

Evaluation and Implementation of an Evidence-Based Loaned Surgical Instrumentation

Management Program Utilizing the Plan, Do, Study, Act Cycle

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Abstract

Phase II Site: Fort Belvoir Community Hospital (FBCH)

DNP Project Title: Evaluation and Implementation of an Evidence-Based Loaned Surgical Instrumentation Management Program Utilizing the Plan, Do, Study, Act Cycle.

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Background or Problem/Issue: Fort Belvoir Community Hospital's (FBCH) goal is to provide Ready Reliable Care (RRC). Ready Reliable Care outcomes are quality, safety, and continuous process improvement. Currently, the loaned surgical instrumentation (LSI) program does not evaluate quality issue identification in the practice of loaned surgical instrumentation management (LSIM). Fort Belvoir Community Hospital processes approximately five LSI sets per day, averaging 500 sets per quarter. Last year there were 12 occurrences of bioburden reported at FBCH. Surgical instruments contaminated with bioburden places the patient at risk for debilitating surgical site infections.

Clinical Question or Purpose: Does an evidence-based LSIM program evaluation, compared to current practice, achieve FBCH's goal of providing RRC?

Project Design: The Plan, Do, Study, Act Cycle was the overarching framework for this project. Additional frameworks such as the Audit Quality Loop and CDC Program Evaluation were utilized to carry out several audit iterations. Patient centered care, leadership commitment, culture of safety, and continuous process improvement are all pivotal to the Defense Health Agency's (DHA) goal of RRC. These domains of change serve as the outcomes for this quality improvement project.

Results: Within the organization four iterations of audit and feedback cycles were completed. Compliance was measured using an evidence-based audit checklist containing 59 elements to

evaluate the LSIM program. Loaned surgical instrumentation management performance increased 17% with the implementation of 11 improvements for practice, from 80% to 97%. Further system/process evaluations resulted in an additional 24 initiatives that improved LSIM compliance. These improvements impacted the operating room and sterile processing department in addition to other areas within the organization to include logistics, post anesthesia care unit, anesthesia department, and hospital bed management.

Organizational Impact/Implications for Practice: Four audit and feedback cycles were conducted using a 59 element evidence-based checklist. which affected clinical practice and policy development within the organization. The clinical practices implemented contributed to the multistep process of safely decontaminating, sterilizing, and handling LSIM and helped to reduce the risk of exposing patients to contaminated surgical instruments or delaying surgical care. The use of audit and feedback cycles supported by leadership and other stakeholders created an environment in which the Defense Health Agency's Ready Reliable Care domains of change are adopted to increase high reliability across the Military Health System.

Evaluation and Implementation of an Evidence-Based Loaned Surgical Instrumentation Management Program Utilizing the Plan, Do, Study, Act Cycle

In today's surgical environment, both surgical techniques and the technology of surgical instrumentation used to perform them are constantly advancing. These advancements can be difficult to keep abreast of because military healthcare facilities experience frequent turnover of active-duty service members to include surgeons and perioperative nurses. The circumstances of rapidly changing technology and high staff turnover in the surgical setting, combined with individual surgeon preference for surgical instrumentation based on training and experience, are the primary reasons why hospitals choose to use loaned surgical instrumentation (LSI) instead of purchasing new expensive instrumentation on a regular basis. Although the practice of borrowing can have cost, access, and quality advantages, there are challenges the organization must recognize when it decides to use LSI. The lack of vendor-staff communication and planning, insufficient written policies and procedures for processing items, the availability of processing equipment, and instrument complexity and familiarity that increases staff workload when processing LSI are all factors that can prevent proper processing and increase risk to staff and patient safety (Seavey, 2010).

The complexity of LSI for surgeries results in a unique process that necessitates collaboration among multiple groups. While the LSI are owned by the company and remain the vendor's property, the healthcare facility accepting the instruments accepts responsibility for it, including payment and processing during the temporary loaned period. Processing surgical instrumentation necessitates proper logistical accounting, inventory, cleaning, sterilization, storage, and use so that stakeholders from the vendor, perioperative, and sterile processing department (SPD) can collaborate to implement best practices to maximize patient safety. All

aspects must be considered to ensure that everyone involved has enough time to handle and safely process the loaned surgical sets and that all expectations are met on time (DeLuca, 2018).

Fort Belvoir Community Hospital (FBCH) averages 5,000 surgical cases annually that require the use of LSI averaging approximately 100 loaned set requests per month. The primary services that request LSI are Orthopedics, Podiatry, and Oral Maxillofacial (OMFS) services. These three services make up for 90% of loaned instrument use at FBCH with an average of 35 cases monthly specific to total joint replacements (D. Turnage, personal communication, Jan, 4, 2023). The frequency with which LSI is used necessitates the development of a strong loaned instrument management program that includes policies to properly request, fund, educate, inventory, decontaminate, sterilize, store, and use LSI. The success of a loaned surgical instrumentation management (LSIM) program requires collaboration across multiple hospital sections. This includes prompt requests from surgeons, surgical scheduling, hospital bed availability, adequate time for proper processing and handling according to the manufacturer's instructions that should be approved by the Federal Drug Administration (FDA), return to the vendor, and record keeping (DeLuca, 2018).

Problem Synthesis

Surgical Site Infection Risk

In the United States, the risk for a surgical site infection (SSI) is between 0.5% to 3% and results in a hospitalization stay 7 to 11 days longer than a surgical patient who does not get an infection (Seidelman et al., 2023). According to the Agency for Healthcare Research and Quality (AHRQ), surgical infections also increase the mortality rate of patients to 26 excess deaths for every 1,000 surgical infections (2017). A recent national scorecard published by AHRQ stated that although hospital acquired conditions from 2014 to 2017 have fallen by 13% overall, SSIs

have increased by 8% (2020). The burden of an infection is not only an inconvenience to the patient and their family, but has financial implications as well. As claimed by AHRQ, each SSI costs the hospital organization an additional \$28,219 (AHRQ, 2017). These SSIs cost the United States healthcare system an additional \$3.5-10 billion every year (Seidelman et al., 2023).

Surgical site infections are most often caused by organisms that are present at or near the surgical site and risk is dependent upon the surgical location, wound classification, and the procedure performed (Young & Khadaroo, 2014). The risk factors for SSIs are not limited to the wound itself, but include intrinsic and extrinsic factors, such as the patient and the perioperative environment. Related patient risk factors include their age, nutritional status, obesity, smoking, and immunosuppression while perioperative factors include time of surgical scrub, patient shaving/skin antisepsis, surgery duration and technique, antibiotic prophylaxis, and inadequate sterilization of surgical instruments (Mangram et al., 1999). An article written by Subramanyam et al. (2015) reported that there is a link between SSIs that is proportional to the instrumentation and number of implants. Although it is difficult to ascertain the source of an SSI, healthcare organizations can reduce the risk by identifying extrinsic factors that can be prevented. This approach includes the condition of surgical instruments, especially since LSI requires specific attention to care when being used by the hospital.

Loaned Surgical Instrumentation Processing

Even though the practice of using LSI is common in both military and civilian healthcare facilities throughout the world, several challenges arise when it comes to processing LSI and implants. First, design complexity can make them exceptionally difficult to clean (Costa et al., 2018). This must be considered when evaluating the facility SPD's capability to process the instruments according to the manufacturers' Instructions for Use (IFU), which outline processing

procedures. The IFU is published by the manufacturer and approved by the FDA. Table 1 outlines an example of the IFU steps that must be followed to properly clean reusable surgical instrumentation after each use regardless of the decontamination method used. To ensure proper sterilization procedures, healthcare facilities must develop specific training programs dedicated to processing LSI and confirm that staff members understand what must be done to achieve proper disinfection and sterility without sacrificing quality or productivity (Passut et al., 2015).

Table 1

Sample Instructions for use for loaned instruments

Step	Instructions for use example
1	The loaned instrument set must be soaked in enzymatic detergent according to the manufacturer's instructions for use.
2	All faces of the instrument must be scrubbed at least five times with the correct brushes.
3	The appropriately sized brush must be used for instrumentation that has lumens.
4	The instrumentation must be rinsed with water and lumens must be flushed with a water gun at the appropriate pressure. (Costa et al., 2018)

Note: Sample instructions for use adapted from “Reprocessing safety issues associated with complex-design orthopaedic loaned surgical instruments and implants,” by Costa et al., 2018, *Injury*, 49(11), 2005–2012 (<https://doi.org/10.1016/j.injury.2018.09.006>).

A second challenge is delayed delivery of LSI. Whether these delays occur because of high demand for LSI by surgical staff or delayed delivery of the LSI to another facility, these time constraints escalate the challenge for SPD staff to properly reprocess the set to appropriate standards (Costa et al., 2018). This demand increases the chance of retention of debris and microbiological soil thereby increasing the risk for transmission of infectious agents across patients. In some instances, LSI and implants will leave one hospital contaminated with organic

debris and viable bacteria and be then delivered to the next facility in a contaminated state. This negatively impacts quality and safety and accentuates the need for a multidisciplinary approach to ensure the appropriate policies and procedures are followed to process the LSI upon arrival, through point of use in the operating room, and decontamination after the procedure are adhered to (2018).

Although surgical instrument reprocessing guidelines and procedures should already exist within the facility, it is vital to audit actual practice versus the written policies to ensure the quality of the work matches the proper workflow processes. A study focusing on common implants used in spinal fusion trays found that the steps most negatively impacting the quality of the reprocessed implants the most were poor performance of visual inspection by staff and the lack of validated reprocessing methods (Agarwal et al., 2019). The Association for the Advancement of Medical Instrumentation (AAMI) recommends that staff members should visually inspect each processed item, aided either by lighted magnification or video borescope (2017). At the same time, visual inspection can be subjective to the staff member and might not be enough to verify the cleaning process. In order to remove subjective biases, AAMI recommends measuring or detecting the presence of organic residue to objectively validate that the processed item is ready for sterilization (2017). However, this method is not a requirement.

Utilizing LSI in both military and civilian healthcare organizations inherently brings additional workload to SPD. For the large military medical centers, it is not uncommon to have an average of 20-40 LSI trays dropped off to SPD by three different vendors per day (B. Fernandez, personal communication, October 30, 2021). This creates a burden whereby SPD staff must review multiple IFUs if the LSI has distinct requirements for reprocessing or if the staff is unfamiliar with the instrument. It is the responsibility of SPD leadership to ensure that

their staff are appropriately trained and qualified to clean surgical instrumentation, and that the LSI are processed according to their respective IFUs. Processing unique LSI can be challenging for staff members who have not handled the instrumentation in a long time. Extra time may be required for staff unfamiliar with certain LSI to reference the IFU in order to process the item correctly. Additionally, following the IFU is an element of performance observed by The Joint Commission (TJC). The Joint Commission requires all hospital organizations to follow IFUs when cleaning and disinfecting medical instruments (TJC, 2021). Therefore, it is critical that staff understand the requirements for processing LSI, and leadership ensures the quality of the process to safeguard patients and staff so as to ensure the principles of Ready Reliable Care (RRC) are met in military healthcare facilities.

Relevance to Military Nursing

The Military Health System (MHS) is responsible for providing care to uniformed service members, military retirees, and other beneficiaries (MHS, n.d.). The National Defense Authorization Act (NDAA) of 2017 has legislated the Defense Health Agency (DHA) with the responsibility of the MHS's mission to deliver high quality health care to beneficiaries and uniformed service members through maintaining a medically ready force and a ready medical force (DHA, 2020). To accomplish this mission and provide RRC, the MHS has developed a quadruple aim strategy focused on delivering healthcare that improves readiness, provides better health, better care, all at a low cost (DHA, 2021).

Problems within a healthcare organization can be examined as involving three different spheres: the patient, clinical staff, or the organization. Military Clinical Nurse Specialists (CNS) are uniquely trained to operate within these spheres in order to transform organizations. This evolution is achieved through the roles that a CNS can provide: leader, consultant, clinical

expert, educator, and researcher. The CNS translates research into practice by mentoring and influencing the multidisciplinary team providing care to MHS beneficiaries (Sanchez, 2022). Improperly processed LSI has the potential to bring harm to MHS beneficiaries by way of a surgical site infection, delay in care, and case cancellation. Not following the IFU is a patient safety risk and does not align with the elements of RRC nor the DHA quadruple aim strategy. Additionally, it is an expectation from TJC that hospital organizations are to follow IFUs when cleaning and disinfecting medical instruments (2021). By supporting an evidence-based evaluation of the MTF's management of LSI, the organization is being proactive in ensuring the safety of the surgical care delivered.

Clinical Question

At FBCH, does an evidence-based LSIM program evaluation, compared to current practice, achieve FBCH goals of providing RRC?

Literature Search and Appraisal

A database search of PubMed and CINAHL was conducted to identify relevant articles from peer-reviewed journals using the following search terms: audit, audit science, perioperative, decontamination, interventions to improve compliance, surgical instrument, sterile processing department, surgical site infection, loaned instruments, bioburden, reprocessing, patient safety, and patient outcomes. The search yielded 149 studies. In addition to the online database search, the most recent Association of periOperative Registered Nurses (AORN, 2021), the Association for the Advancement of Medical Instrumentation (AAMI, 2017), and the International Association for Healthcare Central Service Material Management (IAHCSMM, 2016) guidelines and recommendations for perioperative practice reference materials were included for review.

Using the Covidence program, 15 articles were removed for duplication. For the 134 articles, title and abstracts, if available, were reviewed for relevance. Ninety articles were excluded and a full text examination of the remaining 44 articles was performed. Thirty-five additional articles were excluded because they were unrelated to the topic of interest, did not reflect industry standards, did not provide sufficient evidence or were not conducted in a similar setting. See appendix E, Figure 1 for PRISMA reporting guidelines. The remaining nine studies were appraised utilizing the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) tools (Dang & Dearholt, 2017). See appendix F, for a full review and grading of the evidence.

Literature Synthesis

Loaned surgical instrumentation (LSI) brings an increased level of complexity and burden to SPD. However, the accepting hospital assumes the responsibility for ensuring LSI is processed according to the manufacturer's IFUs, regulatory requirements, and organizational policies and procedures (AMMI, 2014). The appropriate decontamination of surgical instruments is a multistep process that, if not followed correctly, can influence staff and patient safety (Chobin, 2019). Whether the goal is to improve compliance with perioperative antibiotic prophylaxis (PAP), surgical site infection (SSI) care bundles, clinical practice guidelines, or other aspects of professional practice, evidence demonstrates that an audit and feedback intervention is effective to improve compliance (Manivannan et al., 2018; Chan et al., 2017; Brink et al., 2017; Ivers et al., 2012). The literature supports implementation of an evidence-based audit process to ensure all regulatory requirements, industry guidelines, recommendations, and organizational policies and procedures are followed.

Establishing written policies and procedures that reflect current industry guidelines and recommendations help ensure staff practice is compliant with sterile processing best practices. A

Cochrane systematic review of 140 randomized controlled studies concluded that implementation of an audit and feedback process “generally leads to small but potentially important improvements in professional practice” (Ivers et al., 2012, p. 2). Ivers et al. found that audit and feedback is most effective in settings where: the baseline performance is low, feedback is provided multiple times and comes from supervisors or senior colleagues in a verbal or written manner, attempts to reduce current behaviors, and includes an action plan. Similar results were found in a summary of systematic reviews conducted by Chan et al. (2017). The summary examined if strategies such as educational outreach, audit and feedback, reminders, and provider incentives improved provider adoption and implementation of clinical practice guidelines. As an intervention to improve process and clinical outcomes, audit and feedback were found to be generally effective (2017).

Quasi-experimental prospective studies conducted by Brink et al. (2017) and Manivannan et al. (2018) examined how audits would affect healthcare provider practice and outcomes within their organizations. The study by Brink et al. (2017) established an audit and feedback initiative that improved compliance with perioperative antibiotic prophylaxis (PAP) guidelines from 66.8% to 83.3% and an overall reduction in SSIs in the post-implementation phase when compared to pre-implementation. This phenomenon of improved patient outcomes when compliance of measurable behaviors increased was also found by Manivanna et al. (2018) when assessing staff compliance with SSI care bundle practices. After implementation of a surveillance, auditing, and feedback (SAF) method, compliance with SSI care bundle components increased from 88% pre-implementation to 99% by the end of the study timeframe. This study also demonstrated an inverse correlation between SSI rate and care bundle compliance post-implementation of their SAF method. These studies demonstrated improved

compliance with certain behaviors with use of an audit and feedback process, suggesting an opportunity for improved patient outcomes.

While evidence shows that auditing can improve compliance, results are dependent upon the elements or behaviors that are being evaluated. When it comes to processing LSI, there are several contributors to improper preparation or inconsistency during the decontamination process. These reasons include: a lack of planning and communication, insufficient reprocessing time, additional workload, complex instrumentation, instruments sets that exceed recommended weight limits, monitoring, inspection, and inventory (Seavy, 2010). AORN, AAMI, and IAHCMM provide recommended evidence-based practices to mitigate these challenges and decrease risks associated with processing LSI.

Clear and detailed policies and procedures are a first step towards maintaining a safe loaned instrument program. The Association of periOperative Registered Nurses (2021) recommends development of a written policy by an interdisciplinary team and contains standard operating procedures for LSI. These procedural recommendations are listed below in Table 2.

Table 2

AORN recommended components of a loaned instrument program

Element	Components of a loaned instrument program
1.	Establishing processes for requesting, approving, and communicating issues related to LSI.
2.	Establishing preprocedural requirements for the lender to specify delivery timing, documentation requirements, communication, and delivery of manufacturers' IFU.
3.	Education for personnel before processing and use.
4.	Method for obtaining processing accessories required by the IFU.
5.	A process for taking inventory.

6.	A process for handling, decontaminating, inspecting, packaging, and sterilizing the LSI before use.
7.	Weight limits.
8.	Method for point of use treatment.
9.	A process for post procedure transport and decontamination.
10.	Procedure for returning LSI to lender.
11.	Documentation of processes and transactions related to LSI items.
12.	Time requirement for vendor retrieval.

An audit checklist comprised of these and other evidence-based elements will allow supervisors to monitor and evaluate staff compliance and establish policies and procedures to guide safe behaviors. The goal is to address elements that are not performed or missing and provide feedback to improve compliance with processing LSI and ensure safe patient care is delivered.

Focus Area

The focus area of this project will include all perioperative venues that are involved in the request, acquisition, processing, point of use, and return to vendor of LSI. At FBCH, initial requests are initiated by the surgeon to the logistics department for acquisition from the vendor or company representative. Then, SPD is where acquisition of LSI is delivered by the sales representative or courier to the designated area for decontamination and sterilization before use in the operating room. Upon receipt, the loaned instruments must be inspected, documented, decontaminated, and sterilized. Recommendations from AORN (2021) state that LSI should not be accepted without an FDA approved IFU manual from the manufacturer. The IFU will include written instructions for disassembly, cleaning/decontamination, packaging, and sterilization

methods within the established timeline by the organization for proper reprocessing, sterilization, and delivery to the operating room (IAHCSMM, 2012).

This quality improvement project will evaluate recommended practices versus the organization's current practices and policies. Correctly processing surgical instrumentation, especially LSI, is a complex endeavor that begins with the acquisition of the loaned instruments that must be delivered with the IFU and evaluates the duties to be performed between the sales representative and SPD staff members. Each member has specific responsibilities for preparation of the instrumentation before surgery, delivery to the operating room for use, responsibility of staff in the operating room to begin point of use cleaning, transport to SPD for decontamination, and return to the sales representative (IAHCSMM, 2012). All this must be performed according to the IFU, the organization's policies, and state and federal regulations. An evidence-based checklist will be developed to assess the compliance of actual practices in the organization.

Business Case Analysis

The motivation for this project from a business perspective is rooted in several opportunities that exist and are listed in Appendix E, Figure 6. Confirming that LSI is processed correctly is one way to ensure that contaminated instruments are not used on surgical patients. This action enables the organization to verify compliance with regulatory requirements related to the processing of FDA approved surgical devices, which contributes to the prevention of an SSI. There is a cost avoidance advantage for the organization when LSI is being processed appropriately and not suspected as a promoting factor for a potential infection. For example, an infection in a spinal surgery utilizing implants can cost the organization \$16,970 while a non-infected patient only requires \$7,658 (Eli, Whitmore, & Ghogawala, 2021). The implementation of our project will enable the organization to support RRC goals and promote HRO principles of

preoccupation with failure, reluctance to simplify, sensitivity to operations, deference to expertise, and commitment to resilience (Oster & Braaten, 2016). Utilizing evidence-based methods to ensure proper processing of LSI will help to avoid SSIs, ensure staff and patient safety, decrease costs related to preventing potential SSIs, and maintain an image as an HRO.

Organizing Framework

The success of this project relies on the convergence of multiple evidence-based frameworks nested together to support the DHA's goal of RRC. Ready Reliable Care describes the MHS's efforts towards becoming a HRO aimed at preventing patient harm, supporting a commitment to learning, and enacting improvements in areas of high risk (DHA, 2021). The four domains of RRC serve as the overarching outcome measures of this project: leadership commitment, culture of safety, continuous process improvement, and patient centeredness (2021). Figure 1 illustrates the DHA domains of change for RRC.

Figure 1

Ready Reliable Care Domains of Change



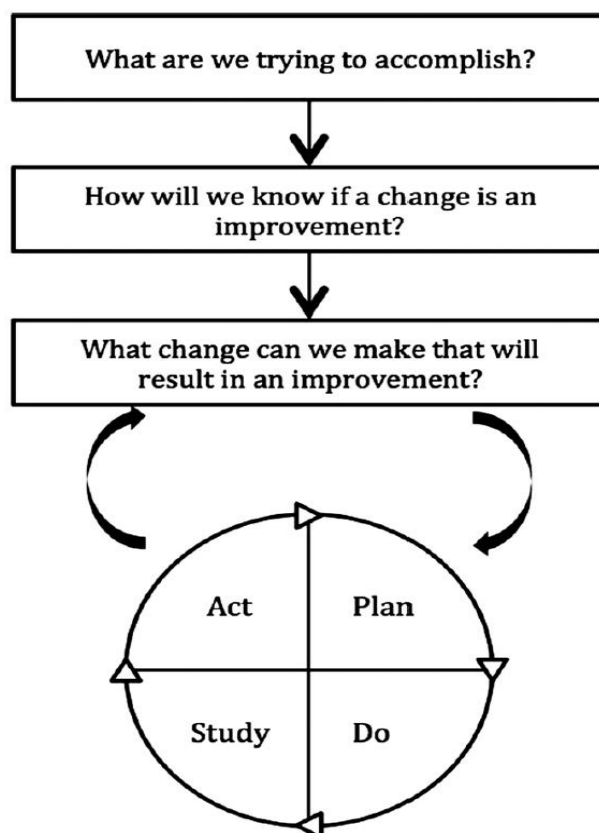
Note. From "Ready Reliable Domains of Change," by Defense Health Agency, 2021, retrieved from <https://health.mil/Reference-Center/Publications/2021/06/07/Ready-Reliable-Care-Placemat>.

In order to achieve the RRC domains as outcomes, this doctoral project will operationalize the Plan, Do, Study, Act (PDSA) cycle. The PDSA cycle provides structure and

supports development for change. PDSA starts with the plan stage where quality improvement tasks are identified (Taylor et al., 2014). The Plan stage involves identifying the objective for improvement and acknowledging who will carry out the cycle, when, and how it is performed. The Do stage of the cycle is executing the plan, documenting problems, and performing data analysis. The Study stage consists of completing the data analysis, comparing prior iterations and baseline data, and a summary of lessons learned. The Act stage involves the opportunity to adopt, abandon, or revise changes to support continuous process improvement. The PDSA format can be implemented as a single method, or integrated with other frameworks, to achieve quality improvement practices (2014). Figure 2 shows the steps of the PDSA cycle utilized to support this quality improvement project.

Figure 2

Plan, Do, Study, Act Cycle



Note. Modified from “Systematic review of the application of the plan-do-study-act method to improve quality” by Taylor et al., 2014, *BMJ Journals*, 23:290-298, p. 292 (<https://doi.org/10.1136/bmjqs-2013-001862>).

The intent of this project includes the evaluation of the loaned surgical instrument management (LSIM) program at FBCH, therefore the selection of a framework that evaluates organizational programs is needed. The CDC’s Framework for Program Evaluation (CDC, 1999), represented in figure 3, emphasizes holistic ongoing evaluation efforts including all stakeholders and evaluation experts. These holistic elements within the CDC framework for program evaluation supports this project's goal of quality improvement of a successful LSIM program. The CDC’s Framework for Program Evaluation (1999) will be grouped with specific

phases within the PDSA cycle (Taylor et al., 2014) and the audit quality loop (AQL) (Esposito & Canton, 2014).

Figure 3

Centers for Disease Control's Framework for Program Evaluation



Note. From “Framework for Program Evaluation,” by the *Centers for Disease Control*, 2017b, retrieved from <https://www.cdc.gov/evaluation/framework/index.htm>.

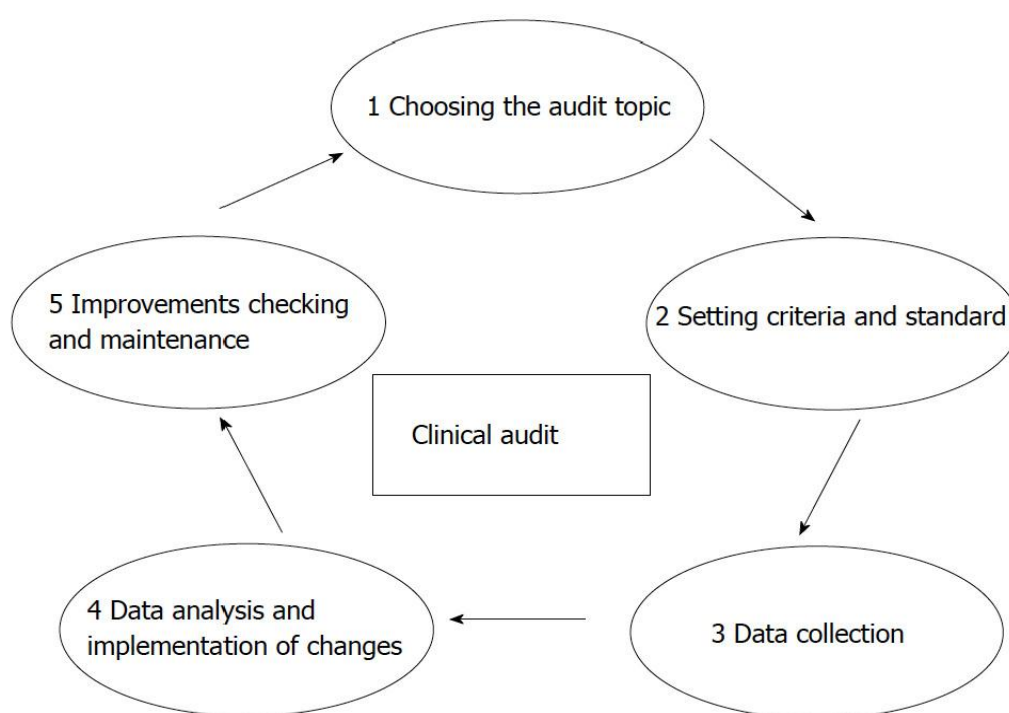
The AQL allows for a comparison between clinical practice and highlights any deviation from established standards so that practice change is identified to improve quality of care (Esposito & Canton, 2014). The high-risk nature of LSIM, and surgical instrument reprocessing

are best served by utilizing frameworks that facilitate continuous process improvement.

Therefore, the AQL has been integrated with this project’s frameworks to support the DHA’s goal to transform to RRC (DHA, 2021). Figure 4 illustrates the AQL key elements of clinical audits, data collection, and project management.

Figure 4

Audit Quality Loop



Note. Modified from “Clinical audit, a valuable tool to improve quality of care: General methodology and applications in nephrology” by Esposito, P., and Canton A., 2014, *World Journal of Nephrology*, 3(4), p. 250 (<https://doi.org/10.5527/wjn.v3.i4.249>).

To achieve organizational transformation, the military CNS utilizes multiple evidence-based frameworks throughout the process to accomplish impact across the three spheres. Figure

5 emphasizes the relationship between RRC domains of change, PDSA cycle elements, CDC's framework for program evaluation, and AQL steps for clinical audits.

Figure 5

Loaned Surgical Instrumentation Management Framework



Note. Project organizing framework created utilizing elements from the Defense Health Agency's (2021) domains of change, Taylor et al. (2014) plan, do, study, act cycle, Centers for Disease Control's (2017b) framework for program evaluation, and Esposito & Canton's (2014) audit quality loop.

Project Design

General Approach

The project will be implemented after receiving the determination letter from the Institutional Review Board (IRB) at FBCH. The success of this project relies on the convergence

of multiple evidence-based frameworks nested together to support the DHA's goal of RRC. Ready Reliable Care describes the MHS's efforts towards becoming an HRO aimed at preventing patient harm, supporting a commitment to learning, and enacting improvements in areas of high risk (DHA, 2021). The four domains of RRC serve as the overarching outcome measures of this project: leadership commitment, culture of safety, continuous process improvement, and patient centeredness (2021).

Setting and Population

Fort Belvoir Community Hospital is a modern hospital located in Fort Belvoir, Virginia as a part of the National Capital Region Medical Directorate. This community hospital consists of four ambulatory clinical centers that includes 44 clinics, a seven-story tower with 120 inpatient beds including an intensive care unit, and 10 operating rooms to help care for the more than 250,000 beneficiaries in the National Capital Region (DHA, n.d.). The 10 operating rooms are supported by the staff in the sterile processing department who are responsible for receiving, decontaminating, prepping, packing, sterilizing, storing, and issuing surgical instrumentation. FBCH processes and handles an average of five LSI sets daily. Surgeons are also involved because they are the ones initiating the request for LSI, which has to be processed by the SPD staff before use in the patient. Table 3 below represents a sample of surgical services at FBCH that utilize LSI.

Table 3

Surgical services with LSI use

Surgical Service	Loaned Surgical Set
Orthopedic joint arthroplasty	Total knee arthroplasty and total hip arthroplasty

Orthopedic sports medicine	Arthroscopic shaver and Anterior Cruciate Ligament repair sizers
Orthopedic foot and ankle	Foot and ankle instruments and implants
Orthopedic trauma	Clavicle instruments & implants, distal radius fracture instruments and implants
Oral & Maxillofacial Surgery	Instruments and implants
Orthopedic Spine	Cervical and lumbar instruments and implants

Procedural Steps

I. RRC domains of change: Leadership Commitment → Culture of Safety: The DHA's first domain of change involves garnering commitment from the organization's leadership. Leadership commitment prioritizes patient safety by reviewing how the organization is structured to facilitate the delivery of care by addressing how staff and resources are allocated (DHA, 2022). Leadership commitment also involves an HRO principle of deference to expertise. Leaders that support this principle create an environment where decision making is made by staff members who have the most expertise with a problem with no regard to their authority (Oster & Braaten, 2016).

A. Plan: The PDSA cycle starts with the plan stage where quality improvement tasks are identified (Taylor et al., 2014). For this project, there is an opportunity to enact a program that evaluates the management of LSI to achieve the elements of RRC.

1. CDC Program Evaluation Step 1: Engage stakeholders.

- a) Identification of stakeholders. This will include staff members who are involved with the procurement, processing, storage, and use of LSI. These stakeholders represent a multidisciplinary cross section of several departments including the operating room, logistics, nursing bed manager, anesthesia, post anesthesia care unit, and sterile processing.
- b) “Stakeholders must be engaged in the inquiry to ensure that their perspectives are understood” (CDC, 1999, p. 5). Identification of the stakeholders that are involved with loaned surgical instrumentation. Once involved, these stakeholders will help to execute the other steps.
- c) Engage the areas within the organization that are involved with loaned surgical instrument (LSI) procurement, processing, storage, and use. This is accomplished by attending the perioperative leadership daily safety brief.

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

- a) A literature review is performed in order to identify best practices related to the management of LSI. This search will help to establish elements within an audit checklist that will be used to evaluate FBCH’s LSI program.
- b) Perform an assessment of leadership/stakeholder involvement in order to establish a foundation for baseline evaluation.

- c) Perform an assessment of workflow processes involving all departments related to LSI.
- d) Present baseline information to identified stakeholders within the perioperative leadership daily safety brief and other departments involved with LSI.

3. CDC Program Evaluation Step 3: Focus the evaluation design.

- a) From the literature review, identify standards and recommendations from professional organizations such as AAMI, AORN, and IAHCMM that will be used to establish best practices for LSIM at FBCH. These evidence-based elements will be used to develop the audit checklist.
- b) From the baseline information given to stakeholders, receive feedback related to LSIM at FBCH.
- c) Establish specific expectation objectives and criteria that will define the program evaluation as a success over four iterations.

4. Audit Quality Loop Step 1: Choose the topic.

- a) Evaluation of LSIM at FBCH.

5. Audit Quality Loop Step 2: Set criteria and standards.

- a) Set standards that current clinical practice will be compared to. These standards are developed from the literature review and recommendations from previously mentioned professional organizations into the audit checklist.

- b) Set the standard by which the quality of the LSI program can be evaluated. Establish criteria that can measure change and guide the decisions made from the results of the audit over four iterations. This will be represented by a percentage of compliance to the identified elements within the checklist.

II. RRC Domains of change: Culture of Safety → Continuous Process Improvement:

The second domain of RRC highlights a culture of safety to commit to patient safety and harm prevention. This is necessary to implement a LSIM that adheres to the standardization of loaned surgical instrumentation management and enforcing standards that align with best practices to reduce risk of a contaminated surgical set to the operating room. Adhering to best practices and measuring the compliance of the actions by stakeholders to ensure application of those tasks assist in commitment to a culture of safety. Evaluating the program and the practices of all stakeholders permit for outward review and implementation of steps that lead to process improvement (DHA, 2022).

A. Do: The second phase of PDSA cycle is the Do stage to model change towards the goals and test effectiveness of the implementations (Taylor et al., 2014). This project implemented the Do stage into the practice for LSIM to formalize current practices at FBCH. This is completed in multiple iterations using other supporting frameworks with small-scale approaches by delivering recommendations from the completed audits.

- 1. CDC Program Evaluation Step 4:** Gather credible evidence to communicate the intentions of the LSIM program at FBCH.

- a) The data collected should be believable and used to strengthen interventions from system observations.
- b) Consult with stakeholders and experts for program bundles and LSIM implementation after each audit period. Permit time to implement those changes into practice.
- c) The evaluation of evidence supports the judgments of the multidisciplinary team involved and guides the judgment and recommendations for quality improvement. The multidisciplinary team will consult and evaluate the necessary tasks to improve LSIM.

2. **Audit Quality Loop Step 3:** Data Collection and clear expectations of the data collection activities; not to be aligned with actual data collection activities (Esposito & Canton, 2014).

- a) Data collection activities include the 59-step audit tool created to evaluate compliance of a LSIM management program

III. Continuous Process Improvement → Patient Centeredness: The DHA's domain of change of continuous process improvement is the main feature of RRC. Continuous process improvement requires the constant innovation of solutions to problems while also disseminating leading practices. This domain is "focused on reducing unwarranted variation across the system, eliminating waste, and lowering costs" (DHA, 2022).

A. Study: The Study phase of the PDSA cycle involves reviewing the results of the information gathered during the Do phase. The study phase is an inward examination of what the results mean and which aspects of the Do phase went

right. Areas from the checklist where compliance was deficient will guide evidence-based interventions to improve performance.

1. CDC Program Evaluation Step 5: Justify conclusions.

- a) For each iteration of the Study cycle, perform a longitudinal synthesis of audit results gathered from the Do phase. Present results to identified stakeholders.
- b) Perform literature search to identify evidence-based interventions that can be used to improve compliance performance based off of the deficient elements identified from the audit.
- c) Provide evidence-based interventions for LSIM improvement and sustainment to stakeholders and receive feedback. The interventions are justified when they are connected to the evidence gathered and judged by the criteria set by the stakeholders (CDC, 1999).

2. Audit Quality Loop Step 4: Data analysis and implementation of changes.

- a) Examination of audit results and compare against baseline information.
- b) Devise a method for implementation of evidence-based recommendations for compliance improvement utilizing feedback from stakeholders.

IV. Patient Centeredness: The final domain of the RRC focuses on the patients' safety and quality of care experience. The management of a LSIM management program at FBCH is

essential in achieving the by evaluating compliance on proper LSI practices supported by evidence-based recommendations and evaluation of those practices to avoid deviation from best practices (DHA, 2022). Doing this permits FBCH to reevaluate practices and implement steps that permit all stakeholders involved to strive for implementation of best practices to strive for a culture of zero harm; proper LSIM is the primary goal for delivery of a high-quality product to the scheduled surgical case.

A. Act: The fourth phase of the PDSA cycle is the step to Act which identifies the adjustments necessary, and steps needed for implementations to proceed to the next cycle. This is achieved through an iterative approach over the previously mentioned four iterations to achieve the final implementation of the LSIM bundle. This is necessary to inform the next stage and close the loop for the next phase in the PDSA cycle; Plan (Taylor et al., 2014). The Act stage requires evaluation of quality improvement recommendations over four audit and is structured to suggest recommendations for improvement on a continuous cycle.

1. CDC Program Evaluation Step 6: Ensuring use and share lessons.

- a) The audits are conducted in four iterations at FBCH. Deliberate and disseminate the data of each iteration to stakeholders to make decisions on the appropriate action for prepare for next cycle
- b) Design a plan for evaluation to conduct the evaluation of the LSIM at FBCH.
- c) Discuss this plan of action amongst the LSI multidisciplinary team to implement the new knowledge gained. This is completed at the end of each iteration at FBCH to prepare for the next iteration.

- d) Recommendation for a continuous feedback, follow-up, and dissemination of LSIM at FBCH. Recommendation is to audit practices monthly

2. Audit Quality Loop Step 5: Improvements checking and maintenance.

- a) Evaluate the efficacy of the clinical audit by assessing the compliance, outcomes, and steps for successful LSIM management.
- b) Create a monitoring plan embedded into daily practices to measure efficacy of the provided audits and policy documents. This document is supported by scientific evidence and must be evaluated as determined by FBCH but should not hinder practices of the end user (Esposito & Canton, 2014).

Timeline

See Appendix I.

Data Analysis Plan

The intent was to collect data using an evidence-based audit checklist to gather quantitative data that measures compliance specific to the quality of LSI delivered and utilized by FBCH. The checklist used to direct these audits was developed to assess practices and measure compliance of the amount of organizational practices that met standards with a ‘Yes’ versus ‘No’ result. Compliance was measured by surveying the entire process from LSI request, acquisition, and return of the LSI to the vendor. Result data was continually shared among the four audit and feedback iterations. The audit checklist compared evidence-based recommendations against current practice at the time of the audit. A gap analysis was performed

with the findings that highlighted opportunities for improvement in practice at FBCH to distribute LSIM practice changes that aim to achieve the four elements of RRC: patient centeredness, leadership commitment, culture of safety, and continuous process improvement.

Potential Barriers and Dissemination Plan

There are five barriers anticipated when implementing this project associated with the principles of an HRO. These five key principles of an HRO are sensitivity to operations, reluctance to simplify, deference of expertise, commitment to resilience, and preoccupation with failure (Oster & Braaten, 2016). The first barrier is sensitivity to operations, the stakeholder's response and awareness of the state of what systems and processes are relevant to the reprocessing of loaned instrumentation is important to consider. The next barrier is the reluctance to simplify by assuming that the work is too complex, and the system will fail in unexpected ways. The third barrier is the preoccupation with failure and keeps stakeholders from being mindful that near misses are an opportunity to improve and do not view practice improvement processes as opportunities to achieve success. A fourth barrier is the deference to expertise where stakeholders with greater seniority may provide most resistance to change because of their expertise levels, or other staff members with less expertise are not receptive to the insights from those who have greater seniority. Finally, practicing resilience by anticipating failures and practicing how to overcome them to achieve minimal errors despite the complexity of the sterile processing department relative to loaned instrument reprocessing requires that all 5 barriers are acknowledged and implementation strategies are developed for dissemination to stakeholders (Veazie et al., 2019). Once this is measured and methods to improve practices are disseminated to stakeholders, systems for sustainment must be enacted.

The use of an audit and feedback strategy within the organizing framework will assist in overcoming barriers by evaluating the current practices of reprocessing loaned instrumentation at FBCH. Focusing on sensitivity to operation, assessing and comparing current policies and practices with an evaluation tool developed from evidence-based practices and the IFU to develop a Lean Six Sigma approach will assist in determining a baseline to recommend process improvement and allows the organization to overcome the barriers to achieve safety. This improves quality and efficiency goals and is applicable to methods for re-processing loaned instrumentation for use in the OR (Veazie et al., 2019).

Performing a gap analysis of current practices by utilizing the evaluation tool is necessary to gather information and put into practice basic error prevention techniques and training for staff. Not only is this applicable to staff, but to leadership to understand what principles or practices are crucial when enacting the policies. Sustainment is achieved by conducting root cause analyses (RCAs) with data collected from the evaluation tool and data in electronic tracking systems, safety huddles, and routing sharing of information to meet the steps of the framework. Once implementation costs and schedules are determined, the quadruple aim improvement will contribute to the MHS quality of care. This results in better health, better care, lower cost, and increased readiness (DHA, 2019).

HIPAA and Ethical Considerations

The Institutional Review Board (IRB) should determine this project as not research as it is considered an evidence-based quality improvement project. The project will focus on the management of LSI at FBCH and includes interview/discussion with staff, and observing the behavior of nurses, technicians, and leaders. Some elements within the evaluation of LSIM will require observing staff in the operating room while a patient is present. Personal Identifiable

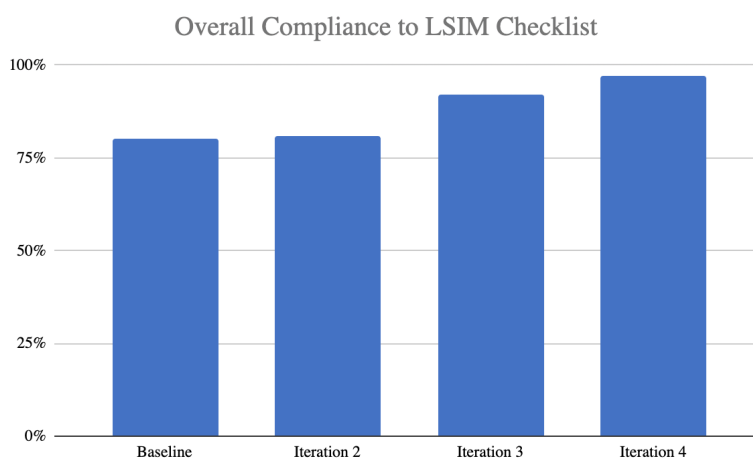
Information (PII) related to the staff or patient will not be collected throughout this project and is not required to perform an evaluation of the LSI program at FBCH. The interventions identified to improve compliance to the LSIM checklist will correlate to the RRC domains of change principles.

Project Results

The LSIM project results audited the nine phases of LSIM and established baseline compliance to measure the end result compliance percentage to support DHA and the elements of RRC. As represented in Figure 6, the baseline compliance that was established from the first iterative review was 80%. The final compliance measurement was 97%. This quality improvement project resulted in an overall 17% improvement in LSIM compliance across four iterations every three months. Audit and feedback given to the multidisciplinary team and stakeholders supported achievement of quality, safety, and continuous process improvement. The four elements of RRC were met and include patient centeredness, leadership commitment, culture of safety, and continuous process improvement.

Figure 6

Overall Compliance to LSIM Checklist



LSIM Audit Results and Longitudinal Synthesis

Longitudinal evaluation included four iterative audit and feedback cycles utilizing an evidence-based audit checklist. Evidence-based recommendations related to LSIM from AORN and AAMI provided the elements for improvement. The results of these daily practices occurred over a 12-month period (2021: November; 2022: March, September, & November) and are represented in Table 4.

Table 4

Audit results of the nine LSIM Phases

Nine LSIM Phases	Baseline	Audit 2	Audit 3	Audit 4
Phase I: Pre-Request Evaluation	33%	66%	100%	100%
Phase II: Loan Request	100%	100%	100%	100%
Phase III: Loan Drop Off	40%	60%	80%	100%
Phase IV: Decontamination	100%	0%	100%	100%
Phase V: Assembly & Packing	80%	80%	80%	100%
Phase VI: Sterilization	93%	93%	100%	100%
Phase VII: Sterile Storage	91%	100%	100%	100%
Phase VIII: Point of Use	71%	79%	79%	86%
Phase IX: Decontamination & Return	100%	50%	100%	100%

Table 4 represents the results of the LSIM audits and how performing audits followed by feedback with evidence-based recommendations for practice and process improvement resulted in an increase in compliance for overall process improvement. The data demonstrates an increase in compliance across the nine phases of LSIM.

Analysis of Results

Overall compliance improved by 17% across the nine phases of the LSIM project. Each phase improved from the baseline compliance to the end result. Education and feedback occurred after each audit iteration to achieve compliance improvement from the baseline. Table 5 presents an analysis of results of the audit iterations for the nine phases of LSIM from baseline to fourth and final audit.

Table 5

Analysis of audit results, impacts, and improvements

LSIM Audit Phase and Compliance Percentage	Baseline vs. Final Audit Score	Impact & Improvements
Phase I: Pre-Request Evaluation Initial audit score 33% Final audit score 100%	67% Improvement	● Policy was developed establishing daily perioperative leadership safety huddle. ○ 6 departments. ● Created LSI request workflow process. ○ Request is initiated by surgeon and approved through logistics. ● Established process empowering SPD to not accept LSI without logistics' approval. ● SPD determines if the facility's reprocessing capabilities are compatible with the LSI IFU.
Pre-Request Evaluation ■ Baseline ■ Iteration 2 ■ Iteration 3 ■ Iteration 4 1. Deficiency: IFU not verified. a. Intervention. Educated staff to speak up during daily huddles for SPD reprocessing capabilities. i. Corrected as of November 2021.		

2. Deficiency: IFU application not witnessed.

a. Intervention: Staff educated to review LSI IFU prior to acceptance.

i. Corrected as of September 2022.

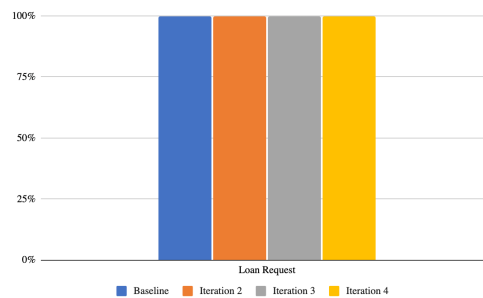
Phase II: Loaned Instrument Request

100% Sustainment

Initial audit score
100%

Final audit score
100%

- Policy implemented establishing time requirements.
- Enabled workflow for SPD to establish volume dependent management of LSI dropoff time.



No deficiency identified. Loan request process was streamlined and performed correctly across all four audits.

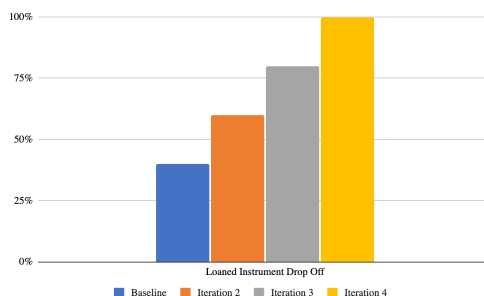
Phase III: Loaned Instrument Drop Off

60% Improvement

Initial audit score
40%

Final audit score
100%

- Policy established enforcing documentation of LSI drop off.
 - LSI is documented to include the type of set and contents.
- Staff inspect LSI and perform functionality tests with manufacturer present prior to acceptance.
 - Staff presence required during LSI drop off.



1. Deficiency: Staff member not present during LSI drop off.
 - a. Intervention: Policy creation, staff education, and enforcement for staff presence.
 - i. Corrected as of November 2021.
2. Deficiency: Inventory not documented at time of drop off.
 - a. Intervention: Policy creation, staff education, and enforcement for documentation accuracy.
 - i. Corrected as of November 2022.
3. Deficiency: Instruments not inspected for defects and correct function.
 - a. Intervention: Policy creation, staff education, and enforcement.
 - i. Corrected as of September 2022.

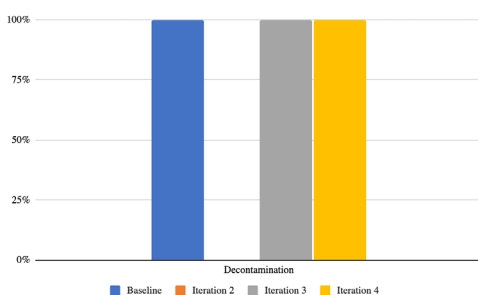
Phase IV: Decontamination

100% Sustainment

Initial audit score
100%

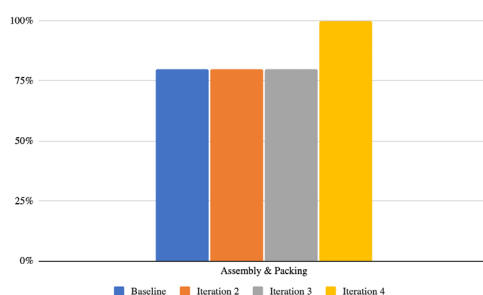
Final audit score
100%

- IFU manual available.
 - Provided subscription service for electronic IFU access at work stations.



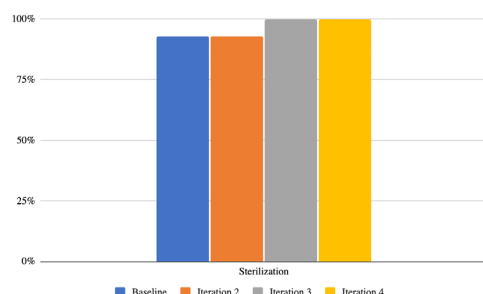
1. Deficiency: Staff member observed to not decontaminate LSI according to IFU.
 - a. Intervention: SPD staff educated towards correct processing of LSI.
 - i. Corrected as of March 2022.

Phase V: Assembly & Packing Initial audit score 80% Final audit score 100%	20% Improvement	● Development and implementation of borescope policy. ● ATP policy implementation to objectively verify decontamination of LSI. ○ 100% testing of sets. ● Instrument air installed at each workstation.
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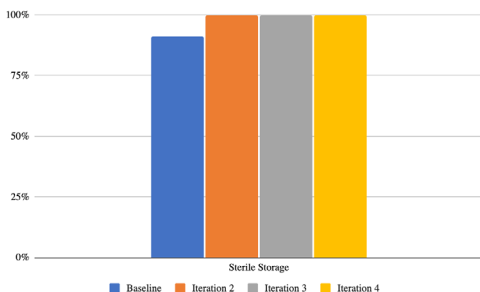
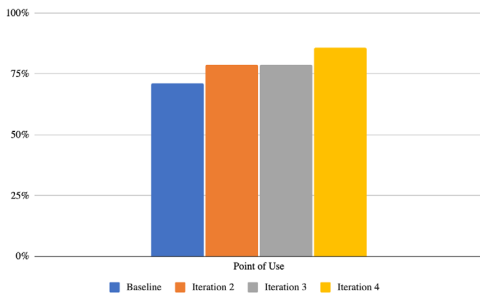


1. Deficiency: No method in place to objectively validate cleanliness of the instrument.
 - a. Intervention: Procurement of ATP testing device. Development of policy and staff training for ATP testing deployment.
 - i. Corrected as of November 2022.

Phase VI: Sterilization Initial audit score 93% Final audit score 100%	7% Improvement	● LSI weight measurements for proper loading of steam sterilizers.
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1. Deficiency: Instrument sets exceeded recommended weight limit.
 - a. Intervention: Overweight sets identified, reduced, reassembled, and weighing practices established.
 - i. Corrected as of September 2022.

Phase VII: Sterile Storage Initial audit score 91% Final audit score 100%	9% Improvement	● Facility documentation of environmental parameters in the sterile storage area. ● Staff knowledgeable of environmental parameters and actions when parameters are out of range. ● Designated location for all LSI storage.
 1. Deficiency: Documentation of sterile storage environmental parameters missing. a. Intervention: Staff educated and enforcement of daily environmental documentation. i. Corrected as of March 2022.		
Phase VIII: Point of use Initial audit score 71% Final audit score 86%	15% Improvement	● Education of the appropriate personal protective equipment during point of use; includes OR & SPD. ● Adjustments to time-out audit checklist to ensure appropriate fluid availability. ● Implementation of OR Debrief tracker.
 1. Deficiency: Staff not wearing appropriate personal protective equipment. a. Intervention: Staff educated towards use of personal protective equipment. i. Although compliant during the second and third audits, staff found to be		

non-compliant in the final audit.

2. Deficiency: Staff not visually inspecting instruments for residual soil, fluids, tissue, and gross material on instrument.
 - a. Intervention: Policy enforcement and staff education.
 - i. Corrected as of November 2022.
3. Deficiency: Instruments not wiped of gross soil with sterile surgical sponges and sterile water.
 - a. Intervention: Policy enforcement and staff education.
 - i. Although performed by a majority of staff members, recommended practice was not observed during all surgical procedures audited.
4. Deficiency: Lumened instruments not irrigated with sterile water throughout the procedure.
 - a. Intervention: Policy enforcement and staff education.
 - i. Corrected as of November 2022.

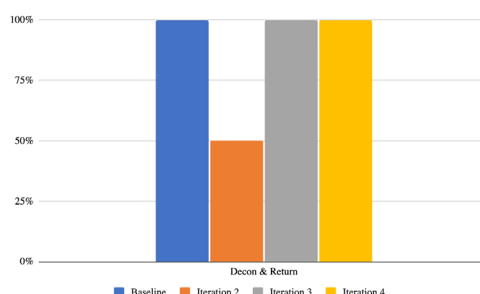
Phase IX: Decontamination & Return

Initial audit score
100%

Final audit score
100%

100% Sustainment

- Designated area for LSIM pick up.
- Policy implementation for requirements of pickup of LSI.
- Vendors and staff members will be present during all exchanges of LSI.



1. Deficiency: LSI not delivered to the decontamination section to be cleaned and decontaminated according to IFU in preparation for assembly or return to company representative.
 - a. Intervention: Policy enforcement and staff education.
 - i. Corrected as of March 2022.
2. Deficiency: Loaned instrument return not documented according to policy.
 - a. Intervention: Policy enforcement and staff education.
 - i. Corrected as of March 2022.

Organizational Impact

The results from this evidence-based quality improvement project impacted the organization by achieving the DHA's RRC domains of change: leadership commitment, culture of safety, continuous process improvement, and patient centeredness. The efforts to improve care to advance a ready and reliable MHS resulted from four iterations of audit and feedback cycles across nine phases of LSI. The results of each audit and feedback cycle indicated practice and process improvement opportunities, for which evidence-based recommendations were provided to enhance the quality of LSI management at FBCH. In addition to the 17% increase in LSI from 80% to 97% compliance, organizational impact included 23 changes across six departments and 28 outlying clinics. Organizational impacts included the development of five policies to support improved performance and practice changes among 144 staff members in the operating room, sterile processing department, post-anesthesia care unit, logistics, anesthesia, and nursing bed management. Table 6 outlines the policy changes implemented and the organizational outcomes related to RRC.

Table 6

Organizational Impacts

Policy Changes	Organizational Impact	Departments Impacted
Loaned Surgical Instrumentation Management (LSIM)	1. Standardized the process for LSI request, time of delivery, processing, documentation, storage, and return to the vendor. 2. Policy revision allowed for variable delivery time frame for LSI according to agreement between FBCH and the vendor.	• SPD • OR • Logistics
Borescope management	1. Standardized process for correct use, decontamination, and sterilization of borescope	• SPD

	equipment in the sterile processing department. 2. Training provided to sterile processing staff for appropriate borescope management and use. 3. Correct use resulted in the prevention of cross contamination between clean and dirty surgical instruments before sterilization.	
Bioburden reporting process	1. A policy was developed based on evidence-based recommendations for reporting identified or suspected bioburden. 2. The bioburden policy supported closed-loop communication between the operating room and the sterile processing department to capture suspected and actual bioburden incidents in the patient safety report and operating room debrief tool. 3. The instrument defect communication tool also closed the loop between the sterile processing department and 28 outlying clinics.	• SPD • OR • Outlying clinics
Adenosine Triphosphate (ATP) testing	1. Implementation of an evidence-based recommendation for an objective quality assurance verification of the decontamination process in the sterile processing department. 2. ATP testing education and training provided to all sterile process staff. 3. FBCH documents all ATP failures in order to identify the surgical sets or individual instrumentation that require additional reprocessing training for staff during the decontamination phase of	• SPD

	reprocessing. 4. Identification of 139 ATP failures helped to contribute to the prevention of surgical site infections.	
Perioperative leadership daily safety brief	1. Established the formation of a perioperative multidisciplinary team to evaluate the surgical schedule and identify surgical cases that utilize LSI. 2. Zero canceled cases from improved accountability of LSI funding requests. 3. Improved LSIM processing accuracy by 17%. 4. Identification of training needs for 35 sterile processing staff. 5. Zero case cancellations due to inpatient bed availability.	● SPD ● OR ● Logistics ● PACU ● Anesthesia ● Bed management
Ready Reliable Care	Outcome(s)	Sections Impacted
Culture of safety	1. Use of revised time-out audit form verifying the presence and use of sterile water on the surgical field during procedures. 2. Achieved 95% of operating room debriefs submitted to help identify issues with LSI.	● OR ● SPD ● Outlying clinics
Continuous process improvement	1. From zero to 100% testing for the presence of ATP on surgical sets/instrumentation after decontamination. 2. Implementation of computer-based tracking of surgical instrumentation for improved documentation of instrument processing.	● OR ● SPD
Patient centeredness	1. Decrease from four to zero reported incidents of bioburden identified in the operating room and outlying clinics during the time of the audit and feedback cycles.	● OR ● SPD ● Outlying clinics

Leadership commitment	1. Daily perioperative leadership safety huddle brief to address appropriate requirements for LSI acquisition and use. 2. Staff empowered to speak up when identifying proper equipment and training to process LSI.	● OR ● SPD ● Logistics
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Future Directions for Research and Practice

Ready reliable care domains of change include patient centeredness, leadership commitment, culture of safety, and continuous process improvement. Evolving surgical instrument innovation will continue to be a threat to high reliability organizations in healthcare. In order to support the future direction of RRC and to ensure high quality LSIM, organizational leaders must prioritize SPD's crucial role is to remove organic and non-organic contaminants prior to high-level disinfection or sterilization. Few studies have evaluated the systems process within SPD (Alfred et al., 2020). Although there is no regulatory requirement to evaluate the management of LSI, it is important that healthcare organizations implement an audit and feedback process. Similar to this quality improvement project, areas at risk and improvement opportunities can be identified using this low-cost methodology for improving critical processes.

Each step in the systematic processing of LSI is critical to preventing the patient and staff from being exposed to contaminated instrumentation. As a result, the condition of the surgical instrumentation when it arrives at SPD from the OR or clinic is dependent on the staff members performing point of use care during the surgical procedure. The following section will discuss the significance of point of use care and handling for reusable surgical instrumentation, including LSI. For future consideration, an emphasis on point of care is fundamental to ensure the prevention of bioburden on LSI.

Importance of Point of Use Care

The role of the sterile processing department is to decontaminate and sterilize surgical instrumentation so that it is safe for patient use. The decontamination process begins in the OR where sterile instrumentation is exposed to gross soil contaminants during surgery. According to AAMI (2017) instruments should be wiped clean with sterile sponges moistened with sterile water in order to remove gross soil during surgical procedures. The removal of gross soil during surgery is considered the most important step in reprocessing because it reduces microbial load, limits the formation of biofilm, and permits effective decontamination and sterilization (de Melo Costa et al., 2022).

Biofilm formation is the reason supporting the prompt removal of gross soil. Biofilm forms when bacteria opportunistically forms a polysaccharide matrix that sticks to the surface of the instrument. Biofilm that is subjected to frequent cycles of decontamination can become exponentially denser as the polysaccharide matrix continues to attract additional biofilm layers. Biofilm is laborious to remove because it is resistant to decontamination processes (AAMI, 2017; de Melo Costa et al., 2022).

Not only is it vital for organizations to recognize the importance of point of use care for the prevention of biofilm formation, it is an important element in achieving accreditation. Military treatment facilities within the MHS are subjected to accreditation through The Joint Commission. An element of performance related to TJC infection control standard 02.02.01 directly relates to point of use care and involves a surveyor to observe a surgical procedure to determine if instruments are being wiped appropriately (TJC, 2023). For these reasons, healthcare organization's leadership should value the impact that point of use has on biofilm formation, decontamination, and Joint Commission accreditation.

Implementation Across the Military Health System

Implementation of an audit and feedback process using the evidence-based checklist does not require the purchase of any proprietary equipment or supplies, and can be used at any time to assess current performance. Other military health facilities within the MHS that utilize LSI can employ an audit and feedback process using the evidence-based checklist to ensure RRC outcomes and quad aim goals are met. Each systematic stage is essential for processing LSI in order to guarantee safety and prevent exposure to contaminated instruments. This quality improvement project's outcomes demonstrated that an audit and feedback process increased overall LSIM compliance.

Ensuring that all steps within a critical process are correctly performed is one way for organizations to address areas for improvement. When considering the management of LSI, recommendations from professional organizations such as AORN, AAMI, IAHCSMM, and peer reviewed articles were used to develop the checklist. This checklist was composed of 59 evidence-based elements that were used to evaluate the management and practices related to management and processing of LSI. With the assistance of FBCH's leadership, advancements were made in the areas of practice, local policy standardization, and organization-wide training. Leadership and stakeholders from other military facilities can support the interventions required to improve LSIM performance that are identified from the audit and feedback cycles.

Conclusion

This project has demonstrated that an audit and feedback cycle utilizing an evidence-based checklist can have a positive impact on the quality of LSIM when supported by leadership. The results from performing an evidence-based audit and feedback process utilizing recommendations for LSIM showed an improvement of 17% from a baseline of 80%. The audit

and feedback cycle is a cost effective method to improve the quality of care provided. As one of the largest community hospitals within the MHS, FBCH can serve as the model for improving LSIM across other treatment facilities within the DHA. The successful implementation and low cost for achieving high quality LSIM directly aligns with the DHA's quad aim goals. Continued success of high quality LSIM programs can be managed by the distinctive attributes associated with a CNS. A CNS can directly guide practice changes through the education and implementation of best evidence-based practices to influence patient care outcomes across the MHS.

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[hospital/leadership-ld/000002250/](https://www.jointcommission.org/standards/standard-faqs/critical-access-hospital/leadership-ld/000002250/)

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Appendices

Appendix A: CITI Certifications

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS*

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

- **Name:** Gaston Baza (ID: 10065033)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** gaston.baza@usuhs.edu
- **Phone:** 9156137297
- **Curriculum Group:** OUSD P&R Human Research
- **Course Learner Group:** Biomedical Investigators and Research Study Team
- **Stage:** Stage 1 - Basic Course
- **Record ID:** 42102934
- **Completion Date:** 17-Apr-2021
- **Expiration Date:** 16-Apr-2024
- **Minimum Passing:** 80
- **Reported Score:** 92

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	14-Apr-2021	No Quiz
Belmont Report and Its Principles (ID: 1127)	14-Apr-2021	3/3 (100%)
History and Ethics of Human Subjects Research (ID: 498)	14-Apr-2021	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	17-Apr-2021	5/5 (100%)
Informed Consent (ID: 3)	14-Apr-2021	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	14-Apr-2021	4/4 (100%)
Records-Based Research (ID: 5)	16-Apr-2021	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	16-Apr-2021	4/5 (80%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	16-Apr-2021	4/5 (80%)
Research Involving Prisoners (ID: 8)	16-Apr-2021	4/4 (100%)
Research Involving Children (ID: 9)	16-Apr-2021	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	16-Apr-2021	3/3 (100%)
FDA-Regulated Research (ID: 12)	16-Apr-2021	5/5 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	17-Apr-2021	4/5 (80%)
Research and HIPAA Privacy Protections (ID: 14)	16-Apr-2021	4/5 (80%)
Conflicts of Interest in Human Subjects Research (ID: 17464)	16-Apr-2021	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	16-Apr-2021	4/5 (80%)
The Federal Regulations - SBE (ID: 502)	16-Apr-2021	5/5 (100%)
Assessing Risk - SBE (ID: 503)	17-Apr-2021	4/5 (80%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	17-Apr-2021	4/5 (80%)
Internet-Based Research - SBE (ID: 510)	17-Apr-2021	5/5 (100%)
International Studies (ID: 971)	17-Apr-2021	3/3 (100%)
The IRB Member Module - 'What Every New IRB Member Needs to Know' (ID: 816)	17-Apr-2021	5/5 (100%)
Informed Consent and Confidentiality in Public Health Research (ID: 17639)	17-Apr-2021	4/5 (80%)

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

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

• **Name:** Jesse Hartmann (ID: 10051553)
 • **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
 • **Institution Email:** jesse.m.hartmann.mil@mail.mil
 • **Phone:** 7196488431

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

• **Record ID:** 42073321
 • **Completion Date:** 13-Apr-2021
 • **Expiration Date:** 12-Apr-2024
 • **Minimum Passing:** 80
 • **Reported Score*:** 92

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	13-Apr-2021	No Quiz
Belmont Report and Its Principles (ID: 1127)	13-Apr-2021	3/3 (100%)
History and Ethics of Human Subjects Research (ID: 498)	13-Apr-2021	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	13-Apr-2021	5/5 (100%)
Informed Consent (ID: 3)	13-Apr-2021	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	13-Apr-2021	4/4 (100%)
Records-Based Research (ID: 5)	13-Apr-2021	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	13-Apr-2021	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	13-Apr-2021	4/5 (80%)
Research Involving Prisoners (ID: 8)	13-Apr-2021	4/4 (100%)
Research Involving Children (ID: 9)	13-Apr-2021	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	13-Apr-2021	3/3 (100%)
FDA-Regulated Research (ID: 12)	13-Apr-2021	5/5 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	13-Apr-2021	4/5 (80%)
Research and HIPAA Privacy Protections (ID: 14)	13-Apr-2021	4/5 (80%)
Conflicts of Interest in Human Subjects Research (ID: 17464)	13-Apr-2021	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	13-Apr-2021	4/5 (80%)
The Federal Regulations - SBE (ID: 502)	13-Apr-2021	5/5 (100%)
Assessing Risk - SBE (ID: 503)	13-Apr-2021	5/5 (100%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	13-Apr-2021	4/5 (80%)
Internet-Based Research - SBE (ID: 510)	13-Apr-2021	4/5 (80%)
International Studies (ID: 971)	13-Apr-2021	3/3 (100%)
The IRB Member Module - 'What Every New IRB Member Needs to Know' (ID: 816)	13-Apr-2021	4/5 (80%)
Informed Consent and Confidentiality in Public Health Research (ID: 17639)	13-Apr-2021	4/5 (80%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	13-Apr-2021	No Quiz

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

Verify at: www.citiprogram.org/verify/?kc101038a-675f-40dd-8f46-9f6e2927b801-42073321

Collaborative Institutional Training Initiative (CITI Program)

Email: support@citiprogram.org

Phone: 888-529-5929

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

Appendix B: USU form 3202N

USUHS FORM 3202N

DANIEL K. INOUE GRADUATE SCHOOL OF NURSING

EVIDENCE-BASED PRACTICE/PERFORMANCE IMPROVEMENT PROPOSAL

VPR Date Stamp

Project Number: _____ (VPR will assign)

Project Title: **Evaluation and Implementation of an Evidence-Based Loaned Surgical Instrumentation Management Program Utilizing the Plan, Do, Study, Act Cycle**

SECTION A: STUDENT POC INFORMATION	
1. Name (Last, First, MI): Hartmann, Jesse, M. & Baza, Gaston	Student E-mail: jesse.hartmann@usuhs.edu & gaston.baza@usuhs.edu
2. Home Address: _____	Cell Number: _____
SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION	
3. Name (Last, First, MI): Taylor, Laura	
4. Telephone: _____ Fax: _____	E-mail: laura.taylor@usuhs.edu
5. USUHS Building/ Room No.: Building E, Room #1014	
SECTION C: PROJECT INFORMATION	
6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.	
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? ☐ Yes ☒ No If yes, complete below; if no, proceed to Part 8. Project Number: _____ Project Title: _____ Project Start Date: _____ Project End Date: _____	
8. Anticipated period of performance: Project Start Date: 8/1/2022 Project End Date: 3/9/2023	
9. Performance Site(s): Fort Belvoir Community Hospital	
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) ☐ Yes ☒ No	
11. Do you have a funding source for this project? ☐ Yes ☐ No ☒ NA If yes, specify the funding agency and the amount provided: _____	
SECTION D: SIGNATURES	
The following signatures attest to the validity of the above information:	
HARTMANN.JESSE.MICHAEL.1042821299 Digitally signed by HARTMANN.JESSE.MICHAEL.1042821299 Date: 2022.05.19 14:13:25 -04'00' Student (Project Point of Contact for the Group) (Signature and Date)	ROMITO.KENNETH.J.1280261862 Digitally signed by ROMITO.KENNETH.J.1280261862 Date: 2022.08.04 10:53:36 -04'00' Chair/Senior Mentor (Signature and Date)
_____ Chair/Program Director (Signature and Date)	Laura Taylor, PhD, RN, ANEF, FAAN Digitally signed by Laura Taylor, PhD, RN, ANEF, FAAN Date: 2022.07.27 10:55:00 -04'00' Chair/Program Director (Signature and Date)
_____ DNP Project Director or PhD Director (Signature and Date)	Laura Taylor, PhD, RN, ANEF, FAAN Digitally signed by Laura Taylor, PhD, RN, ANEF, FAAN Date: 2022.09.08 13:56:52 -04'00' Associate Dean for Academic Affairs, GSN (Signature and Date)
SIMMONS.ANGELA.MARIE.1143313375 Digitally signed by SIMMONS.ANGELA.MARIE.1143313375 Date: 2022.09.09 09:58:23 -04'00' Associate Dean for Research, GSN (Signature and Date)	ROMANO.CAROL.A.1032050294 Digitally signed by ROMANO.CAROL.A.1032050294 Date: 2022.09.09 10:37:17 -04'00' Dean, DKI Graduate School of Nursing (Signature and Date)
In light of the above signatures, the project is approved. WOODBERRY.MITCHEL.L.WAYNE.1060957114 Digitally signed by WOODBERRY.MITCHEL.L.WAYNE.1060957114 Date: 2023.02.23 10:28:16 -05'00' USUHS Vice President for Research _____ Date _____	

Appendix C: MTF IRB/PI Letter of Determination



DEFENSE HEALTH AGENCY
 FORT BELVOIR COMMUNITY HOSPITAL
 OFFICE OF THE DIRECTOR
 9300 DEWITT LOOP
 FORT BELVOIR, VIRGINIA 22060-5901

FBCH DRP

27 January 2023

FROM: Fort Belvoir Community Hospital (FBCH) Department of Research Programs (DRP)

TO: Hassan Ali Brown, CDR, USN, DHA, FBCH, MBA

SUBJECT: FBCH DRP Determinations Review of QI/PI Project Number 956160

PROJECT TITLE: "Evaluation and Implementation of an Evidence-Based Loaned Surgical Instrumentation Management Program Utilizing the Plan, Do, Study, Act Cycle"

SUBMISSION TYPE: New Project

ACTION: Determination of "Not-Research" (Quality Improvement/Performance Improvement)

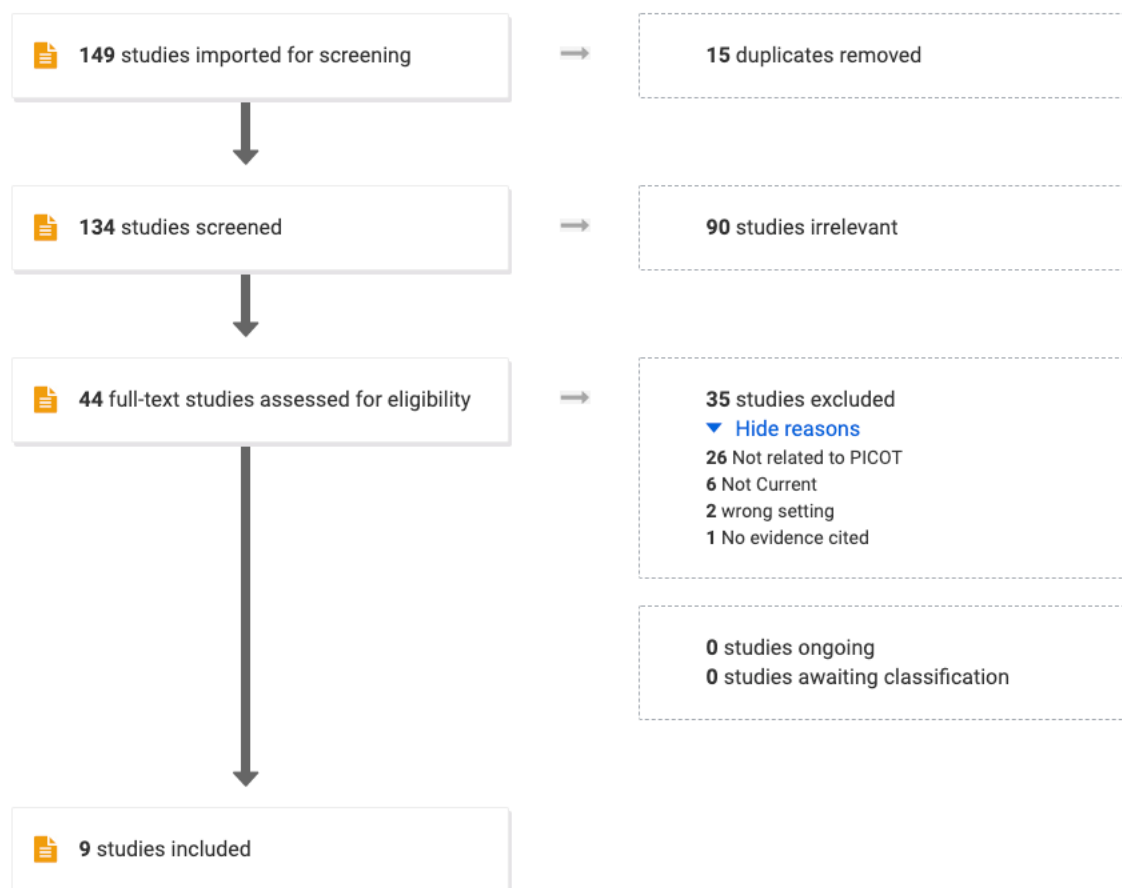
DECISION DATE: 27 January 2023

1. An FBCH HRPP determinations official has reviewed your submitted documents and determined the activities do not meet the full definition of research as defined in 32 Code of Federal Regulations 219.102(l). The determination of Not Research was reached based on the project's design and objectives, which are to evaluate compliance specific to loaned surgical instrument (LSI) reprocessing throughout the entire process from acquisition, processing, point of use, and return to the representative who loaned it to FBCH. The goal is to measure compliance with the audit checklist created that is supported by the association for the Advancement of Medical Instrumentation (AAMI) and the Association of PeriOperative Registered Nurses (AORN) that provide the recommendations for an LSI practice bundle and handled according to the manufacturer's IFU.
2. This project consists of using PDSA, audit and feedback iterations, program evaluation cycles, and checklist elements developed from professional organizations' recommendations and literature synthesis. Completion of each iteration will longitudinally measure compliance percentage with the 59 elements of the LSIM checklist. In support of RRC, leadership outbriefs will be provided to stakeholders to establish a culture of safety to identify QSCPI.
3. Please register your project with the FBCH Department of Quality Management at <https://fbchintranet.departments.med.ds.osd.mil/qualitymgt/SitePages/Home.aspx>
4. Please notify FBCH DRP of substantive changes to the project's design or intent. An appointed Determinations Official may need to review the project again to ensure that the proposed changes do not impact the original determination of "Not-Research".
5. This is not an approval to receive extramural resources (i.e., personnel, drugs, supplies, equipment, money, and gifts from any source outside of FBCH). You must coordinate

Appendix D: PAO Clearance

REQUEST FOR PUBLIC RELEASE		
<i>(This form is to be used at Fort Belvoir Community Hospital in requesting review and clearance of DoD information for public release in accordance with DoDD 5230.09)</i>		
1. DOCUMENT DESCRIPTION		
a. TYPE Quality Improvement Poster	b. TITLE Evaluation and Implementation of an Evidence-Based Loaned Surgical Instrumentation Management Program Utilizing the Plan, Do, Study Act Cycle	
c. DATE OF SUBMISSION 5 April 2023	d. PAGE COUNT 15	e. RESEARCH OR PUBLIC CLEARANCE? Public Clearance
f. CLEARANCE REQUESTED BY (YYYYMMDD) (All submissions require a minimum of 10 days for review) 18 May 2023		
2. AUTHOR/SPEAKER (If more than one author, include names of additional authors on separate sheet.)		
a. NAME (Last, First, Middle Initial) Baza, Gaston and Hartmann, Jesse M.	b. AFFILIATION (Armed service, civilian, contractor) Armed Services	c. RANK MAJ/04
d. DEPARTMENT/CLINIC Perioperative		
3. PRESENTATION/PUBLICATION DATA (Date, Place, Event) The request will be provided as a poster presentation during the Uniformed Services University of the Health Sciences Research Day.		
4. POINT OF CONTACT		
a. NAME (Last, First, Middle Initial) Baza, Gaston	b. EMAIL gaston.baza@usuhs.edu	c. TELEPHONE NO. [REDACTED]
5. STAFF JUDGE ADVOCATE (SJA) COORDINATION		
a. NAME (Last, First, Middle Initial) Wheeler, Sherri A.		
b. REMARKS I. Template - USU II. PATIENT DATA - No PII identified III. IMAGES - Computer generated image, needs creator identified; Organizing Framework, cited; QR Code "Campaign has been disabled for some reason" unable to verify LSIM checklist with QR code. Recommendation: Provide LSIM checklist with Form 1910 for review. IV DISCLAIMER - provided		
c. SUBMISSION IS: ☐ APPROVED ☒ APPROVED WITH QUALIFICATIONS (See REMARKS, block 5b) ☐ NOT APPROVED		
d. SIGNATURE WHEELER.SHERRI.ANN.108047 1084	Digitally signed by WHEELER.SHERRI.ANN.1080471084 Date: 2023.04.17 19:20:07 -0400	e. DATE SIGNED (YYYYMMDD) 20230417
6. PUBLIC AFFAIRS OFFICER (PAO) COORDINATION		
a. NAME (Last, First, Middle Initial) Brown, R. P.		
b. REMARKS Conditional clearance granted for poster presentation upon completion of recommendations listed in SJA remarks.		
c. SUBMISSION IS: ☐ APPROVED ☒ APPROVED WITH QUALIFICATIONS (See REMARKS, block 6b) ☐ NOT APPROVED		
d. SIGNATURE BROWN.R.PARRISH.1047805780	Digitally signed by BROWN.R.PARRISH.1047805780 Date: 2023.05.01 13:24:30 -0400	e. DATE SIGNED (YYYYMMDD) 20240501
Submitted documents require both Staff Judge Advocate (SJA) and Public Affairs Officer (PAO) approval in blocks 5c and 6c above before public release. Please note any qualifications for approval, which will be included in the REMARKS block (if applicable). If approved by both SJA and PAO, the material is approved for public release and clearance for open publication is recommended under the provisions of DoDD 5230.09		

Appendix E: PRISMA Diagram

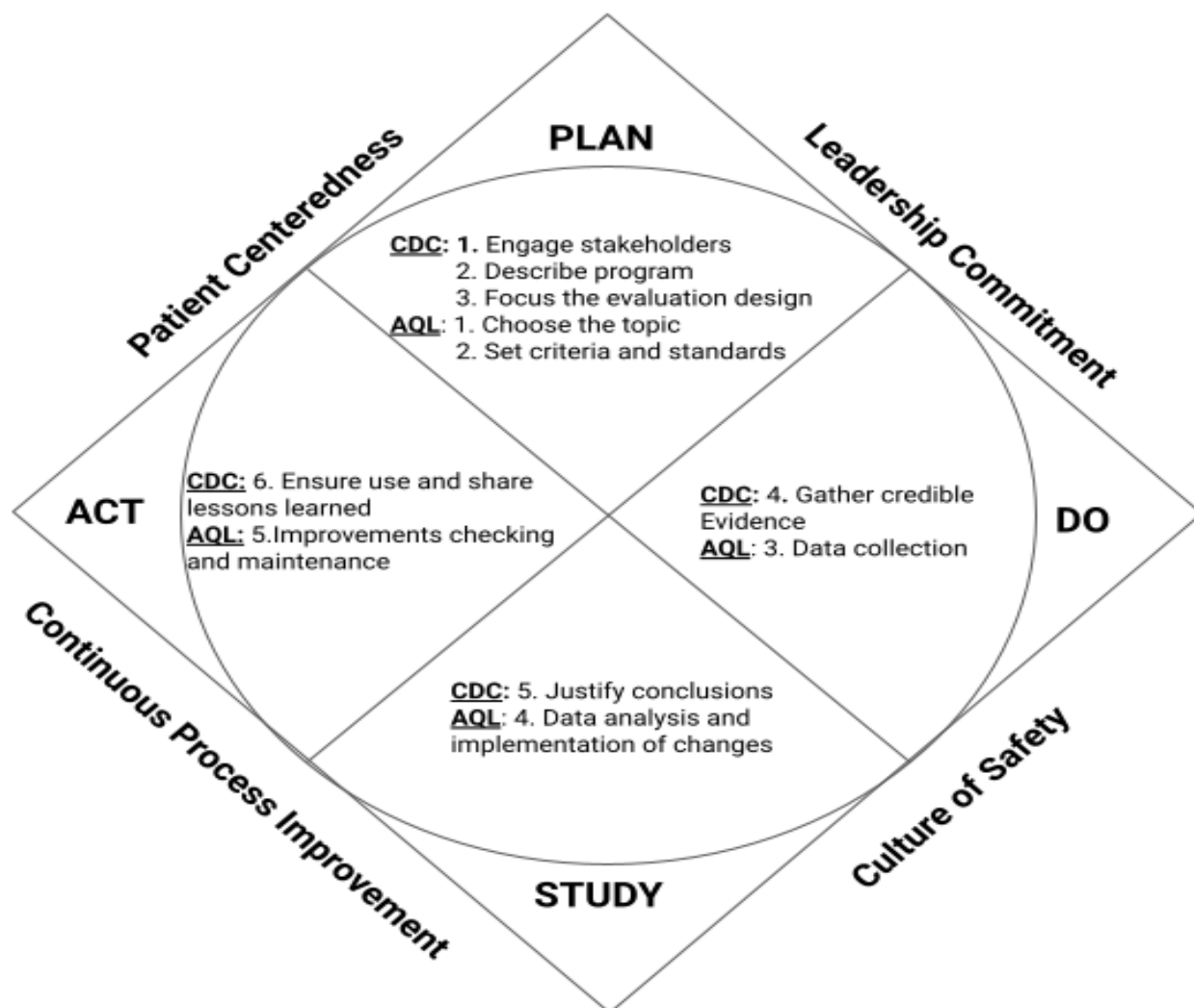


Appendix F: Evidence table

1st Author Name (Publication Yr)	Category	Study Purpose/Aims	Study Design	Sample Size	Results	JHNEBP Level of Evidence
Costa et al., 2015	LSI processing	- Determine condition of orthopedic LSI delivered to the hospital - Assess quality of complex reusable instruments reprocessed by manual cleaning - Evaluate effect of multiple reprocessing on single-use implants not used in surgery	Quasi-experimental assessing for residual ATP, protein, bacterial contamination, endotoxin and/or biofilm at delivery at the hospital, following cleaning and steam sterilisation.	- FMRs=73 - DGs=19 - Screws=12	- Amount of ATP on surface of FMRs decreased following cleaning. No significant difference in luminal ATP before and after cleaning - Visual inspection showed visible soil in the "impossible to clean areas" of the FMRs with a convex electron microscope - FMRs cultured for bacteria were all negative for endotoxin after cleaning and sterilisation but microscopic sampling showed biofilm on 100% of the FMRs - Depth gauges were visually clean but contained biofilm following microscopic scanning 80% of the screws showed bacterial contamination. These were single use implants that have never been implanted but continue to be reprocessed in the tray	IIA
Brink et al., 2017	Audit and feedback	- Promote multidisciplinary, collaborative action across 34 urban and rural South African hospitals to implement a non-specialized, pharmacist-driven audit and feedback improvement model for PAP - To achieve a sustainable reduction in SSIb.	Quasi-experimental prospective study comparing pre-intervention compliance to post intervention of audit feedback compliance rate	34 hospitals participated 24,206 surgical cases reviewed to compare pre and post implementation compliance rate	All four process measures and overall compliance were significantly increased compared to pre-intervention data	III
Manivannan et al., 2015	Audit and feedback	Demonstrate the efficacy of audit and feedback on care bundle compliance rate in reducing SSIb by comparing SSI rates in pre-SAF and post-SAF	- Quasi-experimental prospective cohort study where SSI rate was monitored during pre-SAF, early post-SAF, and late post-SAF phases - Correlation between compliance rate and SSI noted	- Total surgical cases: n=32,814 - Pre-SAF: n=10,026 - Post-SAF: n=21,358	- Decrease in SSI rate from 0.0% pre-SAF to 0.2% post-SAF - Compliance with care bundle components increased from 52.7% to 99% - SSI rate was inversely correlated with care bundle compliance rate	III
Ivers et al., 2012	Audit and feedback	- Assess effects of audit/feedback on practice of healthcare professionals - Patient Outcomes - Examine factors and variations influencing effectiveness of audit and feedback	Cochrane systematic review of Randomized Controlled trials	140 studies	- Increase in compliance with desired practice (dichotomous and continuous outcomes) - Increase in measurable patient outcomes (dichotomous and continuous)	IA
Chan et al., 2017	Audit and feedback	Review published literature evidence to identify effective strategies to increase implementation of clinical practice guidelines	Systematic review of effectiveness of intervention techniques including reminders, educational outreach visits, audit and feedback, and provider incentives	39 systematic reviews 10 overviews of systematic reviews	- Audit and feedback and outreach visits are generally effective in improving process of care and clinical outcomes - Reminders and provider incentives were either ineffective or showed mixed effectiveness - Gaps in evidence on effectiveness of implementation interventions related to clinical outcomes, cost effectiveness, and issues affecting successful implementation - Instrument cleaning/disinfection is a critical multi-step process for sterilisation - SFD staff should comply with manufacturer's IFU to clean, decontaminate and sterilise LSI to effectively facilitate safe patient care.	III
Chidier, 2019	LSI processing	- Review steps of instrument cleaning and decontamination and - Provide framework to help perioperative staff facilitate these steps in their work environments appropriately	Expert opinion	Not applicable	- Instrument cleaning/disinfection is a critical multi-step process for sterilisation - SFD staff should comply with manufacturer's IFU to clean, decontaminate and sterilise LSI to effectively facilitate safe patient care.	VB
Soave, 2010	LSI processing	Evaluate the improvement of communication, policies, and procedures for process improvement of the quality and safety of LSI	Expert opinion	Not applicable	- All loaned sets require specific handling and reprocessing - SFD staff must be knowledgeable in the policies and procedures to properly handle the LSI - Intra-departmental policy and monitoring is promotes safe practices to decrease risk for SSI	VB
Agarwal et al., 2019	Surgical Instrumentation processing evaluation	- Evaluation of screws for presence of residual nonmicrobial contaminants - Structuring minimum steps and time required to properly reprocess the implants according to recent guidelines	Randomized Controlled Trial	6 screws randomly selected from 4 trays 4 major manufacturer's IFU	- Corrosion claims on outer surface of implants and inner rim of screw - Saccharides and soap in internal region of screw 100% lack of validated reprocessing method	IIIA
Pascul et al., 2016	LSI processing	- Discuss the difficulty and challenges of processing LSI - Discuss issues staff in SFDs have to process LSI	Expert opinion	Not applicable	Recommend utilizing evidence based practice to develop policies and procedures for processing LSI in addition to following manufacturer's IFU	VB

Abbreviations: ATP= Adenosine Triphosphate; CPGs= Clinical Practice Guidelines; DG= Depth Gauge; FMR= Flexible Modular Roomers; IFU= Instructions for Use; LSI= Loaned surgical Instrument; PAP= Perioperative Antibiotic Prophylaxis; SFD= Sterile Processing Department; SSI= Surgical Site Infection; SAF= Surveillance Audit Feedback.

Appendix G: Organizing Framework



Appendix H: LSIM Audit Checklist

Loaned Surgical Instrument Management Audit			
Pre-Request Evaluation	Yes	No	Notes
1. Before initial use, is there an interdisciplinary team that has developed a policy and standardized process to select reusable medical devices and equipment and supplies that will be used for processing? (AORN, 2022)			
2. Before purchase, does the organization have the resources and capabilities to process the surgical item requested according to the methods provided in the manufacturer's validated IFU? (AORN, 2022; IAHCSMM, 2016)			
3. Has the staff been educated on the proper decontamination, assembly/disassembly, and function check for the loaned instrument? (AORN, 2022)			
Loan Request	Yes	No	Notes
1. Was the loaned instrument requested in an appropriate amount of time to be properly processed for scheduled procedures? (IAHCSMM, 2016)			
Loaned Instrument Drop Off	Yes	No	Notes
1. Was a staff member and loaned instrument representative present at the time of drop off? (AORN, 2022)			
2. Was inventory completed between the loaned instrument and staff member and documented? (AORN, 2022)			
3. Is there documentation with proof of receipt of loaned instrumentation with information including; date, time, delivery person, receiving person, surgeon's name, patient name/identifier, number of trays, and number of implants? (IAHCSMM, 2016)			
4. Are the instructions for use for the loaned instruments available to the facility? (AORN, 2022; IAHCSMM, 2016)			
5. Were the instruments inspected for defects and correct function? (AORN, 2022; IAHCSMM, 2016)			
Decontamination	Yes	No	Notes
1. Is the responsible staff member cleaning and decontaminating the loaned instrument according to the manufacturer's IFU? (AAMI ST 79, 2017; AORN, 2022; IAHCSMM, 2016)			

Assembly/Prep & Pack	Yes	No	Notes
1. Does the organization have a policy and process in place for:			
a. How cleaning effectiveness will be evaluated?			
b. Is there a method in place used to objectively validate cleanliness?			
c. How to verify that the instrument is functioning correctly and that the instrument set is properly assembled prior.			
d. How to communicate between sterile processing and surgical staff?			
2. Are loaned instruments wrapped/packaged according to the manufacturer's IFU?			
Sterilization – Steam, Low Temperature & Quality Assurance	Yes	No	Notes
1. Are steam sterilizers being loaded properly and instrument sets being checked for weight validation?			
2. Are steam sterilizer cycles selected in accordance with instrument IFUs?			
3. Are MFR's IFUs readily accessible for personnel who are processing instruments?			
4. When IUSS occurs, is it performed correctly, (i.e., approved container, cycle, and indicators?)			
5. Are instruments that need IUSS sent to the decontamination area for cleaning?			
6. Are all items sterilized labeled with the sterilizer used, the cycle or load number, and the date of sterilization?			
7. Are terminally processed loads allowed to cool to room temperature before handling?			
8. Is each sterilizer cycle printout reviewed noting time, temperature, pressure, sterilization cycle time, and initialed before load removal?			
9. Does each sterilization package have an external and internal chemical indicator?			
10. Are biological indicators (BIs) used daily and with every load containing an implant?			
11. Do personnel activate and incubate BIs properly?			
12. Is an unprocessed BI from the same lot being incubated daily in each incubator as the control?			
13. Are pre-vacuum steam sterilizers tested daily for air removal using a Bowie-Dick type test pack?			
14. Are positive BIs sent to microbiology laboratory for gram staining to protect against false positive readings?			
15. Are all sterilization records complete, accurate and legible?			

Sterile Storage & Housekeeping	Yes	No	Notes
1. Are sterile items located in a clean, restricted designated storage area?			
2. Is the sterile storage environment monitored and recorded daily? (positive pressure, temperature, humidity)			
3. Is storage shelving appropriate (i.e., bottom shelves covered, all smooth surfaces, clean)?			
4. Are sterile items are stored at least 18" from sprinklers, 2" from walls, and 8-10" from floor?			
5. Is ceiling or ceiling tiles made of an appropriate construction (i.e., not particulate-fiber shedding)?			
6. Are sterile wrapped packages positioned so that they are not crushed, bent, compressed, or punctured?			
7. Does each sterile package have a load label with sterilizer no., load no. and date of processing?			
8. Is there an "event-related" sterility assurance policy?			
9. Are floors cleaned and disinfected at least daily for all instrument reprocessing areas?			
10. Are work surfaces (and frequently touch items) cleaned and disinfected daily for all areas?			
11. Are walls, equipment, ducts, light fixtures, and storage shelves on a routine cleaning schedule?			

Point Of Use Cleaning - Instrument Preparation & Transport	Yes	No	Notes
1. Is staff wearing appropriate PPE when handling medical devices?			
2. Are point of use instructions in place within soiled utility rooms?			
3. Can staff articulate the process for point of use cleaning?			
4. Did staff visually inspect instruments for residual soil, fluids, tissue, and gross material?			
5. Are instruments wiped of gross soil with sterile surgical sponges and sterile water?			
6. Are lumens irrigated with sterile water throughout the procedure to remove gross soil?			
7. Are multi-part instruments opened, disassembled, and arranged within their original set?			
8. Are hinged instruments kept fully open using stringers, racks and/or instrument pegs?			
9. Are light instruments placed on top of heavy instruments or placed in separate containers?			
10. Are instruments kept moist until they are cleaned by either saturation with an enzymatic pretreatment product or a towel moistened with water?			
11. Are instruments contained properly during transport to Decontamination area?			
12. Are transport containers (i.e., bags, carts and/or containers) labeled biohazard?			
13. Are instruments being transported as soon as possible to prevent blood from drying?			
14. Are staff training and competencies for precleaning and handling of instruments up to date?			
Decontamination for Sterile Storage/ Return to Rep	Yes	No	Notes
1. Loaned set is delivered to decontamination to be cleaned and decontaminated according to IFU in preparation for assembly or return to company representative.			
2. If the loaned is being returned to representative, are the following actions performed:			
a. Completion of the loaned instrument form per local policy.			
b. Is there a location designated in SPD for loaned sets to be picked up?			
c. Does the loaned instrument form indicate agreement between the present SPD staff and representative for condition of instruments and inventory at time of pick up?			

Appendix I: Project timeline

[illegible]

Appendix J: Business Case Analysis

GSN705: Healthcare Economics and Advanced Practice
Module 2 Assignment: Business Case with Value Based Care

NAME: MAJ Jesse Hartmann and MAJ Gaston Baza

DATE: 29OCT2021

Student Name:

Date:

BUSINESS CASE with VALUE BASED CARE ASSESSMENT

Proposed Title for Project/Initiative/Opportunity to Improve *Proposed Title*

Evidence Based Program Evaluation to Increase Compliance with Industry Guidelines and Recommendations for Processing Loaner Surgical Instrumentation.

Opportunity Statement *(Description of proposed project/initiative/opportunity to improve)* *Opportunity statement*

Utilizing evidence-based methods to ensure proper processing of loaner surgical instrumentation will help to prevent surgical site infections (SSIs), ensure staff and patient safety, decrease costs related to SSIs, and maintain image as a high reliable organization (HRO).

Business Opportunity/Objectives *(Prioritize listing – macro and micro objectives)* *Business Opportunity*

1. Improve patient safety by contributing to preventing SSIs.
2. Cost avoidance from SSI payouts.
3. Ensure sterile processing staff are compliant with processing complex loaner instrumentation according to industry guidelines and recommendations.
4. Organization maintains image as a HRO.

Potential Impact of the Initiative/Project *(Identify outcome metrics & benchmarks/and how objectives align with Quadruple Aim, Value Based Care, and HRO goals)* *Potential Impact*

1. Infection rates for surgical procedures involving loaner instrumentation.
2. Organization avoids cost burden of care delivered for patients who get an infection that underwent a surgical procedure using loaner instrumentation.
3. Project is nested within the principals of a HRO of preoccupation with failure, reluctance to simplify, sensitivity to operations, deference to expertise, and commitment to resilience (Oster & Braaten, 2016).
4. Organization maintains or improves its image as a HRO.

Alternatives *(courses of action)* chosen for Analysis *Alternatives*

1. Implementation of an evidence based evaluation tool to determine compliance with industry guidelines and recommendations for processing loaner surgical instrumentation.
2. No observation or evaluation of loaner instrumentation processing in the sterile processing department.
3. "Status Quo": Compare current practice of loaner instrumentation to industry guidelines and recommendations.

Analysis of Alternatives *Alternatives*

Alternative 1: Implementation of an evidence-based evaluation tool to audit compliance with industry guidelines and recommendations for processing loaner surgical instrumentation.

Pros	Cons
-Improve patient outcomes by raising awareness on processing. -Quick way to measure current practices to create a benchmark and measure outcomes before and after the implementation of the evaluation tool.	-Negatively accepted by staff by assuming this is targeting their performance. -Organizational culture is impacted due to assumptions that professional standards and targets are not being met.

Alternative 2: No observation or evaluation of loaner instrumentation processing in the sterile processing department.

Pros	Cons
-Influence a sense of confidence while processing instrumentation guided by an evidence-based tool. -Allows staff the autonomy to conduct a follow-up analysis to pinpoint barriers within the organization and how to improve it.	-Daily hands on experience does not correlate with processes of the evaluation tool and does not align with elements of the evaluation tool when members of the EBP team are not present. -Outcomes outside the designated area of operations where the evaluation is being recorded and measured are not documented, planned, or assumed for.

Alternative 3: "Status Quo": Compare current practice of loaner instrumentation to industry guidelines and recommendations.

Pros	Cons
-Highlights processes performing well and those in need of improvement with the specific surveillance tool. -Ensures the incorporation of evidence based practice from data collected from informatics for best outcomes.	-Identifies underperforming processes or negative trends and can be looked at negatively by the public. Opinion may have a negative outcome on this.

Appendix K: Team Mentor Agreement Form



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

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

Graduation Year: 2023

Name(s) of DNP Project Student Team:

1. Gaston Baza Phase II Site: AGCNS ☒ FNP ☐ PMHNP ☐ RNA ☐ WHNP ☐
2. Jesse Hartmann Phase II Site: AGCNS ☒ FNP ☐ PMHNP ☐ RNA ☐ WHNP ☐
3. _____ Phase II Site: AGCNS ☐ FNP ☐ PMHNP ☐ RNA ☐ WHNP ☐
4. _____ Phase II Site: AGCNS ☐ FNP ☐ PMHNP ☐ RNA ☐ WHNP ☐
5. _____ Phase II Site: AGCNS ☐ FNP ☐ PMHNP ☐ RNA ☐ WHNP ☐
6. _____ Phase II Site: AGCNS ☐ FNP ☐ PMHNP ☐ RNA ☐ WHNP ☐

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

Evaluation and Implementation of an Evidence-Based Loaned Surgical Instrumentation Management Program
Utilizing the Plan, Do, Study, Act Cycle.

Committee Approved DNP Project Clinical Question:

At Fort Belvoir Community Hospital does an evidence-based LSIM program evaluation, compared
to current practice, achieve Fort Belvoir Community Hospital goals of providing RRC?

?

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

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

Form Version: 1 Jun 2016



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

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

Senior Mentor (Chair):	Dr. Kenneth Romito	Signature: Kenneth Romito	Digitally signed by Kenneth Romito Date: 2023.03.16 10:57:34 +0400'	Date: 16Mar23
Team Mentor (Committee):	_____	Signature: _____		Date: _____
Team Mentor (Committee):	_____	Signature: _____		Date: _____
Team Mentor (Committee):	_____	Signature: _____		Date: _____

Appendix L: DNP Project Completion Verification



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

DOCTOR OF NURSING PRACTICE PROJECT Completion Verification Form

The DNP Project titled:

Evaluation and Implementation of an Evidence-Based Loaned Surgical Instrumentation Management Program Utilizing the Plan, Do, Study, Act Cycle.

was completed at: Fort Belvoir Community Hospital

by the following student(s):

(type student name)	(signature)	(date)
Gaston Baza	BAZA.GASTON.1125002508 Digitally signed by BAZA.GASTON.1125002508 Date: 2023.04.20 21:24:55 -04'00'	04/20/2023
Jesse Hartmann	HARTMANN.JESSE.MICHAEL.1042821299 Digitally signed by HARTMANN.JESSE.MICHAEL.1042821299 Date: 2023.04.20 21:07:26 -04'00'	04/20/2023
	STUDENT NAME	
	STUDENT NAME	
	STUDENT NAME	

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

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

Verified by:

	(type name)	(signature)	(date)
Senior Mentor:	Dr. Laura Taylor	Laura Taylor, PhD, RN, ANEF, FAAN Digitally signed by Laura Taylor, PhD, RN, ANEF, FAAN Date: 2023.04.27 15:11:11 -04'00'	
Team Mentor:	Dr. Kenneth Romito	Kenneth Romito Digitally signed by Kenneth Romito Date: 2023.04.27 15:41:42 -04'00'	4/27/23
Team Mentor:		STUDENT NAME	
Phase II Site Director:	Dr. David Bradley	BRADLEY.DAVID.FRANKLIN.JR.1134185488 Digitally signed by BRADLEY.DAVID.FRANKLIN.JR.1134185488 Date: 2023.04.27 18:47:00 -04'00'	

For RNA Students only - add the following additional signature for final verification of project completion:

	STUDENT NAME	
RNA Project Director (type name)	(Signature)	(Date)