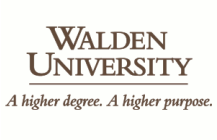

2018

Cross Contamination in Levered Endoscopes

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This is to certify that the doctoral study by

Ernest L. Thomason Jr.

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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Walden University
2018

Abstract

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by

Ernest L Thomason Jr.

MS, Walden University, 2014

BS, King College, 2001

Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

October 2018

Abstract

Contamination is a prevalent issue with reprocessed levered endoscopes. The number of infections caused by resistant enterobacteriaceae in patients due to contaminated endoscopes increased to the point that the United States Food and Drug Administration released a safety alert to health care facilities that perform cholangiopancreatography. The purpose of this descriptive project was to evaluate if levered endoscopes used in Endoscopic Retrograde Cholangiopancreatography ERCP procedures met high level disinfection criteria, were properly processed, and were germ free after reprocessing. The project was supported by 2 theories: the middle range theory of patient advocacy and the germ theory. The descriptive project consisted of data collection from 4 facilities within an organization regarding the reprocessing of levered endoscopes and comparing the results post cleaning. According to study findings, there was a 7% average germ-free failure rate across the sites after the initial reprocessing. The cleaning process of the levered endoscopes allowed bacteria to remain on the scopes after the manufacturer-recommended cleaning was completed at the sites. Standardization of the organization's cleaning process and improvement in the national protocols were recommended. The project supported protecting the safety of endoscopy patients by identifying that the cleaning process could be improved to prevent infection introduction through a procedure. The results will be informative for laboratory staff who clean levered endoscopes, physicians who use the scopes in patient procedures, patients who undergo the procedures, and nurses who are tasked with improving patient safety in perioperative environments.

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Dedication

I would like to take this opportunity to thank the many health care providers who assisted me along this journey. It is only their knowledge that has brought together my understanding of the role of a nurse in leadership and administrative roles. I would especially like to dedicate this project to my wife for allowing me the many hours that were required to complete the clinical hours as well as a sounding board when I found myself at wits end. She has been the driving force that has led me to be an advocate for those in our community who are less fortunate and in need of quality health care.

Acknowledgments

I would like to recognize and acknowledge my committee who had the challenge of leading me through this process, my chair Dr. Sue Bell, my member at large Dr. Mirella Brooks, and my URR Dr. Jennifer Nixon. Dr. Bell has been extremely inspirational as I have taken this journey and kept me in a positive frame of mind even during the roadblocks.

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Section 1: Nature of the Project

Introduction

Technological advancements introduce a new tool that allows for lifesaving treatment. Nursing leaders must be patient advocates as new technology comes with a new set of problems to be addressed. The levered scopes that are used to perform endoscopic retrograde cholangiopancreatography (ERCP) can contain a cross contamination problem in the form of carbapenem-resistant enterobacteriaceae (CRE), a disease process that has risen in hospitals with the use of levered endoscopes that are difficult to clean manually and disinfect chemically. CRE is a life-threatening disease that is challenging to treat due to a high level of resistance to antibiotics (Centers for Disease Control and Prevention [CDC], 2015).

Problem Statement

There was a lack of information about the postreprocessing, germ-free status of levered endoscopes used in ERCP procedures in a health care system. The number of infections caused by CRE in patients who have undergone ERCPs increased to the point that the United States Food and Drug Administration (FDA) issued a safety alert to health care facilities that perform ERCPs (FDA, 2015). The manufacturer of the levered endoscopes used in the study site facilities (specifically the levered scopes) has admitted to having a design flaw that prohibits proper high-level disinfection (Petersen, Koch, & Ginsberg, 2016). Nationally, health care workers were concerned with the rising incidence of CRE infections due to improper disinfection process for levered endoscopes. The disinfection process is carried out within the endoscopy lab where ERCPs are

performed, and scopes are reprocessed post procedure. The primary project concern was the effectiveness of the reprocessing process. The most common method for cleaning levered endoscopes, and the method used at the four facilities, is manual cleaning, which is the removal of visible material and then high-level disinfection. Levered endoscopes are made of polypropylene, polyethylene, polystyrene, polycarbonate, nylon, and other similar materials that do not withstand heat or steam sterilization. Therefore, the primary methods for rendering levered endoscopes germ free are manual cleaning and high-level chemical disinfection.

There is a gap in health care in validating that the levered endoscopes are germ free after the manual cleaning and chemical disinfection processes. There is currently not a national standard for validating that the scope has met high-level disinfection before being used on a patient (Olafsdottir, Whelan, & Snyder, 2018). The current process only validates that the scope was exposed to a high-level disinfection process. In this doctor of nursing practice (DNP) project, I identified the germ-free failure rate of the levered endoscopes that had been processed with the current manual and high-level disinfection protocol at four sites within a local health care system.

The U.S. News and World (2015) reported that gallstone disease is the most common gastrointestinal disorder requiring hospitalization with 800,000 operations being performed annually. The population for this project was levered endoscopes used in patients who had undergone a cholecystectomy and required an ERCP. An ERCP is performed to retrieve gallstones that have migrated into the biliary tract (National

Institute of Health [NIH], 2015), and it is the lever in the scope that retains the bacteria that cause CRE infections (Smith et al., 2015).

Based on the FDA warning, the CDC (2015) issued the Interim Duodenoscopy Surveillance Protocol to help monitor the quality of U.S. facilities' endoscope reprocessing procedures. The protocol was written for surveillance only and did not provide clarity for point of care validation of germ-free endoscope status. Additionally, the protocol was only required in states or local areas with certain legislation or requirements and was not to be used to certify that the endoscope was sterile. The American Society for Microbiology (ASM, 2015) issued a policy statement on culturing of levered endoscopes. The ASM recommended the following:

1. Use the latest approved cleaning, high-level disinfection, or chemical sterilization protocols from manufacturers for duodenoscope reprocessing.
2. Enforce strict adherence to both manual and automated reprocessing protocols.
3. Do not perform routine duodenoscope cultures in the clinical diagnostic laboratory. If culturing is deemed necessary as part of an outbreak investigation, consider sending to an appropriate reference laboratory (para. 8).

Rutala and Weber (2016) suggested that duodenoscopic procedures in health care settings should continue and that these cleaning processes and the current methods of germ-free status validation be used until better options become available.

Purpose Statement

The purpose of this project was to evaluate if levered endoscopes used in ERCP procedures met high-level disinfection criteria, were properly processed, and were germ

free after reprocessing. Adenosine triphosphate (ATP) testing was the initial point of care test for indicating the absence of proteins after disinfection. The ATP testing was discussed in the literature as a real-time testing option for the presence of CRE and other bacteria in levered endoscopes after cleaning and reprocessing of levered endoscopes (O'Malley, Millward, Eggbeer, Williams, & Cooper, 2016). The ATP protocol can be performed in the endoscopy suite immediately before the procedure (Rutala & Weber, 2016). The FDA (2018) stated that ATP tests cannot distinguish between high-concern and low/moderate-concern organisms, and it is not sufficiently sensitive to be used as a marker for the adequacy of the high-level disinfection process. The Resi Test has been introduced to the market, but minimal information is available on its accuracy in point of care testing. Therefore, cultures are the standard of care, but each scope must be sequestered for 36 hours until the results are completed, and reference laboratories should be considered for the testing (CDC 2018). Because the typical endoscopy center does not have an excess of levered endoscopes due to the high cost of renting or purchasing the equipment, a wait of 72 hours (CDC, 2018) to clear an endoscope for use based on culture would be impractical.

There are multiple levered endoscopes in use and, with advances in technology and changes in practice, more scopes will be developed. As the most susceptible point for germ growth is the levered section of the scope, validation that the levered section of the ERCP scope is germ-free would be invaluable to practice.

Project Question

The question for this clinical practice project was the following: Does the current protocol render levered endoscopes bacteria free after manual and high-level chemical disinfection reprocessing at four sites within a system?

Nature for the Doctoral Project

The levered endoscopes are sent to sterile processing where they are manually decontaminated and then run through a chemical wash cycle. In this project, I reviewed what testing was done postcleaning to evaluate whether the scopes met high-level disinfection criteria. If the scopes failed the initial processing, there should be a process in place validating that the scope was reprocessed.

For this project, four facilities were asked to answer three questions:

1. Have the scopes been manually cleaned per manufactures guidelines?
2. Have the scopes been through a mechanical processor?
3. Has any type of posttesting been completed and, if so, what were the results of the testing?

Staff members did not change their normal processes. The project was intended to evaluate the processes in place and determine the failure rate of the processes as a needs assessment for future quality improvement.

Significance of the Project

Many facilities do not understand the importance of having a trained sterile processing department, and many hire staff that are not educated in medical instrumentation and, instead, receive their training on the job. As it is a low paying job,

there is a high turnover rate. The results of this study can be used to ensure that the instruments being used on patients are properly processed and bacteria free before reusage, no matter who was the processing technician. Patient safety was the primary concern for this project. The primary stakeholders were the staff that was properly trained to process the instruments, the physicians who needed to know they were not introducing a contaminated scope to a patient and the patients who might acquire a life-threatening illness due to improper processing of the instruments.

The project was important to nurses because the endoscopy nurse is the person who sets up instruments and tools before the procedure, checks for cleanliness, and makes sure all equipment is appropriate for the procedure. Additionally, advanced practice nurses are often employed as the supervisor or administrator of an endoscopy lab. The safety of endoscopy patients is central to this nursing role. According to the Society of Gastroenterology Nurses and Associates, Inc. (SGNA, n.d.), the nurses' practice reduces environmental risks, identifies and communicates risks and exposure reduction strategies, and participates in strategic planning to ensure risk reduction.

Summary

CRE belong to a family of germs that are difficult to treat due to a high level of resistance to antibiotics (CDC, 2015). The number of infections caused by CRE in patients who have undergone ERCP has increased to the point that a safety alert was issued to health care facilities that perform ERCPs (FDA, 2015). Facilities need an option to obtain real-time data and provide an element of assurance that the scopes used in the ERCP procedure are germ free. In this instance, all four facilities had a different

protocol for their testing process. For this project, the organization collected and provided the data to me to analyze on the protocol used in the four facilities and the germ-free failure rate in the reprocessed levered endoscopes. The results will be informative for lab staff that cleans the levered endoscopes, the physicians who use the scopes in patient procedures, the patients who undergo the procedures, and the nurses who are expected to ensure patient safety.

Section 2: Background and Context

Introduction

There is a worldwide antibiotic crisis due to mutations in CRE phenotypes with the result being carbapenemase-producing enterobacteriaceae (CPE) that have proven successful at spreading within health care settings (Rossolini, 2015). The number of infections caused by CRE in patients who have undergone an ERCP has increased in the United States (FDA, 2015). The purpose of the project was to evaluate if levered endoscopes used in ERCP procedures met high-level disinfection criteria, were properly processed, and were germ free after reprocessing. Data collected by the organization were used to determine the incidence of contaminated levered endoscopes after the facilities' reprocessing procedure (manual and chemical cleaning of the levered endoscopes).

Concepts, Models, and Theories

The concept of patient advocacy and the germ theory were used as the theoretical basis of the project. This project was directed at patient safety through advocacy. Bu and Jezewski (2007) described patient advocacy as a part of the nursing role. The concept of patient advocacy is evidenced in three core nursing attributes: ensuring patient autonomy, acting on behalf of patients, and promoting social justice in health care delivery (Bu & Jezewski, 2007). Patient advocacy is situated between antecedents for nursing actions and consequences (positive or negative) of the nursing actions (Bu & Jezewski, 2007). Nurses' interventions to decrease the risk of endoscope contamination reflect adherence to the second core attribute: acting on behalf of patients. The validation of properly

processed and germ-free levered scopes for endoscopic procedures is, therefore, a nursing advocacy action.

The germ theory played a role in this project. Since the late 1800s, medical providers have accepted the germ theory of infection causation. Pasteur, Lister, and Koch made the connection between bacteria and human infection. According to the germ theory, infectious diseases are caused by one agent. If the portal of entry of that agent can be altered by changes to the host or the environment, the infectious disease will not be transmitted (Maurer & Smith, 2017). Identifying the safety gaps and assessing outcomes of current policies, procedures, and protocols to benefit patients' wellbeing is a role responsibility of the DNP (Mughal & Irshad Ali, 2017). This project was aimed at breaking the chain of infection by changing the portal of entry for CRE by assessing whether endoscopes are germ free before reuse in patient procedures.

For this project to be beneficial, combinations of different aspects of an descriptive study were used. The project included an observational aspect from the in-house supervisors reporting that the reprocessing team was meeting manufacturer's guidelines. Cross-sectional data were collected by the organization that documented the incidence of bacteria in the reprocessed scopes at four hospital sites within the organization. The project was completed in the reprocessing area where postreprocessing testing was carried out according to each facility's existing testing protocol on levered endoscopes.

Relevance to Nursing Practice

Patients are at risk for cross contamination when levered scopes are used that has not been properly cleaned and disinfected. The nurses' role is to validate that the scopes have been properly reprocessed and are safe for patient use. A mechanical process sometimes has been removed from the typical reprocessing protocol with the introduction of automated reprocessors. The manufacturers of the reprocessors have stated that the mechanical process is no longer needed (Catalone & Drosnock, 2011). However, SGNA (2012) stated, "complex endoscope design features may allow organic debris and microorganisms to accumulate, making manual cleaning essential" (p. 6). All four of the facilities where the project took place used both a manual cleaning and a chemical reprocessing procedure.

Local Background and Context

On multiple occasions, debris has fallen out of the scopes when taken out of the carrying case before use. Also, two documented cases of E. *coli* were linked to endoscopes in a root cause analysis at the facilities. Although the E. *coli* were not contracted from levered scopes, the scopes went through the same cleaning process as do the levered ERCP scopes.

The manufacturer of the levered endoscopes used in the facilities, specifically the levered scopes, has admitted to having a design flaw that prohibits proper high-level disinfection (Petersen et al., 2016). It is this flaw that has required the facility to provide additional instruction to laboratory technicians who clean the scopes and each scope that comes through the laboratory goes through an additional manual cleaning process.

Although the mechanical portion of this issue has been resolved, there is no consistent testing process to validate the absence of proteins and potential for decreasing cross contamination.

Although the patient is at the forefront of this project, from a payer standpoint, hospital-acquired infections (HAIs) are not reimbursable (Averill, Fuller, McCullough, & Hughes, 2016). There is a potential of infection incidence of

> 2.93 per 100,000 population in the USA (9418 infections) [which] would cost hospitals $275 million (95% CR $217–334 million), third-party payers $147 million (95% CR $129–172 million), and society $553 million (95% CR $303–1593 million) with a 25% attributable mortality, and would result in the loss of 8841 (95% CR 5805–12,420) quality-adjusted life years. (Bartsch et al., 2017, p. 48e12)

From the financial perspective, not properly maintaining and processing levered scopes can put a health care facility out of business due to the financial liability.

Role of the DNP student

I have practiced within perioperative services for 29 years. I have spent the last 10 years as the director of perioperative services at several facilities and have not been satisfied with the attitude of the endoscopy staff members and what seemed to be a “let’s get done and go home attitude.” That attitude and the FDA warning regarding increased risk for CRE infections caused by cross contamination were the driving forces behind this project.

My role in this project was to highlight the absence of a protocol that validates the levered endoscopes are protein free by obtaining data from the four facilities to determine the failure rate in the mechanical plus high-level disinfection process. My goal was not to change any current process until I had data to show an opportunity for change. Facility leaders need to be proactive in decreasing the opportunities for cross contamination.

Role of the Project Team

The endoscopy technicians were responsible for completing the patient cases and then completing the manual cleaning process, running the scopes through the mechanical processer, testing after reprocessing, and then providing the data to be used in the analysis. I was responsible for analyzing the data and providing recommendations for quality improvement. The in-house supervisors were responsible for observing the cleaning process to validate that the staff were meeting manufacture's guidelines.

Summary

Levered endoscopes have not met proper high-level disinfection parameters to prevent cross contamination between patients. With design changes and additional training in the cleaning process, the levered scopes are now considered by the manufacturers to be safe for patient use. As a DNP practitioner, I must serve as a patient advocate. In this project, I developed a plan to validate whether the scopes were safe for use on patients after manual and chemical cleaning and disinfection, ensuring that the chance of cross contamination was removed.

Section 3: Collection and Analysis of Evidence

Introduction

Advanced practice nurses and DNPs, as the senior patient advocates, are entrusted with the duty to validate that all processes in the health care facility are done properly and in a manner that demonstrates the highest regard for patient safety. The purpose of the project was to validate that the levered endoscopes used in ERCP procedures met high-level disinfection criteria, had been properly processed, and were germ free.

Practice-Focused Question(s)

Does the current protocol render levered endoscopes bacteria free in four sites in a health care system?

Sources of Evidence

Two types of evidence were generated for the project: literature review data and data from the facilities' endoscope reprocessing. After the data were collected by the facilities and the deidentified data were provided to me by the organization, a spreadsheet was created to compare the reprocessing processes used and the failure rates. The results of the collected evidence will be reported in Section 4. The literature below reflects the initial literature review completed prior to initiation of the project, and it reflects the information that precipitated the FDA warning in 2015.

Smith et al. (2015) reported that in a 6-month period, three patients were identified with a strain of NDM-1 E. *coli*, and it was discovered that all three patients had undergone ERCP. The scope that was in question was immediately removed from service and cultured. It was found that the normal high disinfecting process was not

removing the entire bioburden. The use of ethylene oxide (EtO) was the only way to provide a negative culture in this scope.

Wendorf et al. (2015) found an outbreak of AmpC–producing E. *coli* infections among seven patients who had undergone an ERCP was reported. The follow-up evaluation of the scopes found that no breaches in infection control were identified and that the endoscopic reprocessing process exceeded manufacturer's recommended cleaning guidelines. Wendorf et al. concluded that the manufacturer's recommended process was inadequate.

Kola et al. (2015) conducted a study in a European facility where Carbapenem-resistant K. pneumoniae (CRKP) was cultured from 12 patients staying on four different wards. All patients had undergone an ERCP. In one instance, enterococci were cultured from one of the reprocessed scopes, which indicated that the reprocessing procedures were not sufficient.

Evidence Generated for the Doctoral Project

The Walden University Institutional Review Board (IRB) approved the project prior to data collection. The IRB approval number is 07-25-18-0352479. The deidentified data for analysis were provided by the health care system for four sites and were collected under the organization's oversight. Descriptive data were used to report the results of the facilities' reprocessing procedures. A fail rate for each facility and an average fail rate for all four sites was calculated from the data received from the organization. These data reflected the failure rate after reprocessing of the levered endoscopes had occurred according to the manufacturer's specifications.

Analysis and Synthesis

To test the validity of an epidemiological study, the researcher must assess whether the inferences drawn from the study are warranted when account is taken of the methods, the representativeness of the study sample, the nature of the population, and whether there is any bias present to threaten the quality of the study (Zaccai, 2004). In Section 4, additional literature is presented on endoscope contamination and new warnings and FDA recommendations. Additionally, the actual failure rates of the four hospitals are reported. Recommendations for quality improvement are presented.

The results of the DNP project provide current testing protocols that can be presented to other sites that process scopes with the opportunity to prevent cross contamination of various bacteria. When reprocessing procedures do not provide an adequate decrease in bioburden, there will need to be a reevaluation of the current cleaning procedures at facilities. A real-time test for bacteria at the time of scope use would ensure that instruments have been rendered germ-free.

Summary

The number of infections caused by CREs in patients who have undergone an ERCP has increased, and the infections cost hospitals approximately $275 million, third-party payers $147 million, and society $553 million (Bartsch et al., 2017). DNPs have an ethical duty to protect patient safety through advocacy and implementation of evidence-based practices. ATP testing was once considered an option to give real-time data and provide an element of assurance that scopes were germ free. New evidence has demonstrated a lack of specificity in ATP testing, and the FDA is currently not

supporting that testing. The findings from the project and recommendations for the organization are presented in Section 4.

Section 4: Findings and Recommendations

Introduction

The incidence of CRE infections has caused an increasing concern nationally regarding the proper mechanical cleaning and disinfection process for levered endoscopes. The processes are carried out within the endoscopy laboratory where ERCPs are performed, and scopes are reprocessed postprocedure. The primary project concern was the reported ineffectiveness of the reprocessing process to render scopes germ free. As recently as 2016, 35 patients have died (Mangen, 2016), while another 180 patients were potentially exposed due to contaminated levered endoscopes (Terhune, 2015).

Findings and Implications

Findings from the literature after 2015 and the results of the data analysis from the four sites are presented, and recommendations based on the findings are proposed. Lovleva and Doi (2017) showed that the spread of CRE is on the rise on a worldwide level. There are several testing modalities available, but they must be completed in a laboratory. There is a need for a testing protocol that may be used to validate levered endoscopes.

Eser (2017) found that Carbapenem-resistant infections continued with high mortality as rates are increasing despite all precautions. The CDC (2018) recommended CRE active surveillance by health care facilities. Strict control measures should be put in place due to the association with increased mortality and limited treatment alternatives for infections caused by CRE.

Ofstead, Heymann, Quick, Eiland, and Wetaler (2018) studied endoscope reprocessing, drying, and storage in three hospitals. Ofstead et al. conducted visual examinations and testing to detect fluids and contamination on patient-ready scopes. Fluid was detected on 49% of the levered endoscopes, and microbial growth was found on 71% of the levered endoscopes. Reprocessing and drying processes conformed to guidelines at only one of the three hospitals.

Pannala et al. (2018) investigated a point of care testing called Xpert CARBA-R Assay. This testing would provide results in less than an hour, therefore decreasing the CDC recommendation of culture and sequestering the levered endoscope for 72 hours (FDA. 2018) This is one of the first feasible protocols to provide results in a manner that provides an opportunity to decrease CRE cross contamination.

Rex et al. (2018) studied the results of double-reprocessing (manual cleaning followed by automated reprocessing and the process repeated). In cultures on 783 levered endoscopes, Rex et al. found 4.9% of the scopes positive for any microorganism and 0.3% positive for known pathogens.

Thaker et al. (2018) conducted a survey of 249 institutions related to their endoscope cleaning processes. Sixty-three percent of centers used repeat high-level disinfection, 53% used surveillance culturing, 47.8% of centers used forced-air drying after reprocessing, 35% used liquid chemical sterilization, and 12% used ethylene-oxide sterilization, and 15% of the centers routinely screened patients for multidrug resistant organisms.

Cross contamination occurs due to unclean levered endoscopes used in clinical practice. Wendorf et al. (2015) presented a study in which an outbreak of AmpC–producing E. *coli* infections among seven patients who had undergone an ERCP was reported. In the follow up on the levered endoscopes, Wendorf et al. found that no breaches in infection control were identified and that endoscopic reprocessing process exceeded manufacturer's recommended cleaning guidelines. The focus of this study was to investigate what changes in current reprocessing protocols were needed to render the ERCP scope germ free.

To validate that reimplementing the mechanical process will adequately remove the bioburden from the duodenal scopes, The FDA recommended that cultures should be taken postprocedure and postreprocessing and processed by a third-party lab (FDA 2015). This protocol would add validity to the suggested changes and remove any bias. Also suggested would be routine randomized cultures to validate the continued success and accountability of the staff to reprocess properly the duodenal scopes. Similarly, the FDA (2015) recommended

> a validation reprocessing process consisting of soiling the scope with bacteria to simulate use in a procedure and then demonstrate that the device can be adequately disinfected through a sufficient reduction in microbes when the reprocessing instructions are correctly followed. (p. 1)

For purposes of this project, four facilities were asked to answer three questions regarding their endoscope reprocessing protocol:

1. Have the scopes been manually cleaned per manufacture's guidelines?

2. Have the scopes been through a mechanical processor?
3. Has any type of postreprocessing testing been completed and, if so, what were the results?

Staff members did not change their normal processes. For this project, historical to present data were collected for a total of 150 scopes at each facility to have equal distribution. The findings, as presented in Table 1, showed that the average failure rate after initial reprocessing across the four facilities was 7% of scopes.

Table 1

Results

Site	*N*/# Failed	Manual	Reprocessor	Testing	Fail Rate
Facility 1	150/16	100%	100%	Yes	11%
Facility 2	150/9	100%	100%	Yes	6%
Facility 3	150/6	100%	100%	Yes	4%
Facility 4	150/7	100%	100%	Reprocessor Only	5%

Note: Data collected from questionnaire created for this project.. Reprinted with permission..

Fail rate for this project was defined as a positive result using one of the three testing media, failure of the reprocessor to achieve proper validation postprocess, or debris present after the reprocessing process was completed. I found an opportunity in the cleaning process to decrease the chances cross contamination. The variation in findings stem from postreprocessing testing. Four tests were used for testing after the reprocessing. Facility 1 used the Resi-Test. Facility 2 used ATP. Facility 3 did cultures. Facility 4 used the validation from the reprocessor test strips only. Facility 2 was unaware that ATP had been removed as an appropriate testing option by the FDA. I have been unable to find documentation, other than sales brochures, regarding the Resi-Test to

validate its performance. The FDA (2018) recommended a precise culture process that calls for two staff members. Due to the constraints of the IRB and the facilities request that I not be present but collect data only, I was unable to verify whether facility three followed the recommended FDA culture protocol. Facility 4 stated that their facility used a tracer method to follow any issues that arose from postprocedure patients. This method allowed the patients' names to be flagged if they were to return to the facility to validate the reason for the visit was not related to the procedure.

All four facilities used the same type of reprocessor. When this discussion was had with the manufacturer's representative regarding the failures, he stated that he felt that 100% of the failures could be attributed to the manual precleaning. He also stated if the staff was validating the processing cycle by checking the color code test strips, the process was operating properly.

The color code test consists of using a test strip on a test outlet on the machine. If the test strip matches the color on the strip container, that is a validation that the reprocessor has reached its proper exposure, time, and temperature requirements. This is the manufacturer's validation that the reprocessor has provided the requirements for the scopes to meet high-level disinfection criteria.

Recommendations

Based on the findings of the literature over the last 2.5 years and the data collection from four hospitals in a health care system, recommendations for quality improvement and safety are presented.

1. Organizational leadership may need education regarding the gap in practice. The reprocessing of levered endoscopes is not an entry-level position but should be classified as a certified allied health care provider. A qualified person is recommended by ASGE (2018) to direct plans for infection prevention related to levered endoscopes.
2. Personnel involved in the reprocessing of levered endoscopes should be trained in infection control and assessed at least annually to determine competency in reprocessing. The levered endoscope elevator mechanism and the wire channel are particularly difficult to clean. Training should include competency testing of manual cleaning of these parts of the instruments (ASGE (2018).
3. Policies and procedures related to reprocessing failures need to be developed for the organization. These policies and procedures would include who is responsible for notifications after a failure, who should be notified (patients, infection control personnel, the device manufacturer, state or federal agencies), and when notifications should occur (ASGE, 2018). Other remedial actions should be determined.
4. As the CDC provides the guidelines for all cleaning processes of biohazardous material, the CDC needs to assist organizations in providing a uniform cleaning process and include a preprocedure real time testing of scopes.

5. Currently, endoscopes can be stored in a scope cabinet for up to 7 days without any type of preprocedural testing to validate that they still meet high-level disinfection standards. At no time are they placed in any type of protective packaging. There is also a question related to how often the scope cabinets should be cleaned and if they could be a source of cross contamination. Hospitals follow protocols for ensuring that rooms are CRE free after patients with CRE are discharged. It should be assumed that any endoscope has the potential for cross contamination if not cleaned appropriately. Therefore, the organization should develop and implement policies, procedures, and processes related to the length of time an endoscope can be stored and how often the cabinet should undergo disinfection.
6. Thaker et al. (2018) found a large variation in practices across U. S. endoscopy centers. Variations in practices were seen in the sample of four sites reviewed for this project. The organization could improve consistency in practices by developing a written protocol that standardizes the processes for endoscope cleaning.
7. Finally, the organization should follow the most up-to-date guidelines for endoscope cleaning and surveillance testing.

Contribution of the Doctoral Project Team

The team members of the various facilities were an invaluable resource in putting together the data to complete this project. Every person from the physician

Endoscopists to the technicians who processed the scopes had a desire to provide the data in support of the highest quality of care for their patients. They are ready to consider opportunities to improve the process of validating that their equipment has reached the criteria of high-level disinfection, as well as maintaining that status until it is used on a patient.

Strengths and Limitations of the Project

The strengths of this project were the multiple facilities that provided data and that all had different processes. This project provided an opportunity to look at various procedures in a comparative manner. Also, the facilities were all using the equipment manufactured by the same company, which adds strength to the comparison.

The limitations included the lack of direct observation of the process. All information was provided without any validation from a third-party observer. The health system was adamant that the data remain anonymous. I was blinded to which data came from which hospital. The health system released the data to me under a data use agreement that maintained patient, provider, technician, and facility anonymity. This agreement prohibited the opportunity for me to share an early intervention that could lead to preventing further cross contamination issues.

Section 5: Dissemination Plan

Analysis of Self

As a doctoral-prepared practitioner, the opportunity to interject change for the good of patients should be foremost in daily practice. This project was an opportunity to complete such a task. I discovered a problem with the daily practice of the endoscopy team, and I had an opportunity to define and offer recommendations to change the process to keep patients safer. I was not able to resolve the issue, but I have provided new avenues for quality improvement in the local setting that may be used to correct the identified gap in practice. Understanding that there is a fault in the system is the first step in looking for corrective opportunities. I have plans to complete additional research at my current facility, which could lead to a local resolution to this issue. I also plan to submit this project to a regional or national conference because the information is crucial to affecting CDC, FDA, and manufacturer change in the safety of endoscopy instruments.

Summary

The number of infections caused by cross contamination of resistant enterobacteriaceae in patients had increased to the point that the FDA issued safety alert to health care facilities that perform cholangiopancreatography. CRE are difficult to treat due to a high level of resistance to antibiotics. In this project, I validated the inconsistencies in the reprocessing of levered endoscopes within the local health system and the need for a real-time indicator that provides assurance that the levered endoscopes have been properly processed and are ready for use.

The results of the DNP project can be presented to other sites that process levered endoscopes with the opportunity to prevent cross contamination with bacteria to zero. Currently, reprocessing procedures used in endoscopy facilities do not provide the expected decrease in bioburden. A reevaluation of assumptions, processes, and real-time testing needs to occur nationally in order to validate that the scopes are free of bioburden. Based on the results of the project, the current CDC-supported, and evidence-based protocol for reprocessing scopes (CDC, 2018) must be followed to ensure that all patients are as safe as currently possible from iatrogenic infection and injury. The recommendations from this study should be considered interim recommendations while and until a valid and reliable real-time test is developed to ensure endoscope safety.

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Appendix A: Levered Endoscope Questionnaire

Levered Endoscope Questionnaire						
	Was the Levered Scope cleaned per manufactures guidelines?		Was the levered scope processed through a mechanical reprocessor and pass?		Did it have a negative result from the post cleaning testing?	
	Yes	NO	Yes	NO	Yes	NO
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