A Quality Improvement Initiative to Redefine the Process of Instrument Decontamination from the Surgical Field in the Operating Room to the Sterile Processing Department.

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A Quality Improvement Initiative to Redefine the Process of Instrument Decontamination from the Surgical Field in the Operating Room to the Sterile Processing Department.

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NURS 958: Clinical Nurse Leader Capstone

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Abstract

**Background:** The Operating Room (OR) faces a significant challenge with the increasing presence of bioburden on instruments. Research-based on evidence has demonstrated the critical role of precleaning at the point of care with sterile water in reducing bioburden incidence. While current practices recommend the use of an enzymatic solution post-procedure to spray instruments, it is clear that a more comprehensive approach is needed to effectively manage bioburden and reduce the risk of Surgical Site Infections (SSI).

**Methods:** Utilizing the Plan-Do-Study-Act (PDSA) model to create a Quality Improvement (QI) solution, the project leader recommended using sterile water at the point of care to preclean instruments while in use. Staff were observed using sterile water, and data on bioburden were compared pre- and post-intervention to evaluate the initiative's effectiveness.

**Intervention:** An educational service was provided to reeducate staff on the importance of precleaning instruments and their impact on patient safety. Staff were encouraged to use sterile water at the point of care to reduce instrument bioburden.

**Results:** Data analysis showed no significant changes in the presence of bioburden over the project’s 4-week period compared to the previous period. However, using sterile water at the point of care has made a difference in the quality of used instruments upon arrival at the Sterile Processing Department (SPD). A notable increase (90%) in using sterile water to preclean instruments compared to the 5% observed during pre-intervention.

**Conclusion:** Implementing this QI project encouraged using sterile water at the point of care to preclean surgical instruments. The continuous use of sterile water at the point of care use could help reduce the number of instruments found with bioburden. SPD should provide annual educational training to ensure staff are informed on best practices. Creating a policy and educational reinforcement will guide staff on expectations.

**Keywords:** Surgical Instruments, Bioburden, Bioburden on instruments, Quality Improvement, Sterile Water, Surgical Site Infections, SSI, Operating Room, Sterile Processing, Patient Safety
Introduction

Problem Description

In the Operating Room (OR) microsystem of a magnet facility in New England, it has been reported that bioburdens on surgical instruments have increased by 15-18% over the past few months. While the microsystem focused on safety and ways to prevent errors, there was a constant need for quality improvement and various risk management strategies regarding bioburden. *Bioburdens* are any foreign matter or material, such as tissue, bacteria, or fluids visible to the naked eye, present on instruments that should have been removed during cleaning and sterilizing (Rutala et al., 2023). The incidence of bioburdens on surgical instruments created an enormous safety risk and infection concern for patients scheduled to have surgery (Spruce, 2017). It was also an immense problem for those who were directly involved and could have affected outcomes if they were missed during preparation checks for surgery by the surgical team.

*Nature of the Problem*

Before the start of any surgical procedure, the surgical technologist and the nursing circulator were responsible for thoroughly assessing each kit that holsters an instrument before introducing it to the sterile field. They would examine these instruments, looking for rips, tears, or water marks on the interior and exterior surfaces of the container that houses them. Additionally, they inspected ridges, cannulated and hard-to-reach areas of individual pieces of instruments that make up a kit, looking for any debris, particulate, or bioburdens that could have been missed during decontamination and through the sterilization
process. Due to their microscopic sizes, bioburdens have the potential to be missed, which could create exposure to the risk of a Surgical Site Infection (SSI) for patients. When instruments contain biological evidence from previous patients or usage, the sterilization process demonstrated that it was not one hundred percent effective. Therefore, these instruments needed further attention to remove debris adequately (Smith et al., 2018). Surgical procedures are then forced to be canceled due to the potential of bioburdens on instruments, causing a significant loss of time and resources and delay in patient care.

**Significance of the Problem**

Efforts to reduce the incidence of bioburdens by the microsystem included training newly hired staff and providing educational reinforcements through in-services. This approach has helped to cover the gaps between the staffing resources, which has a quarterly turnover rate of 5-10%, with new contractual staff hired for thirteen to twenty-six weeks. The article "Assessment of surgical instrument bioburden after steam sterilization: A pilot study" by Resendiz et al., 2020, highlighted that bioburden formation becomes increasingly difficult to remove as time elapses between instrument cleanings. While still active in a procedure, continuous precleaning of instruments quickly eliminates any foreign matter that may have hardened between the transition from the OR department to the Sterile Processing Department (SPD). This finding could help lower the presence of bioburdens in the microsystem. The findings suggested that thorough precleaning before decontamination and sterilization increased effectiveness (Resendiz et al., 2020). The idea and process of lightly precleaning surgical instruments to remove heavy debris should begin while in surgery at the back table, and this could help to reduce bioburdens noted in already sterilized instruments for future procedures. This approach would also help to minimize
the risk and exposure to surgical site infections, helping to reduce hospital readmissions and length of stay for patients.

**Available Knowledge**

On occasions when surgical instruments are needed for use, sterility issues can compromise the integrity of those items. In the last six months, data collected and verified by the sterile processing manager showed a 15-18% increase in numbers. The data included bioburdens from previous procedures that have persisted through decontamination and sterilization. Such instances usually happen when an instrument was heavily soiled with debris from a surgical procedure. Currently, instruments are sprayed with an enzymatic solution after a procedure but not pre-cleaned on the sterile field, making it difficult for the sterile processors to reach and remove particulates in hard-to-see areas. An Association of Perioperative Registered Nurses (AORN) article by Balena (2022) suggests that precleaning instruments on the back table are imperative to help decrease the presence of bioburden. This approach would help to reduce debris left on instruments after procedures and could potentially prevent the occurrence of bioburdens. The literature reviewed in this section gives an overview of the impact bioburdens have on an operating room and ways the incidence of bioburdens can be mitigated.

**Search Methods**

Search words and phrases were used to assess and examine previous and similar studies. While doing this project, the project lead employed words such as surgical instruments, surgical instrument bioburdens, surgical site infections, contaminated instruments, unprocessed instruments in surgery, sterile processed instruments for surgery, surgery, effects of bioburden on
surgical instruments, and the impact of contaminated surgical instruments in surgery. To support this project, the project lead used the Cumulative Index to Nursing & Allied Health Literature (CINAHL) Complete, MEDLINE (through EBSCO), and the Google Scholar databases to gather information and study data.

Through these online databases, a combination of 126 articles that supported the topic of interest was selected after duplicated materials were identified and removed from a total number of 196 written works. Several critical filters were used to advance the screening of these articles; written work before 2014 was identified as dated and advanced in years, leading to a non-selection, and written work that was literature reviews was automatically dismissed. Of the 126 eligible articles, 90 were excluded, including studies that provided limited access to the author and written work that did not pertain to surgical instruments; 36 full-text articles were further assessed. Of those 36 articles reviewed in full text, 31 were excluded with reasons including nine articles that did not provide adequate information that could assist the author with the project, these articles had research geared towards education and best practices in sterile processing departments, and they did not provide any highlights to safety and the issues of bioburdens or contamination. One article had information on bioburdens in German, but when translated by Google Translate, the result did not provide any clarity to the author. Ten other articles combined studies pertained to the contamination of bioburdens on medical equipment but did not relate to surgical instruments. The other nine articles were educational studies on instrument storage and how facilities can improve storage space. Three articles focused on communication resolution among team members within the sterile processing units. The remaining four articles were selected for a thorough critical appraisal and evidence synthesis.
Critical Appraisal of Study 1

In the article "Glove and Instrument Changing to Prevent Bacterial Contamination in Infected Wound Debridement and Closure Procedures: A Prospective Observational Study" written by Carroll et al. (2021), the authors reviewed the effects and importance of changing used instruments and gloves in debridement procedures and replacing them with clean and sterile processed instruments to do closures. In this level 3 evidence synthesis study, the author indicated that surgeries that do not employ the habit of setting up two tables, one for accessing the infected wound and one for clean instruments to close the surgical site sterile and clean during these procedures, are more than likely will contribute to reinfection of the site (Carroll et al., 2021). Over 17 months, the authors conducted an observational study of 72 surgical cases that compared bacterial growth in 48 hours between using a second clean setup for the primary closing of the surgical site versus using the same instruments throughout the entire case. The authors found that cross-contamination of surgical instruments was reduced by 78% with a dirty and clean table setup. Of the 72 cases observed, 23 (32%) had rapid bacterial growth in 48 hours, and 49 (68%) had no growth in 48 hours when utilizing the one-table setup (Carroll et al., 2021). However, surgical cases that employed a clean and dirty table setup were less likely to re-contaminate the wound in 5 cases, and 67 showed no growth beyond 48 hours. The authors report that limitations included a setting of only one institution to research methodology but provided findings on the importance of having surgically clean instruments during procedures. The author's findings represented three main variables: reinfection, patient outcomes, and bioburdens caused by bacterial growth that can change how debridement procedures are done.

Critical Appraisal of Study 2
"Clean and Confident: Impact of Sterile Instrument Processing Workshops on Knowledge and Confidence in Five Low- and Middle-Income Countries," written by Harrell et al. (2022), assessed the needs of several under-developed countries that lack the essential skills necessary to comply with sterile processing of instruments properly. This level 1 randomized control trial study had 95 trainees re-trained in Training of the Trainer (TOT) workshops that sought to increase knowledge and hands-on training to help improve sterile instrument compliance in their respective countries. Another 169 participated in a non-TOT workshop where TOT participants were re-trained on disinfecting instruments, sterilizing and transporting them, and maintaining compliance in their countries (Harrell et al., 2022). The participants in this study improved their aggregated knowledge from 68% to 92%, their confidence improved from 70% to 83%, while another 70-83% were confident about teaching and bringing about change where they are from (Harrell et al., 2022). Despite its weaknesses, this study holds the potential to significantly impact healthcare practices in these countries, instilling hope and optimism in the reader.

Critical Appraisal of Study 3

Saporita et al. (2023) authored the article, "Six Sigma can significantly reduce costs of poor quality of the surgical instruments sterilization process and improve surgeon and operating room personnel satisfaction." In this longitudinal observational study, the authors utilized evidence obtained from well-designed controlled, a level 3 evidence synthesis through a study conducted over 18 months that seeks ways in which Lean Six Sigma can improve the efficiency and cost-effectiveness of ways in which the sterile process was utilized. This study assessed ways in which development by Lean Six Sigma could help reduce
the cost of processing urgently needed surgical instruments and reprocessing them promptly and efficiently. This eventually reduced errors associated with the proper sterilization of instruments and increased the quality of the instruments. Despite several weaknesses, the thoroughness of the study and the validity of the research methods should reassure the reader about the reliability of the findings.

**Critical Appraisal of Study 4**

"Is retained bone debris in cannulated orthopedic instruments sterile after autoclaving?" was an article written and examined by Smith et al. (2018). In this level 2 evidence synthesis quasi-experimental study, the authors created a study to test bone debris found in cannulated surgical instruments after autoclaving in the sterilizer. Fifteen cannulated drills, often used in orthopedics, were used to replicate a scenario after surgery where bone debris would occupy the open ends. These cannulated drills were filled with edible pig scapulae found in grocery stores to create a large volume of debris in the instruments. Twelve of the fifteen instruments were intentionally exposed to a mixture of bacterial inoculum for 60, 120, and 180 minutes before starting the sterile processing phase. Nine of the twelve had sterility exposure, three were not processed, and the remaining three of the fifteen acted as a negative control sample and were sterilized with sterile water alone. The drills were then sterilized in an autoclave at 270°F (132.2°C) for 4-minute and 40-minute dry time, imitating the standard process used in the sterile processing department (Smith et al., 2018). All instruments were examined, and one resulted in an accurate positive result of active bacteria growth after a 3-hour (180-minute) exposure. Smith et al. (2018) suggest higher temperatures and a thorough expeditious decontamination for instruments that will encounter this scenario. One weakness noted was that
the entire decontamination process before sterilization was omitted in parts of this study, which could have contributed to the positive findings.

**Implications for study**

The evidence in the literature reviewed was vital to the problems identified for this quality improvement project, such as the incidence of increasing bioburdens and particulate matter on surgical instruments. They help support the need for an intervention as bioburdens have been increasing on surgical instruments that are sterile, clean, and ready for surgical procedures. Evidence in the literature suggests that surgical instruments should be thoroughly checked and pre-cleaned before transporting them to the sterile processing department (Resendiz et al., 2020). A thorough check and precleaning helped to minimize the time blood and other surgical contaminants lived on the instruments, which was a deciding factor in how effectively these instruments were processed. Decontamination was an imperative step in sterile processing. Cleaning instruments on the back table while actively in surgery can help create a more manageable process of removing heavy bioburdens from cannulated and rigid surfaces. Committing to these steps will also lower the chances of a patient developing a surgical site infection through exposure to an instrument with bioburden on the sterile field.

**Rationale**

SSIs are a significant concern and one of the costliest Healthcare-Acquired Infections (HAI) for hospitals and other healthcare facilities. SSIs are expensive to healthcare facilities and patients, can be detrimental to the patient’s journey to recovery and their well-being, and can affect their ability to cope with the stressors of a prolonged stay in the hospital (Strobel et al.,
2021). They can be associated with bioburdens that contribute to a break in sterile techniques and the unintentional use of instruments not cleaned thoroughly in the lengthy sterile processing. Bioburdens have a 48% chance of being on surgical instruments within the microsystem. Some strict guidelines and processes are in place to help prevent the occurrence of bioburdens on surgical instruments. However, recently, there has been an increase in the number of processed instruments with visible bioburdens on them. George et al. (2024) state that thorough precleaning at the back table helps reduce the time surgical debris is on instruments. The microsystem encourages staff to use an enzymatic solution to spray instruments after surgical procedures but does not enforce precleaning with sterile water. That approach was insufficient and needs revision to increase the desired positive outcomes.

Utilizing the Plan-Do-Study-Act (PDSA) model for quality improvement, a 5P assessment was done by the project leader on the microsystem to assess the problem and propose solutions. During the Planning phase, data collected every month regarding evidence of bioburden on instruments was reviewed to evaluate and determine the current state of the microsystem. When bioburden occurred on an instrument, the evidence was noted on an evaluation form, which detailed the type of evidence and the number corresponding to that instrumentation set. While assessing the data and the current state of the issue, a literature review further supported the need to evaluate the various processes the microsystem had in place. In the Do phase of the project, a proposed intervention was recommended: do a trial with sterile water on the surgical field to preclean and start the decontamination process while in surgery. This intervention started with an educational in-service by creating a poster for staff to focus attention on the current issue and how staff could help resolve the issue. The staff was encouraged to preclean instruments at the point of use to reduce the incidence of bioburdens and
to provide a smooth flow through the decontamination and sterile processing stages. During the project's Study phase, the data collected from June through July and the trial of sterile water on the back table was reviewed and analyzed using the Microsoft Excel spreadsheet to track and identify trends. The Act phase allowed the findings to be presented to the microsystem with the recommendation to adapt and modify the project as necessary.

**Specific Aim**

This quality improvement project's specific aim was to help reduce the incidence of bioburdens by 50% by implementing sterile water use for precleaning on the sterile field at the point of care by July 12, 2024.

**Global Aim**

The global aim of this quality improvement project was to reduce the incidence of bioburden in the operating room. The process began with reinforcing education among staff to increase the awareness of bioburden and introducing sterile water on the back table while in surgery to help remove surgical debris. The process concluded with staff using sterile water on the sterile field to help decrease bioburden on instruments while in surgery. By working on this process, we reduced bioburden on instruments, and staff were more educated about its impact on patients. It was essential to work on this because an increase in bioburden could expose patients to SSI, increasing the risk of HAIs, delaying care for patients, higher healthcare costs, and depleting resources for the microsystem, both financially and operationally. This also tarnishes the facility’s reputation and creates a sense of distrust within the communities in the surrounding area.
Methods

Context

The aim and mission of the facility was to provide care at the highest level to patients requiring surgical intervention in the New England area. The Operating Room (OR) follows the same concept of ensuring that every patient has access to appropriate care and treatment for any surgical needs that may arise. This microsystem provides surgical services to children and adults. Currently, there are approximately 37 full-time, eight part-time, 11 per diem, and 18 contracted staff members comprised of nurses, technicians, surgical aides, and environmental staff. These staff members support a team of surgeons, physician assistants, and advanced practice nurses trained to practice surgery. They provide a clean, sterile, and safe environment to conduct surgery and ensure that all equipment and medical consumables requested by the surgical team are properly functioning and sterilized before the patient enters the OR. Along with the surgical staff, a team of pre-operative nurses ensured patients were prepped for surgical intervention before scheduled procedures. During the recovery phase, Post-Anesthesia Care Unit (PACU) nurses provide care after the completion of procedures until patients are ready to be discharged to another unit or home.

The OR can provide services to patients of all ages, from pediatric to geriatric. Infants and Toddlers are not commonly treated in this microsystem; however, should there be a need to stabilize a patient in this age category, they are treated and then swiftly transferred to a more skilled facility to get the appropriate care. Young children in the age group 3-12 years are treated for minimally invasive procedures, and those with more severe complications are referred to the macrosystem, where there are more specialized healthcare providers. Adolescents
aged 13-18 and adults, especially those older, are the most targeted population in this microsystem. Patients seen in the OR can expect to be cared for at least 30 minutes to several hours, depending on the type and severity of surgery they receive. For the past years, the mortality rate has been at zero percent. However, this does not mean there are no complications after surgeries. Mortality could happen upon transfer to another unit; if this does occur within a 32–48-hour span, then the microsystem would be affected by that mortality rate.

This microsystem specializes in 12 different surgical specialties: Ear, Nose and Throat, Urology, Obstetrics and Gynecology, Oncology, Ophthalmology, Orthopedic and Plastic Reconstructive Podiatry, Spine, Thoracic, and Vascular, and state-of-the-art Robotic Service. General surgeries, especially those that involve the gastrointestinal system, are the top diagnoses for the microsystem. On any given day, there can be 2 to 3 general surgery rooms, including a Robotic operating room; these procedures can be invasive or minimally invasive. The microsystem has a plethora of oncology patients who are also patients of the Cancer Center for the macrosystem. Cancer-stricken patients are treated for various cancers, but many of the diagnoses include female reproductive cancers (cervical, vulva, ovarian, and uterine) and breast cancer. Trauma-related orthopedic procedures of the hands and feet are standard in this microsystem with several specializations. Orthopedic surgeries, including joint replacements such as knee, shoulder, and hip, are also top daily procedures. Hysterectomy procedures are standard in the microsystem; they can be partial or total and sometimes combined with oophorectomy and salpingectomy. The procedures with the highest frequency in children are those performed on the Ears, Nose, and Throat (ENT); they are usually seen for myringotomy, tonsillectomies and adenoidectomies, septoplasty, and cochlear implants. Services for vascular surgery common in this microsystem include amputation, carotid stenting, endarterectomy, and
angioplasty. Urological surgeries such as laparoscopic-assisted percutaneous nephrolithotomy (PCNL), cystoscopy, and ureteroscopy are performed to aid in the removal of kidney stones. Occasionally, a more complex procedure, Nephrectomy, was done to remove the kidneys partially or entirely.

The microsystem will have 30-40 patients scheduled for surgery daily. Within 24 hours, another 3-5 urgent/emergent cases could be added for patients seeking immediate surgical intervention. The microsystem could accommodate approximately 200 surgical cases every week. With these average numbers weekly and daily, the microsystem can care for approximately 1000 patients monthly and 12,000 annually. The microsystem has been challenged lately with bioburdens on sterilized instruments for use. Bioburdens refer to any debris (remnants from previous surgeries) that are found on the instruments after sterilization (Rutala et al., 2023). Currently, instruments are not required to be precleaned at the point of care, making the decontamination and sterilization process challenging. This project aimed to use sterile water to irrigate and preclean instruments at the point of use in the surgical field. This approach helps to decrease bioburdens on ready-to-use items and will save the mesosystem financially (Balena, 2022). A bottle of sterile water costs $5.56, making it an inexpensive consumable that minimally adds to the cost of a surgical procedure. On average, the OR performs four surgeries a day in approximately eleven rooms; if each of those procedures uses a bottle of sterile water, it amounts to $244.46 compared to the considerable time and resources (including personnel) that are used to reprocess an instrument and get it ready to be used. Reprocessing an instrument takes approximately four hours to be completely ready; it takes an hour or two to go through the washing cycle, and it is also required to be dry and sterilized. If a particular instrument were a one-of-one item, this process caused a significant delay in care and
put patients at risk for further complications. A 2023 manuscript by the Centers for Disease Control and Prevention (CDC) estimated that the national cost for an SSI was $3.3 billion and amounted to more extended hospital stays, increasing the admission cost by approximately $20,000 and 10 days. Comparing the trivial cost of using sterile water at the point of care could help minimize patient exposure to potentially infectious diseases. It could also save the macrosystem thousands of dollars for infection and extended hospital stays. Longer hospital stays negatively impact patient experience, satisfaction, and livelihood, causing them needless pain, suffering, and missing work or time at home with their loved ones.

To gather information and prepare an educational in-service for this project, the cost of materials to create a poster and time spent collecting data were included. Posters were created using Canva, an online digital creative platform, and printed in color copies to distribute among staff members for the educational in-service. Thirty-five copies in color cost approximately $10.00 in total, and the project lead dedicated two hundred hours to reviewing and collecting data to assist with this project.

**Intervention**

The intervention for this project was to find ways to decrease bioburden on sterilized instruments using sterile water at the point of use. Currently, the OR does not have a written policy that requires sterile water to be on the surgical field, which staff can use to pre-clean the instruments before sending them to the decontamination area. The team, including the project lead, stakeholders, and mentors, met to discuss improving the current process. The team decided to implement a trial with sterile water on the sterile field during surgery so that scrub personnel could preclean instruments at the point of use. This trial was done for approximately
four weeks at the end of June and the beginning of July, then compared to previous weeks. Doing this has helped decrease the number of particulates left on instruments before they reach the decontamination stage in the SPD. The quality improvement department personnel were aware of this project and assisted by submitting the proposal to the macrosystem QI protocol through an online portal. This ensured that the project proposal did not involve human or animal experiments.

Before implementing sterile water and precleaning, staff were reminded by the project lead about the importance of decreasing bioburdens on instruments and educating them on their impact. A poster was created highlighting evidence for using sterile water while in surgery to decrease the incidence of bioburdens on instruments. This poster and its contents were presented at a morning huddle where OR staff met twice weekly. It was also placed in the staff lounge for quick access and viewing during their free time. They were encouraged to participate in the project by using sterile water to prewash instruments before leaving the operating room for decontamination in SPD.

**Study of the interventions**

An assessment and evaluation compared the weeks' sterile water used during surgery to the previous data. When there was a discrepancy between instruments and bioburdens found before or during surgical procedures, the circulating nurse sent that information to the sterile processing manager. With that and similar information, it was tracked throughout the week to produce a monthly report. When all the data was gathered and available, a comparison was made to analyze the results and the outcome.
Measures

The data collected during the project period was done at the beginning of surgical procedures when scrub personnel and circulating nurses obtained the equipment necessary for surgery. The circulating nurse was responsible for collecting data on instruments with bioburden. When an instrument was identified as contaminated with bioburden, the circulating nurse completed a form noting the type and tracking number for the instrument kit. That tracking number helped to identify the date and time it was processed in SPD and the previous case in which it was used. That form was then placed in a collection box for SPD personnel to collect at the end of the day. The SPD manager then enters this data in a Microsoft Excel Spreadsheet to track any instrument discrepancies. While bioburden were the focus of the study for this project, the SPD manager has the Microsoft Excel Spreadsheet designed to collect other reasons for kit failures, such as hair/fingernails, kit wrap defects, indicator fails, rips, wicks/watermarks, and particulates fail.

Analysis

Data collected was produced in a Microsoft Excel Spreadsheet database to determine a decrease or increase percentage for bioburden presented on instruments. This data was analyzed quantitatively to compare the results to previous benchmarks. The Microsoft Excel spreadsheet data included a monthly running number of the types of defects, including bioburden for instruments collected during that month. This spreadsheet also contained data for other reasons for failure including wet batch and rips and tears in wrappers. The data for bioburden was then compared to the current month and previous months with a cumulative percentage of defects and a total.
Ethical considerations

Ethical considerations were considered during the duration of this project. First, it should be noted that while this was a scholarly project, the project lead was an employee within the microsystem, which may introduce bias. Before initiating the proposal of sterile water at the point of use to preclean surgical instruments, an educational poster was used to discuss the process and how data will be collected for staff. The information collected and analyzed during this project was confidential and private to protect the facility’s and the microsystem’s interests. A quality improvement (QI) protocol was followed per the macrosystem guidelines. Using this protocol, the organization ensured that the project was not affiliated with human or animal experiments. After getting clearance from the macrosystem QI protocol, a full review by the University of New Hampshire Department of Nursing Quality Review Committee was conducted to determine if the proposal was a QI project and not research work to exempt the work from a full Institutional Review Board (IRB) review.

Results

Initial steps of the Intervention

The initial steps for this intervention started with the project leader observing different scenarios where instruments readily available for surgical procedures could not be used due to bioburdens. This discovery then led to an interest where data related to surgical instruments published by SPD were analyzed. In a quarterly review, the bioburden increased 15-18%. Upon seeing the data and analysis, a review of the processes used by the microsystem was done, which
led to a discussion with stakeholders to introduce sterile water at the point of care for precleaning.

After reviewing the literature and meeting a QI team representative, the project leader drafted a project plan and sent it to the macrosystem for review to determine if it was suitable for an IRB exemption. An approval letter was granted to initiate the project in the microsystem. Soon after, an informal educational in-service was held for staff that detailed how the project would be implemented and the purpose of it. A poster was created with detailed information and positive literature findings for reference, along with the in-service. Copies were provided for each staff member, and a copy was affixed to a staff educational board in the staff lounge.

**Figure 1. A timeline of events during the initial Intervention.**

**Process Measures and Outcomes**

In each orthopedic procedure, sterile water was encouraged to be used at the point of care to preclean instruments that were heavily soiled with blood and other bioburden particulates.
Precleaning at the point of care helps reduce the number of bioburdens that could cause an instrument to be defective and unsterile. Data collected daily throughout the project's timeline were compared with previous months to see if the evidence of using sterile water would benefit the microsystem in decreasing the number of sterile instruments presented with bioburdens. A pre-intervention observation was conducted two months prior, revealing that only 5% of all scrub personnel use sterile water in orthopedics surgical cases. Post-intervention, there was a 90% increase in sterile water in the surgical field for orthopedics for precleaning instruments. This increase saw the microsystem at a 95% use of sterile water on the surgical field in orthopedic cases.

Though there was an overall increase in sterile water use at the point of care, data collected at two-week and four-week intervals during the project's timeline showed minor changes in the number of instruments presented with bioburdens. Pre-intervention and observation of data in the microsystem showed a 15-18% increase in bioburdens for the previous quarter. Three instruments with bioburdens were present in January, February, and March. In April, there were no reports of bioburden; however, in May, data analytics showed four instruments with bioburdens. When the quality improvement project was implemented at the end of June, there was no evidence of bioburdens on instruments. Though this data was collected during the implementation of the project, it cannot be assumed that the use of sterile water contributed to this result. During the one month of the quality improvement project, between late June and early July, two instruments were considered unsterile for use with bioburdens during surgical procedures.

**Figure 2.** Staff use of sterile water pre- and post-intervention of the quality improvement project.
Figure 3. Bioburdens found on instruments pre- and post-intervention of the quality improvement project.

Association between Outcomes, Interventions, and relevant Contextual Elements
The microsystem supports more than four surgical services, such as orthopedic, robotic, and OB-GYN, which are more blood-intensive and prone to bioburdens. For this project, the contractual element that interacted with the intervention determined which service area to focus on for data collection on the unit. The stakeholders and project leader discussed that it would be most beneficial to the orthopedic services since they had a higher volume of procedures and the highest track record of “difficult-to-remove bioburdens.”

Further investigation into the orthopedic service area also showed that many instruments had debris because of the timeframe of their procedures. Surgical procedures in these cases were often performed longer, resulting in parched and stale particulates, leading to more frequent occurrences. The stakeholders supported this project and believed it would have benefited the microsystem if implemented over a longer time frame; it would have also helped the staff transition and execute toward change.

Unintended Consequences

Before the project was implemented, there were unforeseen problems related to the submission in the macrosystem database. Those events led to a later start date of the study and forced a shorter study period of two-week intervals instead of a full four weeks. Along with the intervention initiated later, the project leader had unexpected consequences, such as a lack of motivation for change with some individuals and other priorities deemed more important than the project.

Most staff members were supportive of the educational in-service and gave their support; however, during the initiation of the project and subsequent development process, most were
overly concerned that it would delay their work and cause them to lose focus on the main task at hand. It was then decided that the project leader's time at the facility would include visiting each orthopedic procedure room and helping place sterile water on the field for those who wanted it done. Staff were also supported by helping to disassemble instruments and wash them if they had copious amounts of particulates and bioburdens. A few staff members insisted on their dogmatic way of doing things. These staff members incorrectly told the project leader that using sterile water to preserve the instruments would contribute to higher bacterial growth and contamination. A thorough literature review was conducted, and no evidence that supported those claims was found, thus debunking those claims. The project leader spoke with the microsystem educator, mentors, and stakeholders to get confirmation that those claims were false. It was determined that those claims were a long-standing belief from the past before the new evidence and data were found.

**Missing Data**

At the end of week two, a midpoint review of the study was conducted to determine improvements or changes to pre-intervention. The same concept was used to gather information at the end of week four, which was the end of the project timeline. Data and observation suggest missing data due to the staff's lack of participation and motivation for change during the project's first two weeks. Another potential for missing data was that the project leader could not be present in the microsystem daily for the entirety of the workweek to encourage staff use of sterile water.

**Discussion**
Summary

Key Findings

Data collected from this quality improvement project indicated significant potential for this project to be successful by following best practices and evidence-based approaches. The global aim of this quality improvement project was to improve the quality of surgical instruments ready for immediate use by reducing the presence of bioburden using an evidence-based approach with sterile water on the surgical field for precleaning. The specific aim was to reduce the incidence of bioburdens on orthopedic surgical instruments by 50% in four weeks. The project did not have a notable change or reduction in the incidence of bioburden due to the duration of the project and initial resistance by staff during the initial implementation. During the pre-intervention phase, an observation of only 5% of scrub personnel was consistent with the use of sterile water to pre-clean surgical instruments in orthopedic surgeries. After the intervention, 95% of personnel used sterile water for precleaning measures while in surgical procedures. However, the specific aim of decreasing bioburden by 50% was not met for the project's duration, likely due to the time allotted for data collection and change management.

Relevance to the Rationale

The PDSA cycle had some influence on making a change for the microsystem. Through observation during the project's planning phase, it was identified that the microsystem needed an evidence-based intervention to help reduce bioburdens on ready-for-use instruments during surgical procedures. During the planning phase, the project leader met with QI personnel, stakeholders, and project mentors to ensure that the macrosystem and mesosystem approved the
next cycle phase. The "Do" phase consisted of presenting an in-service to staff, educating, and highlighting the importance of precleaning after surgical procedures. Precleaning at the point of care included adding sterile water at the surgical site to help reduce particulates on instruments while in use. This involved rinsing and removing heavy debris, surgical blood, and waste matter before sending the instruments to the SPD. In the "Study" phase, 95% of staff members liked adding sterile water for precleaning, and the reviewed evidence-based findings were presented in the presentation. However, the competing demand for other tasks met with mixed results during that phase. The "Act" phase was used to encourage staff members and key stakeholders about the development and how this evidence-based project if continued, could positively impact the microsystem's future in reducing bioburdens.

Relevance to the Specific Aim

The project's specific aim was to reduce the incidence of bioburdens on instruments by 50% in orthopedic surgeries by using sterile water to pre-clean instruments at point-of-care use. This project would have had a better outcome if the focus had been on one specific orthopedic specialty instead of the entire orthopedic service area. Data analysis and observation showed that this project positively influenced the use of sterile water at point-of-care use by 85% and increased knowledge of the implications for use while actively in surgery.

Project Strengths

The main strength of this project was the overall participation and interaction between staff and the project leader during the educational presentation for the intervention. Staff members were genuinely interested in finding a solution to reduce the number of bioburdens on
instruments. The printed resource also positively impacted their knowledge about the advantages of using sterile water at the point of care. During the presentation, many asked questions and discussed the positive effects they could have if instruments had a reduction in bioburdens and particulate presence. Though using sterile water to reduce the number of bioburdens by precleaning at the point of care was a slow development, this project indicates that the microsystem could improve its processes to reflect better results. Another strength of this project was having stakeholders and mentors working closely to ensure that staff knew the project's aim and how it could benefit the OR and SPD. During the first two weeks of the quality improvement project, staff resisted changes in addition to competing demands while actively in surgery. Upon realizing this, stakeholders constantly communicated with staff, encouraging them to preclean with sterile water at the point of care, especially when the project lead was away from the microsystem. Change that supported an evidenced-based approach was always welcome in the microsystem, and this PDSA project was a visionary effort that stakeholders could use in the future.

**Interpretation**

The quality improvement project highlighted the need for further evaluation and ways the microsystem could reduce bioburdens on sterile instruments ready for surgical use. During the observational and implementation processes, a selection of staff members had dogmatic beliefs regarding using sterile water, stating that it would contribute to a higher infection risk for patients. The project leader reassured those members that evidence-based research suggested otherwise and that the project would be a great opportunity to develop new ideas for the future. According to AORN, the national organization that advocates for patient safety, using sterile
water is an effective method that should be used to help eliminate particulates on instruments by precleaning at the point of use (Sangelilli, 2023). Participants who have used sterile water from other macrosystems were delighted to welcome this new initiative and spoke highly of the impact this could have on the microsystem.

*Unexpected Outcomes*

An unexpected outcome related to the quality improvement project was the lack of participation during the project's first two weeks. After presenting the goals, aim, and literature in a poster, several staff members were excited about this project's potential impact. However, some staff members were noncompliant during the initiation and implementation phase and voiced their opinions about using sterile water at the point of care. This shift in direction was due to the influence of past events, not evidence-based research suggestions.

The project started slowly, with some staff members opting not to use sterile water at the point of care. During the pre-intervention phase, there was an interactive and receptive response from stakeholders and staff members to the educational portion. However, during the implementation and post-intervention phases, the staff team was less enthusiastic about the project. This suggests that it was related to the time it took to incorporate the new approach into their routine and other beliefs, such as the risk of infection exposure to patients, which were not backed by evidence-based research. Stakeholders were still interested in post-intervention and continuously encouraged participants to use the proposed idea.

*Comparison of Results*
Studies in the AORN standards have shown that bioburdens could be reduced gradually by precleaning immediately after use and are the main driver for a change in practices. The results from this quality improvement project showed that if the steps taken during the project's initiation phase are continued, the microsystem will achieve its mission of reducing bioburdens and surgical particulates on instruments. During the implementation and initiation phase of the project, a few staff had concerns that using sterile water would cause serious complications, such as increased bacterial growth and infection. In the study by George et al. (2024), the authors stressed the importance of using sterile water to preclean instruments in the preparation phase before transporting them to decontamination to reduce the contact time with blood and other bioburdens from surgery. This resulted in lowering the risk of infection, and bioburdens on instruments. Subsequently, it also promoted an efficient work cycle from the OR to the SPD.

**Impact of the Project on People and Systems**

The project had the most considerable impact on SPD, who, before implementation, had to spend considerable time cleaning clogged instruments and substantial amounts of dry particulate and surgical matter, making it difficult to remove. Using the enzymatic solution by OR staff without precleaning after surgeries made it more challenging due to particulates adhering to the instruments, especially on busy days when instruments waiting to be cleaned overflowed in the decontamination area. Staff from this area have been vocal in asking for a change in policy to assist with this issue and stressed that the productivity of work was a chain reaction to the challenges they face with instruments that contain heavy debris after surgeries. With the project's positive outcome, stakeholders could identify how they can best support and improve their processes to ensure that the microsystem can function efficiently,
safely, and effectively without interference from a controllable variable. This impact could also affect the performance of the OR in those patients, especially those who are critical are seen promptly without the fear of being rescheduled or delayed due to instrumentation and bioburden incidence.

**Reasons for Differences Between Observed and Anticipated Outcomes**

The project has positively impacted the microsystem and its working relationship with SPD. Both departments have agreed that the project initiation was instrumental in creating a better working environment for staff. There was a significant increase in productivity among the staff; they spent less time struggling to remove heavy and bloody particulates that were once accompanying used instruments. This increase in productivity could be attributed to the rise of OR staff using sterile water to preclean at the point of care. Though the project's specific aim still needed to be met, which was to reduce bioburdens by 50%, this trajectory would have been achieved if there had been full participation in the first two weeks of implementation. However, after championing support from stakeholders and encouraging staff, a noticeable difference was made in participation and the instruments used in surgery. Therefore, using sterile water to preclean at the point of care ensured that the microsystem was on track to become less plagued with the incidence of bioburdens on instruments.

**Project Costs and Strategic Trade-offs**

Compared to this project's benefits and fiscal impact, this was considered an inexpensive investment for the microsystem. For approximately $5.56 additionally per surgical case, the project was accomplished, making it easy to adapt and maintain. The availability of sterile water
already existed in the microsystem purchasing order at the time of implementation, which meant it was uncomplicated to execute the idea. The other cost considered for the project was the printed materials for the presentation, which amounted to $30 for 30 copies posted in the staff lounge. If continued, the project could make a valuable budgetary impact on the microsystem, creating a more efficient use of resources and staffing when the bioburdens are reduced. The allotted time required to reprocess and reschedule surgical procedures can be used to increase the number of patients surgeons see. This additionally could increase patient safety and the risk of infection exposure. It was recommended that the microsystem prioritize this intervention and trade-off to ensure that the mesosystem upholds its reputation as one of the best-performing surgical hospitals in the surrounding region.

**Limitations**

The limitations of this project included several factors, namely the project's timeline, staff participation, and size. Due to its development schedule, the project had a month's timeline, significantly affecting the outcome and its potential impact on the microsystem. The rotation of an instrument from sterilization and assembly to the point of use on a patient in the OR and then back to the sterilizing department can take a few days, especially if there are several other instrument kits in rotation. Knowing this, it was safe to say that even if bioburdens were found on an instrument, it would be challenging to identify if those instruments were from a batch that was prepared before the implementation of the project.

Another limitation of paramount concern was the need for more participation in the project's first two weeks. In the pre-intervention and implementation phases, only 5% of the staff used sterile water, indicating a low percentage for the first two weeks. Low participation in the
most crucial weeks of the project leads to a questionable outcome and validity of the data analytics and results. The project leader also determined the project size to be a limitation factor in the development process. All orthopedic services were a part of the project, and by including all, it was difficult to track the progression, especially on days when the project leader was away from the microsystem. It would have been easier to track and control all metrics and data on one orthopedic service due to the large volume of all services. If stakeholders should continue this project, it would be beneficial to choose one orthopedic service to do multiple PDSA cycles to access validity before they implement it on the entire microsystem.

**Conclusion**

*Usefulness of the work*

The purpose of this quality improvement project was to aid the microsystem in finding a solution to the current problem of an increase in bioburdens on instruments. It was noted that precleaning with sterile water was not enforced at the point of care use for scrub personnel, leading to an excess of instruments that had heavy debris and particulate after surgical procedures. Though the microsystem recommended spraying instruments after use with an enzymatic solution, it was not enough to ensure the removal of particulates, especially on instruments that had lumens, serrated, and rigid edges. During the project's timeline, there was a noted difference and increase in staff using sterile water at the point of care to eliminate excess debris from instruments. Though there was an increase and positive feedback on using sterile water for precleaning at point-of-care use, the specific aim of reducing bioburdens on instruments by 50% was not met. Continuing the project in the same direction could favor the microsystem and its quality improvement endeavors.
Sustainability

The culture within the microsystem has always maintained that surgical instruments are sprayed with an enzymatic solution after a procedure is completed. Attempting to change the norm and implementing sterile water for precleaning while in surgery during a noticeably brief period hindered most staff from participating at the beginning of the project. In the future, when promoting a change of this magnitude, it would be ideal to use a transition period of several weeks to gradually introduce the change in various steps to get everyone on board and ensure they are ready and prepared for such changes.

Potential for spread to other contexts

The OR was a unique setting in the macrosystem and was the only place where this project could be beneficial. However, this quality improvement project was only implemented in orthopedic services areas; it can be used for other services such as OB/GYN, General, or Robotics, where surgeries produce a high volume of blood and surgical particulates on instruments. These services also use scopes that can attract bioburdens in lumens and hard-to-reach areas. The same advice would apply to these services: to start with a specific target area and repeat the PDSA cycle multiple times to get the most accurate data and results.

Implications for practice and further study

For future studies using this project, the microsystem should limit the study to one surgical service to better measure the data. The SPD team has praised the use of sterile water at point-of-use care, which could lead to a significant reduction in instrument bioburden. However,
several PDSA cycles were recommended to ensure consistent data performance and achieve the specific aim.

**Suggested next steps**

The results of this project were shown to be positive but slow towards progress. In the future, the project lead advised stakeholders to consider using the project to improve and develop a culture where using the evidence-based approach to precleaning instruments with sterile water at point-of-care becomes a best practice. Through a debriefing session with stakeholders, the project leader suggested an annual educational training where SPD staff and experts provide a refresher session to staff in the OR, especially those who are new to the operating environment and or coming from other departments or organizations that may have a different approach to instrument management during surgeries or around the microsystem. Providing annual training will ensure that end users in the microsystem understand the process and expectations of precleaning at point-of-care. In addition to providing an educational component for staff, stakeholders should collaborate with the education team and quality management of the mesosystem to create a standard operating procedure (SOP) that will help guide staff members.
References


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Appendix A - Poster Presentation

Decontamination at the Backtable—A Quality Improvement Process Initiative

Decontamination on the sterile field (at the back table) is performed to lessen the number of microorganisms, biofilm, and bioburden on instruments; improve the sterilization process from the surgical field in the OR to the decontamination area in SPD, and advocate for our patients by decreasing the risk of surgical site infections.

SPECIFIC AIMS

This project aims to find ways the microsystem can mitigate the incidence of bioburden on critical instruments needed for surgical procedures. Simultaneously, this project fulfills the course requirement to complete the project leader nursing studies for a Certified Nurse Leader certification at the University of New Hampshire.

HOW ARE WE CURRENTLY DOING?

The microsystem faces an issue where surgical instruments are occasionally presented with particulates and bioburden from previous surgical cases. In these instances, surgeries are often postponed later in the day or canceled, causing a domino effect where patient care is delayed, and resources are misused.

Data collected shows that 15-18% of kit failures result from bioburden on them.

1 in 2 kits are critical need items for same-day surgical procedures.

After surgical procedures instruments are sprayed with an enzymatic solution before transporting to SPD, but sometimes more needs to be done.

In addition to an enzymatic solution, less than 5% of personnel use other means such as sterile water to remove heavy debris, and particulates.

HOW CAN WE HELP?

Studies have shown that continuous pre-washing of instruments while still active in a procedure quickly eliminates any foreign matter that may become hardened between the transition from the OR to SPD and can help lower the concern of bioburden.

Have an open mind to teach, educate and review processes especially with new and incoming staff members.

If you are a service leader, and there are constant issues with kits, work with someone from SPD to find ways to improve the issue.

Suggest ideas to leaders.

Irrigate instruments with lumens during a surgical procedure.

Soak difficult to clean instruments such as acetalubar reamers.

Separate and clean serrated instruments.

QUICK FACTS and COMPARISON

Bioburden on instruments can increase patients’ exposure to an SSI. SSI is the costliest type of HAI & can extend hospital stays by 9.7 days.

(cdc.gov, 2024)

$3.3 BILLION

A bottle of sterile water costs $5.56 making it an inexpensive consumable to add to the cost of a surgical procedure. On average the OR performs four surgeries a day in approximately eleven rooms, if each of those procedures uses a bottle of sterile water, that would amount to $244.46 compared to the time, and resources (including personnel) that are used to reprocess an instrument and not be ready for use.

$5.56

PROJECT PROPOSAL

The proposal for this project is to use sterile water for a month to irrigate preclean instruments at point of use on the surgical field, in Orthopedics services prior to transporting them to sterile processing. As a scholarly QI Initiative, data will be collected in increments of two weeks (totaling to a month) and compared to trends in previous months. At the conclusion of this trial period, a result analysis, and summary with key findings in a scholarly form will be presented to the project advisers, and the OR and SPD managers.

Disclaimer: No personal, or identifiable information will be used in this project. This is solely for educational purposes. The project leader has the option to submit and publish the written work as a Quality Improvement project to the University of New Hampshire Scholar repository, and Google Scholar. However, managers from both the OR and SPD can use results (positive or negative) at their own discretion.

References

