137/171 possible evidence-based recommended practice training content elements for an overall score of 80%. This program met 100% of the training element fulfillment threshold in 7/17 training categories but conversely failed to reach 80% element fulfillment in the following areas of endoscope reprocessing training: precleaning/POU (75%), leak test manual dry (64%), leak test manual wet (47%), mechanical leak test automated endoscope reprocessor (0%), leak test failure (67%), mechanical automated endoscope reprocessing (67%), and storage (69%). In regard to precleaning and manual cleaning, the critical phases of endoscope reprocessing, the IAHCSMM program amassed scores of 75% and 100% element fulfillment in these training categories. The recorded evaluation results for the IAHCSMM HLD FERTEP pertaining to evidence-based recommended practice training element fulfillment totals and corresponding percentages are noted in Table 9.

Table 9. *IAHCSMM HLD FERTEP Results for Evidence-Based Recommended Practice Training**Content Element Fulfillment*

Training Categories	Elements Met	Percent Met
General Knowledge	17/17	100%
Endoscope Inspection	8/8	100%
<i>Precleaning/POU</i>	9/12	75%
Transport ⁵	3/3	100%
Leak Test Manual (Dry)	7/11	64%
Leak Test Manual (Wet)	8/17	47%
Mechanical Leak Test (AER)	0/3	0%
Leak Test Failure	2/3	67%
<i>Manual Cleaning</i>	17/20	85%
Manual Rinse	6/6	100%
Manual Liquid HLD	9/10	90%
Manual Rinse	3/3	100%
Manual Dry	7/7	100%
Mechanical AER	8/12	67%
Storage	11/16	69%
Reprocessing Cycle	16/17	94%
Quality Control	6/6	100%
Totals:	137/171	80%

Steris HLD FERTEP Results for Evidence-Based Recommended Practice Training**Content Element Fulfillment**

Ranking last out of the five evaluated programs for training content fulfillment, the Steris HLD FERTEP fulfilled 110/171 evidence-based recommended practice training content elements, for a total of 64% while achieving the 100% element fulfillment threshold in only 1/17 training categories. Training categories failing to meet 80% of training element fulfillment are as follows: endoscope inspection (75%), precleaning/POU (58%), leak test manual dry (73%), leak test manual wet (76%), mechanical leak test via automated endoscope reprocessor (0%), leak test failure (67%), manual cleaning (50%), manual rinse (50%), manual liquid HLD (40%), manual rinse after manual HLD (33%), mechanical automated endoscope reprocessing (17%), and storage (50%). When reviewing the Steris programs performance in relation to completion

of the critical phases of endoscope reprocessing (e.g., precleaning and manual cleaning), the program scored 58% and 50% respectively in these training categories. Table 10 lists individual evidence-based recommended practice training content category element fulfillment results and associated percentages for the Steris HLD FERTEP.

Table 10. *Steris HLD FERTEP Results for Evidence-Based Recommended Practice Training Content Element Fulfillment*

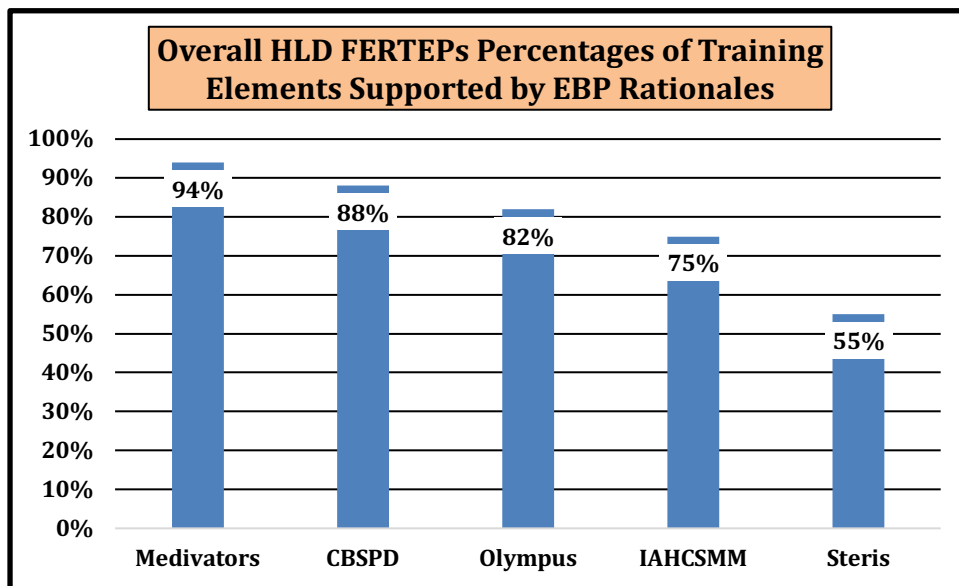
Training Categories	Elements Met	Percent Met
General Knowledge	16/17	94%
Endoscope Inspection	6/8	75%
<i>Precleaning/POU</i>	7/12	58%
Transport	3/3	100%
Leak Test Manual (Dry)	8/11	73%
Leak Test Manual (Wet)	13/17	76%
Mechanical Leak Test (AER)	0/3	0%
Leak Test Failure	2/3	67%
<i>Manual Cleaning</i>	10/20	50%
Manual Rinse	3/6	50%
Manual Liquid HLD	4/10	40%
Manual Rinse	1/3	33%
Manual Dry	6/7	86%
Mechanical AER	2/12	17%
Storage	8/16	50%
Reprocessing Cycle	16/17	94%
Quality Control	5/6	83%
Totals:	110/171	64%

Overall HLD FERTEPs Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements

Providing learners with rationales supporting educational content supplies them a means to articulate the reason and importance of why a task needs to be completed effectively and promotes active learning (Pearce et al., 2015). Failure to incorporate rationales that support learning concepts can severely hinder a students' ability to learn and retain presented information for future recall when needed (Erickson, Boistrup, & Thornbern, 2018). The five HLD

FERTEPs were also evaluated on whether each programs' 171 individual training elements were supported by evidence-based recommended practice rationales. The Medivators HLD FERTEP outperformed the other four evaluated programs, supporting 94% of the total training elements with evidence-based recommended practice rationales, whereas the Steris program only supported 55%. Listed in Table 11 are the overall results, ranked highest to lowest, of all five evaluated HLD FERTEPs in regard to evidence-based supported training content.

Table 11. *Overall HLD FERTEPs Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements*



Medivators HLD FERTEP Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements

The Medivators HLD FERTEP was found to have 161/171 individual training elements supported by evidence-based recommended practice rationales, resulting in an overall program score of 94%. In addition, 10/17 training categories were determined to be 100% buttressed by evidence-based recommended practice rationales. Nevertheless, this program scored below 80% for containing training elements that lacked rationale support in two categories, mechanical leak

testing via automated endoscope reprocessor (33%) and mechanical endoscope reprocessing (75%). Further assessment of the program revealed that 92% and 95% of training elements in the critical phases of endoscope reprocessing, precleaning and manual cleaning, were underscored by evidence-based recommended practice rationales. Listed in Table 12 are the Medivators HLD FERTEP totals for number of training elements with corresponding evidence-based recommended practice rationales and associated fulfillment percentages for each training category.

Table 12. *Medivators HLD FERTEP Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements*

Training Categories	Elements Met	Percent Met
General Knowledge	17/17	100%
Endoscope Inspection	8/8	100%
<i>Precleaning/POU</i>	11/12	92%
Transport	3/3	100%
Leak Test Manual (Dry)	11/11	100%
Leak Test Manual (Wet)	16/17	94%
Mechanical Leak Test (AER)	1/3	33%
Leak Test Failure	3/3	100%
<i>Manual Cleaning</i>	19/20	95%
Manual Rinse	6/6	100%
Manual Liquid HLD	10/10	100%
Manual Rinse	3/3	100%
Manual Dry	7/7	100%
Mechanical AER	9/12	75%
Storage	15/16	94%
Reprocessing Cycle	16/17	94%
Quality Control	6/6	100%
Totals:	161/171	94%

CBSPD HLD FERTEP Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements

The CBSPD HLD FERTEP ranked second amongst evaluated programs, supporting 151/171 of the identified individual training elements with evidence-based recommended

practice rationales for an overall program score of 88%. Moreover, 9/17 training categories were discovered to be supported by rationales 100% of the time. In contrast to this finding, the CBSPD program scored below 80% in providing rationales supporting the following areas of training: mechanical leak test via automated endoscope reprocessor (33%), manual liquid HLD (70%), mechanical automated endoscope reprocessing (58%), and storage (69%). When examining the program to determine if evidence-based recommended practice rationales were given in support of pre-cleaning and manual cleaning, the critical phases of endoscope reprocessing, CBSPD scored 92 and 100% respectively for these training areas. The total number and percentages of training elements supported by evidence-based recommended practice rationales can be viewed in Table 13.

Table 13. *CBSPD HLD FERTEP Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements*

Training Categories	Elements Met	Percent Met
General Knowledge	15/17	88%
Endoscope Inspection	8/8	100%
<i>Precleaning/POU</i>	11/12	92%
Transport	3/3	100%
Leak Test Manual (Dry)	11/11	100%
Leak Test Manual (Wet)	17/17	100%
Mechanical Leak Test (AER)	1/3	33%
Leak Test Failure	3/3	100%
<i>Manual Cleaning</i>	20/20	100%
Manual Rinse	6/6	100%
Manual Liquid HLD	7/10	70%
Manual Rinse	3/3	100%
Manual Dry	6/7	86%
Mechanical AER	7/12	58%
Storage	11/16	69%
Reprocessing Cycle	16/17	94%
Quality Control	6/6	100%
Totals:	151	88%

Olympus HLD FERP Results for Rationales Given to Support Evidence-Based

Recommended Practice Training Elements

The third ranked HLD FERTEP evaluated was Olympus which used evidence-based recommended practice rationales in support of 141/171 individual training elements, equating to an 82% overall score. Also, of note, the Olympus program was recognized as having 6/17 training categories fully supported 100% of the time by rationales. Juxtaposed to this positive finding however, the Olympus program failed to score above 80% in relation to providing rationales for the following areas of training: general knowledge (71%), transport (67%), mechanical leak test via automated endoscope reprocessor (0%), manual rinse (67%), manual liquid HLD (30%), manual dry (57%), mechanical automated endoscope reprocessing (67%), and storage (38%). For the critical phases of endoscope reprocessing, precleaning and manual cleaning, Olympus employed evidence-based recommended practice rationales 92% and 100% of the time in support of these areas of training. In Table 14 are recorded the percentages and overall number of training elements supported by evidence-based recommended practice rationales.

Table 14. *Olympus HLD FERTEP Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements*

Training Categories	Elements Met	Percent Met
General Knowledge	12/17	71%
Endoscope Inspection	8/8	100%
<i>Precleaning/POU</i>	12/12	100%
Transport	2/3	67%
Leak Test Manual (Dry)	11/11	100%
Leak Test Manual (Wet)	17/17	100%
Mechanical Leak Test (AER)	0/3	0%
Leak Test Failure	3/3	100%
<i>Manual Cleaning</i>	19/20	95%
Manual Rinse	4/6	67%
Manual Liquid HLD	3/10	30%
Manual Rinse	3/3	100%
Manual Dry	4/7	57%
Mechanical AER	8/12	67%
Storage	6/16	38%
Reprocessing Cycle	16/17	94%
Quality Control	5/6	83%
Totals:	140/171	82%

IAHCSMM HLD FERTEP Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements

The IAHCSMM HLD FERTEP ranked fourth amongst evaluated programs with evidence-based recommended practice rationales utilized 75% of the time in support of 128/171 individual training elements. Additionally, 7/17 training categories were found to be fully supported 100% of the time by rationales. Incongruous with the abovementioned findings, the IAHCSMM program also had numerous training categories where less than 80% of the individual training elements received rationale support to include: pre-cleaning (75%), leak test manual dry (64%), leak test manual wet (35%), mechanical leak testing via automated endoscope reprocessor (0%), leak test failure (33%), manual rinse (67%), mechanical automated endoscope reprocessing (50%), and storage (69%). As for the critical phases of endoscope reprocessing,

precleaning and manual cleaning, these specific areas of training in the IAHCSSM program by evidence-based rationales only 75% and 85% of the time. The total number and percentages of training elements supported by evidence-based recommended practice rationales can be viewed in Table 15.

Table 15. *IAHCSSM HLD FERTEP Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements*

Training Categories	Elements Met	Percent Met
General Knowledge	17/17	100%
Endoscope Inspection	8/8	100%
<i>Precleaning/POU</i>	9/12	75%
Transport	3/3	100%
Leak Test Manual (Dry)	7/11	64%
Leak Test Manual (Wet)	6/17	35%
Mechanical Leak Test (AER)	0/3	0%
Leak Test Failure	1/3	33%
<i>Manual Cleaning</i>	17/20	85%
Manual Rinse	4/6	67%
Manual Liquid HLD	9/10	90%
Manual Rinse	3/3	100%
Manual Dry	7/7	100%
Mechanical AER	6/6	50%
Storage	11/16	69%
Reprocessing Cycle	16/17	94%
Quality Control	6/6	100%
Totals:	128/171	75%

Steris HLD FERTEP Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements

The fifth ranked HLD FERTEP assessed during this evaluation process was the Steris program which was found to have 94/171 training elements supported by evidence-based recommended practice rationales, equating to an overall program total of 55%. None of the training categories, 0/17, was supported by rationales 100% of the time. Furthermore, 15/17 possible training categories failed to be supported by rationales 80% of the time to include:

endoscope inspection (63%), pre-cleaning/POU (50%), transport (67%), leak test manual dry (64%), leak test manual wet (65%), mechanical leak test via automated endoscope reprocessor (0%), leak test failure (33%), manual cleaning (35%), manual rinse (50%), manual liquid HLD (10%), manual rinse after manual HLD (33%), manual drying (71%), mechanical automated endoscope reprocessing (17%), storage (44%), and quality control (67%). The Steris program, specifically concerning pre-cleaning and manual cleaning, the critical phases of endoscope reprocessing, was shown to support training elements 50% and 35% of the time with evidence-based recommended practice rationales. The training elements aggregate supported by rationales can be seen in Table 16 along with overall program fulfillment percentages.

Table 16. *Steris HLD FERTEP Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements*

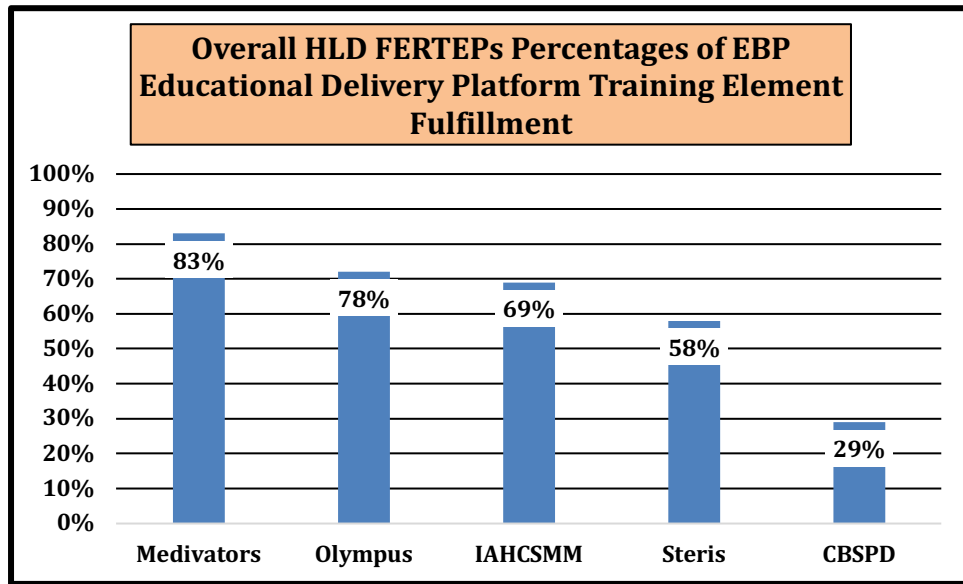
Training Categories	Elements Met	Percent Met
General Knowledge	15/17	88%
Endoscope Inspection	5/8	63%
<i>Pre-cleaning/POU</i>	6/12	50%
Transport	2/3	67%
Leak Test Manual (Dry)	7/11	64%
Leak Test Manual (Wet)	11/17	65%
Mechanical Leak Test (AER)	0/3	0%
Leak Test Failure	1/3	33%
<i>Manual Cleaning</i>	7/20	35%
Manual Rinse	3/6	50%
Manual Liquid HLD	1/9	10%
Manual Rinse	1/3	33%
Manual Dry	5/7	71%
Mechanical AER	2/12	17%
Storage	7/16	44%
Reprocessing Cycle	16/17	94%
Quality Control	4/6	67%
Totals:	94/171	55%

Overall HLD FERTEPs Result for Evidence-Based Recommended Practice Educational Delivery Platform Training Element Fulfilment

Educational delivery platforms (e.g., web-based, face to face, and didactic learning from a training manual) possess inherent challenges that must be overcome by the teacher as well as the student for active learning to take place (Benta, Bologna, & Dzitac, 2014). There are common content and structural elements intrinsic to every type of educational delivery platform (e.g., education curriculum, goals, outcomes, interactive learning modalities, instructor/student feedback, etc.). Failures by FERTEPs to include these content and structural elements into their educational delivery platforms can negatively impact a student's overall academic performance and impede the active learning process (Aghera et al., 2017). To this end, the Medivators program, a face to face educational delivery platform, outpaced the other four evaluated HLD FERTEPs by fulfilling 83% or 15/18 of the evidence-based recommended practice educational delivery platform elements. The bottom performer in this category was the CBSPD HLD FERTEP that only fulfilled 29% or 5/17 of the educational delivery elements. The overall educational delivery element fulfillment totals and corresponding percentages for the five evaluated HLD FERTEPs are recorded in Table 17.

Table 17. Overall HLD FERTEPs Results for Evidence-Based Recommended Practice

Educational Delivery Platform Training Element Fulfillment



Medivators HLD FERTEP Results for Evidence-Based Recommended Practice

Educational Delivery Platform Training Element Fulfillment

Conducted in a face to face setting, Medivators was the highest scoring HLD FERTEP fulfilling 15/18 or 83% of the identified evidence-based recommended practice educational delivery platform elements. This program achieved the 100% element fulfillment threshold in 4/6 assessed categories while scoring \leq 80% in the following two categories: knowledge assessment (67%) and interactive learning (80%). Listed in Table 18 are Medivators HLD FERTEP totals for evidence-based recommended practice educational delivery platform elements met/not met and overall fulfillment percentages for each category.

Table 18. *Medivators HLD FERTEP Results for Evidence-Based Recommended Practice**Educational Delivery Platform Training Element Fulfillment*

Face to Face Evidence-Based Recommended Practice Educational Delivery Platform Training Elements	Met	Not Met
<u>Education programs should have specific:</u>		
A) Education curriculum	X	
B) Goals	X	
C) Outcomes	X	
<u>Knowledge assessment measured by:</u>		
A) Pretest		X
B) Knowledge checks	X	
C) Posttests		X
<u>Interactive learning:</u>		
A) Video	X	
B) Simulations		
a. Real world scenarios	X	
b. Case studies	X	
C) Lab traditional	X	
D) Lab virtual reality		X
<u>Education sessions should be:</u>		
A) Short (30-45 minutes in duration)	X	
B) Small in Size	X	
C) Provide one on one instructions	X	
<u>Instructor feedback:</u>		
A) During training	X	
B) After training	X	
<u>Student feedback:</u>		
A) During training	X	
B) After training	X	
Elements met:	15	3
Percentage met:	83%	17%

Olympus HLD FERTEP Results for Evidence-Based Recommended Practice Educational Delivery Training Element Fulfillment

Olympus, also carried out in a face to face format, was the second highest scoring HLD FERTEP evaluated for this project concerning evidence-based recommended practice educational delivery platform element fulfillment, fulfilling 14/18 or 78% of the identified face to face educational elements. The Olympus program was able to meet the 100% educational

delivery platform element fulfillment threshold in 4/6 assessed categories while failing to score >80% in two categories: knowledge assessment (67%) and interactive learning (60%). Totals for evidence-based recommended practice educational delivery platform elements met/not met and overall fulfillment percentages for each category are represented in Table 19.

Table 19. *Olympus HLD FERTEP Results for Evidence-Based Recommended Practice*

Educational Delivery Platform Training Element Fulfillment

Face to Face Evidence-Based Recommended Practice Educational Delivery Platform Training Elements	Met	Not Met
<u>Education programs should have specific:</u>		
A) Education curriculum	X	
B) Goals	X	
C) Outcomes	X	
<u>Knowledge assessment measured by:</u>		
A) Pretest		X
B) Knowledge checks	X	
C) Posttests		X
<u>Interactive learning:</u>		
A) Video	X	
B) Simulations		
a. Real world scenarios	X	
b. Case studies		X
C) Lab traditional	X	
D) Lab virtual reality		X
<u>Education sessions should be:</u>		
A) Short (30-45 minutes in duration)	X	
B) Small in Size	X	
C) Provide one on one instructions	X	
<u>Instructor feedback:</u>		
A) During training	X	
B) After training	X	
<u>Student feedback:</u>		
A) During training	X	
B) After training	X	
Elements met:	14	4
Percentage met:	78%	22%

IAHCSMM HLD FERTEP Results for Evidence-Based Recommended Practice**Educational Delivery Platform Training Element Fulfillment**

The third highest scoring HLD FERTEP, IAHCSMM, consisted of reading a didactic training manual covering HLD flexible endoscope reprocessing and evaluating 13 evidence-based recommended practice educational delivery platform elements organized into seven categories. The IAHCSMM program fulfilled 9/13 or 69% of the assessed elements and in doing so achieved the 100% element fulfillment threshold in 4/7 evaluated categories. Several evaluated categories, knowledge assessment (33%), length of education session (0%), and student feedback (0%), failed to reach 80% fulfillment. Noted in Table 20 are IAHCSMM HLD FERTEP educational delivery platform element fulfillment percentages and overall category totals.

Table 20. *IAHCSMM HLD FERTEP Results for Evidence-Based Recommended Practice**Educational Delivery Platform Training Element Fulfillment*

Training Manual Educational Delivery Platform Elements	Met	Not Met
<u>Education programs should have:</u>		
A) Education curriculum	X	
B) Goals	X	
C) Outcomes	X	
<u>Knowledge assessment measured by:</u>		
A) Quizzes		X
B) Tests		X
C) Knowledge checks	X	
<u>Interactive learning:</u>		
A) Text	X	
B) Graphics	X	
C) Visual images	X	
<u>Short education sessions</u>		X
<u>Supplemental material provided</u>	X	
<u>Written for target audience</u>	X	
<u>Allow for student feedback</u>		X
Elements met:	9	4
Percentage met:	69%	31%

Steris HLD FERTEP Results for Evidence-Based Recommended Practice Educational Delivery Platform Training Element Fulfillment

Steris, a web-based HLD FERTEP, fulfilled 10/17 or 58% of the identified evidence-based recommended practice educational delivery platform elements, ranking it as the fourth highest scoring program evaluated for this project. This program was only able to achieve the 100% element fulfillment threshold in 1/5 assessed categories, whereas 4/5 evaluated categories, interactive learning through multimedia (57%), length of education sessions (0%), knowledge assessment (67%), and student feedback (33%), scored <80% for element fulfillment. Recorded in Table 21 are Steris HLD FERTEP totals for fulfillment of evidence-based recommended practice educational delivery elements and corresponding percentages.

Table 21. *Steris HLD FERTEP Results for Evidence-Based Recommended Practice Educational Delivery Platform Training Element Fulfillment*

Web-Based Evidence-Based Recommended Practice Educational Delivery Platform Elements	Met	Not Met
<u>Interactive learning through multimedia:</u>		
A) Graphics	X	
B) Audio	X	
C) Animation		X
D) PowerPoint	X	
E) Webinars	X	
F) Virtual reality		X
G) Video conference		X
<u>Short education sessions (30-45 minutes in length)</u>		X
<u>Education programs should have:</u>		
A) Education curriculum	X	
B) Goals	X	
C) Outcomes	X	
<u>Knowledge assessment measured by:</u>		
A) Pretests		X
B) Knowledge checks	X	
C) Posttests	X	
<u>Student feedback:</u>		
A) Before education session starts		X
B) During education session		X
C) After education session is completed	X	
Elements met:	10	7
Percentage met:	58%	41%

CBSPD HLD FERTEP Results for Evidence-Based Recommended Practice Educational Delivery Platform Training Element Fulfillment

Another evaluated web-based HLD FERTEP, CBSPD, was ranked fifth or last for this project, fulfilling only 29% or 5/17 of the identified evidence-based recommended practice educational delivery platform elements. The CBSPD program was able to realize the 100% element fulfillment threshold in 2/5 categories assessed. However, the program was unsuccessful at scoring >80% element fulfillment in the following categories: interactive learning through multimedia (14%), short education sessions (0%), and knowledge assessment

(67%). Listed in Table 22 are CBSPD HLD FERTEP totals for evidence-based recommended practice educational delivery platform elements met/not met and overall fulfillment percentages.

Table 22. *CBSPD HLD FERTEP Results for Evidence-Based Recommended Practice*

Educational Delivery Platform Training Element Fulfillment

Web-Based Evidence-Based Recommended Practice Educational Delivery Platform Training Elements	Met	Not Met
<u>Interactive learning through multimedia:</u>		
A) Graphics	X	
B) Audio		X
C) Animation		X
D) PowerPoint		X
E) Webinars		X
F) Virtual reality		X
G) Video conference		X
<u>Short education sessions (30-45 minutes in length)</u>		X
<u>Education programs should have:</u>		
A) Education curriculum	X	
B) Goals	X	
C) Outcomes	X	
<u>Knowledge assessment measured by:</u>		
A) Pretests		X
B) Knowledge checks		X
C) Posttests	X	
<u>Student feedback:</u>		
A) Before education session starts		X
B) During education session		X
C) After education session is completed		X
Elements met:	5	12
Percentage met:	29%	71%

Discussion

Inadequate reprocessing of endoscopes has been listed as a top ten technology safety hazard for the past five years by the Emergency Care Research Institute (ERCI, 2019). A review of the literature revealed that the major factors contributing to the continuance of endoscope preprocessing safety concerns are a lack of both standardized reprocessing guidelines (AAMI,

2015; AORN, 2018) and education and training protocols (Kenters, et al., 2015). The variances in endoscope reprocessing practices have been directly linked to patients' increased exposures to BBP's (Molloy-Simard, Lemyre, Martel, & Catalone, 2019) contraction of HAI's (Petersen, et al., 2017), and even death (Terhune, 2018). This Evidence Based Practice (EPB) project was undertaken to evaluate commercially available HLD FERTEPs to identify the most comprehensive and robust program that meets the DHA's need for process standardization in an effort to address the noted continuance of endoscope reprocessing variances afflicting the enterprise (Bean, 2018) while at the same time promoting safe evidence-based HLD clinical practices.

HLD FERPs Training Content Element Fulfillment Results for the Critical Phases of Endoscope Reprocessing

This EBP project found that the top three HLD FERTEPs, CBSPD (96%), Olympus (96%), and Medivators (94%), scored above 90% for completion of steps in the critical phases of endoscope reprocessing, whereas the bottom two programs, IAHCSMM and Steris scored 80% and 43% respectively. During the gap analysis portion of this project, training and education deficiency patterns were discovered with a total of 4/5 or 80% of the FERTEPs failing to address the visual inspection of endoscopes for damage during the precleaning phase in their training and education material. Failure to identify damaged endoscopes during the precleaning phase of reprocessing is a known HAI risk factor (Pyrek, 2017). Also, using a damaged endoscope to perform an endoscopic procedure could result in a patient being exposed to BBP's or contraction of an HAI (Kovaleva, Peters, Van der Mei, & Degener, 2013). Consequently, all endoscopes must be inspected for possible damage during the precleaning phase of endoscope reprocessing as an additional patient safety mechanism according to published evidence-based recommended

reprocessing guidelines (RRG's) (AAMI, 2015). This EBP project discovered that regardless of the HLD FERTEP used, variances from established evidence-based RRG's were identified in all programs, which may place a patient at increased risk of harm or injury related to contraction of an HAI (Decristo, et al., 2018).

Moreover, training on cleaning and brushing the elevator and recesses surrounding it on duodenoscopes was limited in the programs with 40% or 2/5 HLD FERTEPs failing to cover this critical topic in their training and education material. This finding is of particular concern related to the numerous recent MDRO outbreaks caused by improperly reprocessed duodenoscopes (Rauwers et al., 2018b) and is further supported by a recent independent root cause analysis conducted by researchers that revealed that one of the leading factors contributing to the continued prevalence of duodenoscope associated MDRO outbreaks is improper reprocessing practices (Rauwers et al., 2018a). Therefore, it is imperative that all steps in the critical phases of endoscope reprocessing be completed by reprocessing personnel on every device after every use (Decristo et al., 2018) in order for patients to receive safe care and eliminate the known risks that are associated with coming into contact with contaminated endoscopes (McCafferty et al., 2018; Mitchell, 2018; Wang, Ngamruengphong, Makary, Kalloo, & Hutfless, 2018). For these reasons, the author of this EBP project recommends all HLD FERTEPs develop a plan to systematically address identified endoscope reprocessing practice variances and make appropriate revisions to their respective training and education programs so that they are better aligned with evidenced-based RRG's and standards, thus promoting safe HLD practices (CDC, 2018).

Overall HLD FERTEPs Evidence-Based Recommended Practice Training Content

Element Fulfillment Results

The HLD FERTEPs overall scores for evidence-based recommended practice training content element fulfillment for all 17 categories and 171 individual training elements were as follows: Medivators (94%), CBSPD (88%), Olympus (82%), IAHCSMM (80%), and Steris (80%). While conducting the gap analysis, training and education deficiency patterns were identified. For the endoscope reprocessing phase related to the training and education category covering automated endoscope reprocessor (AER) mechanical leak testing, 60% or 3/5 of the HLD FERTEPs did not contain any course material discussing this topic. Additionally, another noteworthy training and education deficiency pattern was discovered concerning the endoscope reprocessing category encompassing mechanical AER's which revealed that 5/5 or 100% of the HLD FERTEPs failed to score above 80% for training and education element fulfillment for this topic. These endoscope reprocessing practice variance findings are significant because omission or failure to properly complete even one of the elements within any of the reprocessing phases will increase a patient's risk of contracting an HAI that might require an extensive hospitalization to resolve the infection and treat any secondary complications that might arise (Kenters et al., 2015).

In the eyes of Subject Matter Experts (SME's) (e.g., CNS's), RRG's represent the standard of care that should be consulted when creating or updating endoscope reprocessing practices; therefore, deviation from or fail to adhere to published evidence-based endoscope RRG's prohibits patients from receiving and clinicians from delivering patients with the established standard of care (Barth et al., 2016). One of the main reasons noted in the literature reinforcing the need to follow endoscope RRG's is that doing so results in measurable or

objective improvements in clinical outcomes (Barth et al., 2016). This objective data can then be analyzed in concert with the RRG's framework as a quantitative means to measure the quality of care delivered by clinicians to their patients (Bhaumik, 2017). According to the CDC, all endoscopes should be reprocessed utilizing published RRG's (CDC, 2015b) and per ASGE guidance, the most effective means to prevent patients from contracting HAIs related to contact with contaminated endoscopes is through compliance with RRG's (Calderwood et al., 2018). Consistent adherence to endoscope RRG's helps to prevent reprocessing lapses and improve quality of care provided, thereby enhancing overall patient safety (Kenters et al., 2018), while at the same time promoting the application of standard of care practices to endoscope reprocessing.

Although HLD FERPs are comprised of similar areas of training content (e.g., phases of endoscope reprocessing), all published RRG's have noted variances in the content depth, clarity, and overall comprehensiveness of training material included in each program (AAMI, 2015; AORN, 2018). If an organization chooses to follow only one particular set of RRG's to guide their facilities HLD endoscope reprocessing practices, inadequate reprocessing may take place (Petersen et al., 2017) leaving patients vulnerable to HAIs. Lacking awareness of endoscope RRG's is not a plausible excuse for an organization failing to provide patients with the established standard of care supporting clinical practice (Fischer, Lange, Klose, Greiner, & Kraemer, 2016). All endoscope RRG's are readily available upon request and can be accessed via the internet. Therefore, the author of this EBP project recommends that when organizations are creating or updating their endoscope reprocessing guidelines, they should consult multiple published RRG sources during the process as a way to mitigate reprocessing lapses or variances in practice (Bhaumik, 2017).

HLD FERTEPs Results for Rationales Given to Support Evidence-Based Recommended Practice Training Elements

Upon completion of this EBP project, it was found that evidence-based recommended practice rationales were utilized to support training and education content by HLD FERTEPs in descending order: Medivators (94%), CBSPD (88%), Olympus (82%), IAHCMM 80%), and Steris (64%). A review of these results revealed a 30% practice gap between the highest and lowest scoring programs. Moreover, during the gap analysis, practice variances totaling 53%, Medivators (59%) and Steris (6%), were discovered concerning HLD FERTEPs failures to support 100% of the 17 training and education categories and 171 training elements with evidence-based rationales.

These noted failures by HLD FERTEPs to reinforce training and education content with evidence-based recommended practice rationales diminishes the importance to students of why a certain task must be completed in a specific order or a specific way, essentially becoming an exercise in rote memorization of tasks to be performed (Fagerberg, 2016). Therefore, it is important that a student understands the “why” or rationale that supports the performance of any given task since this concept is an essential element in the active learning process and helps students build retrievable information networks that can be drawn upon when completing complex or multiple step tasks such as endoscope reprocessing (Erickson, Boistrup, & Thornbern, 2018). Routine learning of training concepts without rationale support can lead students to lose focus and possibly misunderstand the training concepts being taught (Ahmed & Ahmad, 2017). The current identified practice variances of failure to integrate rationales supporting training and education content by FERTEPs into their programs severely limits a students’ base knowledge about the adverse consequences of being noncompliant with RRG’s.

Noncompliance with RRG's has resulted in reprocessing steps being missed or performed incorrectly either of which place patients at an increased risk of BP exposure (Kenters et al., 2015). Consequently, this author recommends HLD FERTEP managers review their programs current training and education content to identify practice gaps and include evidence-based rationales as needed to support course material. This process of incorporating rationales into course content will have a positive effect on students active learning capabilities while at the same time improving information retention and recall abilities (Yang, Potts, Shanks, 2018).

HLD FERP Result's for Evidence-Based Recommended Practice Educational Delivery Platform Training Element Fulfilment

For educational delivery platform training element fulfillment, this EBP project found that the evaluated FERTEPs scored in the following order: Medivators (83%), Olympus (78%), IAHCMM (69%), Steris (58%), and CBSPD (29%). The gap analysis exposed a 54% practice variance between the top and bottom performing programs. Likewise, only one program, Medivators, scored >80% for training element fulfillment concerning educational delivery platforms.

Since all students' process information differently (e.g., visual, auditory, and tactile), choosing an educational delivery platform to deliver information in a way that meets the individual students' learning needs is vitally important to the success or failure of any training program (Felszephy et al., 2019). When choosing an education delivery platform, HLD FERTEPs must carefully consider what interactive learning modalities are most effective at delivering training and education content. Educational platforms that do not engage today's technology savvy student's via varied interactive learning modalities (e.g., internet, video conferencing, and virtual reality) have been shown to cause students to have negative attitudes

and perceptions towards delivered training content (Garner, Pack, Syrony, & Beeson, 2013), subsequently adversely affecting student knowledge retention and active engagement in training course work. Furthermore, knowledge deficiencies of and poor student participation in performing the multiple complex tasks required to properly reprocess endoscopes exponentially increases the risk that errors will occur during the reprocessing cycle, consequently putting patients at increased risk of exposure to BBP or contracting an HAI (Dirlam-Langlay et al., 2013). As a result of the findings of this EBP project, the author recommends FERTEPs utilize educational delivery platforms (e.g., web-based, face to face, and didactic learning from a training manual) created from evidence-based best practices as found in the literature. Regardless of what educational delivery platform is implemented, emphasis should be placed on FERTEPs making use of interactive learning modalities (e.g., internet, virtual reality, video conferencing) which have been shown to improve student engagement and overall knowledge retention (Turner & Turner, 2017).

Organizational Impact

Currently, the DHA does not have a standardized training platform in place to train and educate the personnel responsible for reprocessing flexible endoscopes used in MTF's and supporting clinics. Identification and subsequent utilization of a standardized platform would support the DHA's goal of becoming a high reliability organization (HRO) by enhancing the quality of care provided through the reduction or elimination of variability in clinical practices and improvement in clinical competencies through consistent application of knowledge. Moreover, based on the total number of projected endoscopic procedures to be performed annually in military facilities, DHA could reasonably expect to positively impact 424,944

patients and 700 reprocessing personnel by preventing 8,799 HAI's, which translate into approximately \$84,991,600.00 in cost-avoidance (DHA, 2020; Hassan et al., 2010).

Choosing to utilize a standardized FERTEP the DHA could also increase overall patient safety and maximize clinical outcomes, while achieving MHS' Quadruple Aim goals; improving military readiness, provision of better care, and promotion of better health to reduce health care costs (MHS, 2013). Organizational financial optimization could be improved through the reduction of hospital readmissions related to HAI's as a result of patient exposures to improperly reprocessed flexible endoscopes. Literature has shown a direct correlation between measurable outcomes of patient safety, consumer confidence, and satisfaction levels with increased customer retention and the generation of new patient referrals (Xesfingi & Vozikis, 2016). The impact of lost revenues associated with non-reimbursable expenses when a patient contracts an HAI from exposure to a contaminated endoscope can be as high as \$22,685.89 per readmission (Shephard, et al., 2013). Implementation of this type of cost avoidance training and education initiative could significantly decrease TRICARE revenue losses. The revenue generated from new and returning surgical patients would offset any possible costs incurred by DHA when implementing a standardized training and education platform for the reprocessing of flexible endoscopes.

When implementing a new process like HLD endoscope reprocessing, it is vitally important to establish outcome measures to determine if the EBP project is meeting organizational goals (van der Hoek, Groeneveld, & Kuipers, 2018). To assess the effectiveness of the HLD FERTEP chosen by DHA for implementation, this author recommends assessing the quantifiable quality of care metric benchmarks of HAI's and preventable hospital readmissions rates as put forth by the National Surgical Quality Improvement Program (NSQIP) (Al-Mazrou, Zhang, Yu, & Kiran, 2018). These quality of care metrics could be collected before and after the

implementation of the identified standardized FERTEP and analyzed at the one-year mark to determine the selected programs’ effectiveness at decreasing HAI’s and preventable hospital readmission rates per the most current NSQIP data. The organizational impacts that the Medivators HLD FERTEP would bring to the DHA, if chosen as the standardized training and education delivery platform for flexible endoscope reprocessing, have been aligned with the MHS’ Quadruple Aim goals. These organizational impacts can be observed in Table 23.

Table 23: *Medivators HLD FERTEP Organizational Impacts*

MHS’ Quadruple Aim Goals:	Organizational Impacts
<u>Improved Readiness</u>	<ul style="list-style-type: none"> ● <u>Standardized delivery platform:</u> All endoscope reprocessing personnel trained at MTFs using the same evidence-based recommended practice education and training platform equals decreased practice variances and standardized knowledge base. ● <u>Transferrable skills:</u> Endoscope reprocessing skill sets acquired from standardized training transferred with personnel from MTF to MTF negating need for additional training as personnel move to different facilities. ● <u>Limiting practice variances:</u> Decreased variances in endoscope processing clinical practices equates to potential decreased number of servicemembers contracting HAI’s resulting in avoidable hospital readmissions which could limit the number of active duty personnel being medically fit for duty.
<u>Better Health</u>	<ul style="list-style-type: none"> ● <u>Increased patient safety:</u> Since ensuring patient safety is of the utmost importance when trying to promote optimal health, “All endoscopes should be reprocessed with a uniform, standardized reprocessing procedure” (Bielenhoff et al., 2018, p. 5) like the one outlined by the Medivators HLD FERTEP because failure to do so leaves patients vulnerable to infections (AORN, 2018). ● <u>Decreased patient exposure to virulent pathogens:</u> Implementing the Medivators HLD standardized flexible endoscope reprocessing education and training program in the DHA would help prevent reprocessing personnel from missing

	<p>or omitting steps in the endoscope reprocessing cycle which can place patients at an increased risk of contracting diseases like Hepatitis C and Human Immunodeficiency Virus (HIV), as well as, infections from microorganisms such as <i>Escherichia coli</i>, <i>Klebsiella pneumoniae</i>, <i>Pseudomonas aeruginosa</i>, <i>Salmonella enteritidis</i>, and Multiple Drug Resistant Organisms (MDROs) like <i>Carbapenem resistant enterobacteriaceae</i> (CRE) (Kenters et al., 2015; Kovaleva, Peters, van der Mei, & Degener, 2013; McCafferty et al., 2018; Wang, Ngamruengphong, Makary, Kalloo, & Hutfless, 2018).</p> <ul style="list-style-type: none"> • <u>Decreased patient morbidity and mortality rates:</u> The utilization of the Medivators standardized HLD FERTEP platform by the DHA would decrease patients contact with deleterious pathogens. The magnitude of patients being harmed by contaminated endoscopes can be further underscored when looking at the MDRO CRE, which has a mortality rate of up to 40% for patients who become infected following an endoscopic procedure (Eisler, 2015).
<p><u>Better Care</u></p>	<ul style="list-style-type: none"> • <u>Endoscope reprocessing practice standards:</u> The Medivators HLD FERTEP was created using the most current evidence-based recommended practice reprocessing standards/guidelines. • <u>Practice updates:</u> Training content for the Medivators HLD FERTEP is frequently updated pursuant to the publishing of new or amended endoscope reprocessing guidelines or when evidence-based literature supports changes in clinical practice. • <u>Delivery of care:</u> Personnel reprocessing endoscopes per guidance from the Medivators HLD FERTEP consistently provide patients with the “standard of care” as noted in available literature supporting evidence-based recommended reprocessing practices.
<p><u>Lower Costs</u></p>	<ul style="list-style-type: none"> • <u>Organizational costs:</u> “The total direct, indirect, and nonmedical social costs of HAIs are estimated at around \$96 billion to \$146 billion annually, including loss of work, legal costs, and other patient factors” (Beckers Hospital Review, 2015).

	<ul style="list-style-type: none"> • <u>Lost revenues</u>: Non-reimbursable expenses when a patient contracts an HAI can cost as much as \$22,685.89 per preventable hospital readmission (Shephard et al., 2013). • <u>Financial liabilities</u>: New legislation has been passed that allows active duty service members sue the military for medical malpractice (Kime, 2019). • <u>Hospital readmissions</u>: Patients readmitted to the hospital related to HAIs spend between 3.1 to 13.1 additional days in the hospital for treatment (Beckers Hospital Review, 2015) • <u>Program cost</u>: Medivators HLD FERTEP is free of charge if performed as “in kind services” (DHA provides facilities, building, audio and video equipment for program to be performed) (Medivator, 2019).
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Future Directions for Research and Practice

The current lack of universal standardized endoscope reprocessing guidelines continues to place an undue burden on reprocessing personnel and organizational clinical management. Organizations are often times forced to employ multiple sources of available published reprocessing guidelines (e.g., AORN, SGNA, and AAMI) in order to ensure that endoscopes have been properly reprocessed and are safe to use on patients. Future nursing and medical research efforts should be focused on evaluating educational delivery methods to determine the most effective platform to optimize a learners’ knowledge retention and concept understanding as it relates to HLD training and education. In terms of HLD practice, efforts should be undertaken to deconflict current RRG’s through collaboration amongst governing bodies (e.g., AORN, AAMI, SGNA, etc.) in order to produce a universal set of HLD RRG’s to serve as a guide for HLD practices. Universal guidelines combined with the best educational delivery platform could then be utilized by all reprocessing personnel as the “standard of practice” at the local, national, and global level wherever flexible endoscopes are reprocessed to decrease

practice variances, thereby improving patient outcome measures (e.g., decreased HAI's, hospital readmissions, and deaths). Therefore, utilization of a standardized HLD FERTEP should be considered by DHS in all facilities that reprocess flexible endoscopes to decrease practice variances and promote MHS' Quadruple Aim goals of improved military readiness, provision of better care and promotion of better health to reduce health costs.

Conclusion

The results of this HLD FERTEPs evaluation EBP project suggest that implementing the Medivators program would be a viable solution to help the DHA standardize flexible endoscope reprocessing practices throughout the enterprise. The Medivators program was found to be superior to the other evaluated HLD FERTEPs regarding completion of evidence-based recommended practice training and education elements, use of rationales to support training content, and use of multiple interactive learning modalities to enhance learners' engagement and knowledge retention. Moreover, implementation of the Medivators standardized HLD FERTEP by DHA would limit process variability, promote continuous process improvement throughout the enterprise, and improve patient safety. Taking this action would enable the DHA to better address recent findings reported by The Joint Commission (TJC) that highlight the need for an effective standardized endoscope reprocessing training and education programs. This strategy supports the MHS's Quadruple Aim goals and moves the enterprise towards becoming a high reliability organization related to HLD practice. For these stated reasons, this author concludes that the Medivators program was found to be the most complete HLD FERTEP and thus should be considered by DHA as the enterprises' future standardized educational delivery platform to train and educate reprocessing personnel on HLD practices.

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[navy/2019/12/26/explainer-can-you-now-sue-the-military-for-medical-malpractice/](https://www.navytimes.com/news/your-navy/2019/12/26/explainer-can-you-now-sue-the-military-for-medical-malpractice/)

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Project Timeline

Project Year 2019												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Proposal/Approval				X								
USUHS VPR submission and approval					X							
Uniform Services University IRB submission and approval					X	X						
Phase 1: Identify and engage stakeholders					X							
Perform search to identify programs for evaluation					X	X						
Phase 2: Describe the program												
Establish inclusion and exclusion criteria to identify viable programs					X							
Apply the identified inclusion and exclusion criteria to select FERPs for evaluation					X	X						
Perform literature review to aid in formation of audit checklist					X	X						
Develop evidence-based audit checklist					X	X						
Phase 3: Focusing the evaluation design												
Create template for program data storage					X	X						
Establish FERP completion timelines						X						
Phase 4: Gathering credible evidence												
Perform FERP evaluations using audit checklist							X	X	X	X	X	X
Conduct gap analyses							X	X	X	X	X	X

Publication in peer reviewed journal					X							
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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)**COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS***

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Albert Knight (ID: 6533860)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** albert.knight@usuhs.edu
- **Phone:** 4097816154

- **Curriculum Group:** OUSD P&R Human Research
- **Course Learner Group:** Biomedical Investigators and Research Study Team
- **Stage:** Stage 1 - Biomedical Investigators

- **Record ID:** ██████████
- **Completion Date:** 26-Aug-2017
- **Expiration Date:** 25-Aug-2020
- **Minimum Passing:** 80
- **Reported Score*:** 94

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	26-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	26-Aug-2017	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	26-Aug-2017	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	26-Aug-2017	No Quiz
History and Ethics of Human Subjects Research (ID: 498)	26-Aug-2017	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	26-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	26-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	26-Aug-2017	4/4 (100%)
Records-Based Research (ID: 5)	26-Aug-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	26-Aug-2017	5/5 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	26-Aug-2017	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	26-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	26-Aug-2017	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	26-Aug-2017	4/5 (80%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	26-Aug-2017	No Quiz
The Federal Regulations - SBE (ID: 502)	26-Aug-2017	2/5 (40%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kad8c4710-fe4a-48ad-bddd-a8bc11a67c68-24322068

Collaborative Institutional Training Initiative (CITI Program)

Email: support@citiprogram.org

Phone: 888-529-5929

Web: <https://www.citiprogram.org>

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this [Transcript Report](#) reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Albert Knight (ID: 6533860)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** albert.knight@usuhs.edu
- **Phone:** [REDACTED]

- **Curriculum Group:** OUSD P&R Human Research
- **Course Learner Group:** Biomedical Investigators and Research Study Team
- **Stage:** Stage 1 - Biomedical Investigators

- **Record ID:** 24322068
- **Report Date:** 26-Aug-2017
- **Current Score**:** 98

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 498)	26-Aug-2017	7/7 (100%)
Informed Consent (ID: 3)	26-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	26-Aug-2017	4/4 (100%)
Records-Based Research (ID: 5)	26-Aug-2017	3/3 (100%)
The Federal Regulations - SBE (ID: 502)	26-Aug-2017	5/5 (100%)
Genetic Research in Human Populations (ID: 6)	26-Aug-2017	5/5 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	26-Aug-2017	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	26-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	26-Aug-2017	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	26-Aug-2017	No Quiz
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	26-Aug-2017	4/5 (80%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	26-Aug-2017	3/3 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	26-Aug-2017	5/5 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	26-Aug-2017	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	26-Aug-2017	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	26-Aug-2017	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kad8c4710-fe4a-48ad-bddd-a8bc11a67c68-24322068

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PHONE: (301) 295-3303; FAX: (301) 295-6771

NOTICE OF PROJECT APPROVAL

Change Number: Original

VPR Site Number: GSN-61-10769
Principal Investigator: Knight, Albert
Department: Graduate School of Nursing
Project Type: Student
Project Title: Evaluation of Flexible Endoscope Reprocessing Programs
Project Period: 8/1/2019 to 4/30/2020


Assurance and Progress Report Information:

<u>Name</u>	<u>Sup</u>	<u>Approval Type</u>	<u>Status</u>	<u>Approved On</u>	<u>Forms Received</u>
Progress Report	0			To be Submitted	N/A

Remarks:

This Notice of Project Approval has been reviewed and approved. Please remember that you must submit a final Progress Report (Form 3210) upon completion of this project.

Questions regarding this approval should be directed to the following person in the Office of Research:
Sharon McIver, (301) 295-9814.


Yvonne T. Maddox, Ph.D. 2 Aug 2019
Vice President for Research Date
Uniformed Services University of the Health Sciences

cc: Knight, Albert
File
Wanzer, Linda
Taylor, Laura
Radford, Kennett

**USUHS FORM 3202N
DANIEL K. INOUE GRADUATE SCHOOL OF NURSING
EVIDENCE-BASED PRACTICE/PERFORMANCE IMPROVEMENT PROPOSAL**

VPR Date Stamp

Project Number: GSN-61-10769 (VPR will assign)

Project Title: **Evaluation of Flexible Endoscope Reprocessing Programs**

SECTION A: STUDENT POC INFORMATION	
1. Name (Last, First, MI): Knigh, Albert R	Student E-mail: albert.knight@usuhs.edu
2. Home Address: [REDACTED]	
SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION	
3. Name (Last, First, MI): Rodriguez, Jose A	
4. Telephone: 301-295-1852 Fax:	E-mail: jose.rodriguez@usuhs.edu
5. USUHS Building/ Room No.: 74/E-1009	
SECTION C: PROJECT INFORMATION	
6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.	
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, complete below; if no, proceed to Part 8. Project Number: _____ Project Title: _____ Project Start Date: _____ Project End Date: _____	
8. Anticipated period of performance: Project Start Date: 6/1/2019 Project End Date: 4/30/2020	
9. Performance Site(s): USUHS	
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Do you have a funding source for this project? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NA If yes, specify the funding agency and the amount provided:	
SECTION D: SIGNATURES	
The following signatures attest to the validity of the above information:	
KNIGHT,ALBERT.RANDALL [REDACTED] _____ Student (Project Point of Contact for the Group) (Signature and Date)	RODRIGUEZ,JOSE.A. [REDACTED] _____ Chair/Senior Mentor (Signature and Date)
WANZER,LINDA.JEANNE. [REDACTED] _____ Chair/Program Director (Signature and Date)	WANZER,LINDA.JEANNE. [REDACTED] _____ Chair/Program Director (Signature and Date)
WANZER,LINDA.JEANNE. [REDACTED] _____ DNP Project Director or PhD Director (Signature and Date)	SEIBERT,DIANE.C. [REDACTED] _____ Associate Dean for Academic Affairs, GSN (Signature and Date)
WASSERMAN,JOAN.E [REDACTED] _____ Associate Dean for Research, GSN (Signature and Date)	ROMANO,CAROL.A. [REDACTED] _____ Dean, DK1 Graduate School of Nursing (Signature and Date)
In light of the above signatures, the project is approved.	
[REDACTED] _____ USUHS Vice President for Research	<u>2 Aug 2019</u> Date

Appendix C: Letter of Determination



Appendix C: Daniel K. Inouye Graduate School of Nursing
DNP Project Team Mentor (Committee Membership) Agreement Form

DOCTOR OF NURSING PRACTICE PROJECT
DNP Project Clinical Question and Team Mentor (Committee Membership) Agreement Form

Graduation Year:

Name(s) of DNP Project Student Team:

- | | | | | | | | | | | | | |
|----|-----------------|----------------|-------|-------------------------------------|-----|--------------------------|-------|--------------------------|-----|--------------------------|------|--------------------------|
| 1. | Albert R Knight | Phase II Site: | AGCNS | <input checked="" type="checkbox"/> | FNP | <input type="checkbox"/> | PMHNP | <input type="checkbox"/> | RNA | <input type="checkbox"/> | WHNP | <input type="checkbox"/> |
| 2. | | Phase II Site: | AGCNS | <input type="checkbox"/> | FNP | <input type="checkbox"/> | PMHNP | <input type="checkbox"/> | RNA | <input type="checkbox"/> | WHNP | <input type="checkbox"/> |
| 3. | | Phase II Site: | AGCNS | <input type="checkbox"/> | FNP | <input type="checkbox"/> | PMHNP | <input type="checkbox"/> | RNA | <input type="checkbox"/> | WHNP | <input type="checkbox"/> |
| 4. | | Phase II Site: | AGCNS | <input type="checkbox"/> | FNP | <input type="checkbox"/> | PMHNP | <input type="checkbox"/> | RNA | <input type="checkbox"/> | WHNP | <input type="checkbox"/> |
| 5. | | Phase II Site: | AGCNS | <input type="checkbox"/> | FNP | <input type="checkbox"/> | PMHNP | <input type="checkbox"/> | RNA | <input type="checkbox"/> | WHNP | <input type="checkbox"/> |
| 6. | | Phase II Site: | AGCNS | <input type="checkbox"/> | FNP | <input type="checkbox"/> | PMHNP | <input type="checkbox"/> | RNA | <input type="checkbox"/> | WHNP | <input type="checkbox"/> |

The tentative title of the DNP Project Proposal for this student group is:

Standardization of High Level Disinfection Education Project.

Committee Approved DNP Project Clinical Question:

Will performing a program evaluation of a flexible endoscope reprocessing programs from industry partners compared to professional, federal, and regulatory guidelines result in the identification of a program that supports best practices in high level disinfection that can be standardized across the Military Health System (MHS)?

Names of DNP Project Team Mentors (type the name and obtain signatures):

I agree to serve as a member of the DNP Project Team (Team Mentors) for the above DNP Student Project Team. As a Project Team Mentor, I agree to the duties and responsibilities outlined within the DNP Project Manual which include but are not limited to the provision of consultation and guidance supporting the entire DNP project journey and to ensure the DNP project is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation.

NOTE: You may have 3-4 DNP Team Mentors [committee members including your DNP Senior Mentor (Chair)]. The Phase II Site Director may also be a member of the group, as well as other USUHS faculty or others who may serve as content experts. All non-USUHS faculty selected as a Team Mentor must be approved by the DNP Project Director.

Senior Mentor (Chair): Dr. Linda Wanzer	Signature		Date: 2 Aug 2018
Team Mentor (Committee): LtCol Jeffrey Oliver	Signature		Date: 3 Aug 2018
Team Mentor (Committee): MAJ Jose Rodriquez	Signature		Date: 3 Aug 2018

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Appendix D: PAO Clearance for USUHS Archives

Appendix E: Face to Face Best Practices Education Delivery Platform Audit Tool

Face to Face Best Practices Teaching Elements	References
<u>Education programs should have specific:</u>	
A) Education curriculum	Chiu et al., 2018; Dumestre, Yeung, & Temple-Oberle, 2014; Fecso et al., 2017
B) Goals	Bosse et al., 2015; Chiu et al., 2018; Dumestre, Yeung, & Temple-Oberle, 2014; Fecso et al., 2017
C) Outcomes	Chiu et al., 2018; Motola, Devine, Chung, Sullivan, & Issenberg, 2013; Meyers et al., 2011
<u>Knowledge assessment measured by:</u>	
A) Pretest	Grantcharov & Reznick, 2008; McSparron, Vanka, & Smith, 2018; Motola, Devine, Chung, Sullivan, & Issenberg, 2013
B) Knowledge checks	Fecso et al., 2017; Motola, Devine, Chung, Sullivan, & Issenberg, 2013; Safabakhsh, Irajpour, & Yamani, 2017
C) Posttests	Fecso et al., 2017; Landdalen, Abrahamsen, Sollid, Sorskar, & Abrahamsen, 2018; McSparron, Vanka, & Smith, 2018
<u>Interactive learning:</u>	
Video	Bosse et al., 2015; Hope, Garside, & Prescott, 2011; Meyers et al., 2011
<u>Simulations:</u>	
A) Real world scenarios	Chiu et al., 2018; Palter, Orzech, Reznick, & Grantcharov, 2013; Safabakhsh, Irajpour, & Yamani, 2017
B) Case studies	Dumestre, Yeung, & Temple-Oberle, 2014; Nesbitt, Phillips, Searle, & Stansby, 2015; Safabakhsh, Irajpour, & Yamani, 2017
Lab traditional	Fecso et al., 2017; Motola, Devine, Chung, Sullivan, & Issenberg, 2013; Sood, Jeong, Ahlawat, Campbell, & Aggarwal, 2015
Lab (virtual reality)	McSparron, Vanka, & Smith, 2018; Nesbitt, Phillips, Searle, & Stansby, 2015; Palter, Orzech, Reznick, & Grantcharov, 2013
<u>Education sessions should be:</u>	

A) Short in duration	Fecso et al., 2017; Meyers et al., 2011; Palter, Orzech, Reznick, & Grantcharov, 2013
B) Small in size	Bosse et al., 2015; Sood, Jeong, Ahlawat, Campbell, & Aggarwal, 2015; Touchie & Humphrey-Murto, 2013
C) Provide one on one instructions	Dumestre, Yeung, & Temple-Oberle, 2014; Grantcharov & Reznick, 2008; Safabakhsh, Irajpour, & Yamani, 2017
<u>Instructor feedback:</u>	
A. During training	Fecso et al., 2017; Landdalen, Abrahamsen, Sollid, Sorskar, & Abrahamsen, 2018; Motola, Devine, Chung, Sullivan, & Issenberg, 2013
B. After training	Chiu et al., 2018; Nesbitt, Phillips, Searle, & Stansby, 2015; Touchie & Humphrey-Murto, 2013
<u>Student feedback:</u>	
A. During training	Landdalen, Abrahamsen, Sollid, Sorskar, & Abrahamsen, 2018; Motola, Devine, Chung, Sullivan, & Issenberg, 2013; Safabakhsh, Irajpour, & Yamani, 2017
B. After training	Landdalen, Abrahamsen, Sollid, Sorskar, & Abrahamsen, 2018; Sood, Jeong, Ahlawat, Campbell, & Aggarwal, 2015; Touchie & Humphrey-Murto, 2013

Appendix F: Web-Based Best Practices Education Delivery Platform Audit Tool.

Web-Based Best Practices Teaching Elements	References
<u>Interactive learning through multimedia:</u>	
A) Graphics	Pinchevsky & Dunbar, 2015; Sun & Chen, 2016; Wasim, Sharma, Khan, & Siddiqui, 2014
B) Audio	Krebritchi, Lipschuetz, & Santiago, 2017; Pinchevsky & Dunbar, 2015; Roddy et al., 2017
C) Animation	Lehmann et al., 2019; Malamed, 2019; Rusli & Negara, 2017;
D) PowerPoint	Miller, 2015; Moore, 2013; Wanner, 2015
E) Webinars	Ebner & Gegenfurtner, 2019; Lieser, Taff, & Murphy-Hagan, 2018; McKinney, 2017
F) Virtual Reality	Das, 2019; Peck, 2018; Quigley, 2018
G) Video Conference	Al-Samarraie, 2019; Aslam, 2017; Pandey & Pande, 2014
<u>Short education sessions</u>	
<u>Education programs should have:</u>	
A) Education curriculum	Deejring, 2014; Nordin & Alias, 2017; Pinchevsky & Dunbar, 2015; Roddy et al., 2017
B) Goals	Das, 2019; Ebner & Gegenfurtner, 2019; McKinney, 2017; Roddy et al., 2017
C) Outcomes	Cooper, 2016; Deejring, 2014; Greany, 2018; Lieser, Taff, & Murphy-Hagan, 2018
<u>Knowledge assessment measured by:</u>	
A) Pretest	Ebner & Gegenfurtner, 2019; Krebritchi, Lipschuetz, & Santiago, 2017; Nordin & Alias, 2017; Sun & Chen, 2016
B) Knowledge checks	Cooper, 2016; McKinney, 2017; Roddy et al., 2017; Wasim, Sharma, Khan, & Siddiqui, 2014
C) Posttests	McCallum, 2014; Nordin & Alias, 2017; Pinchevsky & Dunbar, 2015; Sun & Chen, 2016
<u>Student feedback:</u>	
A) Before education sessions begin	Deejring, 2014; Ebner & Gegenfurtner, 2019; Roddy et al., 2017; Sun & Chen, 2016
B) During education sessions	Pinchevsky & Dunbar, 2015; Roddy et al., 2017; Sun & Chen, 2016; Wasim, Sharma, Khan, & Siddiqui, 2014

C) After education sessions are completed	Krebitchi, Lipschuetz, & Santiago, 2017; McCallum, 2014; Roddy et al., 2017; Sun & Chen, 2016
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Appendix G: Training Manual Best Practices Education Delivery Platform Audit Tool.

Training Manual Best Practice Teaching Elements	References
<u>Education programs should have specific:</u>	
A) Education curriculum	Amidor, 2016; Gertz, 2017; Jones, 2014; Sembai, 2019
B) Goals	Gertz, 2017; Jones, 2014; Murray, 2011; Sembai, 2019
C) Outcomes	Dalto, 2014; Lanigan, 2010; Parandavar, Rezaee, & Mosallanejad, 2019; Sembai, 2019
<u>Knowledge assessment measured by:</u>	
A) Quizzes	Gertz, 2017; Lanigan, 2010; Murray, 2011; Wagner, Dorrenbacher, & Perels, 2014
B) Tests	Amidor, 2016; Gertz, 2017; Jones, 2014; Sembai, 2019
C) Knowledge checks	Dalto, 2014; Lanigan, 2010; Sembai, 2019; Stodel et al., 2015
<u>Interactive learning:</u>	
A) Text	Amidor, 2016; Jones, 2014; Parandavar, Rezaee, & Mosallanejad, 2019; Sembai, 2019
B) Graphics	Amidor, 2016; Dalto, 2014; Jones, 2014; Sembai, 2019
C) Visual images	Gertz, 2017; Lanigan, 2010; Sembai, 2019; Wagner, Dorrenbacher, & Perels, 2014
Short educational sessions	Dalto, 2014; Gertz, 2017; Lanigan, 2010; Sembai, 2019
Supplemental material provided	Amidor, 2016; Dalto, 2014; Jones, 2014; Sembai, 2019
Written for target audience	Jones, 2014; Lanigan, 2010; Parandavar, Rezaee, & Mosallanejad, 2019; Sembai, 2019
Allow student feedback	Dalto, 2014; Sembai, 2019; Stodel et al., 2015; Wagner, Dorrenbacher, & Perels, 2014

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Appendix H: DNP Project Completion Verification Form