CERTIFICATION OF REPROCESSING STANDARDIZATION:

PREVENTING ENDOSCOPY ASSOCIATED INFECTIONS

by

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ABSTRACT

Background: Between 2012-2015, there were 25 outbreaks linked to contaminated duodenoscopes worldwide, largely due to human error during cleaning and the difficulty of reprocessing. Nationally and internationally, there has been a focus on the education and training of endoscope technicians in response to increasing EAIs. Due to the meticulous nature of the reprocessing protocol, it is essential to create a standardized education and training reprocessing program. **Local Problem:** A Montana endoscopy unit aimed to meet ANSI/AAMI national standards by implementing a mandatory certification requirement for endoscope reprocessing. The unit identified unmet objectives, including certification of endoscopy reprocessing (CER) standard, and aimed to reduce the risk of patient endoscope associated infections (EAIs) to near zero percent with quarterly reviews. **Methods:** The Plan-Do-Study-Act method of quality improvement was used for this project. A pilot study involving one participant was conducted. The baseline assessment included a three-month patient chart review and duodenoscope/endoscopy ultrasound log review preintervention to identify infection incidence and infection risk. Furthermore, a mixed method survey regarding motivation, preparation, a perception of recommended educational materials for CER certification was conducted. **Intervention:** A pilot study involving a single participant attempting to obtain nationally recognized certification for reprocessing to standardize reprocessing protocol and optimize infection control was conducted. Recommended educational materials for CER preparation were provided to the sole participant to pass the CER exam. **Results:** Zero infections occurred during pre- and post-intervention. Pre-intervention, the average infection risk scores per endoscope reprocessing were 12.2 relative light units (RLUs) for the unit and 11.1 RLUs for the CER participant. Post-intervention phase, these numbers were 15.7 RLUs by non-CER technicians and 2.8 RLUs by the CER participant. The CER participants had 4 years of experience, felt somewhat motivated to achieve CER post online presentation, one month preparation with recommended materials promoted readiness for the exam, and felt the endoscopy reprocessing manual/workbook was the most helpful in preparation of the exam. **Conclusion:** Implementing standardized evidence-based practices and certification programs can promote improved reprocessing performance and safer endoscopy procedures and reduce the incidence of EAIs, a serious healthcare concern that can have devastating consequences for patients.

CHAPTER ONE

INADEQUATE REPROCESSING OF ENDOSCOPES AND ITS IMPACT OF INFECTION

Introduction

Endoscopy is a standard procedure to identify gastrointestinal-related disease processes by inserting a long, flexible tube down the throat, esophagus, and up through the anal sphincter. Although it is a relatively low-risk procedure, the rates of infections after endoscopic procedures in the United States are higher than previously thought. One study indicates that post-procedure infection risk can be up to 100 times higher than expected at some outpatient sites (Leitenberger, 2018). The current infection rate is approximately 1.6/1000 for non-screening colonoscopies and more than 3/1000 for esophagogastroduodenoscopy (EGD) procedures. Furthermore, patients with a history of hospitalizations within 30 days before an endoscopic procedure are associated with a higher risk for infection. Within one month of colonoscopy screenings, infections occurred in 45/1000 screenings and more than 59/1000 after EGD procedures (Leitenberger, 2018)

Endoscopy-related infections can occur from endogenous microbiota or exogenous pathogens. Endogenous infections refer to infections caused by the patient's gut flora. Exogenous infection is pathogens from patient to patient by contaminated equipment or from endoscopy personnel to patients (Puri, 2019). The process of disinfection of endoscopes is called reprocessing. Reprocessing is a multistep process that includes precleaning, leak testing, manual cleaning, high-level disinfection, drying, and storage, among other intricate steps. Bioburden, or

residual microorganisms left on endoscopes, are challenging to eradicate, even after reprocessing. In recent years, endoscopy-associated infections (EAIs) have made headlines due to the transmission of multidrug-resistant organisms (MDRO), causing infections and fatalities (Bomman et al., 2022). In 2015 the US Food and Drug Administration (FDA) recommended endoscopy units adopt enhanced surveillance and reprocessing techniques to reduce the risk of infection (Bomman et al., 2022). This literature review is necessary to understand the current state of knowledge of endoscopy equipment infection causes and prevention and identify the prevalence and incidence of EAIs.

Objective

This literature review aimed to identify the prevalence of endoscopy-related infections and potential interventions to reduce such infections. This review also aims to identify best practice guidelines for personnel to adhere to on the frontline. Through an analysis of this literature review, evidenced -based practice should be identified, and deviation from it explored.

Methods

Search Strategies

I searched via Catsearch at MSU, allowing the writer to retrieve research articles from the following databases: MEDLINE, PubMed, Web of Science, Directory of Open Access Journals, and Wiley Online Library. Search terms include: endoscopy-associated Infection OR duodenoscopy associated infection OR endoscopy associated infection rate OR endoscopy associated infection causes OR endoscopy infection education training OR gastroscopy colonoscopy infection OR duodenoscope contamination. Other active filters applied include

refining the date from 2017 to 2022, peer-reviewed, and ultimately 12 articles were selected further to understand the background of endoscopy-related infection and possible solutions. I also searched Google Scholar who found two more articles to augment the search from Catsearch

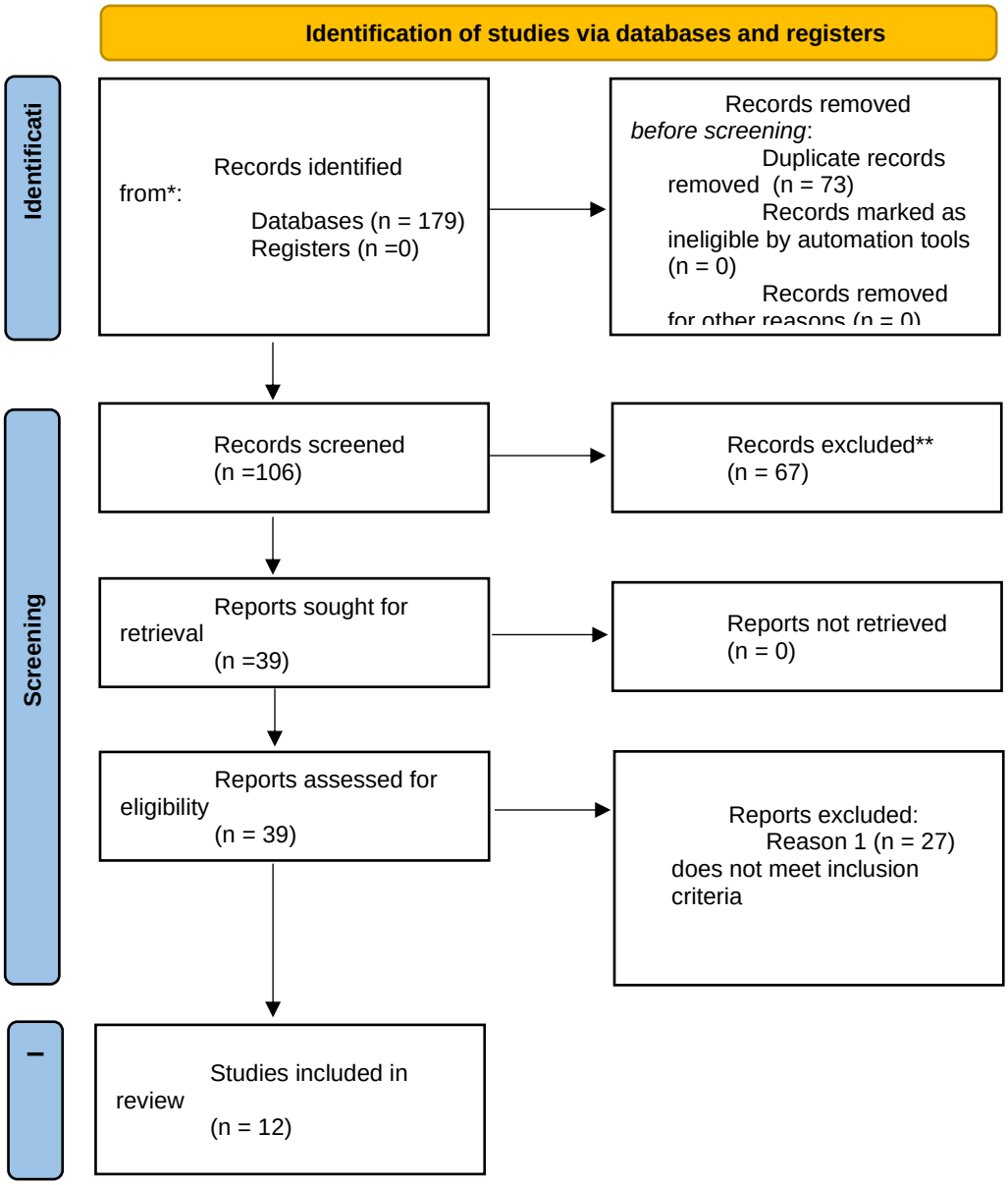
Eligibility-inclusion and Exclusion Criteria

Eligible criteria include discussing the rates of endoscopy-associated infections, contamination rate post reprocessing procedures, and endoscopy training. Articles needed to be published within the past five years (2017-2022). Systematic and Narrative reviews that fit either category were first to be incorporated and analyzed. Exclusion criteria include case studies and small sample size n< 50. This literature review had a total of 12 articles to allow a better insight of endoscopy-associated infections (Figure 1).

Study Selection

Of the 12 articles selected after manually screening inclusion/exclusion criteria, one is a prospective study, three are retrospective, three are descriptive, one is a narrative review, and four are systematic reviews.

Figure 1. PRISMA Endoscopy-associated infections in reprocessing.



Results

Overview of Studies

This literature review ultimately included 12 research studies to illustrate the relationships between endoscopy procedures, equipment, infections, contamination of

endoscopic equipment, and education and training. The literature is divided into three categories and will be analyzed based on endoscopy-associated infection rates, endoscopy contamination rates after reprocessing procedures, and endoscopy training concerns. Four articles discuss endoscopy-associated infection rates, six discuss contamination rates after reprocessing procedures, and two discuss endoscopy training concerns.

Description of Infection Rates

Research studies under review agree that the infection rate depends on the endoscopy procedure type. Endoscopic Retrograde Cholangiopancreatography (ERCPs) procedures had the highest infection incidence, followed by esophagogastroduodenoscopies (EGDs), then colonoscopies (Deb et al., 2020; Wang et al., 2018). An analysis of Medicare patients revealed that the reusable duodenoscope post-ERCP infection rate is 3.5% at seven days and 7.7% at 30 days, compared to the disposable duodenoscope post-ERCP infection rate, which is 1.4% at seven days, and 3.5% at 30 days (Hutfless et al., 2022). Studies identified that pseudomonas aeruginosa is the most common causative pathogen. Ultimately, studies showed that post-endoscopic infections are more common than previously thought and concluded that infections vary widely by facility. (Wang et al., 2018).

Complications of endoscopy can also include transient bacteremia, cholecystitis, cholangitis, and infected pancreatic fluid collections. 15% of diagnostic ERCPs and 28% of therapeutic ERCPs have resulted in transient bacteremia (Ofstead et al., 2020). In other endoscopy procedures, bacteremia resulted in 69.09% of EGDs, 23.64% were from colonoscopies. 61.82% of bacteremia infections were within 7-30 days and 38.18% were within seven days of the procedure. Further, they found that the most frequent bacteremia causative

microorganism is E. Coli which causes approximately 18.18% of all infections. They concluded that bacteremia after endoscopic procedures is more common than initially thought. (Ahuja et al., 2020). A retrospective study reported that infection incidence was higher with post-acute pathologies or gastrointestinal bleeding colonoscopies than with screening colonoscopies (Wang et al., 2018).

Studies reviewed recommended better processing techniques, strict adherence to disinfection methods or adequate sterilization for reprocessing endoscopes with periodic surveillance, and improving infection control (Ahuja et al., 2020; Deb et al., 2022; & Wang et al., 2018).

Description of Contamination Rates

While the previous studies focused on the prevalence of EAI infections, several research teams focused on post-reprocessing contamination rates of endoscopes that pose an increased risk of infection. Investigated studies identified an average contamination rate of patient-ready duodenoscopes of 0.3% to 60% (Okamoto et al., 2022; Larsen et al., 2020; Rauwers et al., 2018; Ofstead et al., 2020). Academic centers with rigorous adherence to reprocessing guidelines and duodenoscope maintenance reflected the lowest contamination rate of 0.3%, 5% in FDA pos-market surveillance studies conducted in 26 US facilities, 22% in 67 dutch hospitals, and 60% in other high-volume settings (Ofstead et al., 2020; Rauwers et al., 2018). Overall, 15% of endoscopes had pathogens, including *Enterobacter cloacae, Escherichia coli, Klebsiella pneumonia,* and/or yeast. (Rauwers et al., 2018).

Goyal et al. (2022) aimed to identify the contamination rate beyond the elevator mechanism on gastrointestinal endoscopes, and their study reviewed 20 articles. It is well known

that duodenoscopes have a complex design involving an elevator mechanism that, in particular, makes it challenging to reprocess. However, microbes can also harbor in the instrument channels and other places in the endoscope. Scratches that may occur with cleaning tools predispose these areas where microbes can harbor and colonize. Goyal et al. (2022) calculated the channel contamination rate as 31.95% for colonoscopes and 28.22% for gastroscopes.

Evaluated studies reported that reprocessing and process control is not adequate. They recommended safe interventions to decrease contamination, such as reducing human errors during reprocessing procedures, ongoing training programs, improved reprocessing control measures, microbial surveillance strategies, and increasing reprocessing environments' cleanliness (Okamoto et al., 2022; Goyal et al., 2022; Rauwers et al., 2018).

Types of Disinfection/Sterilization

Ofstead et al. (2020) note that 7.7% of endoscope ultrasound (EUS) and ERCP endoscopes had microbial growth in the elevator and channel after reprocessing, which can harbor pathogens that increase the risk of EAIs. To alleviate microbial growth bioburden and reduce the risk of infection single-cycle high-level disinfection (HLD), double-cycle HLD (dHLD), and sterilization were compared (Ofstead et al., 2020). HLD refers to endoscopic liquid chemical germicide immersion, followed by a water rinse, alcohol flush, and air drying. HLD is often completed with automated endoscope reprocessing (AER) machines. Reflected infection risks are as follows; Single HLD 7.3-60%, dHLD 1.8-44%, and sterilization 2.2-22.5%. Regardless of microbial growth, non-contaminated duodenoscopes still carry an estimated risk of infection of 1 in 1,1765 ERCP procedures, whereas contaminated duodenoscopes' calculated risk of infection is 10% of ERCP procedures (Ofstead et al., 2020).

Ofstead et al. (2020), concluded that reprocessing does not reliably eliminate soil or bioburden, allowing potential pathogens to remain on endoscopes. They recommended prioritizing reprocessing effectiveness with education/training, shifting to automation of manual cleaning, and quality assurance. The second recommendation was implementing mandatory duodenoscope servicing with evidence-based practice (EBP) schedule and addressing defects. The third recommendation was to enhance EBP risk with ERCP through real-world outcome research, identify risk factors and provide sufficient information when reporting infections outbreaks or breaches. Lastly, partner with manufacturers and biomedical engineers to address endoscope-associated infection risks (Ofstead, 2020).

Next, in response to multiple MDRO outbreaks, Federal Drug Administration (FDA) initiatives recommended dHLD and EtO to combat endoscope contamination and risk of infection. After dHLD or EtO, the overall contamination rate reduced to 9.20%. Researchers concluded that dHLD or EtO indicated some success in lowering endoscope contamination rates, but the fact that duodenoscopes remain contaminated is of concern (reference).

Concerns Regarding Endoscopy Personnel

Four studies identified concerns regarding current untrained or deficiently trained personnel. Subsequently, untrained or deficiently trained personnel place endoscopy patients at risk for future infection, as noted in previous articles.

Evaluated articles indicated that 82% of facilities worldwide have developed standard operating procedures (SOP) in the endoscopy unit, but there is a wide variation of SOPs between facilities. Only 57% of facilities carried out an essential drying process. 15-33% of facilities reported personnel still untrained in reprocessing (Kenter et al. 2018). In conjunction, reported

human factors that hinder effective reprocessing included a dislike of reprocessing tasks, pressure to work quickly, causing reprocessors to cut corners and skip steps, inadequate training, and the lack of supervision (Ofstead et al., 2020). Most personnel also expressed difficulty adhering to the reprocessing protocol (Larsen et al., 2020). Trained and educated reprocessor personnel demonstrated an inability to reprocess endoscopes appropriately. Due to a high staff turnover predisposition, trained staff do not robustly become skilled in reprocessing endoscopes (Larsen et al., 2020). Consequently, these factors lead to non-compliance in reprocessing protocol proliferates.

Unfortunately, since 2009, facilities' non-compliance with reprocessing standards has only increased. 60% of facilities demonstrated noncompliant breaches related to HLD and sterilization. Contamination of endoscopes does not necessarily lead to an infection, but it poses a higher risk to endoscopy patients. Infections may advance to hospital admission, healthcare costs, and expenses for each ERCP patient (Larsen et al., 2020).

Next, the FDA's "Human Factors Studies" investigated human errors associated with the manual reprocessing of duodenoscopes. Guidelines and manuals from endoscopy manufacturers like Olympus and Fujifilm deliver the necessary information to promote adequate reprocessing of endoscopes. However, the Fujifilm manual incorporates 33 critical manual cleaning tasks, yet only two of these tasks were completed by each participant (Larsen et al., 2020). Furthermore, 87% of reprocessors did not demonstrate appropriate methods for completing the elevator brushing task as described by Olympus user manual guidelines. Lastly, participants did not flush endoscope surfaces or inspect movable parts. (Larsen et al., 2020).

Overall, studies indicated less than 15% of workers had formal endoscope reprocessing or infection prevention training before or after joining an endoscopy unit (Larsen et al., 2020). However, 90% of them had high confidence in reprocessing scopes. The average endoscope reprocessing assessment score was 62%. Four individuals who had undergone certification, sterilization, or surgical technician training showed superior competency than their untrained counterparts (Larsen et al., 2020).

Reviewed studies continued to report the need for regulation in training and education to improve reprocessing practice. The literature recommends creating a standardized education and training program with a competency assessment to prevent reprocessing lapses and enhance patient safety. They noted developing online training packages for endoscope reprocessing would help improve access to education for all endoscopic units (Kenters et al., 2018). They stress that endoscopy leaders must observe personnel's techniques and assess their knowledge. Endoscopy leaders must train personnel who have never received formal training or retrain deficient personnel through a formal endoscopic reprocessing training program. Researchers concluded that experienced reprocessors with a high confidence level do not indicate competency (Suresh et al. (2021).

Benefits of Endoscopic Reprocessing and Infection Control Education

Though limited in research, multiple studies illustrated that endoscopic reprocessing and infection control education aids personnel in proficiency, efficiency, and satisfaction (Abd-Elhamid et al., 2016; Malvar et al., 2020; Ofosu & Banerjee, 2022; Shin et al., 2021). One study measuring nurses' knowledge and practice of infection control post ten educational sessions

concluded that knowledge improved to 53.3-80% and lasted 6 months to keep the levels 40% to 76.7% (Abd-Elhamid et al., 2016).

Re-education and scrutinizing technician reprocessing efforts significantly improved bioburden removal in the precleaning phase. With education, training, and surveillance strategies, human error and negligence can reduce the incidence of contamination and the prevalence of infection (Ofosu & Banerjee, 2022). Other facilities around the world have varying standards of practice (SOP) and seek standard formal training to promote effective reprocessing and subsequently reduce the risk of infection to patients (Beilenhofff et al., 2017; Beilenhoff et al., 2018; Chapman et al., 2019; Ofosu and Banerjee, 2022; Shin et al., 2021; Thaker et al., 2018).

One study suggested that participation in a nationwide reprocessing program consisting of lectures and a hands-on endoscopic reprocessing training session promoted adherence to reprocessing guidelines. Practical adherence to reprocessing guidelines was higher for those who completed the nationwide endoscope training program than those who did not participate. 94.5% of respondents reported adhering to endoscope guidelines, and 91% reported satisfaction regarding the current endoscope reprocessing training. Researchers concluded that national endoscope reprocessing could ensure adherence to reprocessing guidelines (Shin et al., 2021).

A Call for Standardization

Nationally and internationally, there has been a focus on the education and training of endoscope technicians in response to increasing EAIs. Due to the meticulous nature of the reprocessing protocol, it is essential to create a standardized education and training reprocessing program.

In 2019, the Korean Society of Gastrointestinal Endoscopy updated the Accreditation of Qualified Endoscopy Unit assessment items for quality indicators, including endoscope disinfection education. Endoscopy reprocessing staff must have acquired at least three credits of disinfection education within three years. Given the changing continuum of endoscopy decontamination procedures, mastering current and future knowledge and techniques must be acquired continuously to prevent the spread of endoscopy-related infection and to guarantee the quality of disinfection in endoscopic examinations. (Shin et al., 2019).

As of 2018, the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology Nurses and Associates (ESGENA) addressed recent MDRO infection outbreaks by implementing measures to prevent or manage such outbreaks. Staff training, reprocessing, and maintenance of duodenoscopes and process validation has become vital in outbreak prevention. They recommend that competent staff be trained in line with national laws and regulations regarding endoscope reprocessing using standardized reprocessing protocol. Similarly to Korea, the ESGE/ESGENA has emphasized the importance of an officially recognized endoscopy reprocessing education and training program with mandatory periodic training to maintain competency. Furthermore, Europe recommends regular audits to assess compliance with guidelines and recommendations (Beilenhoff et al., 2017, Beilenhoff et al., 2018).

In England, endoscopic decontamination practices are based on Joint Advisory Group (JAG) accreditation requirements. JAG evaluates endoscopy units to comply with national decontamination standards promoting best practices. The following are decontamination practices based on JAG requirements: endoscopy units must train all staff, including new

employees involved in the decontamination process, specifically trained in their role and the wide-ranging context of endoscope management, decontamination, and recontamination prevention, and the maintenance of continuing education of meet requirements. Evaluation of staff endoscope decontamination competence occurs within Competence 21, a national endoscopy competence framework that offers a standardized training and assessment tool for manual cleaning endoscopes. Annual competency validation uses this framework (Chapman, 2019).

In the United States, a national survey involving physicians, Society for Gastroenterology Nursing Association members was performed assessing national duodenoscope reprocessing patterns across 249 institutions. 13.2% of nonphysicians and 4.3% of physicians reported the need for better manual cleaning methods. Specifically, this survey researchers identified concerns that diverse national practices and a lack of high-quality comparative data regarding supplemental reprocessing techniques might increase the risk for additional MDRO outbreaks. It calls to question whether local practice differences, inadequate manufacturer-supplied instructions, or lack of implementation of supplementary recommendations are to blame in the absence of uniform practices (Thaker et al., 2018).

Discussion

The examined studies show the prevalence of EAIs with a composite score of 0.2% for endoscope procedures worldwide. Common yet severe complications, including sepsis and cholangitis, account for 77% of EAIs. Additionally, 7.35% of EAIs resulted from transmitting MDRO-causative microorganisms, of which there is limited antibiotic effectiveness (Deb et al., 2022).

Outbreaks from MDRO microorganisms have prompted motivation to research endoscope contamination that threatens patients acquiring EAIs. This review reveals an overall contamination rate of 15.25% in patient-ready endoscopes (Larsen et al., 2020). Most studies agree the risk of infection is related to contamination from residual biofilm and bioburden resulting from reprocessing failures resulting in a risk of infection from contaminated endoscopes (Okamoto et al., 2022; Goyal et al., 2022; Larsen et al., (2020); Rauwers et al., 2018; Ofstead et al., 2020). Post-ERCP, there is a 10% risk of infection from contaminated endoscopes (Ofstead et al., 2020). Reprocessing failures occur due to human-associated elements like skipping steps due to time constraints and inadequate training. Even experienced endoscope reprocessors need continuous training to maintain competency regarding changes to reprocessing protocol and newly designed endoscope models.

The structure and function of the complex design of endoscopes also create challenges for reprocessing procedures to be successful. Reprocessing involves multiple steps that must be followed meticulously to promote the best outcome of residual biofilm, bioburden, and colonization to reduce the risk of infection. Unfortunately, many endoscope reprocessing personnel is left untrained or do not receive formal training, thus increasing the likelihood of contamination. As mentioned, recent outbreaks of endoscopic-associated MDRO infections have led to fatalities. It is imperative to protect our patient population from infection.

Guideline

A multi-society guideline for reprocessing of flexible GI endoscopes and accessories was developed and updated in 2021. The guideline was developed by associated approval agencies,

including the (ASGE, Society of gastroenterology Nurses and Associates (SGNA), and Ambulatory Surgery Center Association (ASCA), among other agencies.

The multi-society guideline identifies the training and competencies required for personnel to reprocess endoscopes (Day et al., 2021).

- Staff are oriented to written environmental disinfection and endoscope reprocessing policy
- Reprocessing personnel will receive model-specific instructions and training to promote proper cleaning, HLD/sterilizations, and documentation of all reprocessing steps. Before being assigned to perform HLD or sterilization of devices personnel should receive instructions training and have competency documented.
- Competency evaluation of endoscopic reprocessors is performed and documented on a schedule that the organization will define. At minimum annual competency evaluation should conducted.
- All endoscopic staff responsible for reprocessing should receive the same training and competency evaluation, regardless of practice setting, and undergo documented brand-and model-specific training when initially hired and at least annually. Should a change in reprocessing guidance be received from an endoscope manufacturer, regulatory agencies, or guidance from professional organizations, additional training, along with updated evaluation and documentation of competency, is required.
- Due to adenosine triphosphate (ATP) testing limitations of duodenoscope surveillance, ATP bioburden assessment may be useful during training, competency testing, and spot surveillance of cleaning steps before and after HLD.

Staff training is the most basic and essential. It is easy to accomplish staff training and reduce human-related errors to ensure disinfection quality ultimately. Evidence also has shown a need or design for effective education and training to promote best endoscopic reprocessing practice to minimize the risk of endoscopic-associated infections. Unfortunately, standardized formal educational programs lack evidence-based research regarding endoscope reprocessing. Such studies are critical in establishing standardized formal education (Day et al., 2021).

Implication for Practice

This literature review revealed that endoscopy-associated infection is concerning as patients do not expect to be infected from a low-risk diagnostic procedure. Multiple sources demonstrated that contamination of the equipment still exists post reprocessing procedures which increase the risk of infections for patients. All articles in this review illustrated that improvement in disinfection of the equipment is essential to ultimately guarantee cleanliness and lower the risk of infection for patients. The staff needs to receive education and adhere to cleaning guidelines to enhance the quality of disinfection of the endoscope equipment.

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CHAPTER TWO

MANDATORY CERTIFICATION OF REPROCESSING

Introduction and Problem

Over 17.7 million gastrointestinal (GI) endoscopic procedures are performed in the United States annually (Deb et al., 2022). Of those, 600,000 are ERCP procedures. ERCP procedures are a less invasive treatment alternative to investigate gall bladder and pancreatic pathologies. Such procedures are performed with reusable duodenoscopes, but due to their complex design, duodenoscopes are difficult to clean properly, posing increased risks of EAIs. Insufficient cleaning of duodenoscopes results in residual bioburden in patient-ready duodenoscopes leading to the potential patient-to-patient cross-contamination of microorganisms, including MDROs like Carbapenem-Resistant Enterobacteriaceae (CRE) (Larsen et al., 2020).

The transmission rate of EAIs was considered extremely rare, with estimated rates being 1 per 1.8 million procedures. However, since 2012, surveillance and tracking of CRE and other MDRO transmission detected several outbreaks of EAIs across the USA and Europe. (Ofosu & Banjeree, 2022). At least 25 separate outbreaks caused by contaminated duodenoscopes have been discovered worldwide between 2012 and 2015 alone, affecting over 250 patients. More concerning is the association of MDROs that portend significantly higher patient morbidity and mortality rates than common organisms. The mortality rates connected with duodenoscope-related MDRO outbreaks can be extremely high. One American study suggested a 1-month mortality rate of over 20% (reference). CRE bacteria are frequently linked to duodenoscope-

related infections and are resistant to almost all available antibiotics. Such outbreaks have led to sepsis and bacteremia in patients (Mccafferty et al., 2018; Ofstead, 2020). Furthermore, a 2018 nationwide European study revealed that after standard reprocessing, nearly 40% of endoscopy facilities had contaminated one or more patient-ready duodenoscopes, indicating that current disinfection protocols are inadequate (Forbes et al., 2020). Outbreaks have been attributed to human error or negligence during reprocessing, inadequate cleaning of complex elevator mechanisms of duodenoscopes, and the narrow margin of safety in endoscope reprocessing (Ofosu & Banjeree, 2022). Endoscopy procedures expose the elevator mechanism, open wires, and channels to bioburden. The complex design of duodenoscopes does not allow for disassembly or direct observation during cleaning, creating challenges during reprocessing (Ofstead et al., 2020). Even the slightest infraction in reprocessing protocol gives rise to the potential contamination of instruments and the risk of infection transmission (Ofosu & Banjeree, 2022).

In 2015 the US Food and Drug Administration (FDA) responded with recommendations for healthcare facilities to adopt one of four interventions, including microbiological culturing, ethylene oxide (EtO) sterilization, use of a liquid chemical sterilant processing system, and repeat high-level disinfection (HLD). Among them, microbiological culturing is the gold standard for the surveillance of endoscopic infections and indicates the temporary removal of endoscopic equipment from service when positive (Ofosu & Banjeree, 2022).

Even with the adoption of one of the four interventions, interim results collected in March 2019 report that up to 3.6% of samples tested positive for low to moderate-concern organisms and up to 5.5% for high-concern microorganisms (Ofosu & Banjeree, 2022).

Problem Statement

Human error or negligence during endoscope reprocessing has been identified in several studies (Ofosu & Banjeree, 2022). According to Rex et al. (2018), two employees were dismissed for skipping manual cleaning steps in one US center. Consequently, the FDA has stressed that education and staff training in reprocessing are vital and may require facility auditing or surveillance to optimize bioburden results (Ofosu & Banjeree, 2022).

Endoscopy-associated infections identified through tracking CRE and MDRO infections have exposed unknown realization of the prevalence of infection transmission through endoscopes contamination worldwide. A Montana endoscopy unit will serve as an investigative microcosm of the prevalence and risk of duodenoscope infection transmission and utilize a recommended multifaceted approach, including education, training, and surveillance.

Organizational Microsystem Assessment

Adopted infection prevention standards were set by the American National Standards Institute and Association for the Advancement of Medical Instrumentation ST91 (ANSI/AAMI ST91). Their certification of endoscopy reprocessing (CER) aims to create reprocessing standardization and protocol through professional knowledge and education to reduce the incidence of EAIs. All endoscopic employees of this project site are not certified in reprocessing but have received formal training and competency verification (ANSI/AAMI, 2021).

In an assessment regarding infection control reprocessing and training, the facility's training program consists of orientation and on-the-job training with competency checkoffs at 30, 60, and 90 days after hire, followed by every six months of education. Similar training

competencies and checkoff time intervals are applied when new endoscopic products or procedures are integrated into unit processes. New hire orientation and training methods have not changed within the past 15 years; however, the most current, up-to-date techniques are conveyed.

This Montana endoscopy unit has not adopted gold-standard microbiological surveillance due to cost and limited resources at the facility. Microbiological surveillance refers to culturing parts of the endoscope and removing the endoscope from service until the results finalize in 48-72 hours. Cost factors include the purchase of additional duodenoscopes to replace duodenoscopes removed from operation due to pending microbiological cultures. Amount per duodenoscope ranges from $2,750 to $6,500.

Furthermore, this facility does not have a robust patient-tracking mechanism for endoscopy-associated infections. Efforts focus on quality assurance measures via adenosine triphosphate bioluminescence (ATP) testing to compensate. ATP testing measures residual bioburden after reprocessing completion to assess infection risk. A multidisciplinary guideline for reprocessing standards reports that ATP testing may help determine the adequacy of reprocessing techniques after the manual cleaning stage. Multiple studies have identified a benchmark of <200 relative light units (RLUs) associated with acceptable "clean" safety standards after manual cleaning. Guideline standards recommend ATP bioburden assessment for training, competency testing, and spot surveillance of the cleaning steps before and after HLD (Day et al., 2021). ATP measures the effectiveness of reprocessing, revealing residual bioburden missed during reprocessing stages.

ATP protocol at the endoscopy unit indicates that eligible endoscopes, including three duodenoscopes and three endoscopic ultrasound scopes (EUS), are tested with ATP after

completion of HLD instead of after manual cleaning. Thus, benchmark scores of less than 100 RLUs of bioburden indicate passing and are recorded in a log book. Passing endoscopes can be reused according to facility policy. The average recorded RLUs over the past six months was 22 RLUs. Also, endoscope technicians reported that when endoscope reprocessing fails with greater than 100 RLUs of residual bioburden, subsequent reprocessing phases occur until goals are reached. Though the average RLU result indicates safe endoscope reuse, the lack of microbiological surveillance testing and limited patient EAI tracking methods make it imperative to promote excellence in reprocessing protocol and reduce human error variance through education, training, and certification. Facility reprocessors reported they have not had to reprocess endoscopes in more than two reprocessing phases to meet bioburden goals.

Of note, endoscope reprocessing failures are not logged or accounted for and potentially skew the quality of endoscope reprocessing performance data and true contamination. Per current unit guidelines, duodenoscopes and EUS scopes are the only endoscopes subject to ATP testing due to associated complex elevator mechanisms and increased infection risk. This facility has three duodenoscopes and three echoendoscopes. On average, five ERCP weekly procedures require duodenoscope use, reprocessing, and ATP testing. Colonoscopes and gastroscopes are not subject to ATP quality assurance measures like duodenoscopes and echoendoscopes.

Rationale

Prompted by adherence to national standards, implementing this quality improvement project involving mandatory CER certification is best visualized through the plan-do-study-act framework. Advantages of this framework include allowing small-scale testing with minimal expenditure of resources and without taking significant risks or using large amounts of time. The

project will begin as a pilot program with one individual participating in the certification exam preparation and participation. Furthermore, it will allow the participant to gain new knowledge and experience to adopt in future reprocessing efforts.

Plan: during this phase, we clearly identify the aim or question, assess potential improvement changes, establish a measurement plan, and predict results during this phase. The project aims to standardize procedures according to the national reprocessing protocol to promote infection prevention. The intervention reflects an adopted mandatory certification requirement. Measurement consists of a pass rate of the certification exam and ATP testing for residual bioburden left on endoscopes measured in RLUs to identify successes or failures.

Do: During this phase, the intervention is tested on a small scale. Our program will begin as a pilot study involving one participant. It will be essential to observe exam certification readiness to promote success. Potential barriers include timeliness in providing essential study guides to exam participants. Also, all applications must be collected at least four weeks before the exam date for application processing.

Study: In this phase, the project will identify three different results. First, the pass or fail certification exam status of the single participant. Second, a reprocessing performance analysis of all endoscopy technicians measured by ATP testing with a goal of fewer than 22 RLUs per unit average will occur. A subsequent comparison analysis of reprocessing of endoscopes between the single certification participant and all other endoscope technicians will ensue. Lastly, a patient chart review for 60 days will occur, identifying EAI incidence via endoscopy patient ED visits presenting with infection symptoms within 72 hours post-endoscopy procedures. Infection symptoms will include abdominal pain and fever. A comparison evaluation

of EAI incidence between the single certification participant and all other endoscope technicians will occur.

Act: This project will evaluate certification attainment to become certified. A qualitative survey regarding successes and failures in exam preparation will ensue regardless of certification status. Evaluation of reprocessing performance and EAI incidence will continue due to increased knowledge related to certification exam preparation. Next, this project will assess reprocessing performance via ATP testing of eligible endoscopes for 60 days. If the single certification participant does not meet goals of < 22 RLU per unit average and/or demonstrates lesser reprocessing performance measures than their peers, a strength, weakness, opportunity and threat (SWOT) or root cause analysis will be conducted and another PDSA cycle will be ran.

Specific Aims

This project's aim and the ultimate goal is to reduce the risk of patient EAIs to near zero percent with a quarterly review. To meet organizational and national standards recommended by the ANSI/AAMI ST91 guidelines, the facility is implementing the mandatory certification requirement to standardize reprocessing protocol and optimize infection control. The endoscopy unit plans to undergo a pilot study involving a single participant attempting to obtain certification. Subsequent short-term and intermediate-term goals are as follows. The first short-term goal is for one eligible endoscope technician to enroll in the CER exam by December 1st, 2022. The facility will provide educational materials and study guides recommended by the Healthcare Sterile Processing Association's (HSPA) accreditation agency via its website by December 10th 2022. These materials include; endoscope reprocessing manuals, guidelines, and standards of infection prevention from the Center for Disease Control and Prevention (CDC), the

Society of Gastrointestinal Nurses Association (SGNA), and ANSI/AAMI (see figure 4) for cost analysis. Next, this individual will report readiness and competency for the CER exam by December 27th, 2022. Lastly, the endoscopy technician will complete the certification and achieve certification on January 2nd, 2022.

An Intermediate goal includes the evaluation of duodenoscope or endoscopic ultrasound scope EUS reprocessing of the newly certified endoscopy technicians via ATP testing for residual bioburden over 30 days, from February 1st to March 2nd, 2022. Performance evaluation will measure residual bioburden via ATP testing. Our goal is < 22 RLUs per on average between eligible endoscopes. Eligible endoscopes at the facility include three duodenoscopes and three EUS scopes.

Context

This facility's mission and values focus on health care, education, research, and committing to the highest quality, safety, and reliability standards to achieve optimal clinical outcomes. By compliance with ANSI/AAMI ST91 standards, this endoscopy unit promotes the highest quality and safety standards in infection prevention.

This endoscopy unit is currently undergoing self-evaluation of ANSI/AAMI ST 91 standards. Among unmet standards, standard 6.3 identifies that, "All personnel performing processing of endoscopes should be certified in flexible endoscope processing within two years of employment and should maintain that certification throughout their employment" (ANSI/AAMI, 2019).

The mandatory certification policy change will comply with ANSI/AAMI ST91 standards. Stakeholders affected by this policy change include patients who undergo endoscopic

procedures, endoscopy technicians requiring further and continuous education in reprocessing, gastroenterologists reusing reprocessed endoscopes, and managerial and administrative staff providing financial support for initial exam fees.

The unit has four endoscopy procedural suites and ten pre/post-procedure rooms. It has a dedicated reprocessing space that is divided into two separate areas. There is a one-way directional workflow with dirty endoscopes brought into the decontamination side, where leak testing and manual decontamination occur. This area has two dual sinks where multiple endoscopes can be decontaminated sequentially. Three automatic endoscopic reprocessing (AER) machines exist in the adjacent "clean" space. ATP testing takes place in this clean space after AER and HLD. Outside the reprocessing room, endoscopes are hung in a drying cabinet and attached to an air compression drying system to dissipate droplets from internal structures and reduce the opportunity for microbial growth.

Figure 2. Endoscope Reprocessing Workflow (Ideate Medical, n.d.).

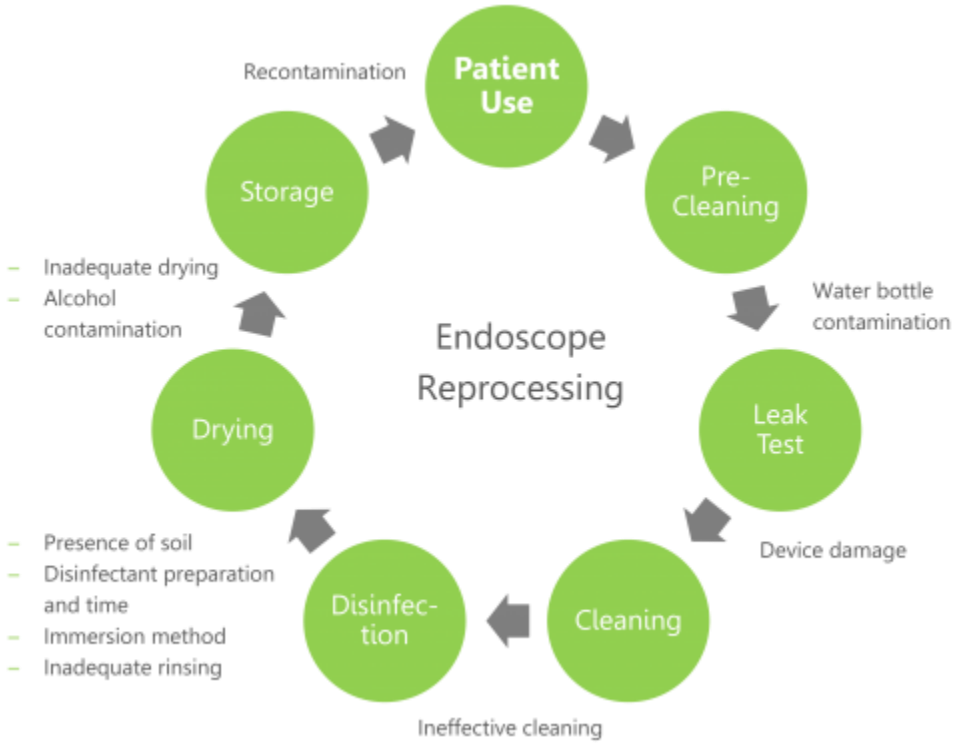
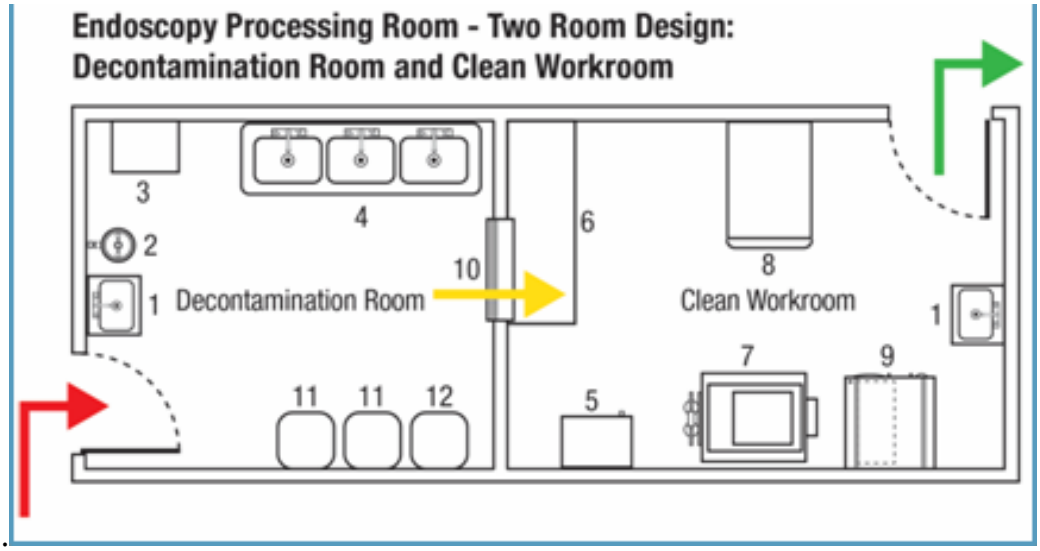


Figure 2 describes potential contamination incidents during each reprocessing stage. Endoscope reprocessing has over 120 critical cleaning steps to follow. Any slight deviation from standardized protocol leads to microorganisms' survival and increases the risk of infection (Thornhill et al., 2015). Effective endoscope reprocessing is dependent on meticulous cleaning. Figure 3 is a sample Endoscope Reprocessing workflow represented by a decontamination area where leak testing and manual cleaning take place. The endoscope will then be transferred to the clean workroom, place into the automatic endoscope reprocessor, tested with ATP strips, then hung to dry.

Figure 3. Sample Endoscope Reprocessing Design (Newton, 2016)



The Intervention and Implementation

To motivate current and future endoscopy technician participation, an in-service will be provided on December 10th, 2022, on the importance and benefits of mandatory CER in relationship to infection prevention and control during endoscopy reprocessing. Additionally, endoscopy technicians will be informed that the unit will maintain payment for the initial CER enrollment, exam, and recommended educational materials.

Figure 4. List of Recommended education materials.

Health Sterile Processing Association	Cost
Endoscope reprocess manual 2nd edition/workbook	$160
ANSI/AAMI book ST91 (2022 ed.)	$349
SGNA Standard of infection prevention in gastroenterology setting (2019)	$100
SGNA Standards of infection prevention reprocessing of flexible gastroenterology Endoscope (2018)	$0
SGNA Guidelines for High-level disinfectants in a Gastroenterology Setting (2017)	$0
CDC's Essential Elements of a Reprocessing Program for Flexible Endoscopes (2017 ed.)	$0
Total	**$609**

Incentives to attend the early morning in-service will include pastries and coffee. A survey will be sent to in-service participants to assess motivation to achieve certification on January 3rd.

Currently, a single committed technician will participate in the pilot study and pursue certification of reprocessing via a nationally recognized exam offered through the HSPA. Per the endoscopy manager, other endoscopy technicians will be encouraged to seek certification, though not required. Future incentives for attaining certification are being investigated on behalf of the manager, including incremental increases in pay per hour.

To facilitate success in achieving mandatory CER, the endoscopy technician will be provided with HSPA-recommended educational materials and an exam outline on November 10th. Among the educational materials is a companion study guide workbook with questions

similar to the exam, which may be a focal point. I will request the endoscopy technician to monitor the time and impressions of knowledge acquired from each workbook. A mixed-method survey will be provided to the endoscopy technician on January 3rd to identify experience, motivation for CER attainment, readiness for the CER exam, time dedicated to studying, educational materials, and perception of HSPA-recommended educational materials for CER. This endoscopy tech will respond to the survey on the same day.

Project Timeline

Identified eligible candidates will be based on HSPA certification for endoscope reprocessing (CER) criteria. Eligibility includes that employees must have at least 3 months of hands-on work experience. All nine endoscope technicians are eligible; however, one has committed to participate in the pilot program. Our first aim is to educate eligible employees on the importance of standardization protocol through certification and assess motivation for attaining the certification in endoscope reprocessing (CER). All eligible endoscope technicians will be encouraged to enroll in CER training. With the endoscopy manager's help, the project leader will provide an educational in-service at an endoscope technician meeting on December 9th. All eligible endoscope technicians will be encouraged to enroll in CER certification. The project team leader will relay application instructions for enrollment in the certification exam on November 1st. The endoscopy manager will provide HSPA-recommended educational materials to aid in exam preparation and deliver to the technicians by November 15th. To ensure timely processing of the enrollment application, the application will be collected by the manager and sent to the HSPA accreditation agency by December 1st. At least one eligible endoscope technician to enroll in the CER exam by December 2nd, 2022.

After obtaining MSU IRB approval, mixed-method survey will be conducted to one endoscopy technician on January 3rd to identify demographic information, motivation, readiness, time dedicated to studying, and educational materials the endoscopy technician thought were more beneficial. Next, this individual will report readiness and competency for the CER exam to the project leader by January 3rd, 2022. Then the endoscopy technician will complete the certification and achieve certification on January 10th, 2022. A mixed-method survey regarding successes and failures in exam preparation will ensue regardless of certification status. Additionally, reprocessing performance and EAI incidence will be continuously evaluated due to increased knowledge related to certification exam preparation..

This project will include two intermediate goals. The first intermediate goal consists of a performance evaluation of the duodenoscope or EUS scope reprocessing of all endoscopy technicians via ATP testing for residual bioburden over 60 days, from January 11th to March 13th, 2023. Reprocessing performance goal is < 22 RLUs per unit average between eligible endoscopes. Following data collection, a comparison reprocessing performance analysis between the certification tech participant and all other staffed reprocessors will be conducted.

The second intermediate goal will identify EAI incidence through endoscopy patient chart review. A patient who presents to the ED with infection symptoms, fever and/or abdominal pain within 72 hours post-endoscopy will be counted as having an EAI. A comparison evaluation of EAI incidence between the single certification participant and all other endoscope technicians will occur.

If this goal is unmet, the manager will conduct a strength, weaknesses, opportunities, threats (SWOT) analysis or root cause analysis (RCA) to identify associated barriers in endoscope reprocessing.

The ultimate goal of the mandatory certification and standardization is a near 0% infection rate of patient EAI transmission with CER tech reprocessed endoscopes for the next 6 months. This pilot study will be trialed for six months in anticipation of meeting short, intermediate, and ultimate goals. If such goals are met, then it will be recommended to continue enrolling eligible staff members in certification exam preparation and exam.

Potential barriers limiting examination participation and preparation include illness and absenteeism during the educational session regarding the importance of certification of endoscope reprocessing in relationship to standardization and infection prevention. Also, the lack of motivation for certification on behalf of the endoscopy technician may hinder passing the certification exam and increase enrollment. It is necessary to stress the importance of standardizing endoscope reprocessing, knowledge gained and endorsed through certification, and its implication on infection prevention and control.

Additional considerations include an ongoing trial of disposable elevator caps to implement infection prevention procedures concurrently. It will be challenging to identify which intervention has affected the EAI incidence. Thus, measuring reprocessing performance between staff members is necessary to incorporate comprehensive infection risk metrics and data.

Evaluation

Figure 5. Smart Goals.

SMART Goal #1: Single participating endoscopy technician will respond to a precertification survey related to skill, experience, and self-knowledge of endoscope reprocessing, motivation, feelings of necessity, readiness for the CER exam and perception of HSPA recommended educational materials for CER certification by January 3rd, 2022.		
Project Leader (Me) • Inform endoscope technician on decision to implement mandatory certification and educate the associated EBP benefits of standardization and infection control via an in-person endoscopy technician in-service • Create a survey to elicit current skill, experience, and self-knowledge of endoscope reprocessing and motivation and readiness for CER certification. This survey will be sent after on January 3rd..		
Data to be collected	Method of Collection	Planned data analysis
Demographic data including: • Length of experience • Motivation and readiness for CER measured with a Likert scale • Preferred educational materials	A informative survey conducted by the project leader.	Summary of quantitative and qualitative data.
SMART Goal #2: Single staffed participating endoscopy technicians will receive certification by 2/1/2023.		
Description of strategies to be utilized to accomplish goal including any needed resources. (Can be in outline or bullet list format.) **Project Leader** • Obtain a privacy agreement with single participant to illicit certification exam pass/fail status. • If the single staffed participating endoscopy technicians unable to pass the certification exam, assess for problems and issues faced during educational sessions, study preparation, and exam content difficulty. Conduct a survey to elicit this information.		
Data to be collected	Method of Collection	Planned data analysis
• Pass fail rate for CER certification • Successes and failures of exam preparation reported by those who did not pass CER certification.	Endoscopy tech reported attainment of CER via email confirmation and/or certification printout. The project leader will provide post exam survey if the exam tech did not pass the certification exam.	Analysis will identify the endoscopy tech's perception of successes and failures of exam preparation methods and materials

Table 2. Smart Goals continued.

SMART Goal #3: One endoscopy technician will excel in performance of standardized reprocessing procedures after preparation for the certification exam to decrease bioburden residue after endoscopic reprocessing with a goal average of less than 22 RLUs per unit average, evaluated from January 11th to March 13th, 2023 with duodenoscope log review.
Project Leader • Collect the duodenoscope reprocessing log that identifies specific reprocessed ERCP and EUS scopes and their overall ATP scores measured in RLU. • Average ATP scores to assess met/unmet goals. • If the average RLU increases rather than decreases, I recommend conducting a SWOT analysis or root cause analysis to evaluate the single staffed participating endoscopy technician

Data to be collected	Method of Collection	Planned data analysis
• Duodenoscope reprocessing bioburden scores	Duodenoscope reprocessing log review completed by project leader.	Collected data will be projected via bar charts. Analysis will identify whether obtaining CER certification and subsequent standardization will reduce infection risk. If goal is not met evaluate via a SWOT or RCA to identify barriers.

SMART Goal #4: Post ERCP patients chart review will identify less than two individual ED visits related to infection symptoms like fever and abdominal pain evaluated from January 11th to March 13th.
Endoscopy Manager • Conduct a patient chart review for ED visits occurring within 72 hours post ERCP related to signs and symptoms of infection including fever and abdominal • Record results and relay to the Project Leader **Projected Leader** • Report collected data in a spread sheet • Assess post-certification relationship with patient outcome.

Table 2. Smart Goals continued.

Data to be collected	Method of Collection	Planned data analysis
• ED visits occurring within 72 hours post ERCP or EUS procedure related to signs and symptoms of infection and designate endoscope and reprocessor associated with EAI.	Patient chart review regarding ED visitation completed by the Endoscopy manager.	Collected data will be projected via bar charts. Analysis will identify EAIs attributed to CER endoscope reprocessors vs. other staffed reprocessors and whether obtaining CER certification and subsequent standardization will reduce infection risk. If goal is not met evaluate via a SWOT or RCA to identify barriers.
SMART Goal #5: Near 0% infection rate of patient EAI transmission with CER tech reprcessed endoscopes via ERCP/EUS procedures during the next six months (March 14 to July 14th).		
Endoscopy Manager • Conduct a patient chart review for ED visits occurring within 72 hours post ERCP related to signs and symptoms of infection including fever and abdominal • Record results and relay to the Project Leader • Report collected data in a spread sheet • Assess post-certification relationship with patient outcome.		

Table 2. Smart Goals continued.

Data to be collected	Method of Collection	Planned data analysis
• ED visits occurring within 72 hours post ERCP or EUS procedure related to signs and symptoms of infection and designate endoscope and reprocessor associated with EAI.	Patient chart review regarding ED visitation completed by the Endoscopy manager.	Collected data will be projected via bar charts. Analysis will identify EAIs attributed to CER endoscope reprocessors vs. other staffed reprocessors and whether obtaining CER certification and subsequent standardization will reduce infection risk. If successful, end trial period and enroll eligible staff in certification exam preparation and exam. If goal is not met evaluate via a SWOT or RCA to identify barriers.

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CHAPTER THREE

CERTIFICATION OF REPROCESSING STANDARDIZATION: PREVENTING ENDOSCOPY-ASSOCIATED INFECTIONS

Abstract

Background: Between 2012-2015, 25 outbreaks were linked to contaminated duodenoscopes worldwide due to human error or negligence during reprocessing. A standardized education and training reprocessing program is necessary to address nationally increasing Endoscopy Associated Infections (EAIs). **Problem:** A Montana endoscopy unit committed to adopting national standards. An unmet objective was the certification of endoscopy reprocessing (CER) requirement. This pilot project sted in developing a mandatory CER protocol to optimize infection control. **Methods**: A Plan-Do-Study-Act (PDSA) quality improvement method was employed, with pre- and post-intervention design to evaluate infection incidence and risk. This involved patient chart review and duodenoscope reprocessing log review. An aggregate comparison was made between a CER participant and eight non-CER technicians. To inform future program development, a survey was conducted to collect data on CER participant motivation, preparation, and perception of recommended educational materials. **Intervention:** A pilot study involving a single participant attempting to obtain nationally recognized CER was conducted. The facility manager shared the facility's intention of mandatory certification and via endoscope technician meeting, including incentives. Created certification-benefit video presentation and exam preparation materials were provided one month before the exam.

Results: Zero infections occurred during pre- and post-intervention. Pre-intervention, the average infection risk scores per endoscope reprocessing were 12.2 relative light units (RLUs) for the unit and 11.1 RLUs for the CER participant. Post-intervention phase, these numbers were 15.7 RLUs by non-CER technicians and 2.8 RLUs by the CER participant. **Conclusion:** This study highlights the effectiveness of mandatory CER in reducing the risk of patient infections. Maintaining infection prevention and control in endoscopy procedures requires ongoing education, training, and motivation. Informing employees of the benefits of standardization may improve motivation.

Background

Despite previous estimations of rare Endoscope-Associated Infections (EAIs) transmission rates, recent surveillance and tracking have detected EAI outbreaks across the USA and Europe (Ofosu & Banjeree, 2022). At least 25 outbreaks caused by contaminated duodenoscopes have been discovered worldwide between 2012 and 2015 alone, affecting over 250 patients. These outbreaks are associated with multi-drug resistant organisms (MDROs) that have significantly higher patient morbidity and mortality rates than common organisms. Such mortality rates can be as high as 20% within one month. Carbapenem-Resistant Enterobacteriaceae (CRE) bacteria, frequently linked to duodenoscope-related infections, are resistant to almost all classes of available antibiotics and have led to sepsis and bacteremia in patients (Mccafferty et al., 2018; Ofstead, 2020). Two additional studies reported inadequate disinfection protocols with concerning results, indicating the need for improved disinfection (Forbes et al., 2020; Ofosu & Banjeree, 2022).

The recent outbreaks of EAIs caused by contaminated duodenoscopes have highlighted the inadequacy of current disinfection protocols. Even after standard reprocessing, the high prevalence of contaminated patient-ready duodenoscopes further supports the need for improved disinfection protocols (Ofosu & Banjeree, 2022).

Problem

EAIs were previously thought to be very uncommon, with an estimated transmission rate of 1 per 1.8 million procedures. However, surveillance of CRE and other MDRO transmission has revealed multiple outbreaks of EAIs in the USA and Europe. Outbreaks have been attributed to human error or negligence during reprocessing, inadequate cleaning of complex elevator mechanisms of duodenoscopes, and the narrow margin of safety in endoscope reprocessing. Consequently, the FDA has stressed the importance of education and staff training in reprocessing and possible facility auditing or surveillance requirements to optimize bioburden results (Ofosu & Banjeree, 2022).

The partnering Montana Endoscopy unit adopted national infection prevention standards set by the ANSI/AAMI ST91, including the Certification of Reprocessing (CER). CER aims to create reprocessing standardization and protocol through the acquisition of professional knowledge and education to reduce the incidence of EAIs. As such, this endoscopy unit served as an investigative microcosm of the prevalence and risk of duodenoscope infection transmission and utilized a recommended multifaceted approach, including education, training, and surveillance.

Rationale

This quality improvement project utilized the plan-do-study-act framework. Advantages of this framework include small-scale testing with minimal expenditure of resources and without taking significant risks or using large amounts of time. The project began as a pilot program with one individual participating in certification exam preparation. Allowing the participant to gain new knowledge and fresh experience, will improve quality care and assist in future reprocessing efforts. To demonstrate the effectiveness of CER, a comparison was conducted between two groups; the CER participant and eight fellow endoscope reprocessors who did not participate in the CER program. The baseline assessment included a three-month patient chart review and duodenoscope/endoscopy ultrasound log review. A two-month post-intervention evaluation was used to compare infection incidence and risk. Furthermore, a mixed-method survey was conducted regarding motivation, preparation, and perception of recommended educational materials for CER.

Specific Aims

This project aimed to adopt and adhere to national standards in endoscope reprocessing protocol to prevent endoscope-associated infections and reduce the risk of infection in reprocessing. To meet organizational and national standards recommended by the ANSI/AAMI ST91 guidelines, the facility is implementing an unmet mandatory certification requirement to standardize reprocessing protocol and optimize infection control. Understanding the intricacies and idiosyncrasies of CER training program development and its effectiveness on infection prevention is essential. With implementing mandatory CER, the ultimate goals were to maintain

a zero percent infection rate and reduce the average infection risk associated with endoscopes. The defined goal for infection risk reduction was any decrease in the CER participant's average infection score over the course of project evaluation.

Context

The Montana Endoscopy Unit is part of a healthcare organization serving the eastern Montana area. The organizational/facility's mission and values focus on health care, education, research, and commitment to the highest quality, safety, and reliability standards to achieve optimal clinical outcomes. By compliance with ANSI/AAMI ST91 standards, this endoscopy unit promotes the highest quality and safety standards in infection prevention by applying the mandatory certification policy change.

The Montana Endoscopy Unit conducts on average six ERCPs to two or three endoscope ultrasound procedures per month. The unit owns three duodenoscope and three EUS scopes. They staff a workforce of nine endoscopy staff members that were trained on site.

The steps involved in this endoscopy unit’s endoscope reprocessing protocol typically include pre-cleaning, leak testing, manual cleaning, disinfection with an automatic endoscope reprocessor, drying, and storage of the endoscope. Post-endoscope reprocessing infection risk scores, measured in RLU, are recorded in a daily logbook. Infection risk reprocessing goal parameters are less than 100 RLUs. If an endoscope infection risk score post reprocessing is greater than 100 RLUs, the endoscope will need to be reprocessed.

Intervention

Phase 1: Development and Initiation

The project leader investigated multiple national CER accreditation agencies. After considering factors such as eligibility criteria, cost, and recommendations from the facilities' sterilization department, the Healthcare Sterile Processing Agency (HSPA) was selected. An endoscope certification in-service presentation was scheduled to motivate current and future endoscopy technician participation but did not occur due to scheduling conflicts. Instead, the project leader recorded a 14-slide and 17-minute PowerPoint (PPT) presentation on the importance and benefits of mandatory CER, distributed to the staff. Eligibility criteria for CER were relayed, including at least three months of hands-on work experience. All nine endoscope technicians were eligible; however, a single participant entered the pilot program.

Phase 2: Implementation of the Pilot Program

The selected accreditation agency, HSPA, provided the project leader with relevant materials to be used for exam preparation. These materials were then provided to the CER participant one month before the proposed exam date of January 11th, 2023. The development of this pilot project included:

1. Delivery of Healthcare Sterile Processing Association's (HSPA) recommended educational materials and study guides to the CER participant one month before CER exam. Six recommended educational materials included:
    - Endoscope reprocessing manual 2nd edition/workbook (~250 pages)
    - ANSI/AAMI book ST91 (2022 ed.) (190 Pages).

- Society of Gastrointestinal Nurses Association (SGNA) Standard of infection prevention in gastroenterology setting (2019) (22 pages).
- SGNA Standards of infection prevention reprocessing of flexible gastroenterology Endoscope (2018) (28 pages).
- SGNA Guidelines for High-level Disinfectants in a Gastroenterology Setting (2017) (15 pages).
- CDC's Essential Elements of a Reprocessing Program for Flexible Endoscopes (2017 ed.) (12 pages).

2. CER participant enrollment in the CER exam.
3. A precertification survey included motivation, preparation, and perception of HSPA-recommended educational materials for CER. The CER participant will take a mixed-method study one week before exam attendance.

Phase 3: Evaluation

Delays on the part of the CER accreditation agency and subsequent testing unavailability postponed the exam date until March 13th, 2023. Relevant data collection could not be achieved within the desired time frame. Since the CER technician reported readiness for the exam on January 11th after completing exam preparation as initially planned, the post-intervention data collection period was set from January 11th to March 11th. The precertification survey was delivered upon new of the delay and reported readiness.

Measures

Three measurements assessed the impact of the educational intervention. These measurements included the preintervention survey, EAI incidence, and infection risk. To illuminate the effects of national certification, the single nationally certified participant was compared to the unit average for infection incidence and risk that occurred at pre- and post-intervention intervals. A mixed-method evaluation of the endoscope technician's motivation, preparation, and readiness for the exam was conducted using multiple choice, Likert scale, and open-ended questions. The survey was conducted post-delivery of the video presentation email to increase motivation and knowledge of how certification can promote infection control.

Infection incidence and risk were collected for three months pre-intervention and two months post-intervention. Infection incidence was measured through post-endoscopy patient chart review. Infection criteria included an emergency department visit within 72 hours post-ERCP procedure with signs and symptoms including at least one of the following: abdominal pain, fever, leukocytosis, or elevated lactic acid,.

Infection risk evaluation utilized adenosine triphosphate (ATP) test strips that measure the presence of organic matter called bioburden. Bioburden can include substances such as blood or tissue that harbor harmful microorganisms. Residual bioburden benchmarks measured are relative light units (RLUs). The national standard is to have less than 100 RLUs post-endoscope reprocessing to be patient-ready to use for the next case. Toward the end of the pre-intervention period, there was a shortage of ATP brand test strips. Consequently, a new ATP testing product, Safestep II test swabs, was used during the post-intervention testing, creating a threat to data reliability.

Analysis

Descriptive statistics were used to analyze the data. The intervention group had only one participant and was compared to a control group of eight participants with an aggregated infection risk score. However, due to the small sample size of the intervention group, statistical significance could not be determined. Instead, comparisons were made between the pre-and post-intervention periods for both the intervention and control groups and anecdotal trends were observed.

Ethical Considerations

This quality improvement project was reviewed and approved by the Institutional Review Board of Montana State University and a subsequent privacy and executive committee at the participating healthcare organization. All members of the endoscopy team were informed of the prospective project during the preintervention period by the endoscopy manager who initially created the project. Confidentiality was maintained through de-identification by the endoscopy team and manager. The endoscopy team conducted data collection and entered them in a secure excel spreadsheet that was shared with the project leader by the endoscopy manager for evaluation.

Results

The results of the mixed method survey assessing motivation showed that the CER participant, who has worked as an endoscope reprocessor for over four years, believed that certification should be mandatory for infection control training and performance improvement.

After viewing the project leader's PPT video presentation (i.e., the importance & benefits of mandatory CER), the participant felt somewhat motivated and found the endoscope reprocessing manual/workbook to be the most helpful in preparing for the exam. The endoscope technician felt confident and well-prepared after the exam preparation period from December 10th to January 11th but did not answer the question about their average study hours.

Figure 6 presents the results of the pre-/post-intervention comparison. Upon evaluation of infection incidence, results indicated zero infection incidence during both the pre-and post-intervention periods. 48 endoscope procedures were evaluated before the intervention, while 39 were assessed after. These endoscopes were handled by all nine endoscope technicians, including the CER participant, working on the unit. Of note, one patient was readmitted to the hospital within 72 hours post-ERCP procedure during the preintervention period. However, the patient did not exhibit infection criteria and was not identified as a true EAI. No patient was readmitted in the post-intervention period.

In the pre-intervention phase, the infection risk assessment showed that the average bioburden benchmarks for the unit and the CER participant after endoscopy reprocessing were 12.2 RLUs and 11.1 RLUs, respectively. A total of 25 endoscopes were evaluated, including 18 duodenoscopes and 7 EUS scopes for infection risk. Among the 25 endoscopes assessed, the CER participant reprocessed seven. Notably, November had the least endoscopes reprocessed and tested due to ATP strip supply issues. With the approval of supplemental testing strips, the evaluation of endoscopes resumed.

In post-intervention, the CER participant performed four duodenoscopes reprocessing, and the ATP tests revealed an average of 2.8 RLUs per endoscope reprocessing. In contrast, the

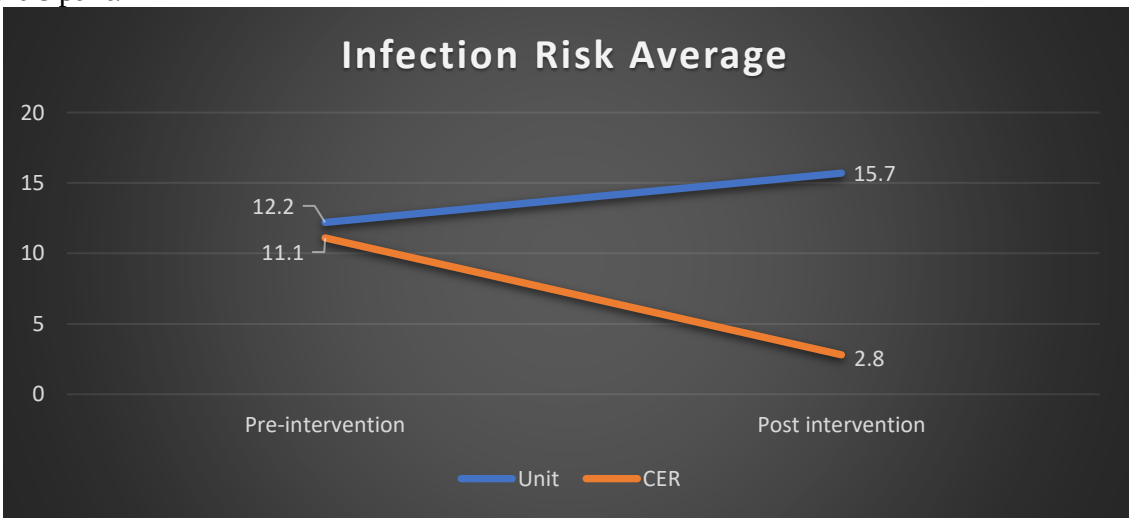
unit average increased to 15.7 RLUs per endoscope reprocessing, with 18 total endoscopes reprocessed (Figure 7); 12 were duodenoscopes, and six were EUS scopes.

Figure 6. Pre-/Post-Intervention Comparison between the Endoscopy Unit and the CER Participant.

	Unit		CER	
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention
Infection Incidence	0	0	0	0
Infection risk	12.2 RLU	15.7 RLU	11.1 RLU	2.8 RLU
# of Scopes (Infection risk)	18	15	7	4

Note. This table reports the average infection risk scores for the Endoscopy Unit and the CER participant during the pre-and post-intervention periods.

Figure 7. Infection Risk Pre-/Post-intervention Comparison between the Endoscopy Unit and the CER participant.

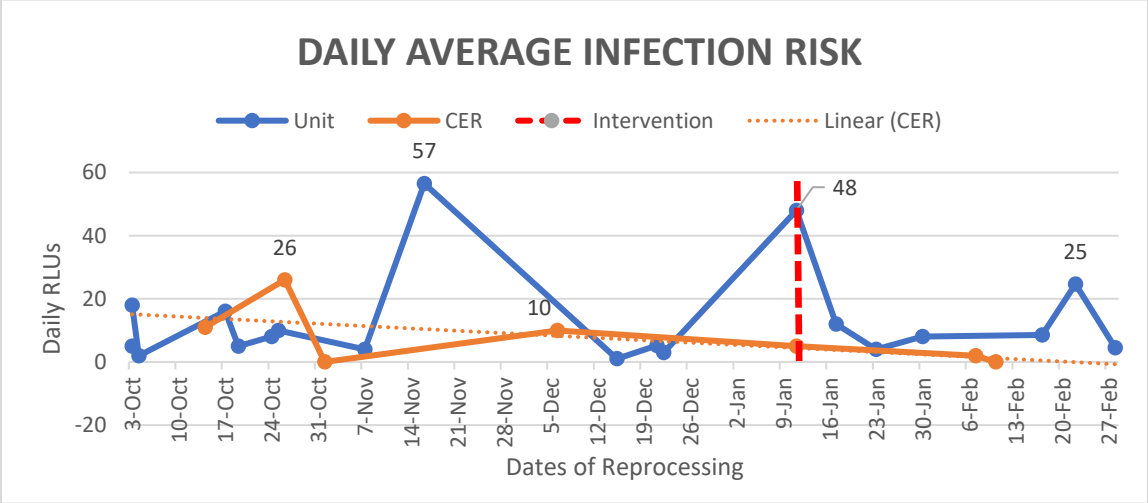


Note. This figure displays average infection risk scores for the Endoscopy Unit and the CER participant during the pre-and post-intervention periods.

Figure 8 illustrates the average daily infection risk trend for the unit and the CER participant over the pre-and post-intervention periods, while Figure 9 shows cumulative per day

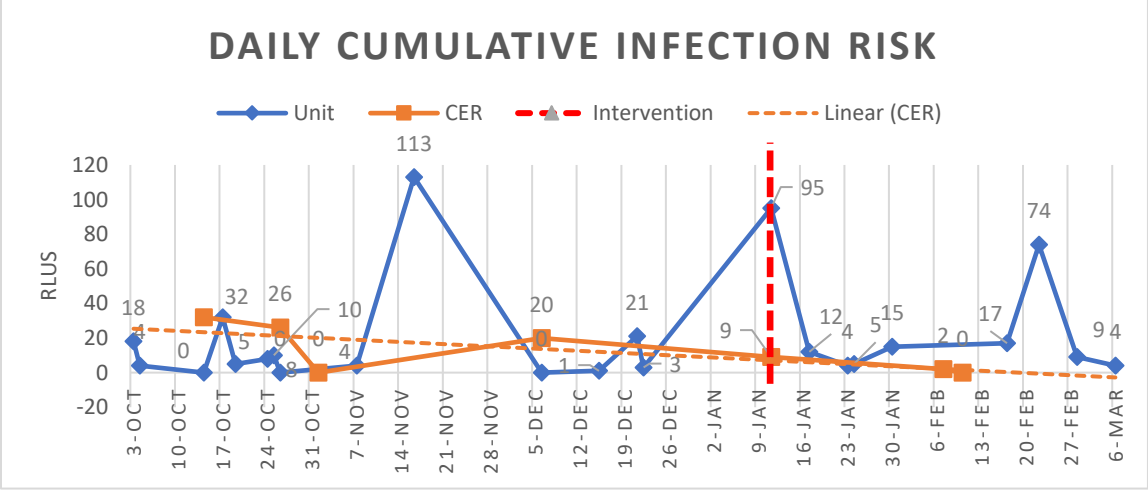
infection risk data. Both figures highlight the contrast in endoscope performance between the unit and the CER participant.

Figure 8. Daily Average Infection Risk.



Note. This figure displays daily average endoscope reprocessing infection risk scores during the pre-intervention period.

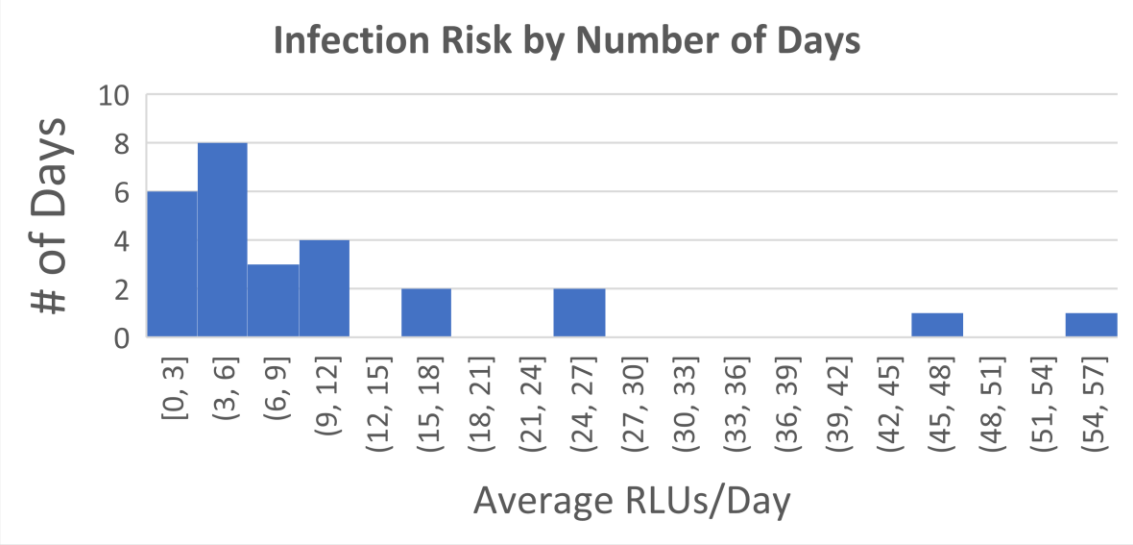
Figure 9. Daily Cumulative Infection Risk.



Note. This figure displays daily cumulative endoscope reprocessing scores for the unit (1 CER and 8 non-CER technicians) during the pre-intervention period.

Next, Figure 10 shows average daily infection risk scores throughout evaluation in an endoscopy unit. It shows that all nine endoscope technicians (1 CER participant and eight non-CER technicians) had mostly low infection risk scores during the evaluation period. For example, Out of the 27 evaluation days, there were six days with an average RLU score of 0-3, suggesting periods of low infection risk. Only a few average daily high scores were observed, with 48 and 56 RLUs as outliers. Even these higher scores were less than 100 RLU, the national standard. This graph shows that the endoscopy unit had relatively low infection risk scores during the monitored timeframe.

Figure 10. Number of days.



Note. This figure displays infection risk scores throughout evaluation in the endoscopy unit.

During the pre-intervention phase, the highest single endoscope infection risk score for the unit was 81 RLUs, while during the post-intervention phase, it was 56 RLUs. The highest single endoscope infection risk score for the CER participant was 31 RLUs during the pre-intervention phase, which decreased to 5 RLUs during the post-intervention phase. Overall, the

daily average infection risk scores for the CER technician ranged from 0-26 RLUs and 0-5 RLUs during the pre-and post-intervention periods, respectively. The minimum to maximum daily average infection risk score for all nine technicians, including CER and non-CER participants, was 0-57 RLUs during the pre-intervention period and 4-48 RLUs during the post-intervention period.

Discussion

Summary

This study aimed to evaluate the effectiveness of a pilot project involving one participant in the CER program. While this pilot project encountered several unforeseeable events, the results showed zero incidences of infections during both pre- and post-intervention periods. One patient was readmitted to the hospital post-ERCP during the pre-intervention period but did not exhibit any infection criteria. The study also assessed reprocessing performance and found that the CER participant averaged 2.8 RLUs per endoscope reprocessing in the post-intervention phase. In comparison, the unit average increased to 15.7 RLUs per endoscope reprocessing.

The findings of a mixed method survey showed that the participants believed that certification should be mandatory for infection control training and performance improvement, watching the PPT presentation increased motivation, and that the endoscope reprocessing manual/workbook was the most helpful in preparing for the CER exam. To improve educational resources available to the endoscopic unit and endoscope technicians, developing accessible online motivational tools and training for endoscope reprocessing may improve desired goals for adequate training (Kenters et al., 2018).

Interpretation

Data collection was limited over the 5-month project duration, but the results suggest adequate infection control. Before the intervention, evaluated three months of data found that the Montana Endoscopy Unit had not had an EAI. Therefore, the goal identified to reduce EAI was changed to maintain a zero-infection incidence post-intervention. Post-intervention data collected over two months revealed zero infection incidence, which aligns with this project goal.

Infection risk was well below the national standard of <100 RLUs. Even during the preintervention period, it was found that the average infection risk score for the unit was 12.2, and the certificated participant was 11.1. This indicates that every reprocessed scope in the unit met the national standard for patient readiness. The post-intervention tests aimed to identify improvements in the certified participant's infection risk scores from pre-intervention levels and compare them with the post-intervention unit average. The average unit infection risk score increased from 11.9 to 12.9 (8%). Although it could be negligible due to ATP test strip change, possible considerations of failure to improve infection risk include neglect of participation in requiring certification and relayed short staffing that ensued during the post-intervention period. On the other hand, the certified participant's average infection risk score improved by 75% from 11.1 RLUs with seven endoscopes reprocessed to 2.8 RLUs with four endoscopes reprocessed. Therefore, it is reasonable to conclude that preparation for the CER exam may promote a reduction in infection risk regardless of short staffing.

Lastly, the mixed method survey reflection shared by the certified participant indicated that a participant may experience the same success in endoscopy reprocessing if they felt that certification was necessary, motivated to complete the exam, and prepared the exam utilizing the endoscope reprocessing manual/workbook. CER participant evaluation of the video PPT

presentation indicated that the PPT presentation should be enhanced to motivate employees to enter the mandatory CER attainment.

In summary, while the Montana Endoscopy Unit has not experienced an Endoscopy Associated Infection (EAI) in the past, outbreaks caused by multidrug-resistant organisms have been reported globally, leading to significant mortality rates. Current disinfection protocols may be inadequate, as studies have shown that a substantial number of endoscopes continue to be contaminated even after standard reprocessing. The post-intervention data collected over two months revealed zero-infection incidence, aligning with our project goal of maintaining a zero-infection rate. However, it is essential to note that the average unit infection risk score increased during the post-intervention period, indicating the need for continuous improvement. On the other hand, the certified participant who underwent CER showed a significant improvement in infection risk scores. Therefore, implementing CER as a mandatory requirement is a proactive measure to ensure patient safety, prevent potential EAIs, and continuously improve processes to prioritize patient well-being. By investing in CER, we are taking necessary steps to maintain the highest standards of care, mitigate risks, and protect our patients in the endoscopy unit.

Limitations

There are a few limitations regarding this project. One limitation included the small sample size for the initial pilot program. Only one participant was included due to the inability to recruit other technicians, partially because of the technicians' time commitment and the manager's creation of a certification training program. The creation of the training program was initially meant to begin during 2023 or 2024. However, this quality improvement project presented a more proximal opportunity. By working together, the certification requirement for

reprocessing was fast-tracked, and small sample size was desired for the initial program. A larger sample size may better provide how certification attainment aids in infection risk, especially for less experienced individuals.

Another limitation is the evaluation periods for both infection incidence and risk. A five-month data snapshot might not produce sound results due to the small sample size of ERCPs, EUS procedures, and endoscopy reprocessing. One year review of infection incidence and risk may provide an accurate portrayal. Other conditions that may have interfered with results include intermittent short staffing and a change in ATP products. Additionally, a change in multiple leadership roles impacted the timelines of decision-making. Of note, there were other disposable endoscope attachment trials during this project. All disposable equipment trials were cut short due to various gastroenterologist complaints. As a result, multiple variables may convolute whether interventions impacted evaluated results.

Next, the project leader could have collected data at a 30-day window instead of 7 days of infection incidence post-ERCP or EUS procedure. In the literature review, a study revealed post-ERCP infection rate is 3.5% at seven days and 7.7% at 30 days (Hutfless et al., 2020). A 30-day evaluation may illuminate true infection incidence.

Unfortunately, the planned post-certification exam mixed method survey review regarding the CER exam experience was impossible due to the rescheduled CER exam falling outside the data collection window. Although the review was not included in this project, an evaluation of recommended HSPA exam preparation and materials should be shared with the manager and facility members.

After discussing the matter with the manager, the topic moved to how evaluating HSPA materials had changed the endoscopy unit. The manager provided feedback from the CER technician about the learning process, which led to positive practice changes. For example, they began testing water quality, ensuring water temperature accuracy, and using critical detergent dosing.

It's important to note that despite the unforeseen circumstances, we could still gather valuable insights from the manager and CER technician on the impact of the CER exam experience and the effectiveness of HSPA materials in promoting change within the endoscopy unit.

Conclusion

The findings of this quality improvement project may have significant implications for other facilities that perform endoscopic procedures. First, this project underscored the importance of continuous education and training for healthcare staff in endoscope reprocessing through mandatory CER preparation and learned reprocessing protocols. The FDA has stressed the need for facilities to standardize training programs and regularly audit and surveil their reprocessing practices to optimize bioburden results and reduce the risk of infection transmission. The results of this project support this recommendation as the CER participant had a lower average RLUs per endoscope reprocessing than the unit average in the post-intervention phase. By prioritizing ongoing improvement and patient safety through CER, we proactively ensure the highest standards of care and mitigate risks in our endoscopy unit.

Furthermore, the study's mixed-method survey findings suggest that informing employees of the benefits of standardization may improve motivation. However, avenues of

delivery should be explored. The endoscopy manager had structured the training program by proposing newly certified technicians to lead CER course instruction. The new structure should be evaluated to increase CER candidates' motivation and successfully attain certification. These suggestions and findings could inform further development of training and certification programs for local healthcare staff involved in endoscope reprocessing, aiming to improve adherence to infection prevention standards and reduce the incidence of EAIs.

Successes of the Mandatory CER QI project include strong involvement and communication from managers throughout project development, implementation, and evaluation. Although weekly check-ins via phone and email were conducted, monthly visits to the facility were, unfortunately the only in-person interactions. It would have been beneficial for the project leader to visit the facility more frequently to improve recruitment efforts and promote better reprocessing performance in the future. Furthermore, challenges faced during the project include difficulties adhering to proposed timeframes and completing the literature review early enough to aid in creating motivational materials for the endoscope technician recruitment meeting. Additionally, the inability to assess infection risk post-certification period as intended, dual interventions involving disposable endoscope parts for infection prevention, and changing ATP products during active data collection all contributed to convoluted infection risk results. Despite these challenges, the project was successful overall, and lessons learned can help inform future development and goals for this project. Facility long-term goals included 80% of staff CER certified, 0% infection rate, and overall improved infection risk measured after one year.

This quality improvement project has important implications for improving patient safety and infection control in the healthcare industry, specifically in endoscopy procedures. The

findings suggest that implementing mandatory CER and ongoing education and training for healthcare staff involved in endoscope reprocessing can effectively reduce the risk of infection transmission and optimize reprocessing practices.

Endoscope reprocessing is a critical aspect of infection prevention in endoscopy procedures. In conjunction with high employee turnover, human error, and negligence during reprocessing have been identified as significant contributors to endoscope-associated infections. Implementing infection prevention standards and certification programs can help standardize reprocessing protocol and optimize infection control. The Montana endoscopy unit's pilot study showed that mandatory CER could effectively reduce the risk of patient infections, with zero incidence of infections during pre- and post-intervention periods. The study also revealed that the CER program's success depends on education, training, and motivation. Thus, continuous education and training of healthcare staff and regular facility auditing and surveillance, as demonstrated in this CER pilot project, are crucial for maintaining effective infection prevention and control measures in endoscopy procedures.

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CHAPTER FOUR

DNP ESSENTIALS REFLECTION

As a registered nurse, I have always been committed to expanding my knowledge and skills to provide the best possible care for my patients. Pursuing a Doctor of Nursing Practice (DNP) degree at Montana State University has furthered this essential part of that journey. Throughout my studies, I have been guided by the eight DNP essentials that serve as the foundation for the program. In this reflection essay, I will discuss my experiences in relationship to the DNP essentials, including how they helped me grow as a future nurse practitioner.

DNP Essential 1 stresses the significance of having a strong scientific foundation in nursing practice, which includes understanding the underlying scientific principles and evidence-based practice that guide patient care. The DNP program at Montana State University has provided a deeper understanding of these scientific principles, as demonstrated through the Evidenced-Based Practice II course. This course involved a literature review on complementary alternative modalities (CAM), specifically meditation-based exercises with statin-related therapies in treating coronary artery disease (CAD). This completion of this project has allowed me to make more informed decisions when developing patient care plans. In conclusion, DNP Essential 1 emphasizes the importance of continually updating and improving scientific knowledge in nursing practice, including considering all available options for improving patient outcomes, such as CAM.

DNP Essential II emphasizes the organization and systems leadership in improving patient outcomes and ensuring safe and effective care delivery. For example, in my Finance and Budgets of Health Care Systems course, I co-led research about a prospective technological new

product line CardioMEMS to meet current and future needs for heart failure patient populations based on evidenced based practice analysis of the heart failure technology. I employed principles of business, finance, economics, and health policy in developing this new line by creating a cost analysis and breakeven analysis that concludes in the potential profitability of the line for the adopting hospital and clinic. In my Design of Healthcare Systems course, I learned how to create and use evaluation and process improvement tools, including fishbone diagrams, flow charts, and value stream maps, to promote efficient and effective organizational changes. This knowledge has prepared me to be an effective leader in my future practice and advocate for my patients' needs.

DNP Essential III emphasizes the importance of clinical scholarship and analytical methods in improving healthcare outcomes. During my Evidence-Based Practice I course, we were responsible for completing our first PICO project involving evaluating articles, producing an evidence-based table, and giving a presentation. Our group project involved hyperbaric oxygen therapy for diabetic pressure ulcers. We were tasked with assessing the effectiveness of this therapy and identifying potential barriers to its implementation in clinical practice. Through our analysis, we found that hyperbaric oxygen therapy effectively promoted wound healing and reduced the risk of amputation in diabetic pressure ulcers. However, the therapy was not widely available in many healthcare settings due to cost and resource limitations.

The PICO group project encouraged students to appraise existing literature on a particular topic of interest and conclusively reject or recommend treatment based on found appraised evidence. Furthermore, an implementation strategy was created utilizing the IOWA process model. Through this experience, I acquired the knowledge for research, concept development,

and design necessary to implement change in practice. I have gained a deeper understanding of the importance of clinical scholarship and analytical methods in nursing practice. As a future nurse practitioner, it is crucial to stay updated with the latest research and evidence-based practices to provide the best possible care to my patients.

DNP Essential IV emphasizes the importance of information systems/technology and patient care technology for improving healthcare outcomes, exemplified by the Health Informatics course. During the Informatics course, a group project charged us with evaluating the effectiveness of the previously mentioned CardioMEMS device that can measure pulmonary pressure to promote enhanced titration of medication therapies. This project taught me how to evaluate new technologies to improve patient care outcomes. Course instruction also taught me about utilizing information systems and patient care technology and the importance of data security and confidentiality when using information systems.

DNP Essential V emphasizes the importance of analyzing, developing, and implementing health policy. In my Ethics, Laws, and Policy course, I was responsible for conducting a healthcare policy analysis and a subsequent advocacy letter. The health care policy chosen was related to RN staffing ratios. It was explained that post-covid, unsafe nurse ratios had become the new norm and management assessment had reinforced this workload citing that completion of tasks occurred. An advocacy letter was drafted backed by a selection of studies discouraging increased nurse-to-patient ratios. Through this project, I gained a better understanding of the investigation and creation of possible healthcare policies and the need for advocacy to promote safe patient care. I also learned how to engage with policymakers and advocacy groups to

promote policies. Overall, DNP Essential V highlights the importance of healthcare policy advocacy in improving healthcare outcomes and promoting health equity.

DNP Essential VI emphasizes the importance of interprofessional collaboration for improving patient and population health outcomes. In my Programming Planning and Evaluation course, we were tasked with a group assignment to complete a QI project regarding diabetic management with mobile applications in rural areas of America. Tasks were divided evenly, and multiple discussions took place to complete this assignment. This collaborative approach allowed us to address diabetic management with unique technology that may optimize diabetes control. During my clinical rotations, I also worked closely with nurse practitioners, nurses, and other healthcare professionals to provide comprehensive patient care. Through collaboration with these healthcare professionals, I developed a better understanding of the patient's needs and provided more effective care. DNP Essential VI highlights the importance of interprofessional collaboration in achieving optimal patient outcomes. As a future nurse practitioner, I recognize collaboration's critical role in providing high-quality care and improving population health.

DNP Essential VII emphasizes the importance of clinical prevention and population health for improving the nation's health. In addition to the previously mention chronic medical conditions management of diabetes with mobile technology and heart failure with the CardioMEMS device, completion of both Advanced Pathophysiology and Advanced Pharmacology courses have promoted the identification and appropriate treatment options of chronic medical conditions using evidence-based practice resources. Clinicians must maintain continuous education and use appropriate evidenced based practice resources to facilitate patient management of chronic diseases. In Advanced Pathophysiology, we were responsible for

system-based pathophysiological disorders, recommended treatment, and prevention options. My case study was the renal system, in which I evaluated the pathophysiology, treatments, and prevention of pyelonephritis and urinary tract infections. Overall, DNP Essential VII highlights the importance of health promotion and disease prevention nationwide and the investigation of the cause and treatments of disease.

DNP Essential VIII, Advanced Nursing Practice, focuses on the skills and knowledge necessary to provide holistic, patient-centered care across various populations and healthcare settings. Through various courses and projects, I have had the opportunity to augment my expertise in assessing, planning, and treating patients across their lifespans.

For instance, in the Women's Health course, I gained insight into the intricacies of genitourinary and breast assessments and gender-specific screening guidelines for women. Likewise, in pediatric and geriatric courses, I honed my ability to perform age-specific assessments, including understanding Beer's criteria and what is necessary for a well-child visit.

Moreover, the Advanced Health Assessment course allowed me to practice history intake, assessment skills, and physical exams using online simulations. We completed full head-to-toe assessments before entering clinical rotations, which provided 1000 clinical hours of hands-on experience that reinforced my ability to provide patient-centered care in diverse settings.

In addition, I learned how to critically analyze patient data, identify potential diagnoses, and develop evidence-based care plans, all of which are crucial to delivering advanced nursing care. DNP Essential VIII underscores the significance of advanced knowledge and skills in

providing patient-centered care. As a DNP graduate, I am well-equipped to assume advanced nursing roles and advocate for the needs of my patients.

Lastly, through my completion of the DNP scholarly quality improvement project focused on reducing endoscopy-associated infections by certifying endoscope reprocessors, I met Essentials I through VIII. To meet Essential I, III, and VIII, I conducted a comprehensive literature review of evidence-based reprocessing protocols and identified potential lapses in reprocessing through flow charts.

To fulfill Essential II, I researched national accreditation for endoscope reprocessing. This involved gathering information on exam dates and times, recommending educational materials to aid in passing the exam, and creating a detailed cost analysis for certification application and recertification. In carrying out this responsibility, I reviewed multiple sources of information to ensure accuracy and comprehensiveness. I also communicated with relevant professional organizations to gain additional insights. My efforts led to a thorough understanding of the certification process and the necessary steps to maintain this certification. This is critical to ensuring high-quality endoscope reprocessing practices and reducing associated infection risk. Additionally, I familiarized myself with relevant endoscope technologies, such as the leak tester, automatic endoscope reprocessor, and bioburden testing machine, which coordinate with Essential IV.

I adopted the plan-do-study-act method to satisfy Essential V, which served as the foundation for implementation and future evaluations. I worked collaboratively with the endoscopy manager to collect and analyze data promptly, which helped me fulfill Essential VI.

Together, we completed the necessary tasks and communicated with the endoscope reprocessors involved in the project.

As outlined in Essential VII, the project's goal is to prevent infections related to ERCP and EUS procedures through evidence-based practice and infection control. To achieve this, it is essential to maintain certification and continuously educate oneself on reprocessing education and guidelines.

Lastly, as someone who was previously unfamiliar with endoscopy procedures and reprocessing stages, I faced a steep learning curve. However, I am proud to have gained proficiency in reprocessing and infection prevention protocols and believe this experience satisfies Essential VIII.

In conclusion, I, a registered nurse pursuing a Doctor of Nursing Practice degree at Montana State University, have reflected on my experiences and growth as a future nurse practitioner through the lens of the eight DNP essentials. I have learned valuable skills and knowledge, including using evaluation and process improvement tools, conducting literature reviews, utilizing information systems and patient care technology, and advocating for patient needs. Through completing the DNP scholarly quality improvement project that focused on reducing endoscopy-associated infections, I have met all eight DNP essentials, demonstrating a thorough understanding of evidence-based practice, infection control, and reprocessing education and guidelines. This project has allowed me to gain proficiency in a previously unfamiliar area. My experiences have prepared me to provide the best possible care for my patients in my future nursing practice.

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APPENDICES

APPENDIX A

ENDOSCOPE REPROCESSING WORKFLOW

Figure 11. Endoscope Reprocessing Workflow (Ideate Medical, n.d.).

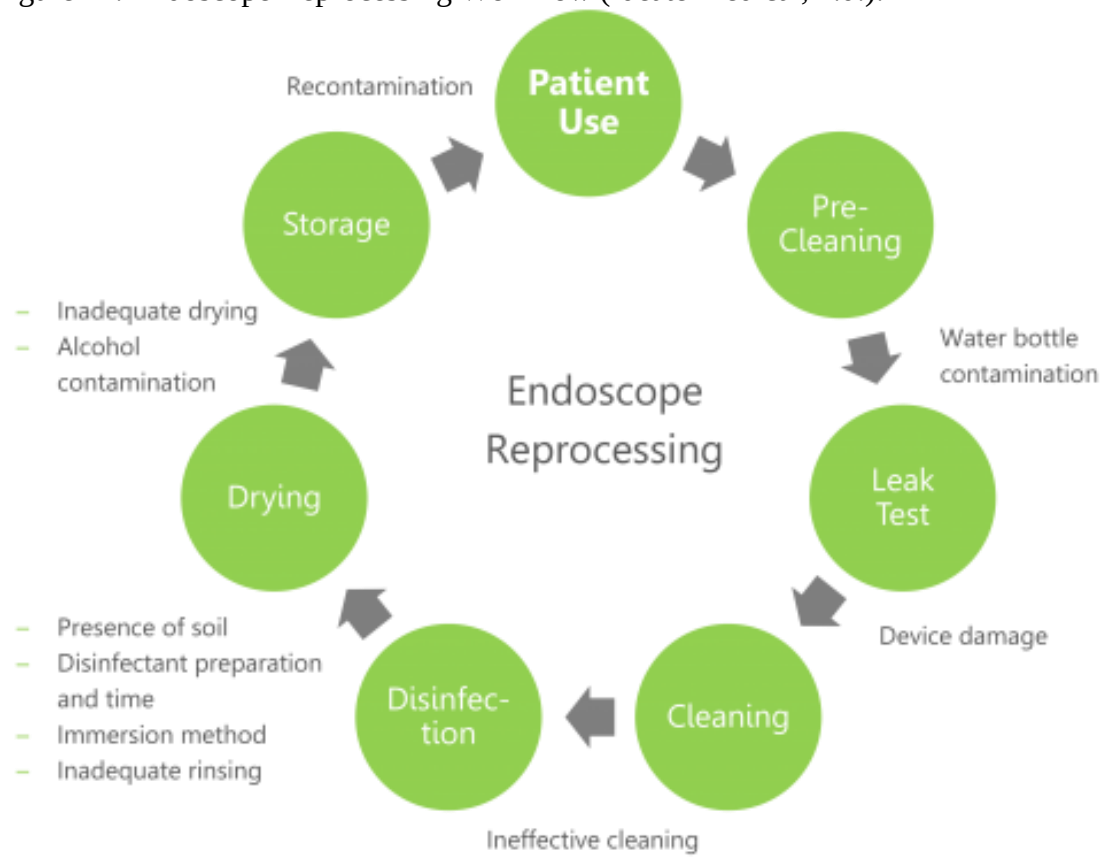
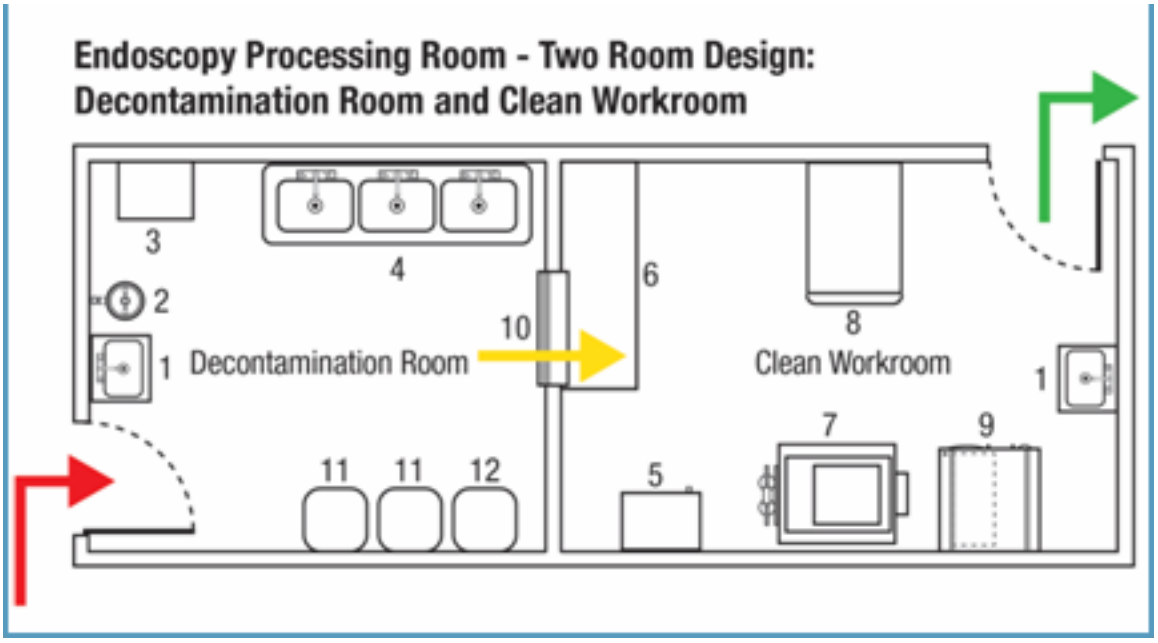


Figure 11 describes potential contamination incidents during each reprocessing stage. Endoscope reprocessing has over 120 critical cleaning steps to follow. Any slight deviation from standardized protocol leads to microorganisms' survival and increases the risk of infection (Thornhill et al., 2015). Effective endoscope reprocessing is dependent on meticulous cleaning.

APPENDIX B

SAMPLE ENDOSCOPE REPROCESSING DESIGN

Figure 12. Sample Endoscope Reprocessing Design (Newton, 2016).



This figure is a sample Endoscope Reprocessing workflow represented by a decontamination area where leak testing and manual cleaning take place. The endoscope will then be transferred to the clean workroom, placed into the automatic endoscope reprocessor, tested with ATP strips, then hung to dry.

APPENDIX C

ONLINE PPT PRESENTATION SAMPLE

Figure 13. Online PPT Presentation Sample.





APPENDIX D

MIXED METHOD SURVEY

Figure 14. Mixed Method Survey.

Certification of Endoscope Reprocessing of Preparation Exam Survey

1.How long have you been an endoscope reprocessor?

- > 3 mos -1 yr
- 1-2 yrs
- 2-3 yrs
- >4 yrs

2.Prior to watching the importance of certification in reprocessing video do you feel that attaining the certification for reprocessing is necessary?

- Agree
- Somewhat Agree
- Neutral
- Somewhat Disagree
- Disagree

3.After watching the importance of certification in reprocessing video how motivated are you to complete the exam?

- Very motivated
- Somewhat motivated
- Neither motivated nor unmotivated
- Somewhat unmotivated
- Very unmotivated

4. Which HSPA recommended educational materials for CER certification did you find the most helpful in preparing for the exam?

- Endoscope reprocessing manual/Workbook
- ANSI/AAMI ST91
- SGNA Standards of infection prevention and guidelines
-

5. On average, how many hours per day did you study? How many cumulative hours would you say you studied prior to the exam?

6.After preparation, how ready do you feel to take the CER exam?

- Not ready
- Somewhat ready
- Ready and Confident

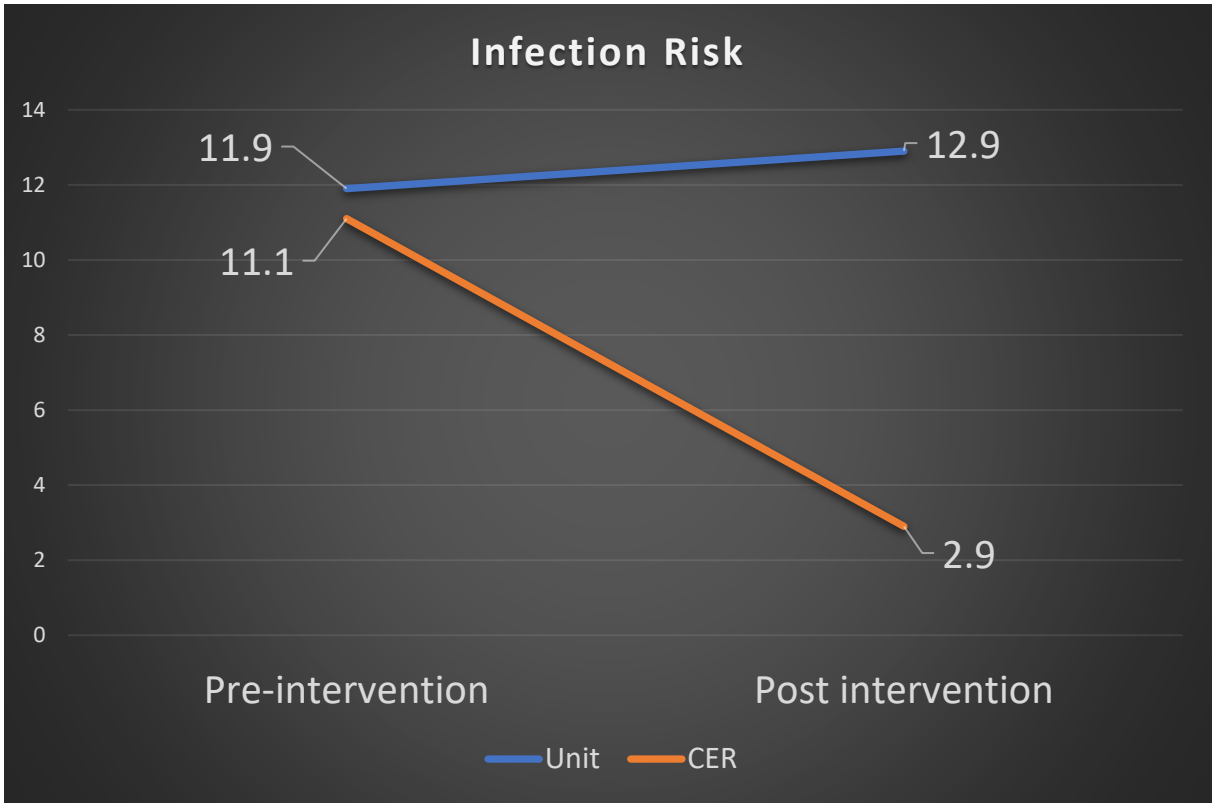
Figure 15. List of Recommended education materials.

Health Sterile Processing Association	Cost
Endoscope reprocess manual 2nd edition/workbook	$160
ANSI/AAMI book ST91 (2022 ed.)	$349
SGNA Standard of infection prevention in gastroenterology setting (2019)	$100
SGNA Standards of infection prevention reprocessing of flexible gastroenterology Endoscope (2018)	$0
SGNA Guidelines for High-level disinfectants in a Gastroenterology Setting (2017)	$0
CDC's Essential Elements of a Reprocessing Program for Flexible Endoscopes (2017 ed.)	$0
Total	**$609**

Figure 15. Pre-/Post-intervention comparison Between the Endoscopy Unit and the CERparticipant.

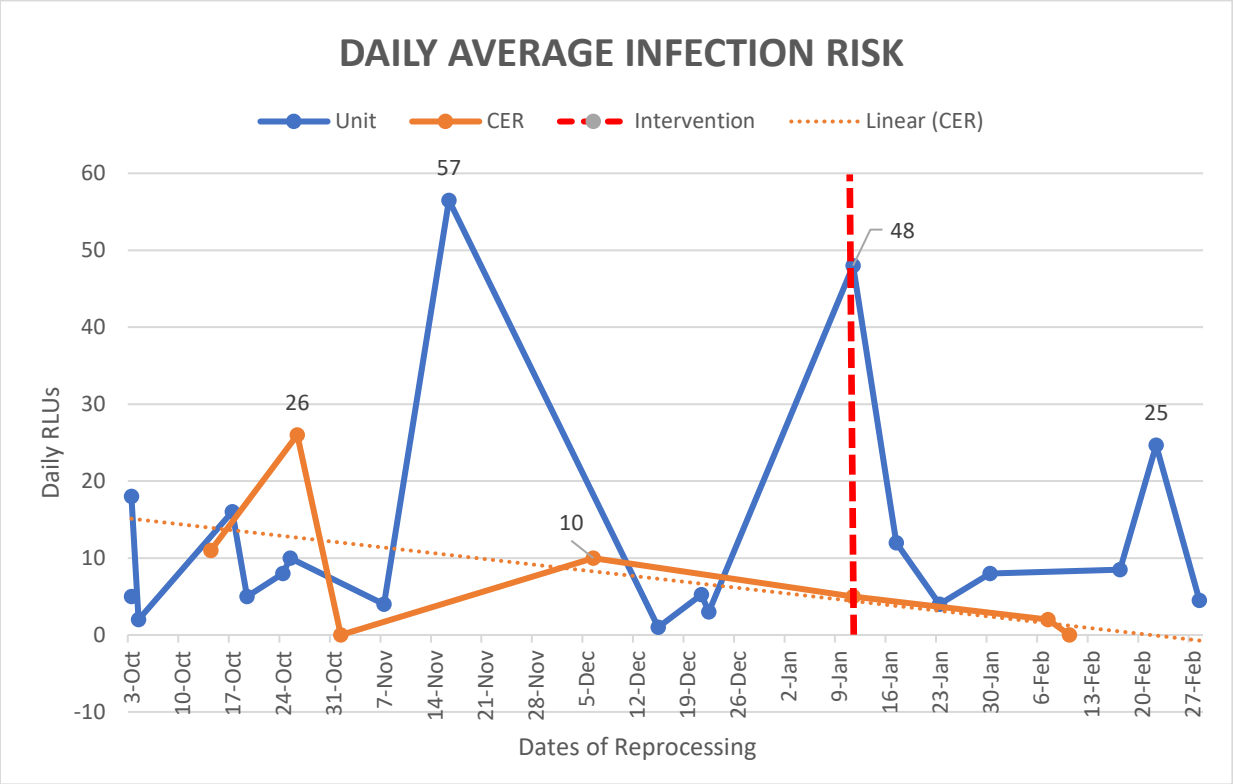
	Unit		CER	
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention
Infection Incidence	0	0	0	0
Infection risk	12.2 RLU	15.7 RLU	11.1 RLU	2.8 RLU
# of Scopes (Infection risk)	18	15	7	4

Figure 16. Infection Risk Comparison Between the Endoscopy Unit and the CER participant.



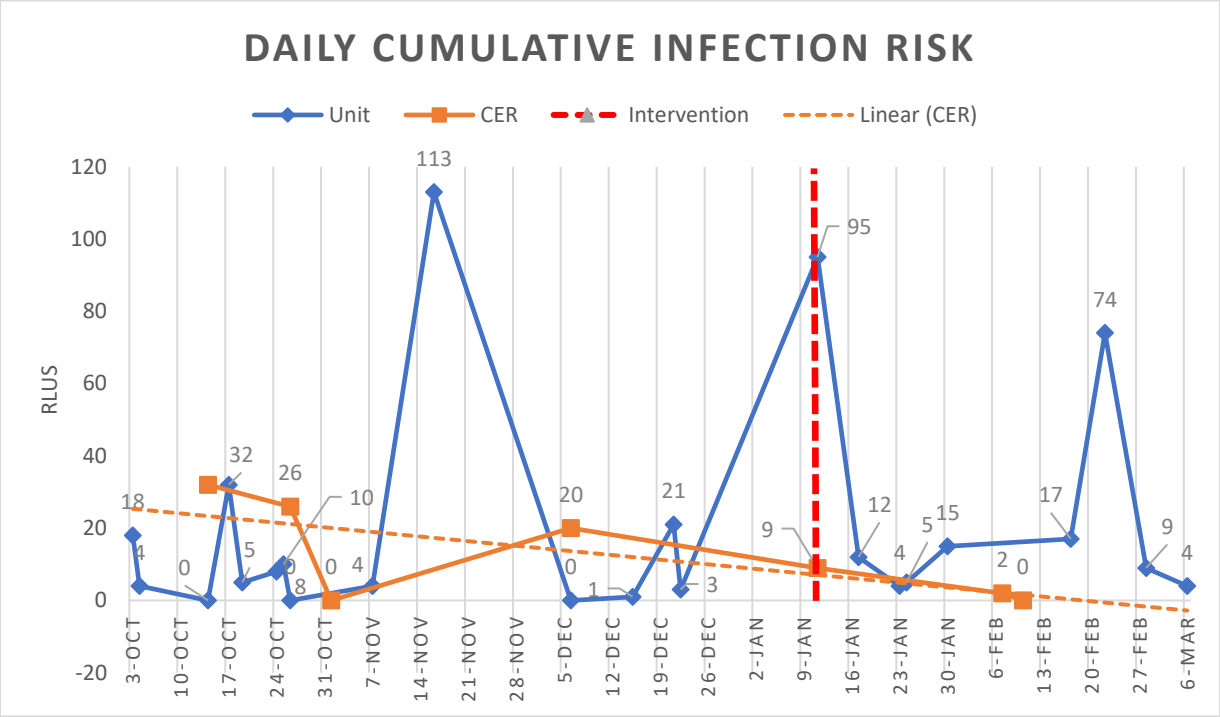
Note. This figure displays average infection risk scores for the Endoscopy Unit and the CER participant during the pre- and post-intervention periods.

Figure 18. Daily Average Infection Risk.



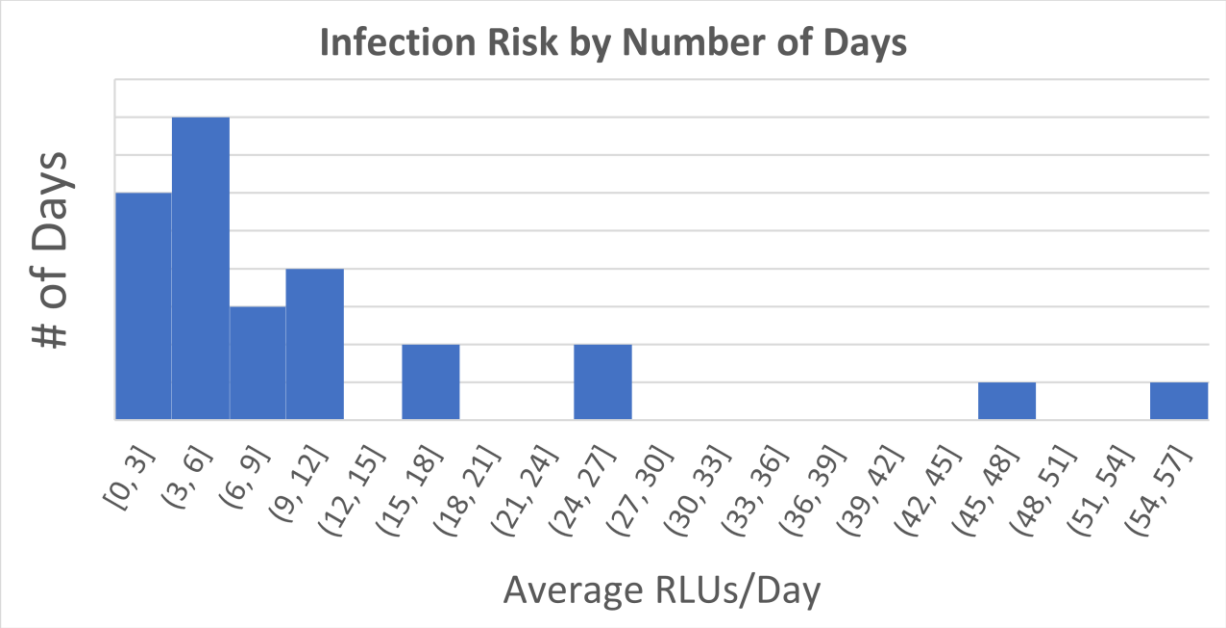
Note. This figure displays daily average endoscope reprocessing infection risk scores during the pre-intervention period.

Figure 19. Daily Cumulative Infection Risk.



Note. This figure displays daily cumulative endoscope reprocessing scores for the unit (non-CER technicians) during the pre-intervention period.

Figure 20. Number of days.



Note. This figure displays infection risk scores over the course of evaluation in the endoscopy unit. Ex: 6 days out of 27 days evaluated reflected an infection risk score (RLU) from 0-3.