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Achieving High Reliability in High-Level Disinfection of Flexible Endoscopes at Walter Reed National Military Medical Center

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Abstract

Phase II Site: Walter Reed National Military Medical Center (WRNMMC)

DNP Project Title: Achieving High Reliability in High-Level Disinfection of Flexible Endoscopes at Walter Reed National Military Medical Center

Authors: Fedderson, D. and Romito, K.

Background or Problem/Issue: The intricate design of flexible endoscopes and multi-step processes for cleaning and high-level disinfection (HLD) make the process of HLD vulnerable to human error. Missing one step or failure to complete any phase in the process can result in patient exposure to harmful contaminants which can lead to infections, increased hospital stays, increased medical costs, and even death.

Clinical Question or Purpose: At WRNMMC, will an evidence-based audit process for program evaluation of HLD, compared to current practice, support a high reliability organization's (HRO) goal to achieve quality, safety, and continuous process improvement?

Project Design: Donabedian's *Lasting Framework for Health Care Quality* was the overarching organizing framework for this project. The CDC *Program Evaluation* and *Audit Quality Loop* frameworks guided the evaluation conducted over 11-months. Variances were identified and analyzed, with evidence-based recommendations and outcome achievements disseminated based on HRO goals.

Results: Four recurrent audit feedback cycles related to measures of adherence to 65 steps in the HLD process were conducted across five clinics. HLD performance improved 5.5% (91.4% to 96.9%) with the identification of 41 clinical discrepancies and 31 practice improvements, as well as, the implementation of 22 system/process initiatives impacting over 135 areas across the

organization. These initiatives included policy changes, process and organizational structure improvements, equipment standardization, and leadership buy-in that fostered a culture of safety.

Organizational Impact/Implications for Practice: Implementing recurrent audits increased compliance of HLD standards, policy, and equipment standardization across all areas conducting HLD at WRNMMC with a third order effect of decreasing patient exposure from contaminated endoscopes. The combined use of audits at prescribed intervals and leadership support created a culture that embraced both HRO goals of quality, safety, and continuous process improvement, and aligned with the Military Health System Quadruple Aim.

Achieving High Reliability in High-Level Disinfection of Flexible Endoscopes at Walter Reed National Military Medical Center

Over 18 million diagnostic and therapeutic procedures are performed using flexible endoscopes in the United States every year (Peery et al., 2012). According to the U.S. Food and Drug Administration (FDA), the complex design of flexible endoscopes may impede cleaning and expose patients to the risk of infection (FDA, 2015). The intricate design of flexible endoscopes involves multiple narrow lumen channels designed to accommodate the passage of instruments, air, tissue, and fluids along the length of the device.

The occurrence of infections associated with endoscopes and increased noncompliance with The Joint Commission's (TJC) Infection Prevention and Control Standard IC.02.02.01 warrants an in-depth evaluation of how endoscopes are being reprocessed in healthcare facilities in the U.S. (TJC, 2015). TJC responded to reprocessing inaccuracies by developing the High-Level Disinfection (HLD) and Sterilization BoosterPak (TJC, 2015). The goal of TJC's BoosterPak is to provide a tool for healthcare organizations to guide the implementation of "regulatory standards and evidence-based guidelines for HLD and sterilization to minimize the potential risk of infection transmission to patients" (TJC, 2015, p. 3).

In 2015, the Centers for Disease Control and Prevention (CDC) issued a call to action in response to the recent adverse events related to inaccurately processed endoscopes (CDC, 2015a). The call to action emphasized the need for the evaluation of the HLD program with the use of audits and feedback (CDC, 2015a). These recommendations were further refined by the Healthcare Infection Control Practices Committee's *Essential Elements of a Reprocessing Program for Flexible Endoscopes* in 2017 (CDC, 2017a). According to the CDC (2017a), a comprehensive HLD program with buy-in from key stakeholders is crucial to achieving high-

reliability in endoscope reprocessing and providing the infrastructure necessary to support, "training and competencies, quality measurement, and management" (p. 1). Shortly after, the Defense Health Agency (DHA) issued a procedural instruction requiring the implementation of a comprehensive infection prevention plan across the Military Health System (MHS) (DHA, 2017). The DHA directive outlines how leadership involvement and accountability is essential to establishing a highly reliable HLD program supporting a culture that embraces Highly Reliable Organizations (HRO) principles. Also in 2017, the Deputy Surgeon Generals of the Army, Air Force, and Navy issued Memos stating that all Military Treatment Facilities (MTF) will evaluate their HLD programs to ensure compliance with manufacturer Instructions For Use (IFU). Walter Reed National Military Medical Center (WRNMMC) responded to these calls to action by establishing a HLD taskforce in August of 2017 to improve care related to endoscopic procedures.

The purpose of this project is to conduct a current state assessment of the HLD program at WRNMMC and perform repetitive audits at prescribed intervals while providing organizational leadership with evidence-based recommendations to improve practice/processes in support of continuous process improvement and a culture supporting HRO.

Significance of the Problem

Endoscope Related Infections

Inaccurate processing of endoscopes places patients at risk for exposure to potentially life-altering infections (Spruce, 2015). Examples of infections from exposure to contaminated endoscopes include hepatitis C, human immunodeficiency virus (HIV), and life-threatening multidrug-resistant organisms (MDRO). Additionally, the cost of hospital acquired infections, such as those transmitted from contaminated endoscopes, costs $16.6 billion annually, which

could lead to three days of hospitalization with an associated cost of over $10,000 per patient (Hassan, Tuckman, Patrick, Kountz & Kohn, 2010).

According to Terhune (2016), over 350 civilian sector patients at 41 different treatment facilities have been exposed to contaminated endoscopes between the years 2010 and 2015. This report represents a significant number of patients impacted by unreliable HLD processes throughout the country. In 2012, an outbreak of the MDRO CRE resulted in over 12 deaths due to improper cleaning of the elevator mechanism of the distal tip of certain endoscopes specialized for endoscopic retrograde cholangiopancreatography (ERCP) (CDC, 2015; Eisler, 2015). TJC responded to these outbreaks by creating Infection Prevention and Control Standard IC.02.02.01 and the HLD and sterilization Boosterpak to help health care organizations achieve high reliability in endoscope reprocessing (TJC, 2015).

Endoscope Reprocessing

There are eight phases of HLD, and with each step careful attention to best practices should be followed to ensure endoscopes are safe for patient use (Drosnock, 2016). Human error in performing recommended reprocessing steps has been identified as the main cause of endoscopy-associated infections (Bourdon, 2015). Although professional organizations have established guidelines for reprocessing endoscopes, it is important to note that each endoscope, reprocessing device, or disinfecting agent used in the HLD process has a manufacturer's IFU that must be followed. Manufacturer IFUs provide validated guidance for the proper use and care of equipment specific to each device. This provides an additional requirement, on top of established HLD steps, that must be followed to ensure safety parameters are met throughout the HLD process. Table 1 outlines and defines the phases of the HLD process.

Table 1. *Terms and Definitions of HLD Steps with Best Practice Recommendations*

Term	Definition/Recommended Practice
Pre-cleaning (Point of Use)	Performed in the treatment room immediately after the endoscope is removed from the patient. It consists of wiping the exterior of the endoscope and flushing the channels with detergent, water, and air. This step is critical in preventing the formation of biofilm, which if formed, could reduce the effectiveness of subsequent cleaning steps (Kim & Muthusamy, 2016).
Transportation	Moving the endoscope from the patient treatment room to the decontamination and HLD area, from the HLD area to storage, and from the storage cabinet to the patient treatment room for use. During transport, the endoscope should be coiled loosely and placed in a container with an impervious barrier to prevent contamination (Klacik, 2015).
Leak Testing	The endoscope is tested manually or by a machine to determine the integrity of or damage to the endoscope. If damage is detected the endoscope must be removed from patient use if there is no leak detected subsequent steps might be performed. Leak testing should be performed as soon as possible on a surface large enough to ensure the endoscope is not coiled too tightly which could mask holes or damage (Drosnock, 2016).
Manual Cleaning	Manual cleaning of the entire endoscope including all valves, channels, elevators, and detachable parts using an approved enzymatic cleaner. Proper detergent concentrations, brushing, flushing, and rinsing instructions should be closely followed as directed by the manufacturer IFU (Kim & Muthusamy, 2016).
HLD	Immersion of the endoscope by a biocidal agent to destroy most microorganisms except for spores, preferably performed in an AER to improve compliance and minimize human error (Kim & Muthusamy, 2016).
Drying	The exterior of the endoscope should be dried with a clean, lint-free cloth, and channels should be flushed with alcohol and medical grade forced air (Drosnock, 2016).
Storage	The endoscope should hang vertically to promote drying, in a closed, ventilated cabinet. Recommended standards have not been established on how many days an endoscope may hang before needing to be reprocessed, but 5-7 days is an average acceptable time according to current literature (Hansen, 2016).

Table 2 highlights best practices in each phase of the HLD process as identified in the literature review. These best practices coincide with current guidance published by national organizations such as AAMI and AORN.

Table 2. *HLD Best Practices*

Best Practices	References
Pre-cleaning should begin in the treatment room immediately after removal of the endoscope from a patient to prevent the development of biofilm. Manufacturer's IFU should always be followed.	Drosnock, 2016; Edmiston & Spencer, 2014b; Humphries & McDonnell, 2015; Mathias, 2015; Roberts, 2013; Young, 2012
Manual cleaning should be performed without delay after leak testing has confirmed that the endoscope is not damaged. Proper detergent should be used, and proper brushing, flushing, and rinsing should be performed by the manufacturer's IFU.	Drosnock, 2016; Kim & Muthusamy, 2016; Kovaleva et al., 2013
HLD should be performed using a validated AER to minimize human error and should strictly adhere to manufacturer's IFU regarding disinfectants used, contact time, and rinsing.	Drosnock, 2016; Humphries & McDonnell, 2015; Kim & Muthusamy, 2016; Kovaleva et al., 2013;
Use of alcohol and medical grade air should be used to ensure that interior channels of the endoscope are dry before storage.	Drosnock, 2016; Humphries & McDonnell, 2015; Kovaleva et al., 2013; Muscarella, 2014; Roberts, 2014
Storage cabinets should be dust free and well ventilated. Endoscopes should hang vertically, however, recommended length of time an endoscope may hang before needing to be reprocessed varies and should be determined by the facility.	Hansen, 2016; Kim & Muthusamy, 2016; Klacik, 2015; Kovaleva et al., 2013; Patterson, 2013

Table 3 highlights the main barriers for inadequate HLD practices. Two major themes related to barriers that emerged from the literature review are complex design of endoscopes and

human error in performing the HLD steps. This table also references adjuncts (biological culture surveillance) and alternatives to the HLD process (endoscope sterilization).

Table 3. *Barriers to Performing HLD*

Barriers to HLD	References
Intricate design of the endoscope, and multiple, complex steps of the HLD process.	Bourdon, 2015; da Costa Luciano et al., 2016; Edmiston & Spencer, 2014a; Edmiston & Spencer, 2014b; Humphries & McDonnell, 2015; Kim & Muthusamy, 2016; Mathias, 2015; Muscarella, 2014; Ofstead et al., 2015; Roberts, 2013
Inadequate training, performance, and oversight.	Bourdon, 2015; Drosnock, 2016; Edmiston & Spencer, 2014a; Hansen, 2016; Humphries & McDonnell, 2015; Kim & Muthusamy, 2016; Klacik, 2015; Mathias, 2015; Mathias, 2014; Muscarella, 2014; Ofstead et al., 2015; Patterson, 2013
Sterilization is an alternative in limited situations; however, it has several drawbacks and has not been proven to be any more effective than HLD for endoscopes.	Humphries & McDonnell, 2015; Kim & Muthusamy, 2016; Kovaleva et al., 2013; Muscarella, 2014
Biological culture surveillance might prove beneficial in verifying HLD performance, but studies are inconclusive.	Drosnock, 2016; Humphries & McDonnell, 2015; Kim & Muthusamy, 2016; Kovaleva et al., 2013; Ofstead et al., 2015; Ofstead et al., 2016; Ofstead et al., 2017; Wicklin, 2016; Young, 2012

Spaulding Classification

How medical devices are reprocessed varies according to their Spaulding Classification of either non-critical, semi-critical, or critical (TJC, 2015). Non-critical items come into contact with intact skin. Examples include blood pressure cuffs, electrocardiogram leads, and stethoscopes. According to the Association of periOperative Registered Nurses (AORN), non-critical items receive low-level or intermediate-level decontamination with low/intermediate-level disinfectants and kill vegetative bacteria, lipid viruses, and some fungi (AORN, 2017).

Semi-critical items come into contact with non-intact skin and mucous membranes. Examples include laryngoscopes, bronchoscopes, and colonoscopes. Semi-critical items require high-level disinfection (HLD) killing all bacteria, viruses, and fungi but do not kill all bacterial spores (AORN, 2017). Critical items come into contact with sterile body spaces. Examples include surgical instruments, urinary catheters, and intravenous catheters. Critical items require sterilization to ensure the killing of all microorganisms and spores (AORN, 2017).

HLD versus Sterilization of Endoscopes

According to the Spaulding Classification, endoscopes are classified as semi-critical devices and require HLD (TJC, 2015). Assumptions could be made that the problems associated with the reprocessing of semi-critical devices would be solved by processing them as critical items and terminal sterilization. However, whether endoscopes are terminally sterilized or receive HLD does not account for reprocessing inaccuracies (Spruce, 2015). The process of HLD requires proper point of use cleaning, transport, leak testing, manual cleaning, flushing, brushing, inspection, exposure to an HLD agent or processor, drying of channels, storage, and record keeping (AAMI, 2017). Endoscopes will remain contaminated and present a potential risk for exposure to infectious agents even if the device was processed with a sterilization cycle if these steps are not performed reliably. However, according to the CDC, sterilization of endoscopes has been found to be incompatible with several endoscopes, can lead to prolonged processing times, aeration times, and can expose healthcare workers to toxic sterilizing agents (CDC, 2015).

HLD Issues within the Federal Healthcare System

The federal health system has encountered problems achieving high-reliability in endoscope reprocessing. An incident involving the exposure of 267 service-connected patients to HIV and Hepatitis C was documented in Roeder's (2016) article about an Air Force Academy

clinic where a technician was not following HLD procedures per regulatory standards, manufacturer's IFU, and evidence-based literature. Another incident between the years 2008 and 2016 involved at least 135 patients exposed to contaminated endoscopes at Al Udeid Air Force Base (Perez, 2017). These two examples illustrate how inaccurate endoscope reprocessing has impacted the military health system. It is important to note that Roeder's (2016) example impacted readiness for service members and their families serving in the continental U.S. The exposure of patients to contaminated endoscopes in Perez's (2017) article is an example of how inaccurate endoscope processing can impact the readiness of the service member who is deployed overseas in an operational environment. Contaminated endoscopes have also impacted The US Department of Veteran Affairs (VA) healthcare facilities. In 2009, more than 10,000 VA patients were exposed to contaminated endoscopes across three different VA facility locations (Pifer-Bixler, 2009).

The Call for High Reliability in the Federal Healthcare System

In 2014 the Secretary of Defense Chuck Hagel called for a comprehensive 90-day review of the Federal Healthcare System (FHS) (Department of Defense, 2014). This was a call to action in response to recent adverse events involving patient care that received national attention. The 90-day review of the MHS resulted in several recommendations set forth to align the FHS with top performing healthcare facilities in the United States (DoD, 2014). The DoD review recommended that the FHS employ principles of Highly Reliable Organizations (HRO). The five principles of HRO include: preoccupation with failure, reluctance to simplify, sensitivity to operations, commitment to resilience, and deference to expertise (Chassin & Loeb, 2013). According to Chassin and Loeb (2013), HRO principles are effective in increasing the quality of programs involving complex processes such as HLD, and fostering a culture where, "errors and

unsafe conditions are recognized early and prevented by rapid remediation from causing harm" (p. 465).

CDC Call to Action

In 2013, a hospital in Illinois reported an outbreak of *carbapenem-resistant enterobacteriaceae* (CRE) attributed to improperly processed endoscopes (Muscarella, 2016). The CRE outbreak prompted the CDC to investigate and review the hospital's HLD program resulting in a report posted to *The Morbidity and Mortality Weekly Report* in 2014 (CDC, 2014). In 2015, the CDC issued a national alert related to endoscope reprocessing citing the complex design of endoscopes as a barrier to reliable reprocessing (CDC, 2015b). The CDC's alert called for organizations to evaluate their HLD programs to determine how endoscopes were being reprocessed, assess staff competency and training, and leadership accountability for the process.

DHA responded to the CDC's alert with the development of the Comprehensive Infection Prevention and Control Program directive (DHA, 2017). This directive established a program for infection prevention that emphasized leadership accountability while achieving improved patient outcomes using the principles of HROs. In 2017, the Deputy Surgeon Generals of the Army, Air Force, and Navy began to operationalize this directive by issuing memorandums related to endoscope reprocessing. These memorandums required the services to evaluate their HLD programs and adherence with manufacturer IFUs, as well as evaluating patient safety concerns and the establishment of a culture of high reliability. In response to these calls to action, the leadership at WRNMMC directed the formation of a multidisciplinary HLD taskforce to assess their HLD program to improve quality of care in line with the organization's goal to achieve high reliability.

Use of Audit Science to Improve HLD

Since the early 1900s, the use of audits has been found to improve outcomes in patient care settings especially when dealing with processes that involve complicated and high-risk steps (Lembke, 1956). The American College of Surgeons and TJC were established as auditing bodies to help bolster the credibility and safety of healthcare since the 1950s (Lembke, 1956). In the clinical setting, audits have been used to measure "a clinical outcome or process, against well-defined standards set on the principles of evidence-based medicine in order to identify the changes needed to improve quality of care" (Esposito & Canton, 2014, p. 249). Based on synthesis of the literature related to healthcare quality and process improvement, best practices and barriers to the use of audits to improve clinical outcomes have been identified. A literature search of CINAHL using the search terms*: audit, clinical outcomes, and healthcare quality* and resulted in 99 articles. The PubMed database was searched using the MeSH terms *medical audit, nursing audit, and clinical audit* and resulted in 145 articles. Articles were excluded if they did not include information about audits leaving 20 articles included for synthesis. An additional four articles were excluded that mentioned the use of clinical audits but did not elaborate on the effects audits had on healthcare quality and process improvement resulted in 16 articles for final synthesis as listed in Table 4.

Table 4. *Best Practice of Clinical Audit Implementation*

Best Practice	References
Utilize audit quality feedback loop administered at regular intervals consistently over time (see Figure 1)	Cooper & Benjamin, 2003; Esposito & Canton, 2014; Gillam & Siriwardena, 2013; Hanskamp-Sebregts et al., 2013; Higginson et al., 1996; Jamtvedt et al., 2003; Patel, 2010; Selman & Harding, 2010; Wilson, 1999
Audit measures clinical practice against well-established standards and/or evidence-based	Duro, 2016; Duro, 2017; Esposito & Canton, 2014; Gillam & Siriwardena, 2013; Hindley,

practice	2014; Hughes, 2008; Johnston et al., 1999; Wilson, 1999
Audits should incorporate a multidisciplinary approach with an established leader or facilitator	Cooper & Benjamin, 2003; Duro, 2017; Hindley, 2014; Johnston et al., 1999; Lord & Littlejohns, 1996; Patel, 2010
Audits should assess leadership, education, training, and competency in addition to clinical practices	Duro, 2016; Higginson et al., 1996; Hindley, 2014; Hughes, 2008; Lembcke, 1956; Selman & Harding, 2010; Wilson, 1999

When performing audits, a quality loop can be used to implement audit best practices to create a cyclic feedback process in order to impact endoscope reprocessing accuracy. According to Esposito and Canton (2014), the audit quality loop is a five-step process and intended to be cyclical (see figure 1). The most important aspect of the audit quality loop is that feedback is shared with stakeholders by completing the audit quality feedback loop. Jamtvedt et al. (2003) described the failure of completing the audit quality loop to be the most common barrier to process improvement.

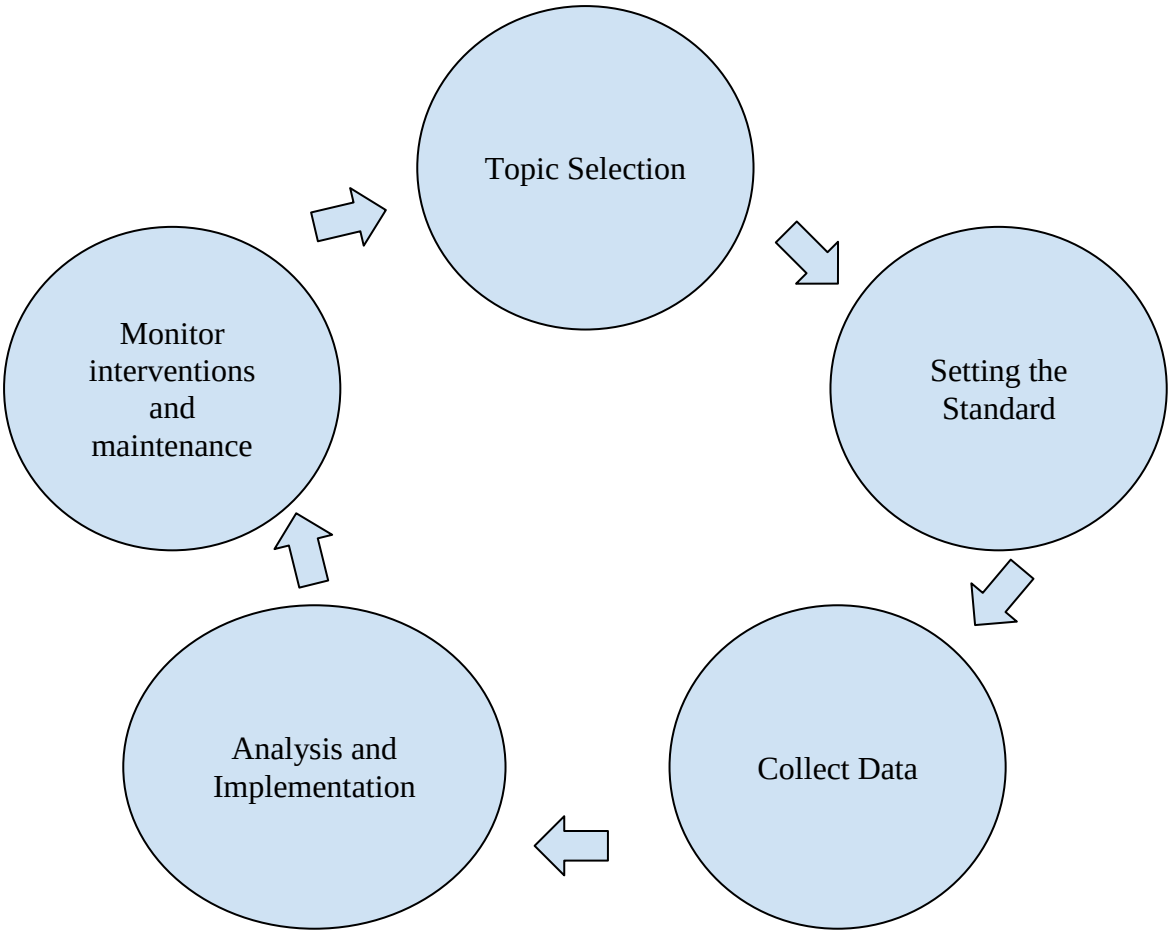


Figure 1. Audit Quality Loop. Modified from "Clinical audit, a valuable tool to improve quality of care: General methodology and applications in nephrology" by Esposito, P., and Canton A., 2014, World Journal of Nephrology, 3(4), p. 250.

According to a systematic review of 140 audit studies, it was found that common barriers to successful audits are failure to follow through with intervention, feedback, recommendations, and monitoring, had zero impact on improving the performance and outcomes in healthcare organizations (Jamtvedt et al., 2003). Additionally, Jamtvedt et al. (2003) suggested that feedback should be given in multiple formats to include written and verbal demonstration. A prescribed frequency or duration for completing the audit quality loop was not uncovered. However, according to Patel (2010), a reasonable timeline for audit projects for healthcare

performance improvement projects is two to three months. Additional barriers to successful audit implementation are listed in Table 5.

Table 5. *Clinical Audit Barriers to Implementation*

Common Barriers	Reference
Audits are resource intensive, increased workload, time-consuming.	Cooper & Benjamin, 2003; Higginson et al., 1996; Hindley, 2014; Johnston et al., 1999; Lord & Littlejohns, 1996
Audits of complex multistep processes can be exhaustive	Duro, 2016; Hanskamp-Sebregts et al., 2013, Johnston et al., 1999
Audits have the greatest impact in areas where compliance is low or where guidelines have not yet been established.	Esposito & Canton, 2014; Hanskamp-Sebregts et al., 2013; Jamtvedt et al., 2003
Audits have zero impact without continuous feedback and consistent audit quality loop cycles.	Esposito & Canton, 2014; Gillam & Siriwardena, 2013; Hanskamp-Sebregts et al., 2013; Higginson et al., 1996; Hindley, 2014; Jamtvedt et al., 2003; Lord & Littlejohns, 1996; Selman & Harding, 2010

Auditing of HLD to improve process compliance with best practices can be used to improve clinical practice if used frequently. The review of the literature revealed if the frequency of auditing were to occur every two to three months, improvement in healthcare outcomes can be achieved. Success of the audit process relies on completion of the audit quality loop (see figure 1) to inform stakeholders of best practices and deficiencies uncovered during the audits to sustain continued progression towards high reliability of a HLD program.

Leadership

The leadership of healthcare organizations represents key stakeholders in determining the success of HLD programs. TJC's standard LD.01.03.01 (2015) holds the leadership "accountable for the safety and quality of care, treatment, and services" (p. 8). Leaders have the opportunity to

impact key decisions involved in HLD processes including the hiring of adequately trained staff, providing appropriate staffing ratios, overseeing initial and ongoing competency training, and empowering key personnel to champion HLD efforts (CDC, 2017). According to Chassin and Loeb (2013), administrative flexibility to value expertise over hierarchical ranking structure can help empower subject matter experts (SME) by employing the HRO principle of deference to expertise. This can be accomplished by engaging stakeholders in the HLD program, identifying SMEs, and cultivating champion users in each HLD setting.

Leadership working as a team with their SMEs can help shape HLD program policy underpinned by regulatory standards, manufacturer's IFUs, and evidence-based literature. The CDC (2017) recommends that policies be developed by a multidisciplinary team facilitating the participation of all stakeholders involved in HLD. The multidisciplinary team should include doctors, nurses, infection preventionists, technicians, and anyone involved with the reprocessing of semi-critical items. The team must align policies with directives from regulatory bodies such as the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the FDA, and the Centers for Medicare and Medicaid Services (CMS). The standards of accrediting agencies, such as TJC should also be included in policy development. Lastly, recommended standards for HLD from professional organizations such as AORN's Guidelines for periOperative Practice, the Association for the Advancement of Medical Instrumentation (AAMI), and the Society of Gastroenterology Nurses and Associates (SGNA) should be used to shape policy development (CDC, 2017).

According to TJC (2017) Leaders of HROs, such as hospital executives, department chiefs, clinic managers, infection preventionists, quality managers, and subject matter experts should engage in standardization of HLD processes. The number and brands of endoscopes and

endoscope reprocessing equipment are to be inventoried and cross-analyzed across organizations to facilitate standardization. AAMI (2017) suggests the centralization of the HLD processes due to the various environment of care design elements such as air exchanges, foot traffic flow design facilitating "clean to dirty" movement through the unit, space, temperature, and humidity. However, if centralized processing is not possible, the leadership oversight is essential to assuring standardization of the regulations, industry standards, policies, and standard operating procedures (SOP) in each satellite HLD location.

HLD at WRNMMC

Audits of HLD processes at WRNMMC have been conducted by Adult Gerontology Clinical Nurse Specialist with a Perioperative Foci (AG-CNS) students at the Uniformed Services University of the Health Sciences (USUHS) Graduate School of Nursing (GSN) annually since 2014. Formal audit reports were provided to the WRNMMC clinical leadership; however, an audit conducted in 2017 discovered that processes have not changed overtime. Based on this data, it was determined that audits conducted once a year were not effective in changing practice in support of best practices for HLD, which was also supported in the literature. A literature review and synthesis of audit science and HLD best practices (see table 2 & table 4) identified that audits conducted at three-month intervals with feedback to stakeholders is an evidence-based approach to drive change toward high reliability in endoscope reprocessing. Leadership at WRNMMC have responded to the recent call to action by the CDC for endoscope reprocessing program evaluation, the DHA Comprehensive Infection Prevention and Control Program directive, and the Deputy Surgeon Generals' memos to evaluate endoscope processing compliance with manufacturer IFUs. The leadership established a multidisciplinary task force for HLD, which included USUHS GSN AG-CNS students with the goal to assess the current state of

HLD across the organization to achieve high reliability and improved patient care related to endoscope reprocessing.

Summary

Exposure to contaminated endoscopes is a problem affecting patients in the civilian sector as well as those within the federal healthcare system. Patients in the civilian sector have died because of exposure to CRE contaminated endoscopes. Within the federal healthcare system, contaminated endoscope exposures have occurred in treatment facilities in the continental US, in austere operational environments during wartime efforts, and at VA treatment facilities. The complexity of endoscope design and reprocessing prevent sterilization from being a solution to reprocessing inaccuracies. TJC, the CDC, the DHA and professional organizations, such as AAMI and AORN, recommend how leadership should oversee the administration of the HLD program and as they are held accountable for the training, competency, and administration of HLD programs. According to the CDC (2017), a thorough evaluation of the HLD program is necessary to decrease infection risks to patients, achieve high-quality endoscope reprocessing, and create a culture of safety tantamount to organizations with the highest reliability. To achieve this goal of sustained high reliability in endoscope reprocessing, the use of audits performed every three months while completing the audit quality loop with each successive iteration is an evidence-based approach to achieve the goal of quality, safety, and continuous process improvement.

Clinical Question

This project will support the CDC and DHA recommendations to thoroughly evaluate HLD programs in an effort to decrease patient risk from endoscopes. This project will conduct a current-state assessment of the HLD program at WRNMMC and determine the impact of

frequent evidence-based audits on improving practice. The clinical question evaluated at a system's level is:

At WRNMMC, will an evidence-based audit process for a program evaluation of HLD, compared to current practice, support a highly reliable organization's goal to achieve quality, safety, and continuous process improvement?

Focus Areas

The focus areas for this project include:

1. Identify the current state of HLD at WRNMMC through an initial audit, gap analysis, and outline evidence-based recommendations.
2. Perform recurring audits and develop evidence-based recommendations for improved practice.
3. Conduct longitudinal synthesis of audit findings to support the organization's goal of quality, safety, and continuous process improvement.

Project Short and Long-Term Goals

There are three short-term goals of this project. They are to standardize HLD practices across the organization at WRNMMC to align with HRO principles; improve leadership oversight for the HLD process; and reduce practice variance to achieve quality, safety, and continuous process improvement. The long-term goal of this project is to create a culture at WRNMMC that embraces HRO principles in performing HLD. Once these goals are achieved, it can establish best practice strategies that other facilities within the MHS can adopt to achieve the DoD's goal to become a high-performing, highly reliable organization (DoD, 2014).

Relevance to Military Nursing

Military nurses provide care to service members, their families, and veterans. As flexible endoscopes have been identified as a potential risk for harm, it is important that precautions are taken to mitigate this risk to military beneficiaries (Spruce, 2015). When a service member is injured, infected, or otherwise unable to perform their duty, it impacts not only them, but the entire mission.

Military nursing is taking the lead in the evaluation of the entire HLD process at WRNMMC. They are leaders and often involved with committees or teams established to improve processes throughout the organization, aligning current HLD practices and policies with HRO principles. The role of the CNS as a leader, consultant, and clinical expert is an integral part of this team to influence practice change in support of quality, safety, and continuous process improvement. With the DoD's goal to become a High Reliable Organization and improve HLD across the MHS, military nurses will be the driving force to change practices and assist in the transformation of healthcare to improve safety and outcomes for our patients.

Organizing Framework

The framework for healthcare quality by Avedis Donabedian will be used to provide the organizing framework for this project. Donabedian's framework was the result of the U.S. Public Health Service's seminal effort to research quality assessment in healthcare organizations shortly after the creation of the CMS in 1965 (Ayanian, 2016). Donabedian's initial paper on the subject, *Evaluating the Quality of Medical Care*, has had a lasting impact on the empirical foundation of healthcare quality improvement research and remains one of the most commonly cited articles on the subject (Ayanian, 2016). Donabedian's framework will be used to outline the steps necessary

to assess the outcome of HLD program's efforts to support quality and safety (see Figure 2) (Donabedian, 1988).

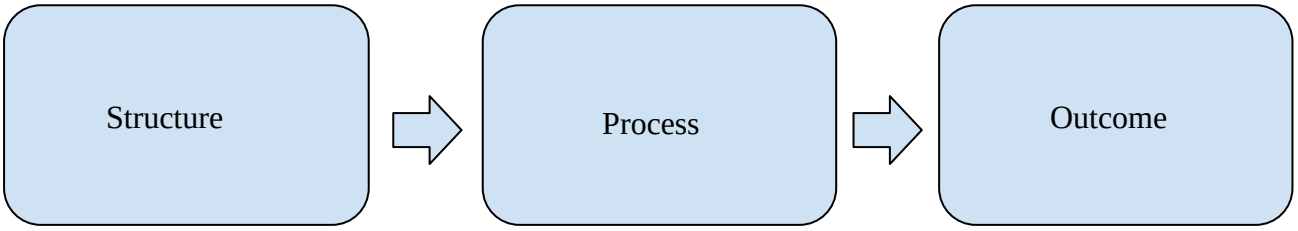


Figure 2. Organizing Framework. Modified from "The quality of care. How can it be assessed?" by Donabedian, A., 1988, Journal of the American Medical Association, 260(12), p. 1745.

Structure

Donabedian approaches the evaluation of healthcare programs with careful consideration of the program structure (Donabedian, 1988). Structure assessment includes evaluation of the healthcare organization's environment of care to include: facilities, materials, utility systems, and equipment (TJC, 2015). Examples of environment of care elements in a structural assessment for HLD includes temperature, humidity, and air exchanges of rooms where HLD takes place (AAMI, 2017). Focusing on the environment of care elements demonstrates the HRO principle of preoccupation with failure. Being able to detect early deviations from the standards, such as temperature, humidity, and air exchanges, can help prevent potential risk exposures during the process of HLD and exposing the patient to a contaminated endoscope (Chassin & Loeb, 2013). Additionally, structural assessment of healthcare programs includes the evaluation of leadership, methods of competency assessment, training, and human resources (Donabedian, 1988). According to TJC (2015), these leadership structures are essential to the quality and safety of the HLD program.

Process

The next step in Donabedian's framework for healthcare quality is to evaluate the program's processes and their potential impact on patient outcomes (Donabedian, 1988). According to Donabedian (2005), "the major mechanism for achieving levels of reliability is the detailed specification of criteria, standards, and procedures used for the assessment of care" (p. 708). When the process of HLD is assessed, practices are compared to regulatory standards, manufacturer's Instructions for Use (IFU), and evidence-based literature (TJC, 2015). Examples include standards and recommendations from organizations like Association for the Advancement of Medical Instrumentation (AAMI), AORN, The Society of Gastroenterology Nurses and Associates (SGNA), and the CDC. Assessing the process allows for key interactions with subject matter experts and identification of areas needing process improvement as highlighted by the HRO principle of deference to expertise (Chassin & Loeb, 2013).

Outcome

The relationship between structure and process improvement has been shown to lead to improved outcomes (Donabedian, 2005). After a thorough evaluation of the program's structure and processes, recommendations can be made to improve HLD outcomes. The gaps identified in practice compared to recommendations by manufacturer IFUs and professional organizations will be shared with stakeholders. This feedback should drive necessary changes to the structure and process of the HLD program to achieve the goal of increased reliability of endoscope reprocessing. By continuously auditing the process, sharing findings with stakeholders, closing the audit feedback cycle, and recommending best practices in HLD, the HLD taskforce should be empowered to "monitor performance to determine whether it continues to remain within acceptable bounds" (Donabedian, 1988, p. 176).

Summary

The progression through Donabedian's framework demonstrates a systematic approach to identify robust interventions within structure and processes leading to improved outcomes to advance to an HRO. Furthermore, in this project outcomes will be measured over time with the use of frequent audits to assess program evolution towards high reliability and the organization's commitment to resilience (Chassin & Loeb, 2013).

Project Design

General Approach

This project will include a current-state assessment of the HLD program at WRNMMC and measure outcomes from implementing multiple evidence-based audit processes. The CDC's framework for program evaluation was selected to be used as a procedural guide to perform an evaluation on HLD processes (see Figure 3). This framework was chosen because of the emphasis on procedural outcomes and reliance on standards from which the program is compared (CDC, 1999). Furthermore, the cyclical nature of this framework supports a process for the continued sustainment, monitoring, and auditing of HLD to enhance a culture of safety and high reliability.

Figure 3. A Framework for Program Evaluation. From "Program Performance and Evaluation" by the CDC, 2017b, Retrieved from https://www.cdc.gov/eval/framework/index.htm

After performing a baseline assessment of HLD practices at WRNMMC, a literature review of HLD best practices and audit science will be used to develop evidence-based recommendations for improved practice to key stakeholders. Recurring audits will be performed to track changes made based on these recommendations, and findings will be reported to leadership involved with the HLD process. Outcomes at the end of each audit will be compared to the baseline assessment to determine improvement of HLD program and progression towards becoming an HRO. Figure 4 illustrates a schematic diagram of how the CDC's Framework for Program Evaluation, Donabedian's Framework for Healthcare Quality, and the principles of HRO support this project's goal of quality, safety, and continuous process improvement.

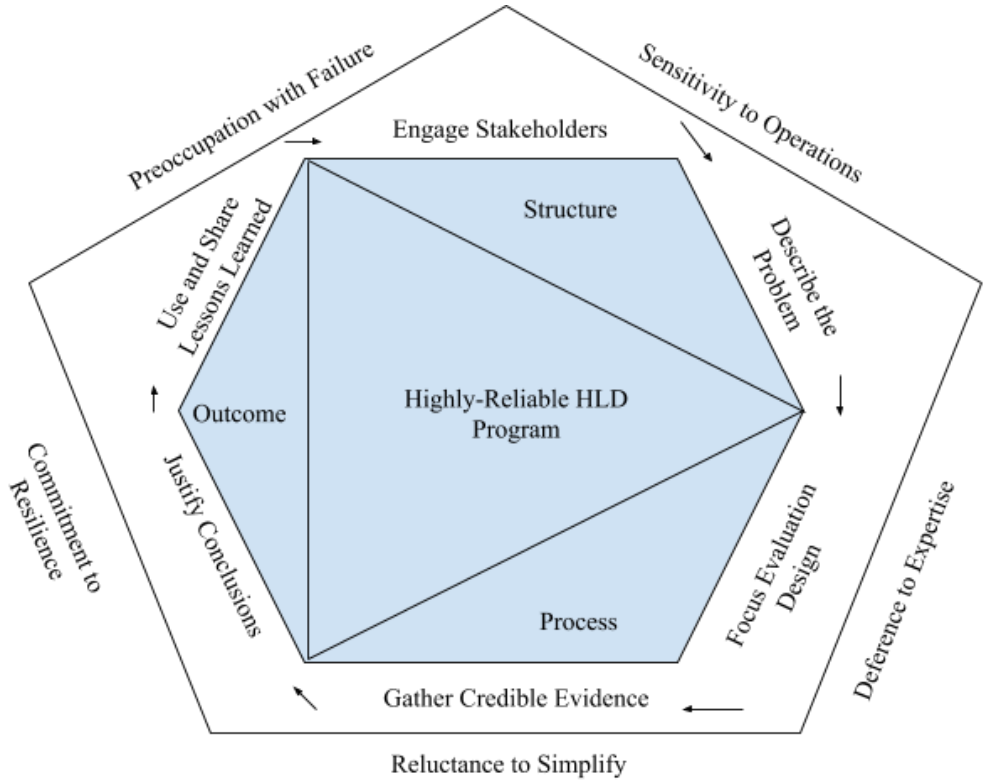


Figure 4. Project Procedural Steps. Modified from "The quality of care. How can it be assessed?" by Donabedian, A., 1988, Journal of the American Medical Association, 260(12), p. 1745, the CDC's (1999) "Framework for program evaluation in public health." Morbidity and Mortality Weekly Report, 48(R-11), p. 4, and Chassin and Loeb's (2013) "High-reliability health care: Getting there from here" Milbank Quarterly, 91(3), 461-462.

Setting

The setting for this project will be WRNMMC in the national capital region (NCR) military treatment facility (MTF). One of the busiest MTFs in the region, WRNMMC sees over one million beneficiaries per year, features 274 beds, and over 13,000 admissions per year (WRNMMC, 2017). At WRNMMC, there are 13 clinical sites involved with the use, transport, and/or reprocessing of endoscopes. Each clinical site will be included in the HLD program evaluation and are listed in Table 6.

Table 6. *WRNMMC Clinical Sites Involved with High-Level Disinfection*

Clinic/Department	HLD Processes Performed
Adult Gastroenterology Endoscopy (GI)	Treatment, POU cleaning, transport, leak testing, cleaning, inspection, HLD, transport, storage
Pediatric Gastroenterology Endoscopy (Peds GI)	Treatment, POU cleaning, transport, leak testing, cleaning, inspection, HLD, transport, storage
Pulmonary Clinic	Treatment, POU cleaning, transport, leak testing, cleaning, inspection, HLD, transport, storage
Respiratory Therapy	Treatment, POU Cleaning, transport
Urology Clinic	Treatment, POU cleaning, transport, leak testing, cleaning, inspection, low-temperature sterilization, transport, storage
Stone Center	Treatment, POU cleaning, transport, leak testing, cleaning, inspection, low-temperature sterilization, transport, storage
Cardiology Clinic	Treatment, POU cleaning, transport, leak testing, cleaning, inspection, HLD, transport, storage
Anesthesia	Treatment, POU Cleaning, transport
Ears, Nose, and Throat Clinic (ENT)	Treatment, POU cleaning, transport, leak testing, cleaning, inspection, HLD, transport, storage
Speech Pathology	Treatment, POU Cleaning, transport
Radiology Oncology	Treatment, POU Cleaning, transport
Allergy Clinic	Treatment, POU Cleaning, transport
Uniformed Services University of the Health Sciences Family Medicine Clinic	Treatment, POU Cleaning, transport

Procedural Steps

Implementation of this project will commence after obtaining a letter of Institutional Review Board/Performance Improvement (IRB/PI) determination from WRNMMC Office of Research. Once approved, the CDC's Framework for Program Evaluation will be used to provide step-by-step procedural guidance for this project (CDC, 2017b). Each step of the framework is linked to specific phases of Donabedian's Framework for Healthcare Quality and principles of HROs as illustrated in Figure 4.

I. Sensitivity to Operations: By assessing the current-state of the HLD program, the HRO principle of sensitivity to operations is being used to determine deviations from HLD best practices. Engaging with stakeholders provides the opportunity for "workers who are most intimately involved in operations" to participate in the program evaluation to achieve high reliability (Chassin & Loeb, 2013, p. 462).

A. Structural Assessment: The first phase of Donabedian's framework for healthcare quality is to assess the environment of care and program participants for deviations from expected performance (Donabedian, 1988).

(1) CDC Program Evaluation Step 1: Engage stakeholders.

a. Identify and engage leadership responsible for administering the HLD program.
b. Identify and engage the departments involved in the HLD program.
c. Identify and engage the end-users carrying out the tasks associated with HLD.

(2) CDC Program Evaluation Step 2: Describe the program.

a. Perform a literature review of HLD program best practices to assist in developing a robust audit tool that will be used to evaluate WRNMMC clinics performing HLD.
b. Perform baseline assessment of workflow processes of all departments participating in HLD at WRNMMC.
c. Perform baseline assessment of leadership involvement with HLD at WRNMMC.
d. Informally present baseline assessment/audit findings to stakeholders at weekly HLD taskforce meetings to provide recommendations for improvement.
e. During weekly HLD taskforce meetings, engage individuals involved with HLD processes for structural assessment feedback regarding the HLD program to establish lines of communication for operation sensitivities to be identified (Chassin & Loeb, 2013).

II. Deference to Expertise: By utilizing the HRO principle of deference to expertise, the healthcare organization is putting "the mechanisms in place to identify individuals with the greatest expertise relevant to managing the new situation and to place decision-making authority in the hands of that person or group" (Chassin & Loeb, 2013, p. 462). WRNMMC has responded to the call to action for HLD program evaluation by establishing an HLD taskforce. The subject matter experts identified to be a part of this task force will focus on performing a HLD program evaluation.

A. Process: Assessing the process allows for key interactions with subject matter experts and identification of areas needing process improvement. The HLD process will be

compared to regulatory standards, manufacturer's IFUs, and evidence-based literature to evaluate the program's processes and their potential impact on patient outcomes (Donabedian, 1988).

(1) CDC Program Evaluation Step 3: Focus evaluation design.

a. Serve as subject matter expert on the newly formed multidisciplinary HLD taskforce.
b. Identify standards from professional organizations such as AAMI, SGNA, the CDC, and AORN that will be used to guide the practice of the HLD program at WRNMMC.
c. Develop short and long-term goals.
d. Utilize the developed evidence-based audit tool to identify gaps in compliance to standards as well as assessing ongoing program changes in HLD practice and leadership.
e. Following the processes assessment of Donabedian's (1988) framework for healthcare quality, observations of the current state will be compared to identified industry standards.

III. Reluctance to Simplify: By conducting a gap analysis and of the initial assessment and comparing observations to regulatory standards, manufacturer's IFUs, and evidence-based literature, the task force will be "able to identify the often subtle difference among threats" to the program's high reliability (Chassin & Loeb, 2013, p. 462).

A. Process: The gathering of credible evidence is a direct observation of the HLD process and how the process compares to the best practices recommended by professional organizations, manufacturer IFUs, and evidence-based literature. The

audit of the HLD process is the foremost instrument in attaining reliability of the HLD program (Donabedian, 2005).

(1) CDC Program Evaluation Step 4: Gather credible evidence.

a. Perform a gap analysis based on initial assessment and develop evidence-based recommendations for improvement.
b. Perform three additional audits two to three months apart with identified evidence-based recommendations while continuing to complete the audit quality loop by providing feedback to stakeholders
c. Perform the initial or recurring iteration (every two to three months) audits of the HLD program and compare findings to identified standards to demonstrate the process assessment phase of Donabedian's framework for healthcare quality process assessment (Donabedian, 1988).

IV: Commitment to Resilience: By providing evidence-based recommendations for program sustainment, to include continuous audit quality loop iterations, the program evaluation is demonstrating the HRO principle of commitment to resilience and sustained process improvement (Chassin & Loeb, 2013).

A: Outcome: After a thorough evaluation of the program's structure and processes, recommendations can be made to sustain process improvement initiatives to establish a highly reliable culture that is committed to resilience and continuous patient outcome improvement. Continued resilience should be conducted to ensure the HLD program remains "within acceptable bounds" (Donabedian, 1988, p. 176).

(1) CDC Program Evaluation Step 5: Justify conclusions.

a. Conduct longitudinal synthesis of audit findings by comparing gathered evidence for compliance improvement, leadership involvement, and development of culture embracing HRO principles by analyzing findings from audits conducted every two to three months. The findings from this analysis will demonstrate the leadership's commitment to compliance improvement and the development of HRO principle resilience by the organization.

b. Provide evidence-based recommendations for program sustainment and continued evaluation while seeking stakeholder feedback. This feedback will foster open communication channels so that areas of improvement can be communicated across all levels of the taskforce to maintain a committed level of resilience within the organization.

V: Preoccupation with Failure: With each audit quality loop iteration, diminishing gaps between observed practices, evidence-based practice recommendations by professional organizations, and manufacturer IFUs demonstrate a healthcare organization that is preoccupied with the prevention of process failures.

A: Outcome: Continued assessment of the HLD program structure and process will continue to improve outcomes for patients undergoing endoscopic procedures at WRNMMC. Improve outcomes through the relationship between the organization's structure and processes (Donabedian, 2005). As part of the outcome portion of the change element of this project, outcomes achieved through the use

of audits at prescribed intervals of every two to three months will be shared with stakeholders and complete the audit quality loop.

(1) CDC Program Evaluation Step 6: Use and share lessons learned.

a. To complete the CDC Framework for Program Evaluation loop (see figure 3), dissemination of lessons learned will be shared with stakeholders during weekly HLD taskforce meetings in support of the short-term goals to standardize HLD practices, to improve leadership oversight, and reduce practice variance. According to the CDC (1999) the dissemination of lessons learned "can be encouraged by holding periodic discussions during each step of the evaluation process and routinely sharing interim findings, and draft reports (p. 24).

b. Continue audit iterations by completing four audit quality loop iterations as external auditors to the organization and disseminate findings every two to three months. After the fourth audit iteration, transition the external auditing process to an internal auditing process governed by the HLD taskforce at WRNMMC. According to Hanskamp-Sebregts, et al. (2013), internal audits "encourage the continuous improvement of patient safety" (p.1). By establishing an internal auditing process and continuing audit quality loop iterations, the long-term goal of establishing a culture that embraces the HRO principles will be accomplished.

c. Disseminate lessons learned to enterprise stakeholders at WRNMMC, DHA, and DoD (i.e., Perioperative Nursing Consultants) during USU Research Day (podium and poster presentation). Submit manuscript to peer-reviewed journal

for dissemination of evidence-based practice to achieve long term goal of sharing project lessons learned and support DoD's goal of becoming a HRO.

HIPAA Concerns (IRB)

The main policy for protecting human research subjects consist of the Code of Federal Regulations (CFR) title 45, Public Welfare Department of Health and Human Services (HHS), part 46, Protection of Human Subjects effective as of 2009 (Office for Human Research Protections, 2016). Based on decision charts developed by the Office for Human Research Protections (OHRP), our project should be considered exempt from the Institutional Review Board (IRB) review as this is an evidence-based practice performance improvement project (OHRP, 2016). Population interactions will be interview procedures and observation of public behaviors of nurses, technicians, managers, and leaders to evaluate the HLD program with no identification of personnel involved. Personally identifiable information (PII) will not be used or paired with the program evaluation information gathered from the population and infection control professionals. PII will not be needed to perform a program evaluation of WRNMMC's HLD program. The anticipated interventions will address the culture of safety from the perspective of nurses, technicians, managers, and leaders involved with HLD in order to achieve and sustain the goals of HROs.

Project Results

This project was implemented to support the CDC and DHA recommendations to thoroughly evaluate HLD programs in an effort to decrease patient risk from improperly processed endoscopes in support of quality, safety, and continuous process improvement to become a high reliability organization. The results of this project consisted of two elements: HLD audit and Leadership and Culture of Safety Results.

HLD Audit Results

A longitudinal assessment of recurring audits with evidence-based recommendations for improved practice was conducted at WRNMMC. The data from these HLD audits were compiled from a synthesis of the audit scores obtained from four assessment points across an 11-month time span (2017: October; 2018: January, March, and September). Illustrated in Figure 5, these HLD audits and associated evidence-based practice recommendations for practice and process shows an upward trend in the combined averages of each HLD element and demonstrates an overall performance improvement of 5.5% across five clinics from 91.4% in October 2017 to 96.9% in September 2018.

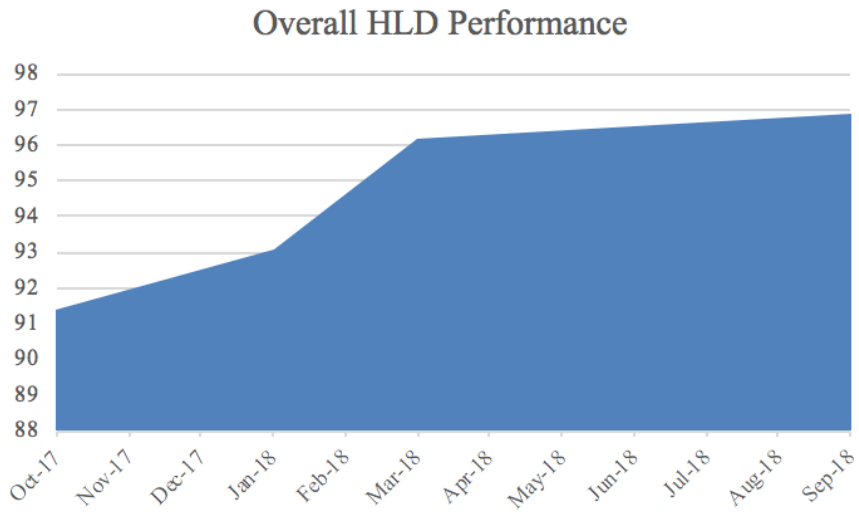


Figure 5. Overall HLD Performance at WRNMMC from October 2017 through September 2018.

Not only did overall HLD performance improve, but the audit results across the four time frames identified improvements within every phase of the HLD process as noted in Table 7.

Table 7. *Summary: Improvements across HLD phases*

Clinic	POU Cleaning/ Transport	Leak Testing	Manual Cleaning/ Rinsing	HLD	Storage	Record Keeping
	Initial % / Final% Audit Variance Improvement %					
Cardiology	91% / 100% **9%**	100% **Sustained**	75% / 83% **8%**	100% **Sustained**	80% / 100% **20%**	100% **Sustained**
ENT	81% / 100% **19%**	100% **Sustained**	75% / 83% **8%**	91% **Sustained**	73% / 86% **13%**	100% **Sustained**
GI	91% / 100% **9%**	100% **Sustained**	91% / 100% **9%**	91% / 100% **9%**	93% / 100% **7%**	83% / 100% **17%**
Peds GI	100% **Sustained**	100% **Sustained**	83% / 91% **8%**	100% **Sustained**	93% / 100% **7%**	100% **Sustained**
Pulmonary	91 %/ 100% **9%**	100% **Sustained**	83% **Sustained**	91% **Sustained**	86% / 100% **14%**	100% **Sustained**
Overall Improvement	90.8% / 100% **9.2%**	**100%** **Sustained**	81.4% / 88% **6.6%**	94.6% / 96.4% **1.8%**	85% / 97.2 **12.2%**	96.6% / 100% **3.4%**

HLD is a complicated, multistep process involving over 65 actions with no safety nets and lacks standardized verification processes. The lack of standardized verification processes highlights the critical nature of HLD. Failure of any one or more of the 65 actions will result in an improperly processed endoscope potentially impacting patient safety and outcomes. Every fractional percentage closer to 100% in HLD performance decreases the risk from exposure to contaminants and MDROs. Commitment to achieving the highest levels of HLD performance is hallmark to a highly reliable organization.

During the structural assessment phase of this project, the HLD taskforce at WRNMMC voted on AAMI ST91 as the guideline for which endoscope reprocessing will be compared and developed. See Appendix E for the HLD audit tool used to conduct the audits for this project. The audit tool addresses six phases within the HLD process: Point of Use Cleaning (11 items),

Leak Testing (10 items), Manual Cleaning and Rinsing (12 items), High Level Disinfection and Rinsing (11 items), Drying and Storage (15 items), and Record Keeping (6 items) for a total of 65 audit line items detailing the reprocessing of endoscopes. Each phase was assigned percentage scores based on the amount of correctly performed steps. For example, if 10 of the 11 steps in the High-Level Disinfection and Cleaning phase were successfully audited, the department would receive a score of 91%. Audit scores for each HLD phase was reviewed with clinic leadership, staff members, and HLD taskforce participants after each audit. Scores were tracked longitudinally using an HLD longitudinal tracking dashboard to monitor performance for each HLD step for each clinic (see Appendix F).

Leadership and Culture of Safety Results

In addition to auditing the 65 items associated with reliable endoscope reprocessing, the robust HLD audit tool addressed components of leadership roles and responsibilities by TJC (2015) as being essential to the success of a high reliability HLD program. This component of the audit tool consists of two sections: Risk Assessment (10 items) and Culture of Safety (6 items).

According to TJC (2015), assessment of the leadership's involvement in support of HLD practices across the organization is pivotal to achieving high reliability. The leadership risk assessment and culture of safety audits conducted for this project describe the leadership's role and responsibility in oversight for the location and volume of endoscope reprocessing, training, education, current practices, and performance improvement efforts. As a result, after the first audit, all clinics were at 100% compliance for use of policies/IFUs and all other aspects of the risk assessment. Audit scores across the five clinics at WRNMMC for Risk Assessment are listed in Table 8.

Table 8. *Risk Assessment.*

	OCT 2017	Jan 2018	Mar 2018	Sep 2018
Cardiology	85	100	100	100
ENT	100	100	100	100
GI Endo	100	100	100	100
Peds GI Endo	85	100	100	100
Pulmonary	85	100	100	100
HLD Clinic Total	**96.6**	**100**	**100**	**100**

The Culture of Safety audits consisted of six questions that addressed stakeholder perceptions of leadership involvement and support of the HLD process. All clinics scored 100% initially and was sustained throughout the audit process indicating the staff's perception of the leadership being fully engaged in the safety, quality, and continuous process improvement in support of the HLD program at WRNMMC (see Table 9). Culture of safety audit questionnaire results were continuously reported to stakeholders (HLD taskforce) after each audit completing the audit quality loop cycle with 100% sustainment of perceived culture of safety and leadership engagement related to HLD at WRNMMC.

Table 9. *Culture of Safety Audit Results.*

	OCT 2017	Jan 2018	Mar 2018	Sep 2018
Cardiology	100	100	100	100
ENT	100	100	100	100
GI Endo	100	100	100	100
Peds GI Endo	100	100	100	100
Pulmonary	100	100	100	100
HLD Clinic Total	**100**	**100**	**100**	**100**

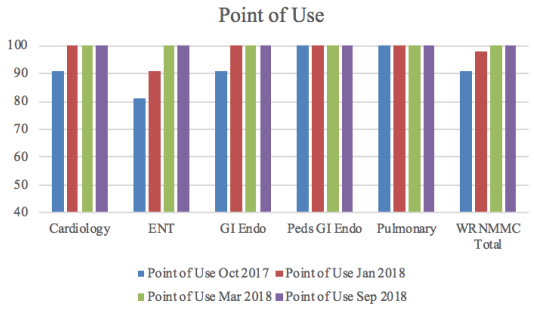
Analysis of Results

The synthesis of the audit scores obtained across an 11-month time span, included four assessment points: October 2017, January 2018, March 2018, and a six-month sustainment validation audit in September 2018. Each audit period reflects completed audit quality loop cycles with evidence-based feedback to key stakeholders. An increase in standards compliance with strong leadership support reflected an overall HLD performance score increase of 5.5% from 91.4% to 96.9%. Additionally, three out of the six HLD reprocessing phases achieved 100% compliance during the audit processes. The remaining three phases that fell short of achieving 100% all demonstrated an upward trend toward improvement in practice: Manual Cleaning and Rinsing improved 6.6%; HLD improved 1.8%; and Drying and Storage improved 12.2%. These percentages represent 40 deficiencies identified of which 28 corrections have been made as a result of the evidence-based recommendations provided; with 12 deficiencies

remaining to be resolved. Of these deficiencies four can be corrected by standardizing the availability and use of magnifying glasses for improved visualization and cleaning verification. Three deficiencies will be resolved with the installation of improved storage cabinets that have been ordered as of September 2018. The remaining three deficiencies can be resolved with the installation of additional sinks for manual cleaning and rinsing. This particular deficiency will be a challenge to rectify due to the physical space in the clinics. Analysis of each HLD process audit score across the five clinics at WRNMMC are presented in Table 10.

Table 10. *Analysis of Audit Results, Impact and Improvements*

Process and average audit score of HLD clinics	**Initial vs. final audit score**	**Impact/Improvements**
<u>Point of Use Cleaning and Transport</u>: Initial audit score 90.8% Final audit score 100%	9.2% Improvement	● GI clinic and ENT clinic changed the workflow in the decontamination room to ensure a clear delineation between the clean and dirty. ● HLD Taskforce voted on standardized POU cleaning products and procedures. ● Standardized rigid biohazard transport containers and PPE were purchased. ● Cardiology clinic implemented proper point of use cleaning practices and products. ● ENT clinic implemented proper point of use cleaning and changed the workflow in the decontamination room to ensure a clear delineation between the clean and dirty. ● Buy-in from physicians was critical to the success of POU cleaning in the ENT clinic.

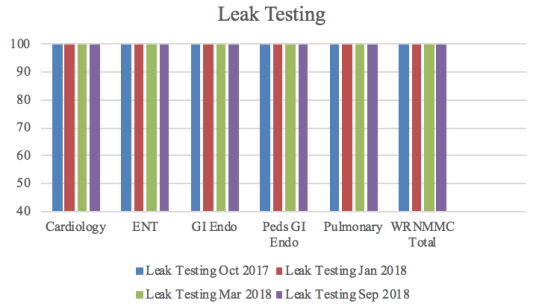


The POU cleaning and transport audit consists of 11 processes.
Deficient Processes Identified:

1. Standard: Endoscope is wiped immediately after removal from the patient with a wet cloth or sponge.
    a. Deficiency noted in Cardiology Clinic, and ENT Clinic.
        i. Cardiology Clinic corrected in January 2018.
        ii. ENT Clinic corrected in March 2018.

2. Standard: Unidirectional workflow and clear markings to separate/identify clean and dirty areas.
    a. Deficiency noted in GI Clinic and ENT Clinic.
        i. GI Clinic corrected in January 2018.
        ii. ENT Clinic corrected in January 2018.

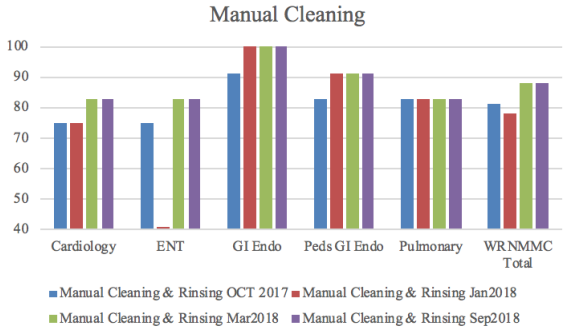
<u>Leak Testing</u>: Initial audit score 100% Final audit score 100%	100% Sustainment	• Pulmonary clinic organized workspace to improve workflow for leak testing. • Standardized leak testing process and products for all HLD sites. • Process mapped leak testing procedures to reinforce importance of performing dry leak testing prior to wet leak testing.



The Leak Testing audit consists of 10 processes.
Deficient Processes Identified: 0

All standards related to performance of leak testing processes were performed consistently across the five clinics.

<u>Manual Cleaning and Rinsing</u>: Initial audit score 81.4% Final audit score 88%	6.6% Improvement	• Cardiology clinic now uses a temperature gun to verify that the detergent used is at the proper temperature. • GI clinic began using a magnifying glass to improve visualization of all flexible endoscopes. • Standardized manual cleaning and rinsing process and products for all HLD sites. • ENT clinic now uses correct detergent measurements and fully submerges endoscopes while cleaning. • 4 out of 5 clinics are not using magnification for improved visualization and do not have three sinks installed.

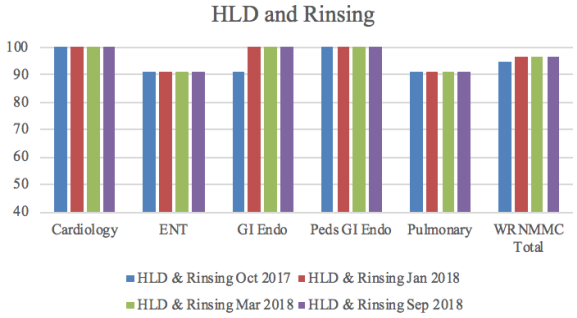


The manual cleaning and rinsing audit consisted of 12 processes.
Deficient Processes Identified:

1. Standard: Visual inspection using lighted magnification for hard to clean areas.
    a. Deficiency noted in Cardiology, ENT, GI, PEDS GI, and Pulmonary Clinics.
        i. GI Clinic corrected January 2018.
        ii. Cardiology, ENT, PEDS GI, and Pulmonary clinics remain deficient.
2. Standard: Adequate workspace for soaking, cleaning, and rinsing.
    a. Deficiency noted in Cardiology, ENT, PEDS GI, and Pulmonary Clinics.
        i. PEDS GI corrected January 2018.
        ii. Cardiology, ENT, and Pulmonary clinics remain deficient.
3. Standard: Basin is filled with fresh water and appropriate detergent.
    a. Deficiency noted in Cardiology and ENT in January 2018.
        i. Cardiology corrected in March 2018.
        ii. ENT was compliant in October 2017. Was deficient in January 2018. And compliant in March and September of 2018.
4. Standard: All channels are flushed with detergent solution and soaked for specified period of time.
    a. Deficiency noted in ENT clinical January 2018.
        i. ENT corrected in March 2018.
5. Standard: All debris is washed and wiped from the exterior while submerged in the

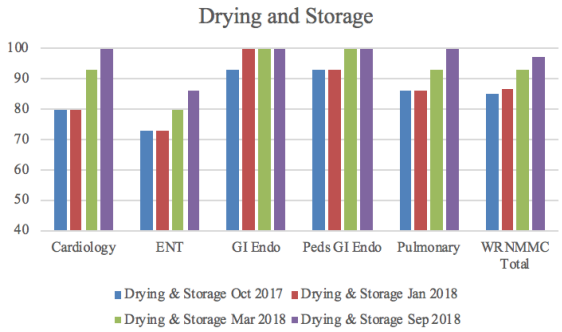
<table>
<tr><td colspan="3">detergent solution.
a. Deficiency noted in ENT clinic January 2018.
i. ENT corrected in March 2018.
6. Standard: After each passage, the cleaning brush is rinsed in detergent solution to remove visible debris.
a. Deficiency noted in ENT clinic January 2018.
i. ENT corrected in March 2018.</td></tr>
<tr><td><u>High-Level Disinfection and Rinsing</u>:

Initial audit score 94.6%

Final audit score 96.4%</td><td>1.8% Improvement</td><td>● GI clinic ensured AERs are used according to the manufacturer’s IFU and ensured they were kept closed after they were wiped down.
● Pulmonary, PEDS GI, and ENT clinics’ AERs were approaching their end-of-life. New AERs were purchased and installed October 2018.
● Standardized AERs were selected for all HLD sites with the exception of the GI clinic who had recently purchased AERs of a different brand prior to the HLD taskforce.
● 100% compliance will be achieved across all clinical sites with the installation of new AERs in Fall 2018.</td></tr>
<tr><td colspan="3"> 

The HLD and rinsing audit consists of 11 processes.
Deficient Processes Identified:
1. Standard: If an AER is used, maintenance or life cycle indicate reliable use.
a. Deficiency noted in Pulmonary, and ENT Clinic.
iii. New AERs purchased for Pulmonary Clinic September 2018.
iv. New AERs purchased for ENT Clinic September 2018.
2. Standard: If automated HLD is used, the AER use is per manufacturer’s IFU.
b. Deficiency noted in GI Clinic.
i. GI clinic corrected January 2018.</td></tr>
<tr><td><u>Drying and Storage</u>:</td><td>12.2% Improvement</td><td>● Risk assessment for endoscope storage conducted for the organization January</td></tr>
</table>

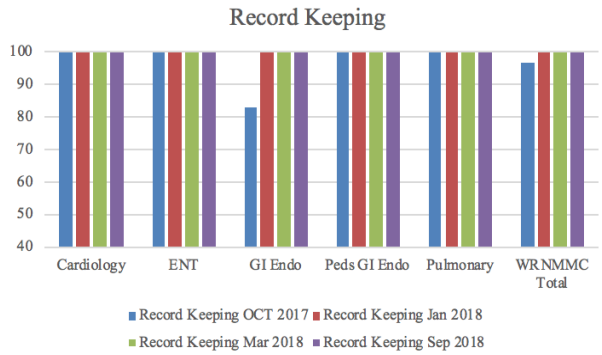
Initial audit score 85% Final audit score 97.2%		2018. ● All HLD clinics adopted a standardized labeling method to clearly indicate when HLD was performed and when the endoscope would expire February 2018. ● Cardiology clinic purchased new storage cabinets that are kept clean and provide adequate air circulation. ● ENT clinic started to ensure their storage cabinet was cleaned at least weekly and removed clutter from the storage room. ● Pulmonary clinic now ensures storage cabinets are kept clean and well ventilated. ● ENT ordered new storage cabinets, when installed audit score improvement expected to 100%. ● Pulmonary and PEDS GI Clinics are researching improved storage cabinets.



The drying and storage audit consists of 15 processes.
Deficient Processes Identified:

1. Standard: Endoscopes are stored in a closed cabinet with venting that allows air to circulate around them.
    a. Deficiency noted in Cardiology, ENT, and Pulmonary Clinics.
        i. Cardiology clinic corrected September 2018.
        ii. ENT clinic ordered new cabinets September 2018.
        iii. Pulmonary clinic corrected September 2018.
2. Standard: Cabinet is kept clean and well ventilated.
    a. Deficiency noted in Cardiology, ENT, and Pulmonary Clinics.
        i. Cardiology clinic corrected March 2018.
        ii. ENT clinic ordered new cabinets September 2018.
        iii. Pulmonary clinic corrected March 2018.
3. Standard: Storage time before next use is measured and monitored.
    a. Deficiency noted in Cardiology, GI, ENT, Peds GI, and Pulmonary.
        i. GI corrected January 2018.
        ii. Cardiology, ENT, PEDS GI, and Pulmonary corrected March 2018.
4. Standard: There is adequate height for endoscopes to hang without touching bottom or each other.
    a. Deficiency noted in ENT clinic.
        i. ENT clinic ordered new cabinets September 2018

<u>Record Keeping</u>: Initial audit score 96.6% Final audit score 100%	3.4% Improvement	• GI clinic began proper documentation for point of use cleaning. • Standardized record keeping policies for all HLD clinics implemented. • Clinics that started with an audit score of 100% were able to maintain it.



The record keeping audit consists of six processes.
Deficient Processes Identified:

1. Standard: Documentation or label indicating time and person that performed point of use cleaning.
    a. Deficiency noted in GI clinic.
        i. GI clinic corrected January 2018.

<u>Risk Assessment:</u> Initial audit score 96.6% Final audit score 100%	3.4% Improvement	• All HLD clinic staff members were educated on the use of the online database to look up manufacturers' IFU. • Standardized HLD policies were implemented across all HLD clinics and organized binders containing these policies were distributed. • The cross-sectional participation of HLD team members at the HLD taskforce meetings promulgated quick dissemination and correction of the appreciated risk assessment audit findings.

The risk assessment audit consists of 14 questions across five clinical sites.
Deficient Processes Identified:

1. Standard: Know the location and accessibility of manufacturer's IFU for products used to support HLD.
    a. Deficiency noted in Cardiology, Peds GI, and Pulmonary clinics.
        i. Cardiology, Peds GI, and Pulmonary clinics corrected January 2018.
2. Standard: Organizational/department policies and procedures reflect evidence-based guidelines, are up to date, and staff have knowledge of and access to the documents.
    a. Deficiency noted in Cardiology, Peds GI, and Pulmonary Clinics.
        i. Cardiology, Peds GI, and Pulmonary Clinics corrected January 2018.

<u>Culture of Safety:</u> Initial audit score 100%	100% Sustainment	• Due to the timely directives from the CDC and DHA, leadership were fully engaged in support of improved HLD practice during the processes of project implementation.

Final audit score 100%		
The culture of safety audit consists of six questions. Deficient Processes Identified: 0 1. All five clinical sites demonstrated 100% compliance and sustainment during all four audits throughout the 11-month time period. a. Feedback on culture of safety audit results presented to stakeholders and leadership during HLD taskforce meetings closing the audit quality feedback loop.		

Organizational Impact

The impacts of this project and the resulting second and third order effects represent the institution's journey towards becoming a high reliability organization with a goal aimed at achieving quality, safety, and continuous process improvement. The audit findings resulted in the identification of evidence-based recommendations for practice and process change in HLD at WRNMMC. The organizational impact from conducting recurrent audits with a sustainment phase in concert with closing the audit quality feedback loop after each audit resulted in an overall HLD improvement score of 96.9% in support of the MHS goal of becoming a high reliability organization. These results were categorized into five themes from which 22 initiatives were executed that had an organizational impact resulting in HLD process improvements: Policy Changes (5 initiatives; 24 areas of impact), Process Improvements (7 initiatives; 43 areas of impact), Organizational Structure Improvement (5 initiatives; 21 areas of impact), Standardization of Equipment (3 initiatives; 29 areas of impact), and Leadership/Culture of Safety (2 initiatives; 18 areas of impact) (see Table 17). The overall impact of this project involves 22 initiatives impacting 135 areas across the organization. The improvements made in support of HLD served as the impetus for additional changes across the organization (e.g. dental,

surgical, medical, and emergency departments) related to POU cleaning and transport of surgical instruments and ultrasound probes.

Table 17 *Organizational Impacts*

Policy Changes	**Organizational Impacts**
Standardized HLD policies	● HLD policies developed and standardized across all clinics at WRNMMC using AAMI ST91 recommended practices at all five clinical sites. ● POU cleaning policy implemented across all 13 clinical sites.
Endoscope storage policy developed	● Due to a lack of standardized endoscope storage times across the organization, a risk assessment was conducted to help determine the best practices and policy related to endoscope storage at WRNMMC. ○ The risk assessment lead to the development of a standardized storage policy across all clinics.
HLD Training and Education Governance	● Shifted governance of HLD training and education from Infection Control to the HLD committee to allow infection control to continue functioning in the more appropriate consultant role instead of the governing body for HLD as per recommendations by TJC (2015).
Process Improvements	**Organizational Impacts**
Workflow Charts	● Collaborated with facilities management, clinic leadership, and the HLD taskforce to strategize the optimal evidence-based workflow for five clinics ○ Workflow schematics from dirty to clean in the reprocessing room were developed and displayed the workflow from dirty to clean in decontamination rooms to reduce potential of cross contamination in five clinics.
Binders	● Standardized binders for HLD policy, competency, and training management across the organization at all 13 clinics.
Positive Negative Pressure Monitoring	● In collaboration with facility engineering services, clinic leadership, and the HLD taskforce, all five sites were visited to check for appropriate positive/negative pressure. ○ Ball-in-the-Wall systems previously in place at two clinical sites were validated and vanometers were provided to all five clinical sites.

	● Positive/negative pressure training implemented into the HLD Training and Education Governance across five clinics. ● Daily pressure checks and logs were implemented across five clinics.
HLD soaking and rinsing fluid temperature monitoring	● Provided handheld laser temperature monitoring devices for five clinical sites to verify fluid temperatures.
Spill Kit Implementation	● With the HAZMAT team at WRNMMC, all five clinic sites were visited to assess the need for spill kits and disposal of HLD waste products.
Organizational Structure Improvement	**Organizational Impacts**
Formation of HLD Committee	● As a result of the recommendations made based on audit findings, the HLD task force grew and was formalized into an official HLD committee. ○ Appointed chair and co-chair positions. ○ Utilized a Lean Six Sigma green belt to facilitate meetings. ○ The evolution of the HLD taskforce to the HLD committee was crucial to the success of the February 2018 TJC accreditation visit and identified by TJC as best-practice. ● Developed HLD Memorandum: outlined policies standardizing workflow processes across the organization: ○ Performance of a daily negative pressure test in endoscope reprocessing rooms. ○ Transportation and labeling of endoscopes. ○ Standardized policy and competency binder information. ○ Room workflow display. ○ Appointment letters for HLD committee representatives.
Developed Administrative Instruction for HLD Education and Training	● Administrative Instruction outlining the following items: ○ Responsibilities of clinic managers, department and service chiefs, and hospital service directors. ○ How the HLD Competency Training Program is carried out. ○ Guidance for education and training for personnel responsible for performing HLD. ○ Incorporates initial and annual competency training with observed performance documented by a designated HLD SME within five clinics.

	○ Staff competencies will be updated periodically as evidence-based recommendations are published or new equipment is purchased.
Closure of Stone Center Clinic	● Audits revealed that the physical space in this clinic was inadequate to perform HLD and halted these processes. HLD was moved to another department.
Tracer Program	● The HLD committee saw the value of regular audits and instituted their own tracer program to regularly evaluate each of the five clinic's adherence to established HLD practices.
Standardization	**Organizational Impacts**
Transportation equipment	● WRNMMC purchased standardized, rigid transportation systems used in all 13 clinics.
Purchase of new AERs	● Three clinics purchased new, standardized AERs, and were installed October 2018.
Enzymatic sponges	● Stakeholders voted on a standardized enzymatic impregnated sponge product for all clinics in the organization to use for POU cleaning taking place in 13 clinics.
Leadership/ Culture of Safety	**Organizational Impacts**
Leadership buy-in/engagement	● Leadership at WRNMMC had a significant amount of buy-in and were supportive of all efforts to increase the reliability of endoscope reprocessing. ● The leadership's buy-in was demonstrated by their willingness to support the HLD taskforce that evolved into the formally supported HLD committee. ● Leadership was supportive of several high-cost capital investments such as HLD consultation, AERs, storage cabinets, trays, carts, and rigid biohazard containers for AAMI compliant transportation of endoscopes from POU through HLD to storage in 13 clinics. ● TJC acknowledged the success of the HLD Committee's leadership and influence on the culture of safety within the organization in preparing WRNMMC for accreditation, demonstrated by a lack of findings related to HLD. ○ The audit results and evidence-based recommendations for improvements that were implemented were identified by TJC representatives as "best practices".
Increasing HLD	● Increased Readiness: An HLD program evaluation with

high reliability in support of the MHS Quadruple Aim	leadership buy-in establishes a culture of care committed to increased readiness through the establishment of safe endoscopic procedures free of contamination exposure through increased reliability. ● Better Health: Increasing the reliability of flexible endoscope HLD results in better health outcomes by providing equipment for treatments such as colonoscopy, bronchoscopes, and upper gastrointestinal interventions that are free from contamination from lethal multidrug resistant organisms such as *CRE* (CDC, 2015). ● Better Care: An HLD program evaluation for highly reliable flexible endoscope reprocessing achieves better care by engaging leadership, stakeholders, middle managers, and end-users to employ reprocessing best practices (TJC, 2015) ● Lower Cost: Establishing high reliability of flexible endoscope HLD prevents costly infections that cost the American healthcare delivery system $16.6 billion annually (Hassan et al., 2010).

Future Directions for Research and Practice

Nursing and medical researchers can help support the future direction of research by improving the identification of processes that involve critical step compliance. Processes like the HLD of flexible endoscopes have no safety nets to prevent potential exposure to lethal contaminants as a result of critical step noncompliance. Additionally, implementation of recurrent audits to improve critical step performance needs to be promulgated into future practice at other facilities in the MHS to evaluate if improvement is appreciated in diverse environments. The following section will discuss the importance of critical step compliance/process identification as a future direction for research. Additionally, implications for implementation of recurrent HLD audits for endoscope reprocessing across the MHS in support of achieving quality, safety, and continuous process improvement.

Improving Critical Step Compliance

Due to the potential exposure of contaminants, each phase of endoscope HLD reprocessing is treated as critical. The critical phases of HLD are POU cleaning/transportation, leak testing, manual cleaning/rinsing, HLD, drying/storage, and record keeping. Additionally, these phases consist of over 65 actions to reliably reprocess an endoscope. There is currently no safety net in place if one of these 65 actions are forgotten, skipped over, or performed inaccurately. Clinical audits were identified as a strategy to identify HLD discrepancies and improve compliance with each critical step in a process that has no safety net.

According to a literature review on audit science, audits have the biggest impact in areas where compliance is low (Esponsio & Canton, 2014). However, the initial overall HLD audit score of WRNMMC was 91.4% which could be considered a high level of compliance. Even though the literature states that the potential impact of audits in areas of high compliance is low, the critical steps of HLD and the lack of safety nets, require strict compliance to ensure patients are not exposed to harmful contaminants.

Contrary to the literature, the results of our recurrent HLD audits have shown that performance improvement is possible in areas with high compliance when dealing with procedures that involve critical steps with no safety nets, in which every step is to be performed 100% accurately. Future research should aim to identify procedures that involve critical steps that lack safety nets requiring 100% compliance with each phase of the process to determine if recurrent audits result in performance improvement. The literature shows that recurrent audits are effective in improving compliance rates; however, the identification of the frequency with which audits should occur to achieve sustainment of the improvement is lacking in the literature supporting the need for additional research.

Implications for Implementation Across the DoD

In response to the CDC's call to action and the DHA's requirement for all MTFs to immediately review HLD practices in the development of a comprehensive infection prevention plan, this project was implemented in concert with the WRNMMC leadership to address this requirement. This required identifying and collaborating with a leadership team that was fully engaged in supporting recurrent audits across all clinics performing HLD of endoscopes. Evidence-based recommendations were created and implemented to address deficiencies and improve quality and safety. After each audit, as a means to close the audit quality loop, leadership was briefed on the progress made towards enhanced compliance rates and gain buy-in for standardizing equipment, practices, policies, and system changes across the organization.

WRNMMC demonstrated their commitment to endoscope reprocessing reliability by creating an HLD committee in order to sustain on-going HLD audit efforts. The cost of implementing an HLD program with recurrent audits to achieve endoscope reprocessing accuracy is low. The highest cost associated with implementing this process is the time attributed to audit implementation and meetings to share feedback with stakeholders. Additionally, the cost avoidance of "never-events" supports the organization's alignment with the quadruple aim for increased readiness (rapid return to duty following endoscopic procedures), better health (establishment of safe endoscopic procedures free of contamination exposure), better care (implementing HLD practices that are evidence-based), at a lower cost (avoidance of consequences from unintended infections). The high cost-avoidance and minimal investment to implement a recurring audit program to improve high reliability of endoscope reprocessing at WRNMMC serves as an example that could be implemented across the MHS enterprise.

Conclusion

As a result of conducting these HLD audits and associated evidence-based practice recommendations for practice and process change, an upward trend in the combined averages of all six HLD phases and demonstrates an overall performance improvement of 5.5% across five clinics. This increase in overall HLD performance resulted in the identification of 40 clinical discrepancies with 28 practice improvements. The impact of this project also resulted in the implementation of 22 system/process initiatives which impacted over 135 areas across the organization. These organizational improvements served as the catalyst for additional changes across the organization (e.g. dental, surgical, medical, and emergency departments).

The upward trend and sustainment of HLD performance supported WRNMMC's goal of becoming a high reliability organization. The culture of WRNMMC embraced HRO principles by demonstrating a commitment to achieve quality, safety, and continuous process improvement. The resulting findings from this project reinforced the premise that audit tools have the greatest impact when used in a cyclical manner by closing the audit quality loop in concert with leadership.

As a flagship of military medicine, WRNMMC's success in HLD can serve as a model for implementation across the newly aligned DHA. The low cost, ease of program implementation, and success of HLD improvement efforts across the organization supports the MHS quadruple aim and DHA's goal of becoming an HRO. To ensure the success of these programs moving forward, the unique skills of the CNS empowers them to guide change, lead and sustain evidence-based practices to improve patient care and impact outcomes transforming the way HLD programs are administered, managed, and overseen across the MHS.

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Timeline

Project Year 1 (2018)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Proposal Approval	**X**	**X**	**X**									
USUHS VPR Submission and Approval				**X**								
Site IRB Submission and Approval				**X**								
Gather Credible Evidence; Perform Literature Review/Synthesis	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Engage Stakeholders; Attend HLD Related Meetings at WRNMMC	**X**	**X**	**X**	**X**	**X**	**X**			**X**	**X**	**X**	**X**
Perform Audit #1				**X**								
Analyze Data from Audit				**X**								
Present Audit Results to Stakeholders and Make Evidence-Based Recommendations					**X**							
Perform Audit #2						**X**						
Analyze Data from Audit						**X**						
Present Audit Results to Stakeholders and Make Evidence-Based Recommendations							**X**					
Perform Audit #3								**X**				
Analyze Data from Audit								**X**				
Present Audit Results to Stakeholders and Make Evidence-Based Recommendations									**X**			
Perform Audit #4 (Final Audit)										**X**		
Analyze Data from Audit										**X**		
Compile Data from All Audits to Identify Improvements and Deficiencies											**X**	
Compare Final Observed Practices with Evidence-Based Recommendations												**X**
Present Final Results to Stakeholders												**X**

Project Year 2 (2019)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Data Compilation of all Project Activities	**X**	**X**	**X**									
Literature Review to Support Recommendations and Project Outcomes	**X**	**X**	**X**									
Prepare Presentation		**X**	**X**	**X**								
USUHS Presentation					**X**							

Appendix A: CITI Certificates

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:** Kenneth Romito (ID: 5744275)
- **Email:** kenneth.romito@usuhs.edu
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Phone:** 3306078681

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

- **Report ID:** 20629446
- **Completion Date:** 28-Aug-2016
- **Expiration Date:** 28-Aug-2019
- **Minimum Passing:** 80
- **Reported Score*:** 90

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2016	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2016	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2016	4/5 (80%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2016	No Quiz
History and Ethics of Human Subjects Research (ID: 498)	28-Aug-2016	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2016	4/5 (80%)
Informed Consent (ID: 3)	28-Aug-2016	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2016	4/4 (100%)
Records-Based Research (ID: 5)	28-Aug-2016	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2016	5/5 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	28-Aug-2016	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	28-Aug-2016	3/3 (100%)
FDA-Regulated Research (ID: 12)	28-Aug-2016	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	28-Aug-2016	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	28-Aug-2016	No Quiz
Cultural Competence in Research (ID: 15166)	28-Aug-2016	1/5 (20%)

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: https://www.citiprogram.org/verify/?42759a47-8484-45ef-92e6-062678c68e37

CITI Program
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

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:** Daniel Fedderson (ID: 5744929)
- **Email:** daniel.fedderson@usuhs.edu
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Phone:** 801-699-7488

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

- **Report ID:** 20630941
- **Completion Date:** 31-Aug-2016
- **Expiration Date:** 31-Aug-2019
- **Minimum Passing:** 80
- **Reported Score*:** 89

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	30-Aug-2016	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	30-Aug-2016	4/5 (80%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	30-Aug-2016	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	30-Aug-2016	No Quiz
History and Ethics of Human Subjects Research (ID: 498)	30-Aug-2016	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	30-Aug-2016	4/5 (80%)
Informed Consent (ID: 3)	30-Aug-2016	4/5 (80%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	31-Aug-2016	4/4 (100%)
Records-Based Research (ID: 5)	31-Aug-2016	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	31-Aug-2016	4/5 (80%)
Vulnerable Subjects - Research Involving Children (ID: 9)	31-Aug-2016	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	31-Aug-2016	3/3 (100%)
FDA-Regulated Research (ID: 12)	31-Aug-2016	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	31-Aug-2016	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	31-Aug-2016	No Quiz
The Federal Regulations - SBE (ID: 502)	31-Aug-2016	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: https://www.citiprogram.org/verify/?99af123b-f198-48de-9038-ab6e14bcbd43

CITI Program
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

Appendix B: 3202N and NOPA

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

VPR Date Stamp

Project Number: _____ (VPR will assign)

Project Title: Achieving High Reliability in Flexible Endoscope High-Level Disinfection at Walter Reed National Military Medical Center

SECTION A: STUDENT POC INFORMATION

1. Name (Last, First, MI): Romito, Kenneth, J — Student E-mail: Kenneth.Romito@usuhs.edu
2. Home Address: [redacted]

SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION

3. Name (Last, First, MI): Hansen, Crystal, L.
4. Telephone: (301) 295-1201 Fax: E-mail: crystal.hansen@usuhs.edu; crystal.l.hansen11.mil@mail.mil
5. USUHS Building/ Room No.: Bldg E, Rm 1058

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? ☐ Yes ☒ 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: 4/30/2018 Project End Date: 4/30/2019
9. Performance Site(s): Walter Reed National Military Medical Center
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) ☐ Yes ☒ No
11. Do you have a funding source for this project? ☐ Yes ☐ No ☒ 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:

[redacted]

Student (Project Point of Contact for the Group) (Signature and Date) — Chair/Senior Mentor (Signature and Date)

[redacted]

Chair/Program Director (Signature and Date) — Chair/Program Director (Signature and Date)

[redacted]

DNP Project Director or PhD Director (Signature and Date) — Associate Dean for Academic Affairs, GSN (Signature and Date)

[redacted]

Associate Dean for Research, GSN (Signature and Date) — Dean, DKI Graduate School of Nursing (Signature and Date)

In light of the above signatures, the project is approved.

USUHS Vice President for Research — Date

USUHS Form 3202N (VPR) - Revised Sep 2015 v1.2
Previous versions are obsolete

USU
Uniformed Services University

OFFICE OF RESEARCH
4301 JONES BRIDGE ROAD
BETHESDA, MAYLAND 20814
PHONE: (301) 295-3303; FAX: (301) 295-6771

NOTICE OF PROJECT APPROVAL

Change Number: Original

VPR Site Number:	GSN-61-10200
Principal Investigator:	Romito, Kenneth
Department:	Graduate School of Nursing
Project Type:	Student
Project Title:	Achieving High Reliability in Flexible Endoscope High-Level Disinfection at Water Reed National Military Medical Center
Project Period:	10/18/2018 to 10/30/2019

Assurance and Progress Report Information:

Name	Sup	Approval Type	Status	Approved On	Forms Received
Progress Report	0		Final	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.

[redacted]

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

cc: Romito, Kenneth
File

Appendix C: WRNMMC Letter of Determination

WALTER REED NATIONAL MILITARY MEDICAL CENTER
Department of Research Programs
8901 WISCONSIN AVENUE
BETHESDA MARYLAND 20889-5600

Date: November 05, 2018

From:	Director, Walter Reed National Military Medical Center, Bethesda, Maryland 20889
To:	MAJ Kenneth J Romito, DNP student MAJ, DNP student, AN
Subject:	DETERMINATION OF **NOT RESEARCH**, WRNMMC-EDO-2018-0230, Achieving High Reliability in Flexible Endoscope High-Level Disinfection at Walter Reed National Military Medical Center
Ref#	908893

1. Thank you for your submission of this project and supporting materials. This project **DOES NOT** meet the definition of **RESEARCH** IAW 32 Code of Federal Regulation 219.102 and DoDI 3216.02.

2. You must register your project with the WRNMMC Quality Management Division. Please contact Mr. Victor Mosley at **victor.c.mosley.civ@mail.mil**.

3. Any changes to this project must be reviewed by the WRNMMC DRP Determinations Official to ensure that the changes do not impact this determination.

3. Any publication arising from this work must be cleared through the publication clearance process.

4. Per IAW DoDD 8910 and DoDI 1100.13, you are reminded that information collection forms (i.e. surveys) must be reviewed by the designated Information Management Control Officer for WRNMMC prior to distribution.

5. Please do not hesitate to contact the Determinations Official for assistance or the undersigned at (301) 295-9316 or david.l.evers.civ@mail.mil with questions or concerns.

RESPECTFULLY,

David LAWRENCE Evers, Ph.D.
DETERMINATION OFFICIAL

DEPARTMENT OF RESEARCH PROGRAMS

Appendix D: PAO Clearance for USUHS Archives

USU Uniformed Services University | GRADUATE NURSING Daniel K. Inouye Graduate School of Nursing

Manuscript/Presentation Approval or Clearance

INITIATOR

1. USU Principal Author/Presenter: Fedderson, Daniel; Romito, Kenneth
2. Academic Title: Student
3. School/Department/Center: **Daniel K. Inouye Graduate School of Nursing**
4. Phone: (330)607-8681
5. Type of clearance (check all that apply): ☑ Paper ☐ Article ☐ Book ☑ Poster ☑ Presentation ☐ Workshop ☑ Abstract ☐ Other
6. Title: Achieving High Reliability in High-Level Disinfection of Flexible Endoscopes at Walter Reed National Military Medical Center
7. Intended publication/meeting: National Capital Region Quality Symposium, AORN Global Surgical Conference and Expo, USUHS
8. "Required by" date: 22-Mar-19
9. Date of submission for USU approval: 05-Mar-19
10. USU Disclaimer Included: ◉ Yes ○ No
11. Conflict of Interest Statement Included: ◉ Yes ○ No ○ NA

CHAIR OR DEPARTMENT HEAD APPROVAL

1. Name: Linda Wanzer, DNP, RN, CNOR, FAAN, COL (Ret.), USA, AGCNS PROGRA
2. School/Dept.: **Daniel K. Inouye Graduate School of Nursing**
3. Date: 05-Mar-19

Note: *It is DoD policy that clearance of information or material shall be granted if classified areas are not jeopardized, and the author accurately portrays official policy, even if the author takes issue with that policy. Material officially representing the view or position of the University, DoD, or the Government is subject to editing or modification by the appropriate approving authority.*

Chair/Department Head Approval: [redacted]

RECEIVED MAR 18 2019

USU Uniformed Services University | GRADUATE NURSING Daniel K. Inouye Graduate School of Nursing

DEAN APPROVAL

1. Name: **Carol A. Romano, PhD, RN, FAAN, Dean and Professor**

2. School: **Daniel K. Inouye Graduate School of Nursing**

3. Date: 13 Mar 2019

4. ☐ Higher approval clearance required (for University-, DoD- or US Gov't-level policy, communications systems or weapons issues review)

*Note: *It is DoD policy that clearance of information or material shall be granted if classified areas are not jeopardized, and the author accurately portrays official policy, even if the author takes issue with that policy. Material officially representing the view or position of the University, DoD, or the Government is subject to editing or modification by the appropriate approving authority.*

Dean Signature Date [redacted]

VICE PRESIDENT FOR EXTERNAL AFFAIRS ACTION

1. Name: [redacted]

2. Date: 19 Mar 2019

3. ☑ USU Approved or ○ DoD Approval/Clearance required

4. ☐ Submitted to DoD (Health Affairs) on (date):

or ☐ Submitted to DoD (Public Affairs) on (date):

5. ☐ DoD approved/cleared (as written) or ☐ DoD approved/cleared (with changes)

6. DoD clearance date:

7. DoD disapproval date:

External Affairs Approval:

Notes:

Approved if the WRNMMC leadership / PAO office approves. [redacted]

Appendix E: HLD Audit Tool

Flexible endoscopes are some of the most challenging devices for healthcare workers to reprocess due to the unique designs and complex reprocessing steps. Use this Reprocessing Checklist to review your facility's compliance with standards and recommended practices published by AAMI, AORN, and SGNA to make quality improvements.

Date:		Auditors:	
Facility:		Location:	

Risk Assessment- Identify the following components:

1. Location where all or part of high-level disinfection (HLD) processes are conducted in the organization?

2. Where are all endoscopes requiring HLD located?3. Know the location and accessibility of manufacturer (MFR) instructions for use (IFU) for products used to support HLD?

4. Location and accessibility of current evidence-based guidelines for the use of end users?

5. Are organizational/department policies and procedures current, reflect evidence-based guidelines, and does the staff have knowledge and access to these documents?

6. What are your department/organization's vulnerabilities with HLD?

7. What is your volume of reprocessing for HLD?

8. How many endoscope procedures do you conduct daily? Weekly?

9. What is your staff turnover like?

10. Do you have frequent/continuing training? Does training adequately reflect details of the HLD process?

11. Review competency verification training of end users and those with oversight for the HLD process:
Is training current? What does the training consist of and how often does it occur?

-Executive leader/department officer in charge (OIC):

-Clinic manager/head nurse:

-End-users:

12. What training does the leadership who oversees/monitors users performing HLD processes have?

13. What is the preventative maintenance policy/practice of equipment or devices used for HLD?

14. Is the leadership auditing the HLD process? How often?

Culture of Safety- Create and maintain a culture of safety and quality

	Yes	No	DNO
1. Do leaders provide opportunities for al individuals to participate in safety and quality initiatives?			
2. Is there a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety?			
3. Have leaders created and implemented a process for managing behaviors that undermine a culture of safety?			
4. Are all individuals, including staff and licensed independent practitioners, able to openly discuss issues of safety and quality?			
5. Do end users feel safe and are they supported to report breaches in high-level disinfection?			
6. Is speaking up to stop an error with high-level disinfection or sterilization encouraged/supported?			

DNO=Did not observe

Point of Use/Transport – Pre-Cleaning

	Yes	No	DNO
1. Appropriate PPE is worn and the endoscope MFR's instructions for use (IFU) are available?			
2. Endoscope is wiped immediately after removal from the patient with a wet cloth or sponge?			
3. Distal tip of endoscope is placed in appropriate detergent solution and suctioned until clear?			
4. Finish by suctioning air?			
5. Air, water and auxiliary channels are flushed according to the endoscope MFR's written IFU?			
6. Detach the endoscope from the light source and suction lamp?			
7. If video source is used, the protective video cap is attached to the endoscope?			
8. Soiled endoscopes are transported to a separate reprocessing area in a closed container?			
9. Transport containers are large enough not to damage endoscope by coiled too tightly?			
10. Transport containers are labeled to indicate biohazardous contents, i.e. sticker or sign?			
11. Unidirectional workflow and clear markings to separate/identify clean and dirty areas?			

DNO=Did not observe

Leak Testing

	Yes	No	DNO
1. Appropriate PPE is worn and the endoscope MFR's instructions for use (IFU) are available?			
2. Suction valves, air water valves and biopsy valves are removed prior to leak testing?			
3. Leak tester is attached, and endoscope is pressurized before submerging into tap water?			
4. While submerged, the distal portion is flexed in all directions before submerging into tap water?			
5. The freeze and release buttons are depressed while observing the control head for bubbles?			
6. The insertion tube, the distal bending section and universal cord are checked for bubbles?			
7. After testing, the endoscope is removed from the basin and the leak tester is turned off?			
8. If applicable, the video cap is disconnected after the leak tester is turned off?			
9. The endoscope is allowed to depressurize (if applicable, the video cap is secure)?			
10. If leak is detected or damage to endoscope is observed, the reprocessing is stopped?			

DNO=Did not observe

Manual Cleaning, Rinsing, and Inspection

	Yes	No	DNO
1. Basin is filled with fresh water and appropriate detergent (i.e. neutral pH, low foaming?)			
2. If applicable, video cap is secured prior to immersion into the detergent solution?			
3. All debris is washed and wiped from the exterior while submerged in the detergent solution?			
4. Removable parts and all channels brushed, including the body insertion tube and the umbilicus?			
5. After each passage, the cleaning brush is rinsed in detergent solution to remove visible debris?			
6. Cleaning adapters are attached for suction, biopsy, air and water channels per the MFR's IFU?			
7. All channels are flushed with detergent solution and soaked for specified period of time?			
8. Endoscope and all removable parts are thoroughly rinsed with clean water to remove debris?			
9. Forced air is used to purge water from all channels of the thoroughly rinsed endoscope?			
10. The exterior of the endoscope is dried with a soft, lint-free cloth?			
11. Visual inspection using lighted magnification for hard to clean areas?			

12. Adequate workspace for soaking, cleaning, and rinsing?			

DNO=Did not observe

High-Level Disinfection and Rinsing

	Yes	No	DNO
1. HLD solution is prepared according to MFR's IFU and in an appropriately sized basin?			
2. The date the HLD solution is poured and the date the reuse life ends is documented?			
3. Prior to use, the HLD solution is tested for minimum effective concentration (MEC)?			
4. The test strip is appropriate for the HLD solution and test results are documented?			
5. The endoscope and all accessories are completely immersed into the HLD solution?			
6. The HLD solution is flushed into all channels until a steady flow is seen exiting each channel?			
7. The HLD solution is covered with a tight-fitting lid for time and temperature per MFR's IFU?			
8. If automated HLD is used, the automated endoscope reprocessor (AER) use is per MFR's IFU?			
9. After HLD, all surfaces and all removable parts are thoroughly rinsed per MFR's IFU?			
10. All channels are flushed with fresh, clean water for each rinse?			
11. If an AER is used, does its maintenance or life cycle indicate reliable use?			

DNO=Did not observe

Drying, Transport, and Storage

	Yes	No	DNO
1. All channels are purged with air until dry?			
2. All channels are flushed with alcohol until the alcohol exits the opposite end of each channel			
3. 70% alcohol is used and is properly stored in a closed container between uses?			
4. All channels are purged with air?			
5. All channel adapters are removed?			
6. The exterior of the endoscope is dried with a soft, clean, lint-free cloth?			
7. All removable parts are thoroughly rinsed and dried?			
8. Removable parts are not attached for storage and all valves are in the open position?			
9. Endoscopes are stored in a closed cabinet with venting that allows air to circulate around them?			
10. Endoscopes are hung in a vertical position and caps and other detachable parts removed?			

HIGH-LEVEL DISINFECTION

11. There is adequate height for endoscopes to hang without touching bottom or each other?			
12. Cabinet is kept clean and well ventilated?			
13. Endoscopes are not allowed to be stored in their original shipment cases?			
14. Storage time before next use is measured and monitored?			
15. Endoscopes are reprocessed before use if evidence of improper drying exists?			

DNO=Did not observe

Record Keeping

	Yes	No	DNO
1. The date and time of reprocessing is documented?			
2. Each endoscope is identified, along with method of cleaning and name of technician?			
3. HLD test strip quality control and MEC test results are documented?			
4. Routine and unscheduled maintenance or repairs are documented?			
5. Disposition of defective equipment is documented?			
6. Documentation or label indicating time and person that performed point of use cleaning?			

DNO=Did not observe

Appendix F: Longitudinal Audit Finding Tables

Point of Use Cleaning and Transport

	OCT 2017	JAN 2018	MAR 2018	SEP 2018
Cardiology	91	100	100	100
ENT	81	91	100	100
GI Endo	91	100	100	100
Peds GI Endo	100	100	100	100
Pulmonary	91	100	100	100
HLD Clinic Total	**90.8**	**98.2**	**100**	**100**

Leak Testing

	OCT 2017	JAN 2018	MAR 2018	SEP 2018
Cardiology	100	100	100	100
ENT	100	100	100	100
GI Endo	100	100	100	100
Peds GI Endo	100	100	100	100
Pulmonary	100	100	100	100
HLD Clinic Total	**100**	**100**	**100**	**100**

Manual Cleaning and Rinsing

	OCT 2017	JAN 2018	MAR 2018	SEP 2018
Cardiology	75	75	83	83
ENT	75	41	83	83
GI Endo	91	100	100	100
Peds GI Endo	83	91	91	91
Pulmonary	83	83	83	83
HLD Clinic Total	**81.4**	**78**	**88**	**88**

HLD

	OCT 2017	JAN 2018	MAR 2018	SEP 2018
Cardiology	100	100	100	100
ENT	91	91	91	91
GI Endo	91	100	100	100
Peds GI Endo	100	100	100	100
Pulmonary	91	91	91	91
HLD Clinic Total	**94.6**	**96.4**	**96.4**	**96.4**

Drying and Storage

	OCT 2017	JAN 2018	MAR 2018	SEP 2018
Cardiology	80	80	93	100
ENT	73	73	80	86
GI Endo	93	100	100	100
Peds GI Endo	93	93	100	100
Pulmonary	86	86	93	100
HLD Clinic Total	**85**	**86.4**	**93.2**	**97.2**

Record Keeping

	OCT 2017	Jan 2018	Mar 2018	Sep 2018
Cardiology	100	100	100	100
ENT	100	100	100	100
GI Endo	83	100	100	100
Peds GI Endo	100	100	100	100
Pulmonary	100	100	100	100
HLD Clinic Total	**96.6**	**100**	**100**	**100**

Risk Assessment

	OCT 2017	Jan 2018	Mar 2018	Sep 2018
Cardiology	85	100	100	100
ENT	100	100	100	100
GI Endo	100	100	100	100
Peds GI Endo	85	100	100	100
Pulmonary	85	100	100	100
HLD Clinic Total	**96.6**	**100**	**100**	**100**

Culture of Safety

	OCT 2017	Jan 2018	Mar 2018	Sep 2018
Cardiology	100	100	100	100
ENT	100	100	100	100
GI Endo	100	100	100	100
Peds GI Endo	100	100	100	100
Pulmonary	100	100	100	100
HLD Clinic Total	**100**	**100**	**100**	**100**

Appendix G: DNP Project Completion Verification Form

Appendix G: Daniel K. Inouye Graduate School of Nursing
DNP Project Completion Verification Form

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled: __Achieving High Reliability in High-Level Disinfection of Flexible Endoscopes at Walter Reed National Military Medical Center was completed at Walter Reed National Military Medical Center by the following student(s):

(type student name)	*(signature)*	*(date)*
Kenneth Romito_	[redacted]	_09APR2019
Daniel Fedderson_	[redacted]	_09APR2019

The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report.

Verified by:

(type name)	*(signature)*	*(date)*	
Dr. Linda Wanzer	[redacted]	_____	Senior Mentor
Lt. Col. Jeffrey Olive		11 Apr 2019	Team Mentor
MAJ Jose Rodrigue		11 Apr 2019	Team Mentor & Phase II Site Director

Form Version: 26 Aug 2017