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Is the Prophylactic Administration of Povidone Iodine Intranasally Preoperatively in Elective Total Knee Replacement as Effective as MRSA Prophylactic Screening and Mupirocin Treatment?—A Retrospective Analysis

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Abstract

Surgical Site Infections (SSIs) remain a prevalent issue in healthcare. An average of 2% to 4% of all Total Knee Arthroplasties (TKA/TKR) result in a Prosthetic Joint Infection (PJI) (Ashraf *et al.*, 2018). These surgical site infections cause significant distress to the patient and require extended courses of antibiotic treatment and revision surgery of the infected joint. SSIs also reduce financial reimbursement to the surgery facility and affect the performing surgeon's performance scores. To prevent surgical infection, healthcare facilities have implemented various screening or decolonization methods to prevent surgical infection to may cause infection. Various treatment methods exist for managing MRSA preoperatively which include Povidone Iodine (PI) application as a universal decolonization method and/or screening every patient preoperatively for MRSA and treating MRSA-positive patients with Mupirocin ointment. Both interventions are well-established in the literature. At the author's facility, the elective TKR populations were analyzed while each intervention was implemented. In 2019 TKR patients underwent MRSA swabbing and testing and in 2021 PI decolonization was the decolonization method of choice. The study revealed that MRSA testing and swabbing were better at reducing SSI related to MRSA than Povidone Iodine decolonization.

Keywords

Povidone Iodine, MRSA, Mupirocin, Total Knee Replacement

1. Introduction

Total knee arthroplasties/Total knee replacements (TKA/TKR) are one of the most common elective orthopedic surgeries. TKA's are the surgical intervention required for patients with severe knee osteoarthritis and other knee arthroplasties [1]. TKA's are projected to increase to approximately 4 million procedures per year by the year 2030 in the United States [1] Surgical Site Infections (SSIs) after TKA are the 2nd serious complications that can occur after surgery and the most frequent cause of total knee revision after initial surgery [1] Surgical Site Infections have been attributed to patient readmission, revision surgery, increased hospital length of stay, and disability. 3% of all surgical site infections can result in patient mortality [1].

Varying practices of MRSA decolonization are in effect to prevent postoperative infection. These include MRSA nasal swabbing and treatment if found positive, Povidone Iodine application intranasally without testing, and the use of Chlorhexidine Wipes (HCG). This retrospective study seeks to evaluate the effectiveness of two different prevention methods performed preoperatively before the TKR; MRSA swabbing and treatment, and universal PI decolonization, and to determine which therapy is more effective at preventing infection in the TKR population.

2. Background

Surgical Site Infections are defined as an infection that occurs after surgery, at or near the incision site, within 30 days of a procedure, or 90 days after a prosthetic material was placed [2]. Surgical Site Infections often involve the skin and subcutaneous tissue of the incision, and the classification of the infection is relative to the location of the body and its depth. Superficial incision infections involve the skin and subcutaneous tissues and account for 50% of all SSI while deep incisional infections involve deeper tissues such as the muscle or fascia [3]. Organ tissue infections involve an organ apart from the incision site but must be correlated with the surgical procedure that was performed [3]. Surgical Site Infections may include purulent drainage from the incision site, positive fluid, or tissue cultures aseptically aspirated or obtained from samples, wound dehiscence, or wound exploration by the surgeon. This wound exploration would be warranted due to patients' reports of fever, disproportionate pain to expected surgical site pain, tenderness, localized swelling, and erythema to the incision site [2].

Surgical Site Infections occur in 2% to 4% of all patients undergoing inpatient surgical procedures [4]. Surgical Site Infections occur in 1% to 2% of all primary total knee replacements and 3 to 5 percent in all secondary TKR revisions [4]. In most SSI cases, the source of infection is the native flora found in the patient's skin, mucous membranes, or hollow viscera [4]. In TKA's, aerobic gram-positive cocci such as Staphylococcus are the most common bacterial contaminant, with resistant strains such as Methicillin-Resistant Staphylococcus aureus (MRSA) or Methicillin Susceptible Staphylococcus aureus (MSSA) representing an increased proportion of SSI infections [4].

Identifying an infection status post-TKR requires a combination of diagnostic testing and clinical presentations. Patients can present with a fever, erythema, drainage, and disproportionate pain related to the TKR to the surgeon's office [4]. Based on these findings the surgeon will order labs to obtain a larger clinical picture. Labs such as a complete blood cell count, complete metabolic panel, and inflammatory markers such as a C-Reactive Protein (CRP, Erythrocyte Sedimentation Rate (ESR), and Creatine Phosphokinase (CPK) will be ordered.

These labs are used as inflammatory markers present in the presence of infections, autoimmune conditions, and cancers [5]. The surgeon will draw synovial fluid from the incision site. Two positive cultures from synovial fluid or tissue samples and or the presence of a sinus tract infection are definitive of an infection [6]. Elevated CRP, CPK, White Blood Cells (WBCS), and ESR are also used for definitive infection criteria alongside positive fluid or tissue samples [5].

Once a patient's joint has been identified as infected, the surgeon must take the patient back to the operating room. The surgeon has several options for the treatment of the Prosthetic Joint Infection. These include Debridement, Antibiotics, Implant Retention (DAIR), 1-stage versus 2-stage revision, arthrodesis (fusion of the adjacent bones involved in the surgery), and or amputation [7]. Surgical intervention is most often required, as an antibiotic treatment alone is not sufficient in addressing joint replacement infections [7]. The surgical intervention warranted is dependent on the injected joints fascia's presentation, how many days post-op since the surgery, lab results, and the patient's comorbidities and medical history [7].

To avoid PJIs, facilities implement testing and prevention methods to reduce their surgical site infection rates. At our facility, testing for MRSA was previously completed in the preoperative class. Patients arrive a week before their scheduled surgery and are instructed on what to anticipate for their upcoming surgery. While attending the class they are swabbed intranasally for MRSA. If the patient tested positive for MRSA or MSSA they are given a 5-day treatment of Mupirocin cream and washed daily with CHG wipes. The preoperative class was suspended in 2020 due to the COVID-19 pandemic. After the pandemic levels decreased to allow elective surgeries in 2020 and 2021, the preoperative class was held in an online format via Zoom. Patients are now treated on the day of surgery with a PI solution decolonization therapy intranasally.

Currently, the hospital is evaluating whether to reinstate the preoperative teaching class in person. The objective of this retrospective study is to create a new hospital policy regarding hospital decolonization policies before elective knee surgery based on the results of the study. This study seeks to compare both therapies on efficacy, effectiveness, and cost of implementation regarding the prevention of surgical site infections related to MRSA and to implement a policy that best suits the results.

3. Problem Statement

Surgical Site Infections are serious complications that can occur after surgery.

SSIs stand at 2% to 4% of all surgical cases nationwide [2]. Surgical Site Infections cause patients emotional distress, pain, and decreased ability to ambulate and the ability to perform activities of daily living. Surgical Site Infections are a severe strain on our national healthcare system while reducing reimbursement to the operating facility. MRSA has been identified as one of the leading bacteria attributed to surgical site infections after TKR. Having identified MRSA as a major causative bacterium to infection implementing the appropriate identification and decolonization therapies will lead to decreased SSIs in our TKR population. Two decolonization methods are equally successful in treating MRSA infection. Patients can be tested for MRSA in the preoperative setting with nasal swabs and treated with Mupirocin or universally decolonized with PI therapy. This study compared both interventions and analyzed which intervention is better at reducing SSI related to MRSA. This study is important to patient outcomes as it has the potential to provide an evidence-based approach to reducing SSIs in the patient population undergoing TKR while reducing the costs associated with SSIs in this operating facility.

4. PICO

The PICO question is: is the prophylactic administration of Povidone Iodine intranasally preoperatively in elective total knee replacement as effective as MRSA prophylactic screening and Mupirocin treatment? The proposed population received elective knee surgeries at our facility Lenox Hill Hospital in New York City, NY. The intervention is applying Povidone Iodine intranasally prophylactically versus MRSA prophylactic screening and treatment before each elective total knee replacement surgery. Each intervention period was observed over a 1-year period. The Control is the results of preoperative testing for MRSA swabbing compared to Povidone Iodine therapy. The Outcome is that there was no decrease in surgical site infections present at a facility after the application of PI compared to MRSA swabbing and Mupirocin treatment.

P—Elective Total knee replacements.

I—Universally applying PI as prophylactic treatment for MRSA versus MRSA prophylactic screening and treatment before all elective total knee replacement surgeries over two 1-year periods.

C—The results of preoperative testing for MRSA swabbing compared to Povidone Iodine therapy.

O—Reduction in postoperative surgical site infections while implementing the therapy with the most efficacy and cost-effectiveness.

5. Review of Literature

This literature review is a search regarding preoperative MRSA swabbing, PI decolonization before elective orthopedic surgery, and the cost of implementing these therapies. This project's independent variable is the type of preoperative swabbing protocol used with patients undergoing elective total knee replace-

ments. The nursing staff and providers will need to be educated on the new policy once it is created. The dependent variable is MRSA and MRSA colonization infection rates in patients undergoing total knee replacement. A collection of retrospective studies, systematic reviews, prospective cohort studies, and other assorted studies of TKR surgeries in various countries shows the prevalence of MRSA in hospitals around the world.

6. Educating Nursing Staff and Patients on Swabbing

Psychomotor skills such as swabbing for MRSA require repetitive practice and review.

As per Oermann *et al.* (2016), the instructor must demonstrate to the staff that is learning the skills of clinical reasoning and its implication in clinical practice. The goal of performing a motor skill such as swabbing is the ability to perform the skill accurately, in a reasonable time, and consistently over time [8]. Teaching a new skill is conducted in various stages which will be discussed below.

The first phase is the cognitive phase. In the cognitive phase, the learner is introduced to the skill, the rationale for the skills performance, and the resources required to implement the skill [8]. Regarding the MRSA swabbing and Povidone Iodine applications, learners would need to be taught about the percentage of patients who are MRSA colonized, and its relevance in surgical site infections. Learners would also have to learn how to properly hold the cotton swab, the technique for swabbing the anterior nares, how many seconds to swab the nares, and how to properly insert the swab into a container.

In the associative phase, learners must practice the skill to refine their performance [8]. This practice requires mastering intricate details such as timing while also applying subtle adjustments in movements [8]. The goal is to be consistent in motor skills. Learners who are now performing the motor portion of intranasal swabbing would be assigned in pairs to demonstrate the skill. The educator would observe each learner opening the swab, inserting the swab into the nares, and swabbing in a circular motion several times before inserting it into the collection container.

The third phase or the autonomous phase requires practice and proficiency in the skill [8]. The instructor would focus on the skill with each group perfecting the technique and method of application. The instructor should encourage active feedback regarding the learning technique. The article refers to positive feedback as a constructive form of criticism that is more likely to be retained by the learner [8]. Deliberate practice is also necessary for the retention of skills. Deliberate practice requires a focused repetitive practice of skills combined with informative feedback from an expert in the skill [8].

This will help avoid skill decay, master expertise, and correct errors in performance [8]. The swabbing skill can be demonstrated to the patient in the preoperative patient education class or online format. For providers and nurses, a yearly in-service can be done to ensure there is no skill decay.

7. Risk Factors for Postoperative Infection in the TKR Population

A 2019 systematic review by Alamanda *et al.*, revealed 12 specific risk factors in patients identified as having high risks for infection. These included glycemic control, obesity, malnutrition, smoking, Vitamin D levels, preoperative Staph Aureus screening, managing of anti-rheumatic medication, use of perioperative antibiotic prophylaxis, pre-surgical skin preparation, operating room environment, irritant options, and anticoagulation. Similarly, a prospective cohort study by researchers Marusic *et al.* (2021) evaluated the incidence of infections and risk factors of 30-day surgical infections after primary total joint arthroplasties in Belgrade, Serbia [9]. Of the 1073 patients studied, 787 had a THA and 286 TKAS. Infection rates were 5.4% in the THA and TKR populations combined with risk factors such as a patient's current smoking, history, history of diabetes, and peripheral vascular disease all attributing to higher infection rates.

Various risk factors can be modified before the patient engages in elective surgery.

Patients can attempt to lose weight, have a better-controlled HGBA1C (a test reflecting 3-month glycemic control), take Vitamin D supplements, and increase their physical activity levels.

Patients can be asked to return in 3 to 6 months after their initial preoperative visit to reassess if these modifiable lifestyle changes have been made. If patients address these modifiable risk factors, they have an increased chance of joint replacement surgery success.

Providers can implement the appropriate postoperative antibiotics and anticoagulation after surgery as demonstrated by the literature to decrease infections. Preoperatively postoperative antibiotics such as Vancomycin should be given within 2 hours of the incision for Vancomycin and should be discontinued within 24 hours after the surgical procedure as demonstrated in the article for maximum effect [4]. Operating rooms can initiate the most up-to-date guidelines regarding skin preparation in the preoperative setting and operating room temperature to reduce SSIs. The literature recommends the use of Chlorhexidine Gluconate-based solutions for surgical site preparations over Iodine-based solutions to decrease bacterial loads and has been shown to have the longest effect of all surgical preps [10]. Hair removal reduces surgical site infection as well as the use of electric clippers over shavers [10].

Methicillin-Resistant Staphylococcus aureus was identified as the most common bacteria for SSIs in the TKR population as well as the leading bacteria in healthcare-related infections with bacteremia, endocarditis, osteomyelitis, and SSIs in orthopedics [11]. As much as 30% of the world population is colonized intranasally with Staphylococcus aureus [12]. Staph aureus inhibits several patient body sites such as the nose, throat, armpits, and perineum [4]. For patients undergoing surgery requiring a peri-prosthetic implant, nasal colonization with Staph aureus was considered the most important independent risk factor for the

development of joint infection [11]. Various decolonization techniques exist to reduce SSI related to MRSA colonization.

8. MRSA Swabbing Effectiveness and Implementation

Mupirocin is a wide-spectrum antibiotic activity in gram-positive bacteria such as Staphylococci and Streptococcus and works well at treating MRSA [13]. Mupirocin is bactericidal and works by inhibiting bacterial protein synthesis by binding to the bacteria transferring RNA, and it has a unique chemical compound that does not allow for antibiotic cross-reaction [13]. Mupirocin has shown a 90% efficacy rate in reducing biofilms in MRSA and inhibition rates within 3.5 hours of application [13].

Methicillin-Resistant Staphylococcus aureus testing should ideally be conducted in the office or preoperative class setting and not on the day of surgery. Patients who are swabbed in their nares, throat, groin, and axillae, should only have a negative MRSA swab to be allowed to proceed to surgery. Ahmad *et al.* (2019) completed a 6096-patient study over 2 years between December 2012 to December 2014. The researchers found that of the sampled orthopedic patients 138 patients were positive for MRSA [11]. Of the MRSA-positive patients, 69% of positive swabs were located on the patients' nares swabs, 26% from the groin, 23% from the throat, and 8% from the axilla. A retrospective study conducted by Xavier *et al.* (2019), reviewed the reduction of peri-prosthetic Staphylococcus aureus infections by perioperative screening and decolonization of nasal carriers undergoing total knee arthroplasty. In the intervention group, 403 patients were screened for Staph aureus intranasally. If patients were positive, they were treated with Mupirocin nasal ointment and Chlorhexidine soap for 5 days preoperatively. The control group of 400 patients did not receive preoperative screening for MRSA. The results showed the control group had a 4.2% infection with 2% being Staph aureus and 2.2% for other organisms while the intervention group had a 1.2% infection rate with 0.2% due to Staph aureus and 1% for other organisms.

A retrospective cohort study published by researchers Allport *et al.* (2022), reviewed the efficacy of Mupirocin, Neomycin, and Ocetenidine in nasal Staph aureus decolonization [14]. In a cohort of 3129 MSSA carrier patients, Mupirocin and Neomycin were significantly more effective at MSSA/MRSA decolonization (89% and 91% of patients decolonized) than the Ocetenidine ending (50% decolonized) intervention. Wagner M. *et al.* (2019), implemented an operating room project to reduce PJI in their respective facilities [15]. This researcher implemented an MRSA nasal decolonization policy within their facility in which all elective total hip, knee, and spinal fusions were nasally decolonized with PI. A total of 47 THAS and 79 TKAS were nasally decolonized with a reduction in surgical site infections from 0.002% to 0.006% during the 3-month nasal decolonization protocol implementation. The researchers state that the implementation of the nasal decolonization protocol was not only a success in reducing PJIs,

but the project also inspired several of the surgeons in their facility to undertake MRSA decolonization in their practices. Researchers Rezapoor *et al.* (2017) conducted a randomized placebo-controlled study regarding Staphylococcus aureus decolonization preoperatively. In total, 445 orthopedic patients (primary or revision total joint arthroplasty, femoral acetabular osteoplasty, pelvic osteotomy, and total shoulder patients) were enrolled in the study over 2 years and divided into 3 groups [16]. Group 1 received nasal decolonization with over the counter 10% PI nasal swabs (n = 143), group 2 received specific manufactured 5% PI applicators (n = 143) and group 3 received saline swabs (n = 143). Each patient's nares were swabbed for MRSA and patients were treated with their respective group's interventions for MRSA. Methicillin-Resistant Staphylococcus aureus swabbing was repeated at the 4-hour and 24-hour mark. Results showed 95 of the 429 patients (22.1%) were positive for Staph aureus with 13 patients (3%) positive for MRSA. At 4 hours post treatment Staph aureus cultures were positive in 52% of the over-the-counter PI group (15 of 29), 21% of the specialized PI group, and 59% of the saline group (19 of 32). After 24 hours of post-treatment, the over-the-counter PI group was 72% positive (21 of 29), 59% of the specialized PI group (20 of 34), and 69% of the saline group (22 of 32). The results show a higher incidence of positive samples at the 24-hour results than at the 4-hour testing time. The finding of this study was that companies that manufactured PI were more effective at treating patients with MRSA than over-the-counter PI, and PI is more effective than placebo at MRSA decolonization. The researchers determined that the efficacy of either PI treatment is maximally effective up to 12 hours after treatment; the researchers recommend surgery within that 12-hour window of PI application. The researchers found that PI has several benefits compared to Mupirocin therapy. PI is not affected by antibacterial sensitivity; it has a single application versus multiple (twice a day for Mupirocin). PI works within 1 minute of applications versus 180 minutes for Mupirocin ointment.

Various studies listed above have demonstrated the effectiveness of Mupirocin in decolonization for MRSA. However, some authors suggest that universally applying Mupirocin to all preoperative patients may cause antibiotic resistance and decrease the effectiveness of Mupirocin. This may increase healthcare spending while interventions such as PI are just as effective [16]. To reduce the incidence of bacterial resistance, Mupirocin therapy should only be used in high-risk patients with multiple risk factors.

9. Povidone Iodine Universal Decolonization Effectiveness

Povidone Iodine is a well-established alternative to MRSA swabbing and Mupirocin treatment in the patient decolonization of MRSA. Povidone Iodine's mechanism of action works by rapidly penetrating deep into bacteria. This causes the oxidizing of bacteria proteins, nucleotides, and fatty acids which causes cell death [17]. Povidone Iodine has a broad antimicrobial spectrum working against gram-positive and negative bacteria, various fungi, protozoa, some spores, and

mature bacterial and fungal films [17]. Its effect is rapid, and it has been shown to begin working within 15 to 60 seconds of a single application [17]. Povidone Iodine's application is successful in emergency surgery use where the 5-day course of mupirocin may not be a treatment option [17]. Studies have even shown that PI has reduced bacterial activity even in Mupirocin-resistant strains of MRSA [17]. Literature has shown that repeated application of PI has not been demonstrated to have a successful effect in reducing MRSA presence in the colonized patient [17].

An evaluation of PI in numerous studies also shows its effectiveness in decolonization. Ghaddara *et al.* (2020), evaluated the efficacy of PI preparation in reducing MRSA in colonized patients [18]. The study reviewed a sample of 11 patients preoperatively and showed a single application of PI significantly decreased MRSA at the 1-hour and 6-hour application but not after 12 or 24 hours. The study demonstrated that twice daily application of PI did not reduce MRSA in the swab compared to a placebo group. Similarly, Saidel *et al.* (2020), conducted a semi-quantitative study regarding PI 5% application for MRSA decolonization before orthopedic surgery in total joint and spine surgeries. The 2018-2019 patients saw 0% hip and 0.99% spine infection rates compared to 0.29% hip and 4.0% spine patients before the treatment was implemented.

Rezappor *et al.*, (2017) conducted a randomized controlled study at a single institution where 429 patients underwent primary and total joint arthroplasties [16]. Patients were divided into 3 groups, 1 group received 10% over-the-counter PI, one group received 5% PI-saline based and one group received a saline placebo. Baseline cultures were taken immediately preoperatively followed by treatment of both nares twice for 2 minutes. A repeat test was conducted at the 4-hour and 24-hour window. Of the 429 patients in the study, 22% tested positive for Staph aureus and 3% for MRSA. At the 4-hour post-treatment, 52% of the Staph aureus cultures were positive in the PI 10% group, 21% in the saline group, and 59% in the saline group. At the 24-hour treatment point, Staph aureus cultures were positive in 72% of the 10% PI, 59% positive cultures in the 5% PI group, and 69% in the saline placebo group. Rezappor *et al.* (2017) found that there is no significant difference between 5% and 10% PI, and PI application is not as effective 4 hours after application as when it was immediately applied.

The effectiveness of PI application intranasally immediately before surgery is as an alternative to Mupirocin for MRSA decolonization. The recommendation of the literature is to use either Mupirocin or PI therapies in combination with other decolonization methods for optimal MRSA reduction [17]. Each intervention has been identified as a suitable decolonization practice for patients with MRSA preoperatively. Analyzing the cost of implementing each therapy will be a key determining factor in the implementation of each intervention at the authors' facility.

10. Cost of Implementing MRSA Swabbing and Test

According to the Centers for Disease Control (2022), SSIs costs $3.3 billion an-

nually with a hospital length of stay of approximately 9.7 days, with each admission costing more than $20,000 in 2022 [19]. The average cost of a TKR revision was $25,692 and $39,399 for a THA [20]. A 2-stage septic revision cost ranged from $66,629 to $81,938, while a 1- or 2-stage septic revision without re-revision ranged from $24,027 - $38,109 [21]. The major cost components were broken into the perioperative cost (33%), prosthesis cost and replacement (28%), and hospital length of stay cost (22%) [21]. If there is a marginal difference in surgical site infection reduction with MRSA swabbing versus universal PI application, it may not be cost-effective in implementing an MRSA swabbing intervention.

Stirton MD *et al.* (2017), analyzed empiric treatment of mupirocin for all patients compared to MRSA swabbing and treatment in total joint arthroplasty [22]. The researchers calculated the cost of a 5-day course of 2% percent Mupirocin topical ointment applied intranasally twice daily to all Total Joint Arthroplasties (TJA) patients preoperatively empirically and preoperative nasal swabbing of all TJA patients sent for Staph Aureus culture, review of culture and selective decolonization of Mupirocin. A 5-day course of 2% Mupirocin ointment was calculated at $24.65 per patient. A medical assistant (MA) was calculated to earn $15.65 an hour and instructed each patient on how to apply Mupirocin. This took an average of 10 minutes. The total cost for a MA to explain and implement a 5-day course of 2% Mupirocin ointment was calculated at $2465.00 per 100 patients. At the researcher's facility screening and decolonizing for MRSA therapy cost $60.32 per patient and $6032.00 per 100 patients. The research then calculated each intervention by the total number of TJAS performed per year. For the standard Staph aureus screening and decolonization of $60.32 × 1,051,000 TJAS, a year total of $63,396,320 while empiric Mupirocin treatment of $24.65 patient x 1,051,000 TJAS a year total was $25,907,150. The price difference in savings was $37,489,170 per year. The researchers concluded that empiric treatment with Mupirocin without testing for MRSA was significantly cheaper and just as effective as routine Staph aureus screening in elective total joint arthroplasties.

Rieser & Moskal (2018), conducted a retrospective review of prospectively collected quality control data for THAs and TKA's at their institution [23]. The policy at the researcher's facility was to screen patients preoperatively for MRSA. If a patient was found to be positive, they would undergo a 5-day course of twice-a-day nasal Mupirocin treatment. The patients would then be tested again for MRSA colonization and would receive preoperative Vancomycin and Cefazolin prophylaxis to include MRSA coverage. All patients would additionally receive Chlorhexidine baths for 5 days preoperatively. During the 4-year study, a total of 3400 TKA's and 2184 THA for a total of 5584 cases were analyzed. The incidence of MRSA-positive patients in the community during the study period was 3.5%. Of the patients treated with the Mupirocin decolonization protocol, 21 (0.54%) patients had surgical site infections. During the year 2016, 809 TKAs and 551 THAs were performed by the researcher's facility. During the year 2016, the MRSA screening and Mupirocin decolonization cohort resulted in a total

cost of $594,351.16 compared to $492,729.08 PI decolonization costs. Mupirocin therapy cost an average of $437.02 per patient compared to $362.30 per patient for PI therapy, a $74.72 per patient difference. The results showed PI as a cost-effective and effective intervention compared to Mupirocin in the treatment of MRSA decolonization. The researchers also discussed using Mupirocin intranasally as a decolonization method without testing for MRSA to reduce costs as an alternative intervention to swabbing and treating MRSA.

Franklin, RN (2020) published a study regarding universal versus targeted perioperative decolonization therapies [24]. At the researcher's facility, the hospital's surgical value analysis committee instituted a policy change in which the hospital would initiate a 12-month trial on the application of alcohol-based nasal antiseptic preoperatively in all THR and TKR. Previously patients were screened for MRSA and treated with Mupirocin. PI was paired with CHG bathing for all patients before surgery. The povidone-iodine was applied to each nare once in the perioperative area and twice a day postoperatively while the patient was hospitalized. The study protocol required the application of nasal antiseptics several times during the admission, once during the preoperative period, and twice each day postoperatively until discharge. The results compared November 2015 through October 2018 policy implementation period to November 2018 through October 2019 policy implementation period. The results show a reduction from 0.91% to 0.00% infections per 100 procedures and a reduction in total knee replacement SSI from 0.36% to 0.00% in 100 procedures with the implementation of the new antiseptic application.

Kerbel MD *et al.* (2018) conducted a breakdown analysis for the preoperative Staphylococcus aureus colonization screening and decolonization protocols in THR and TKR in 2018 [20]. An economic model determined cost-effectiveness given the overall infection rate, the total cost of treating an infection, and the cost of preventing infections at the researcher's facility. Baseline infection rates were 2.18% for TKA and THAs, however, the researchers adjusted the infection rate to 1.10% for TKAS and 1.63% for THAs at their facility. The average estimated cost per screening was $117.00 with an adjusted level of $144.07 for the research study. The results found that the adjusted $144.07 cost per nasal screening would be the most expensive intervention followed $37.57 for a combined decolonization protocol of 2% intranasal Mupirocin ointment, HCG wipes, HCG shower, and prophylactic Vancomycin IV (2 doses at 1 gram intravenous). The most inexpensive intervention was 2% intranasal Mupirocin at $5.09 per use.

The researchers determined that universal decolonization was more cost-effective than nasal screening and decolonization for all patients. The researchers do not recommend all facilities completely switch from decolonization to a screening MRSA protocol but rather that providers analyze the cost-effective variables and apply this in their decision-making policies at their respective facilities.

Reviewing the studies listed above, it is safe to conclude that implementing a PI decolonization protocol is a cost-effective and equally effaceable MRSA decolonization intervention as compared to the Mupirocin 5-day course application. Povidone Iodine is easier to implement as it can be applied immediately before surgery and does not require the patient to be tested before surgery. This eliminates the overhead cost of hiring medical staff to implement and interpret the MRSA swabbing results. Patients are much more comfortable with a one-time application and are more likely to complete the therapeutic regimen compared to a 5-day twice-a-day application. Reviewing the results of the author's retrospective study will help determine which therapy has been more effective in SSI reduction in our facility.

11. Clinical Question

Is the prophylactic administration of Povidone Iodine intranasally preoperatively in elective total knee replacement as effective as MRSA prophylactic screening and Mupirocin treatment?

11.1. Research Objectives

Many surgical site infections have been attributed to the colonization of MRSA. These bacteria reside on the patient's skin, in the nose, axilla, or groin [11]. The objective of conducting this retrospective study is to analyze the MRSA swabbing interventions between MRSA swabbing and Povidone Iodine swabbing and to determine which method was more effective at reducing surgical site infections. The data collected would then influence the ongoing preoperative MRSA decolonization policy and protocol at the facility.

The following is a step-by-step plan for implementing the new preoperative MRSA swabbing protocol:

1) Conduct a retrospective study based on the results from implementing MRSA swabbing and Povidone Iodine decolonization therapies over two 1-year periods.

2) Review findings from data and determine which infection prevention therapy is more effective at reducing MRSA-related surgical site infections.

3) Establish a hospital-wide policy regarding MRSA treatment before surgery based on the results of the study and implement it for all admissions of total knee replacement surgery patients preoperatively.

4) Educate nursing staff and advance care providers regarding the new policy with I-learn education programs and services regarding swabbing techniques.

11.2. Conceptual/Theoretical Framework

Healthcare institutions are complex, adaptive organizations overseen and managed by various medical and nursing personnel. Implementing a planned change in policy requires a purposeful, calculated, and collaborative effort among various departments. The overall goal of policy change is to promote improvement in the

standard of care at that facility [25]. Changes in nursing or medical policies often fail or fall short because of unstructured approaches to implementation. When implementing change policies, we should refer to the theoretical framework of Kurt Lewin's three-step change as a guideline and framework to transform patient care at the bedside [26].

Kurt Lewin's theory suggests that individuals are influenced by various restraining forces and counter-restraining forces that aim at keeping a status quo or equilibrium [26]. To elicit a change of the status quo or equilibrium one must implement a planned change activity strong enough to counter the current restraining force. Stage 1 of his change model or the unfreezing stage refers to letting go of an old pattern of behavior [25]. Disequilibrium or disrupting the current system is needed to ultimately weaken the restraining forces and begin the process of change [25]. Resistance in the form of stress or an expression of discontent can develop among staff to combat the changes [25]. Stress or discontent should be addressed during this step of change through an open discussion forum and reeducation as to the importance of the policy change [26].

In the second or moving stage, the process of change begins in behavior or actions [27]. The driving forces of change must outweigh the restraining ones to break the status quo [27]. Change is a complex process, so adequate timing, clear and concise planning, and easy-to-understand goals are necessary for the change to successfully occur [27]. Nursing Leadership can help ease these changes by building trust, promoting policy changes, and making policy changes a priority for the unit [27].

The third phase, or refreezing, involves establishing the change as a new habit. The goal is for the new habit to stick and for a new equilibrium [27]. If unsuccessful the change will be ineffective, and the previous behavior will persist [27]. Ensuring the proper implementation of the new policy can be monitored with quarterly performance indicators and retraining of staff [27].

11.3. Design/Methods

11.3.1. Population/Sample Size

Farrokhi & Mahmoudi-Hamidabad (2012) state that the sample size is a subset of a population or universe. The population refers to the total quantity of cases in which subjects are studied [28]. When defining a sample size, the researcher should make sure the sample size is not too narrowly or broadly defined as this can ultimately affect the research outcome (Mackewski, 2018). In this retrospective study, all patients that have undergone elective total knee replacements will be included. The sample size of patients who will meet the criteria to be included in this study are as follows: any consentable patient over the age of 18, and patients who electively undergo total knee replacement of either knee. If a language barrier is present, hospital-designated interpreters who would consent to the patient for surgery would also explain the purpose of the MRSA swab. Patients who present to the hospital for a fracture, are unable to consent to surgery, are allergic to betadine, present to the hospital with an ongoing infection related to

knee replacement, present for a washout and hardware removal and replacement of knee hardware, and or any other knee related surgery that is not a total knee replacement will be excluded from the study. Demographic data to be collected of the patient population will include age at the time of surgery, body mass index (BMI), and gender. Of the infected cases, demographic data collected will include the BMI, history of diabetes, surgeon, infectious organism, discharge antibiotics, gender, age, and disposition after surgery.

11.3.2. Setting/Ethical Considerations

This retrospective study was conducted at a 450-bed tertiary research and academic hospital. The retrospective analysis study implements a well-documented and researched intervention as demonstrated in the literature review. This intervention would potentially reduce the incidence of infection in the knee replacement population. The implementation of a policy change would implement either MRSA swabbing or PI application before the total knee replacement surgery would occur. The intervention is considered a part of testing or care and consent would be included under the initial consent required to obtain surgery and interventions related to surgery. No additional consent would be needed from patients. The study was approved as a Quality Improvement Project. HIPPA or the Health Insurance Portability and Accountability Act was utilized in safeguarding and protecting all patient-sensitive data and limiting interaction to only individuals directly involved in the research conducted in this retrospective study.

12. Key Individuals

Several key individuals have been imperative to the implementation of this research project. Consent for implementation of the Quality Improvement project has been obtained from Virgine Lafage AVP of clinical research at our facility. Deirdre O'Flaherty, Director of Orthopedics, has been instrumental in helping gather data, overseeing the implementation of the project, and connecting the author with the appropriate individuals to start the project. Anne Marie Liston Sullivan is the Infectious Disease Prevention and Control in Quality and Improvement coordinator at our facility and has been instrumental in helping gather data on the infected patients in our facility during the study period. Emily Krol RN, MSN, ONC Orthopedics manager has contributed greatly to organizing and assigning demographic data in the orthopedic patients relevant to the study. Dr. Kathleen Ahern, Director of Graduate Studies at Wagner College has been monumental in coordinating and analyzing the data for the project as well as using the Intellectus Data analysis software. The success and completion of this project would not be possible without the contributions of those listed above.

13. Analysis

The data was obtained using the Research Electronic Data Capture or RED

CAPS Program at our facility. RED Caps is a program for gathering clinical research and creating databases for clinical databseas and research based projects [29].

In this study, two interventions were compared regarding infection rates. Total knee replacements that had PI swabbing preoperatively and those that had MRSA screening and decolonization. Information was obtained on the gender and ages of all the participants and then analyzed with descriptive statistics as well as Independent T-tests to determine differences between the patient populations of the designated years. Intellectus Statistical program was used to calculate the results. In addition, the number of infections occurring in the year 2019 was compared to 2021. Absolute risk reduction, relative risk reduction, and the number needed to treat to prevent one infection were calculated. A case analysis was done on each infected case.

14. Results

In 2019 there were a total of 698 TKR procedures at the facility with 660 TKR meeting the criteria to be included in this study. A total of 4 surgical site infections occurred in 2019 with the following bacteria in the growth culture: Pseudomonas Aeruginosa/Methicillin Susceptible Staph aureus (25%, 1 of 4 cases), MRSA (25%, 1 of 4 cases), and Staph aureus (50%, 2 of 4 cases). In the 2021 group, there were a total of 462 cases included in the study. There was a total of 5 SSIs in 2021 with the following bacteria growing in the culture's Staph aureus (60% 3 of 5 cases), MRSA (20% 1 out of 5 cases), and multiple organisms (Enterobacter cloacae, Staph hominis, Enterococcus faecalis 20% 1 of 5 cases). In 2019, 75% (3 out of the 4 cases) were obese and 25% (1 out of 4 cases) had Diabetes Type 2. In 2021, 40% (2 out of 5) cases were obese and 40% (2 out of 5 cases) had a history of Diabetes Type 2. Each infection case is presented with demographic and case-related data.

2019 Infections

Case 1—67 y/o female with BMI 21.5 with Past medical history (PMH) of depression, anxiety, hepatitis C, hypertension, and melanoma underwent a Left TKA and was readmitted with wound dehiscence. The patient then underwent an left knee washout, antibiotic spacer placement, and wound vac on 07/05. The wound vac was changed on 07/08 and 07/11 with an antibiotic spacer removal and long-term spacer placement with rectus-free flap closure and split thickness sterile graft on 07/15. The wound culture grew MRSA. The patient was discharged to Subacute Rehab (SAR) with Doxycycline PO × 3 months.

Case 2—63 y/o female, BMI 35.1, PMH of Juvenile Arthritis, Hypertension, Dry Eye Syndrome, presented for a Right TKR with aseptic loosening of hardware. The patient underwent a right knee revision on 7/22 and then presented on 8/2019 with wound dehiscence and increasing purulence. The patient underwent a right knee washout, poly exchange, and a wound vac placement on 8/23 with joint capsule repair on 8/25 followed by wound closure scar revision

and Jackson Pratt drain (JP) placement on 8/26 with plastics closure. A Peripherally Inserted Central Line Catheter (PICC) was placed. The patient's cultures grew Staph aureus. The patient has been discharged to SAR with Rifampin 300 mg by mouth (PO) twice a day (BID) and Cefazolin 2 grams intravenous (IV) every 8 hours (Q8h) × 6 weeks.

Case 3—86 y/o female BMI 31.8, PMH/PSH, Depression, Macular Degeneration, Hypertension, Hyperlipidemia, Aortic Valve Replacement, Tonsillectomy, Appendectomy, s/p Right TKA 8/7/19 and right knee Incision and Drainage (I & D), right knee washout on 8/28/19 after wound dehiscence from mechanical fall. The patient underwent a washout, synovectomy, and poly exchange in 9/2019 with polyethylene liner exchange in 10/18, During her admission, a stroke code was called and then when she was medically stable was discharged to SAR. The patient was discharged on Cefepime 2 grams IV Q12h × 6 weeks. The wound culture showed Methicillin Susceptible Staph aureus (MSSA) and Pseudomonas Aeruginosa growth.

Case 4—62 y/o Male, BMI-31.1 with PMH Diabetes Type 2, Congestive Heart Failure, Coronary Artery Disease, Myocardial Infarction, Right Coronary Artery Stent Placement, s/p Right TKA on 10 - 21 - 19 with readmission for right knee infection, s/p washout. The patient was discharged to SAR on IV Vancomycin and then readmitted for wound dehiscence and necrosis on 12/22/2019, The patient was evaluated by the plastics team and the wound care team. Once the wound was re-cultured and the patient was deemed medically stable, a PICC line was placed, and the patient was discharged home with Rifampin 300 mg PO Q12h and Vanco IV Q12h × 6 weeks. The culture grew MRSA.

2021 Infections

Case 1—59 y/o Male BMI 38.8, PMH/Depression, Type 2 Diabetes, Hypertension, Gastroesophageal Reflux Disease, Hyperlipidemia, Osteoarthritis, Obstructive Sleep Apnea, Herpes Simplex Virus, Insomnia, presented with a septic knee joint after Left TKR and underwent a left knee I & D, poly exchange (of prosthetic knee hardware), and antibiotic bead placement. Cultures grew Staph aureus. A PICC line was placed, and the patient was discharged home with Nafcillin 2 grams IV Q4h and Rifampin 600 mg PO daily for 6 weeks.

Case 2—74 y/o Female, BMI 39.2, PMH: Hypertension, Hyperlipidemia, Osteoarthritis, Gastroesophageal Reflux Disease, Morbid Obesity, s/p Right TKR on 6/2021, presented with periprosthetic infection and underwent a right knee I & D and poly exchange. The patient's culture grew Enterobacter Cloacae, Staph hominins, and Enterococcus faecalis. After a complicated clinical course due to a drug reaction to Vancomycin, a PICC line was placed, and the patient was discharged home with an Ertapenem and IV Daptomycin × 6 weeks. The patient developed a rash and was switched to IV cefepime. The patient underwent a right knee explant and spacer placement on 7/30 followed by 6 weeks of oral antibiotics with Linezolid and Ciprofloxacin PO. The patient then presented in 9/2021 with erythema to the surgical site and was found to grow MSSA and Candida Albicans. The patient underwent I & D, spacer exchange, and was dis-

charged with Ancef 2 grams IV Q8h, Micafungin 100 mg by mouth daily and Levaquin 750 mg orally daily × 6 weeks. The patient returned to the hospital in 10/2021 due to an occluded PICC line, which was replaced. The PICC line was fixed, and the patient was discharged home on the same regimen.

Case 3—58 y/o Male, BMI 22.2. PMH: Hypertension, Type 2 Diabetes, Obstructive Sleep Apnea, Depression presented with prosthetic joint infections and underwent a Left Knee I & D, poly exchange in 5/2021. Operating room cultures MSSA. A PICC line was placed, and the patient was discharged to SAR with Nafcillin 2 grams IV Q4h and rifampin 600 mg by mouth daily × 6 weeks.

Case 4—70 y/o Male, BMI 22.2, PMH: Alzheimer's, Hyperlipidemia, Bipolar Depression, Severe Mitral Regurgitation presented with right knee pain and swelling after a Right TKR and underwent a washout and poly exchange. The operating room culture grew Staph aureus. The patient has been discharged to SAR on Ancef 2 grams IV Q8h hours and rifampin by mouth 600 mg daily for 6 weeks.

Case 5—70 y/o Male, BMI 24.3. PMH, Stroke without residual deficits, Hypertension, Benign Prostate Hypertrophy, s/p Left Mako (robot assisted) TKA presented with increased knee pain and dehiscence. The patient underwent an I & D and Poly exchange of the left knee. The cultures grew Staph aureus. A PICC line was placed, and the patient was discharged home on Nafcillin 2 grams IV Q4h and rifampin 600 mg by mouth daily for 6 weeks.

Descriptive statistics were conducted on ages and gender for cases in the years 2019 and 2021. Table 1 depicts the descriptive results for ages and Table 2 for gender.

A t-test was done to determine if ages differed based on gender. The result of the two-tailed independent samples *t*-test was not significant based on an alpha value of 0.05, $t(460) = -1.00$, $p = 0.318$, indicating the null hypothesis cannot be rejected. This finding suggests the mean of Age_2021 was not significantly different between the Female and Male categories of Gender_2021. A bar plot of the means is presented in Figure 1.

Two-Tailed Independent Samples *t*-Test

A two-tailed independent samples *t*-test was conducted to examine whether the mean of Age_2019 was significantly different between the Male and Female categories of Gender_2019. The result of the two-tailed independent samples *t*-test was not significant based on an alpha value of 0.05, $t(658) = -0.33$, $p = 0.742$, indicating the null hypothesis cannot be rejected. This finding suggests the mean of Age_2019 was not significantly different between the Male and Female categories of Gender_2019. A bar plot of the means is presented in Figure 2.

Table 1. Descriptive results for ages.

Variable	*M*	*SD*	*n*	*SEM*	Min	Max	*Mdn*	Mode
Age_2019	69.93	9.98	660	0.39	6.49	97.17	70.49	75.60
Age_2021	69.02	9.98	462	0.46	5.49	96.17	69.64	72.39

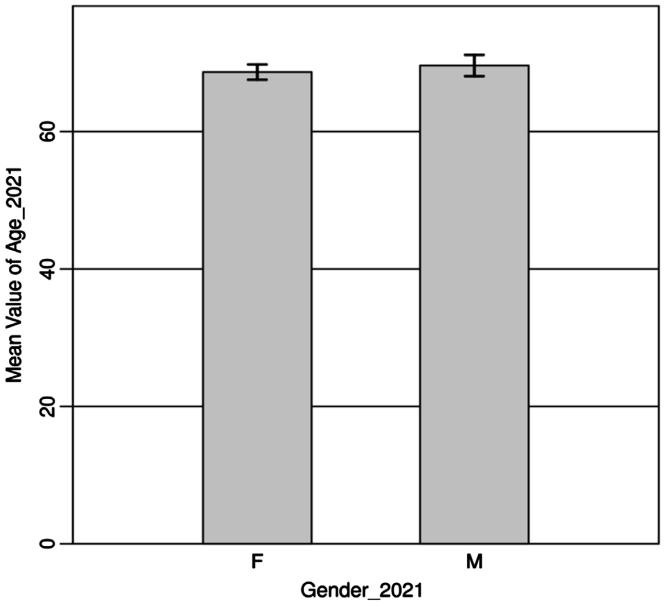

Figure 1. The mean of Age_2021 by levels of Gender_2021 with 95.00% CI error bars.

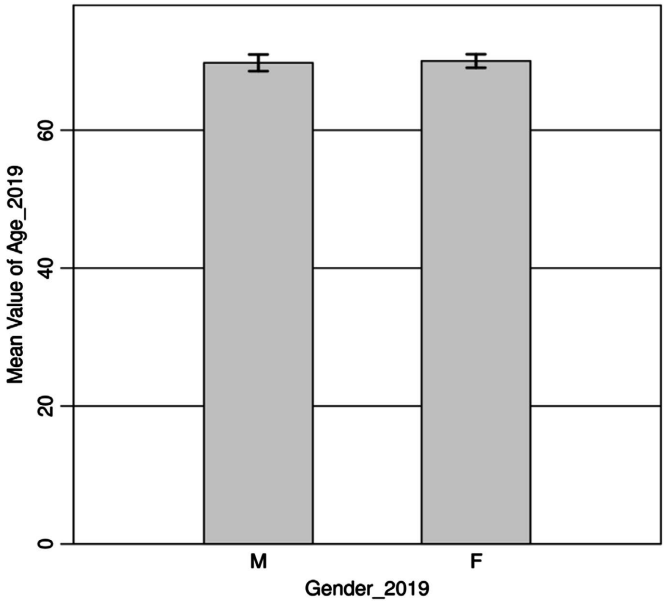

Figure 2. The mean of Age_2021 by levels of Gender_2021 with 95.00% CI Error Bars.

Table 2. Frequency table for gender.

Variable	n	%	Cumulative %
Gender_2019			
Male	247	37.42	37.42
Female	413	62.58	100.00
Gender_2021			
Male	182	27.58	27.58
Female	280	42.42	100.00

A total of 462 procedures were performed in 2021 with five infections identified that year. In 2019 there were 660 procedures with 4 identified infections. Betadine nasal applications were used in 2021 and in 2019 MRSA nasal swabs treatment of positive results. The data were examined to determine absolute risk reduction, relative risk reduction, and the number needed to treat to prevent one infection. Absolute risk reduction represents the proportion of patients who are spared the adverse outcome because of implementing the experimental intervention rather than the control therapy [30]. The absolute risk reduction was calculated with a result of 0.0048 or 48%. (5/462 = 0.0108) and 4/660 = 0.006 then event rate 0.0108 − 0.006 = 0.0048. Another way of expressing this is that in the Betadine group the infection rate per 1000 procedures would be 10.8 and the infection rate in the MRSA swab group would be 6 per 1000 procedures. The relative risk reduction is an estimate of the percentage of baseline risk that is reduced because of implementing a new intervention or therapy [30].

Relative risk reduction for the infection event is 0.0108 − 0.006/0.0108 = 0.44 or 44%. The number needed to prevent one infection is 1/ARR therefore 1/0.0048 = 208.33 rounded down to 208. For every 208 patients treated with MRSA swabs, one infection could be prevented compared to PI.

15. Discussion

From an analysis of the data the age of patients who underwent TKR was relatively the same in 2019 and 2021 at 69 years of age. There was also an equal number of Male and Female patients who underwent TKR in 2019 and 2021 as demonstrated in the graphs. The MRSA swabbing intervention has been demonstrated to be more effective at reducing MRSA-related surgical site infections in the TKR compared to the betadine group. Implementation of the MRSA-related intervention would ultimately prevent 1 infection in every 208 cases treated with MRSA swabbing compared to the PI in a group of 1000 patients. Both interventions are well documented in the literature to reduce SSI in orthopedic patients. It is not surprising however to have determined that MRSA swabbing and Mupirocin treatment work better at reducing MRSA-related infections than PI decolonization alone. Mupirocin is a treatment for MRSA and PI is intended as a decolonization procedure before surgery.

16. Limitations

There are various limitations in the implementation of this study. Obtaining the data needed to complete the study was difficult as it was not in one concise location. The units where orthopedic surgeries were admitted collected demographic data related to the patients admitted to their respective units and not based on all orthopedic knee admissions. The data collected using floor admission-related data was more concise per patient. It included total admission time, positive MRSA swab results, feet ambulation after surgery, surgeon operating, and other data related to the patient's length of stay. This data was not captured on the

hospital Red Cap system. Since the patient data collected on the orthopedic unit was different from that compared to the Red Cap system there were limitations to the data that could have been analyzed. Standardization of data collection or using the same format would benefit future studies in the orthopedic population.

The time the data was collected also must be taken into consideration. Elective orthopedic cases were all but stopped during the COVID-19 pandemic in 2020, except for emergencies and traumas. The implementation of the in-person preoperative class was discontinued and moved into an online format. In 2021 elective orthopedic cases were reinstated, however, the class remained in an online format. Patients were treated on the day of surgery with PI and MRSA swabbing and testing was not used preoperatively. For a patient to be tested for MRSA the patient would have to be tested at their respective surgeon's office and or primary care doctor weeks before surgery. If the patient were to test positive, they would need to receive the full course of mupirocin therapy and be retested. This would ultimately delay elective surgery and could not be implemented on the day of surgery. This could not be implemented the day of unless. As discussed in the literature the facility could treat high-risk patients with Mupirocin only without testing, however, this would bring up the risk of Mupirocin resistance in long-term use.

The need for an inpatient preoperative class and testing has come into question since the facilities transitioned into a 100% online format. A 100% online format allows the patient to receive preoperative patient education without commuting to the hospital and allows the hospital to assure there is a greater adherence to class attendance. The hospital, however, may be losing some of the benefits of inpatient education. Research has demonstrated that inpatient preoperative patient education and postoperative care navigation has been identified to reduce pain, anxiety, and length of stay, as well as motivate patients to adhere to rehabilitation programs after discharge [31]. The hospital could consider creating a hybrid online and in-person education and testing format. This would allow patients and providers to continue online education and receive preadmission clearance and testing in the hospital. Patients can also be tested at this time for MRSA if the decolonization policy is reinstated.

Creating preadmission testing would allow patients to be tested for MRSA without the need for an inpatient education program. If a preadmission testing program is too expensive to implement the hospital can implement a patient self-swabbing program that can send swabs to the patient's home. Since COVID-19 the public has had more exposure to anterior nares swabbing and has likely performed their own nasal swabbing to test for COVID-19 at home. Patients would have an MRSA self-swabbing kit sent to their homes with a postage-enclosed sealed envelope. The proper demonstration technique can be reviewed in the online class and the patient can then self-swab and mail out the results to the appropriate medical laboratory. Patients with positive results would be notified and advised to follow up with their primary care doctor where they will be treated with Mupirocin. Facilities could also consider sending MRSA swabs on

high-risk patients on the day of surgery while still implementing povidone iodine decolonization afterward. If a patient is positive, they can be treated in the patient setting.

The implementation of the MRSA intervention cannot be fully taken into consideration without its cost to implement. As stated in the results section for every 208 cases tested with the MRSA swabbing and decolonization intervention, 1 SSI was prevented. A hospital-acquired infection costs approximately $25,692 for a TKR revision and a 2-stage revision costs $66,629 to $81,938 [20]. There is a significant difference in the cost of implementing each intervention. Referring to the study by Yehuda *et al.* in 2018, MRSA swabbing per patient costs approximately $117 to implement per test compared to $37.57 for the PI decolonization intervention. The hospital could consider continuing the PI decolonization program and consider swabbing only for patients identified as high-risk to reduce costs.

17. Conclusion

Surgical site infection (SSI) remains a prominent issue in healthcare. Surgical site infections cause significant distress to the patient, require extended courses of antibiotic treatment, revision surgery of the infected joint, and decreased financial reimbursement for the facility. Surgical site infection decolonization methods such as the implementation of chlorhexidine swabs, PI decolonization, and MRSA swabbing are well-established interventions to prevent infection. In this study, two well-established literature-based prevention interventions were compared to evaluate effectiveness in SSI prevention. While MRSA swabbing showed a reduction in TKR infections compared to PI, several factors cause limitations in its potential establishment as a preoperative decolonization protocol. These include lack of preoperative class or location to test patients, risk of bacterial resistance from implementing prophylactic Mupirocin on all patients, and cost to implement this intervention. There were also limitations in the collection of patient data as well as including all patients for this study. The study has identified the need for more research involving decolonization interventions to prevent SSIs in the orthopedic and TKR populations.

Conflicts of Interest

I have no conflicts of interest to disclose.

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