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MRSA Decolonization: Infection Prevention for Total Hip and Total Knee Arthroplasty

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MRSA Decolonization: Infection Prevention For Total Hip And Total Knee Arthroplasty

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This is to certify that I have examined this
Doctor of Nursing Practice systems change project
written by

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and have found that it is complete and satisfactory in all respects,
and that any and all revisions required by
the final examining committee have been made.

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Executive Summary

Staphylococcal carriage, particularly Methicillin-resistant *Staphylococcus aureus* (MRSA), is a risk factor for surgical site infection (SSI). The purpose of this project was to determine whether adult patients undergoing total hip and total knee arthroplasty could be successfully decolonized of MRSA beginning on the day of surgery, and if decolonization would reduce surgical site infection (SSI) rates.

The study employed two theoretical frameworks: Nola Pender's Health Promotion Model and Kurt Lewin's Change Theory. The sample consisted of 50 patients, 10 cases and 40 controls, selected from a convenience sample of 299 patients who underwent total hip or total knee arthroplasty from May 1, 2012 to May 1, 2013 at a large Midwestern teaching hospital. A case-control study design was utilized. Data was collected using retrospective chart review.

Characteristics of cases and controls were compared on categorical variables using Chi-square statistics. Fisher Exact tests were used when expected cell frequencies were less than 5. For continuous variables, independent group t-tests were used for comparisons. Evaluation of change in infection rates pre to post surgery was done using the Wilcoxon test. The small sample size precluded meaningful inferential statistical tests related to these variables.

MRSA colonization in the cases was reduced from 100% to 30% (7/10) pre to post surgery in the case patients. No prediction can be made about reducing SSI related to the limited sample size. A multisite study is recommended to address this limitation.

This pilot project suggests that screening for existing nasal MRSA and beginning decolonization on the day of surgery for patients undergoing THA or TKA surgery may effectively result in temporary decolonization during the perioperative period and may potentially prevent a MRSA SSI.

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Chapter 1

Background and Significance of the Project

Patients colonized with methicillin-resistant *Staphylococcus aureus* (MRSA) who are planning to undergo total hip or total knee arthroplasty may be at greater risk for acquiring a surgical site infection (SSI). The National Healthcare Safety Network (NHSN) at the Centers for Disease Control and Prevention (CDC) reports that MRSA has been found to be a pathogen in SSIs and other complications that can occur during the post-operative period (Hidron et al., 2008). Surgical site infections result in prolonged hospital stays, readmissions and increased mortality rates (Anderson & Kaye, 2009; Gupta, Strymish, Abi-Hadar, Williams, & Itani, 2011; Whitehouse, Friedman, Kirkland, Richardson, & Sexton, 2002). Such adverse health outcomes unfavorably affect patient safety and impact the rising costs of health care.

Anderson and Kaye (2009), report that *S. aureus* is the most frequent causative agent of SSIs. *Staphylococcus aureus* resistance to antibiotics is growing. Jernigan (2004, p. 458), of the CDC, stated:

> Data from National Nosocomial Infections Surveillance (NNIS) System hospitals reported between 1992 and 2002 show that among SSIs following CABG, cholecystectomy, colectomy, and total hip replacement, the overall proportion caused by *S. aureus* increased from 16.6% to 30.9%; the proportion of *S. aureus* infections attributable to MRSA increased from 9.2% to 49.3% (Centers for Disease Control and Prevention, National Nosocomial Infection Surveillance [NNIS] System, unpublished data, May 5, 2004).

The increase in MRSA is a factor impacting quality medical care.

Up to 15 million operations are performed each year in the United States (U.S.) alone (Anderson & Kaye, 2009). According to the Society for Healthcare Epidemiology in America (SHEA)/Infectious Diseases Society of America (IDSA) Practice Recommendations, "SSIs occur in 2%-5% of patients having inpatient surgery in the U.S., and approximately 500,000 SSIs occur

annually" (Anderson et al., 2008, p.1). SSIs increase morbidity and mortality in surgical patients. Hospital length of stay can be increased by 7-10 days related to SSIs, and if one has an SSI the risk of death increases 2-11 times when compared to that of a patient without an SSI (Anderson et al., 2008). Studies suggest that from an economic perspective, preoperative screening and decolonization of patients undergoing orthopedic surgery is a simple and cost-effective patient safety measure that may reduce the risk of SSI, while saving money for hospitals and third-party payers (Courville et al., 2012; Lee et al., 2010).

This paper describes a pilot project in a large teaching hospital system in the Midwest. Currently the nares of all patients in this facility are screened for MRSA on admission, transfer, discharge and death. Admission swabs are analyzed by polymerase chain reaction (PCR) and results are available within one hour. Given the availability of admission MRSA screening results, the Orthopedic surgery group believed preoperative MRSA decolonization might be a strategy to consider to further decrease their already low SSI rate in total hip arthroplasty (THA) and total knee arthroplasty (TKA) patients. An infection preventionist, orthopedic surgeon, and the hospital epidemiologist were interested in adding MRSA decolonization to the perioperative routine which would change the standard of care for THA and TKA surgeries at this facility by temporarily decolonizing patients and possibly reduce the risk of a MRSA SSI.

A proposal for a systems change project (SCP) to implement decolonization of patients undergoing total hip and total knee surgery at the time of surgery was submitted to the health facility's Institutional Review Board (IRB) as well as to the St Catherine University IRB, and was approved. The goal of the project was to implement MRSA decolonization at the time of surgery in adult patients undergoing total hip or total knee arthroplasty, who were known or newly screened positive, and to determine what proportion of these patients could be temporarily

decolonized. It was further hypothesized that temporary decolonization might reduce SSIs when compared to the standard of care at the facility, which at the time the project was proposed was no decolonization at all.

Quality improvement could be measured and evaluated by implementing such a project. Patients colonized with MRSA would receive a more appropriate prophylactic antibiotic and may be temporarily decolonized during the perioperative and immediate postoperative period, when the risk of SSI is the greatest. Decolonization of MRSA positive THA/TKA patients could potentially decrease the risk of SSI for this patient population, and decrease the MRSA burden in the hospital overall as well. As noted earlier, the orthopedic subspecialty historically has a low SSI rate for clean surgical procedures such as THAs and TKAs. However, the group indicated an interest in reducing the SSI rate even further by using an evidence-based approach and implementing decolonization.

Decolonization of MRSA positive THA/TKA patients as a project implemented over one year as a proposed innovation would require an interdisciplinary approach. Unit nurses, CRNAs, orthopedic physicians, lab and pharmacy were involved. Communication with all partners would be critical, including union involvement related to participation of unit nurses and CRNAs at the time of project implementation. Initial diffusion would occur as the protocol was implemented with discussion taking place among the various groups. Diffusion would continue to occur as the results of the project were evaluated and disseminated.

Project Objectives

The project objective was to determine the short term success of methicillin-resistant MRSA decolonization at the time of surgery for patients undergoing total hip and total knee procedures and to determine whether decolonization at the time of surgery is effective in

reducing the rate of surgical site infection (SSI). The primary endpoint for this project is to identify the proportion of patients undergoing total hip or total knee arthroplasty successfully decolonized beginning on the day of surgery. Positive outcomes for this project will simplify and target the management of surgical patients by reducing the risk of MRSA SSIs. This could be significant at the local level and beyond.

Systems change and principles of social justice. Access to quality medical care is a social justice issue. Patients should expect quality care that addresses not only physical aspects of care but psychological and spiritual aspects as well. The facility is a regional referral center for orthopedic surgeries. Patients may be referred from other Midwestern states. Many of the patients scheduled for these procedures are aging individuals, without other health care coverage. A decolonization procedure would decrease the risk of MRSA SSIs for individuals having surgeries that require orthopedic implants. This intervention will not change accessibility for patients. It may minimize the risk of SSI which will improve the quality of care, health outcomes and contribute to patient satisfaction. It is socially responsible to provide this service for this group of patients.

Beyond the physical signs and symptoms, acquisition of a MRSA infection can have an undesirable psychological effect on patients and families as isolation will be required. Isolation precautions not only sequester the patient, they may reduce the frequency and duration of encounters between patients and their health care providers (Kirkland, 2009). If healthcare facilities have a high prevalence of MRSA, a decolonization procedure may decrease the risk of MRSA SSIs for surgical patients that require orthopedic implants. If successful, decolonization will improve the quality of care, health outcomes and contribute to patient and family

satisfaction by reducing the burden of MRSA in a hospital. It is socially responsible to attempt MRSA preoperative nasal decolonization.

Social justice, racial disparity, and joint replacement surgery. An additional aspect of TKA surgery related to social justice is that of racial disparity. A Healthy People 2010 objective called for eliminating racial disparities in the rate of total knee replacement among persons ≥ 65 years (CDC, 2009, p. 133). This disparity was not explained by varying risk for knee osteoarthritis. The CDC indicated disparate access to health care probably did not explain the disparity. It was further stated "Several reports have indicated that racial disparity in Total Knee Replacements (TKR) procedures persists even after adjusting for access to clinical care" (CDC, 2009, p. 137). Non-white Medicare beneficiaries are more likely to have the procedure at a hospital that performs fewer TKRs per year and where adverse outcomes are more common (CDC, 2009).

According to research by Ibrahim, Siminoff, Burant and Kwoh (2002), African-American patients had more concerns about postoperative pain and ambulation than whites. The authors also found joint replacement itself to be less well known to African-Americans. Similar to the findings in the CDC article, disparities were found related to knowledge and what to expect after surgery.

Differences in knowledge, attitudes and beliefs regarding TKR may have an influence on this disparity. Low outcome expectations as a result of communication gaps with health care providers or inaccurate information from peers may have an effect. Culturally sensitive educational resources must be developed and available for providers and their patients so this health disparity can be overcome.

As a regional referral site the facility performs a higher volume of joint replacement surgeries, and already demonstrates low infection rates without MRSA decolonization. While temporary decolonization may decrease the risk of infection during the perioperative period, this action in and of itself will not address racial disparity and joint replacement. As stated above, providers must have an awareness of and be culturally sensitive when discussing this topic with African-American patients.

Social justice and Catholic teachings. The U.S. Conference of Catholic Bishops (USCCB) offered this "*Pastoral Reflection on Lay Discipleship for Justice in a New Millennium 1998*:

> Catholicism does not call us to abandon the world, but to help shape it. This does not mean leaving worldly tasks and responsibilities, but transforming them. Catholics are everywhere in this society. We are corporate executives and migrant farm workers, senators and welfare recipients, university presidents and day care workers, tradesmen and farmers, office and factory workers, union leaders and small business owners. Our entire community of faith must help Catholics to be instruments of God's grace and creative power in business and politics, factories and offices, in homes and schools and in all the events of daily life. Social justice and the common good are built up or torn down day by day in the countless decisions and choices we make. This vocation to pursue justice is not simply an individual task -- it is a call to work with others to humanize and shape the institutions that touch so many people. The lay vocation for justice cannot be carried forward alone, but only as members of a community called to be the "leaven" of the Gospel. (2013, paragraph 10).

We are invited to expand and grow social justice in organizations from the inside through systems change.

The Joint Commission (2010), a hospital accreditation organization, developed the monograph: *Advancing Effective Communication, Cultural Competence, and Patient-and Family-Centered Care: A Roadmap for Hospitals.* This document is designed to assist hospitals in meeting the particular needs of each patient regarding language, culture, health literacy, other communication barriers, mobility needs and concerns of lesbian, gay, bisexual and transgender

populations (Joint Commission, 2010). Practice examples are included in addition to recommendations, with chapters identifying these specific points along the continuum of care: admission, assessment, treatment, end-of-life care, discharge and transfer, and organization readiness (Joint Commission, 2010). The important theme of patient centered care is supported throughout this monograph from the perspective of social justice.

Conclusion. This project addresses the responsibility of pursuing social justice. Decolonization may prevent infection and further complications, even death, that could result from a SSI. Implementing decolonization may increase the likelihood of a quality health outcome that will impact psychological, spiritual, and physical aspects of care for patients. Quality health outcomes not only contribute to patient satisfaction, but affect the psychological, spiritual and physical well-being of family members who are instrumental in supporting the patient at the time of surgery as well.

Chapter 2

Theoretical Frameworks

This chapter will discuss two models that were selected to support the project as a theoretical framework. One model is grounded in the field of social and behavioral science, and was chosen as an approach to encourage and sustain staff from the various disciplines to participate fully in the project (Kurt Lewin's Change Theory). The second model supports preventive health behaviors and was selected to motivate and positively influence patients to complete the decolonization process following discharge from the hospital (Nola Pender's Health Promotion Model).

The chapter will further address the clinical questions in PICO design (patient population, intervention, comparison group, and outcome) that formulated the basis of the project. A review and synthesis of literature that is relevant to MRSA decolonization, orthopedic surgery, surgical site infection and total hip/total knee arthroplasty is included in the chapter as well.

A theoretical framework provides guidance as a project evolves. The end results will determine whether the knowledge learned from implementing a project should create a change in practice (Sinclair, 2007). The theoretical framework of this project relies on Nola Pender's Health Promotion Model (HPM) and Kurt Lewin's Change Theory. Both theories are applicable to the project, one relative to the patients and one to the health care workers. Pender's model will directly affect the patient participation component of MRSA decolonization. Lewin's model will be utilized to facilitate the change in work practices for health care workers. It is necessary for both groups to engage in this project if the goal of temporary MRSA decolonization and prevention of SSIs will be achieved.

In the Health Promotion Model (HPM), Pender contends that nurses can assist people to care for themselves and achieve self-efficacy (1996). Nurses can accomplish this by recognizing the complex biological and psychosocial processes that motivate people to participate in behaviors that will improve health (Pender, 1996). A diagram of Pender's model (Appendix A) flows from left to right, structured in three columns or pillars representing individual characteristics and experiences, behavior specific cognitions and affect, and behavioral outcomes (Pender, 1996).

Pender's model has fourteen assertions. Two of the assertions in particular apply to this project. One is that "persons commit to engaging in behaviors from which they anticipate deriving personally valued benefits" (as cited in Sakraida, 2002, p. 630). A second assertion is that "perceived competence or self-efficacy to execute a given behavior increases the likelihood of commitment to action and actual performance of the behavior" (as cited in Sakraida, 2002, p. 630). Applying mupirocin to one's nares to decolonize MRSA in the postoperative period which will be required of participant's in this systems change project demonstrates an individual's commitment to a plan of action and health promoting behavior. The positive health outcome will be temporary MRSA decolonization and possible prevention of a MRSA SSI.

Kurt Levin's Change Theory (Nursing Theories, 2011) is a second theoretical framework applied to this SCP. Burnes (2004) asserts that although Lewin developed this three-step model over 60 years ago, it continues to be a commonly cited framework to support successful change projects. The three steps are unfreezing, moving and refreezing. Lewin determined in Step 1, unfreezing, that human behavior is held in equilibrium by driving and restraining forces. He believed this equilibrium needs to be disrupted in order for change to occur (Burnes, 2004). Old

behaviors would need to be rejected and replaced by new, thus his use of the term unfreezing (Burnes, 2004; Medley & Akan, 2008).

Step 2 or moving, involves learning. Learning includes knowledge of what the possible options are and moving on from previous behaviors to new behaviors which will enable the planned change to occur. Assessment and reinforcement are necessary during this step, or it is possible that the change may be temporary (Burnes, 2004; Medley & Akan, 2008).

In Refreezing or Step 3 the new equilibrium is established. New behaviors are sustained and it is posited that old behavior will be unlikely to be resumed (Burnes, 2004). It would be expected that innovative work practices would be fully implemented as part of a system change project during this step in the change process (Medley & Akan, 2008).

Lewin's model is relevant to this system's change project in several ways. Unit nurses will be responsible for identifying on the lab request that a patient is being admitted for a THA or TKA. When a patient's admission MRSA swab is positive the CRNA will be responsible for notifying the surgeon to order vancomycin rather than cefazolin, and in addition to order mupirocin to begin decolonization. Applying Lewin's model may assist in promoting acceptance of these changes and limit resistance from the health care providers.

Literature Review and Synthesis

Prior to beginning the literature review two PICO questions were formulated. The first PICO question associated with this literature review was: In adult patients undergoing total hip and total knee arthroplasty, what proportion of MRSA positive patients can be temporarily decolonized when compared to the standard of care (no decolonization)? A second PICO question associated with this literature review was: In adult patients undergoing total hip and

total knee arthroplasty, does decolonization of MRSA positive patients reduce surgical site infection when compared to the standard of care (no decolonization)?

Database Search/Articles Selected

The National Library of Medicine Medical Subjects Headings (MeSH) browser was used to review and to relate chosen descriptor words. Key search terms included: MRSA, decolonization, orthopedic surgery, surgical site infection and total joint arthroplasty. The databases utilized for journal searches from 2007-2012, were CINAHL and PubMed. Articles selected were from peer reviewed journals. Limiters such as evidence based practice, English only, human subjects, gender all, and adult age groupings were applied. Randomized controlled trials (RCTs) and cohort studies were preferred for offering evidence-based practice. Cohort studies were prevalent in the search and selected because the study designs and the findings identified were comparable to the PICO question. Although review articles were included in the search and were examined, they will not be incorporated into this paper. Exclusion criteria were books/texts, and articles with heavy emphases on clinical microbiology, specific prosthetics, and other MRSA related post-operative complications. Articles selected for this literature review are included in the Table 1 (Appendix B).

Critical Analysis of Evidence Related to the Clinical Question

Literature or articles. Overall the articles examine the impact of MRSA decolonization on outcomes of patient care. More specific categorization identifies three subgroups: patients screened for MRSA decolonization with the hypothesis that this would decrease SSI rates (Kim et al., 2010; Hadley, Immerman, Hutzler, Slover, & Bosco, 2010; Price et al., 2008); screening and factors associated with poor post-operative outcomes (Gupta, Strymish, Abi-Haidar, Williams, & Itani, 2011; Yano et al., 2009); and factors influencing failure to decolonize

(Buehlmann et al., 2008; Lee et al., 2011). The primary objective of Price et al. (2008) was to determine the prevalence of nasal colonization with *S. aureus*. Prevalence, an important factor in decision-making about per-screening and decolonization, was quantified in another of the earlier articles (Buehlmann et al., 2008) and one of the most recent (Lee et al., 2011). Knowledge about prevalence influences positive patient outcomes and can impact resource utilization.

Population/sample. Patients sampled in five of the seven studies included preoperative patients scheduled for elective surgery (Kim et al., 2010; Gupta et al., 2011; Yano et al., 2009; Hadley et al., 2010; Price et al., 2008). Four of the five studies focused on orthopedic patients. Gupta et al. (2011) included all surgical subspecialties at a Veterans Affairs hospital except dental and ophthalmology. The patients sampled in the remaining two studies included hospitalized patients, not necessarily scheduled for surgery. All studies used a convenience sample of consecutive patients. Only Gupta et al. (2011) described the patients selected as having clean or clean-contaminated wound classes. The other authors may have assumed common knowledge that most index orthopedic procedures are clean cases. Wound classification is an important defining term for all surgical subspecialties. Clean and clean-contaminated wound classifications are not considered a risk factor for SSI (Mangram, Horan, Pearson, Silver, & Jarvis, 1999).

Research designs. Four of the studies utilized a prospective cohort study design (Kim et al., 2010; Yano et al., 2009; Hadley et al., 2010; Buehlmann et al., 2008), one (Gupta et al., 2011) a retrospective design, one a case control design (Lee et al., 2011) and one a cross-sectional design (Price et al., 2008). Kim et al. (2010) used historical controls. Five of the studies occurred in hospital setting (Kim et al., 2010; Gupta et al., 2011; Hadley et al., 2010; Buehlmann et al., 2008; Lee et al., 2011). Yano et al. (2009) and Price et al. (2008) screened

patients in the community setting during pre-operative outpatient clinic appointments. While this strategy is useful for identifying community trends, patient characteristics may not be similar to those in the hospital setting.

Interventions. Three of the seven studies reviewed included an intervention (Kim et al., 2010; Hadley et al., 2010; Buehlmann et al., 2008). All interventions included 2% mupirocin ointment to the nares BID x 5 days. Kim et al. (2010) added 2% CHG showers x 5 days, and Hadley et al. (2010) a single CHG (2% or 4% not specified) shower on the day of surgery. The most comprehensive/complex intervention by Buehlmann et al. (2008) included 2% mupirocin to the nares BID x 5 days, oral rinsing with 2% CHG TID, daily body washing with 4% CHG, and oral antimicrobials once or twice daily depending on the site for urogenital and gastrointestinal decolonization. Perioperative vancomycin was used by Kim et al. (2010) and Hadley et al. (2010) for better MRSA coverage rather than cefazolin. Vancomycin was given perioperatively in some of the cases analyzed by Gupta et al. (2011). The type of case was not detailed but was adjusted for in the analysis. Buehlmann et al. (2008) ordered oral vancomycin for patients requiring gastrointestinal decolonization. This study did not focus on surgical patients, but hospital patients overall.

Comparisons. Only two of the seven studies used a case-control design so comparison was not possible. Kim et al. (2010) utilized a historical control group for comparison that immediately preceded the study group. This close temporal association may have reduced confounding that occurs with historical controls related to changing demographic characteristics over time. Hadley et al. (2010) identified a control group by selecting those patients who did not participate in MRSA screening before surgery. This may influence results. Bias exists because these patients self-selected out of the opportunity for screening. Kim et al. (2010)

compared SSI rates between carriers and non-carriers during the study period, giving some insight into the non-intervention, non-historical control subjects in the study group, rather than only comparing with the historical controls. All participants in the study were matched by age and gender. Buehlmann et al. (2008) compared the proportion of patients positive on admission to those positive following decolonization. There was no control group. Without a control group the results may have been influenced by extraneous variables. Lee et al. (2011) compared characteristics of the cases to controls to determine factors influencing persistent MRSA colonization related to mupirocin and CHG use.

Outcome Measures. Decolonization of patients who were MRSA positive on admission and the effect on SSI rates was described in five of the studies (Kim et al., 2010; Gupta et al., 2011; Yano et al., 2009; Hadley et al., 2010; Price et al., 2008). In each of these studies SSIs were determined using the standard National Healthcare Safety Network (NHSN) surveillance definitions. These definitions limit an SSI to within 30 days past surgery, or up to one year from surgery if the case involved an implant. In addition, the definitions determine the depth of the infection: superficial, deep, or organ/space. A superficial infection cannot occur after 30 days from the day of surgery.

Carrier status following decolonization was an outcome measure included in three of the studies (Kim et al., 2010; Buehlmann et al., 2008; Lee et al., 2011). Age, previous hospitalization, and antimicrobial use were some of the variables associated with persistent colonization. Age is also a factor associated with the need for joint implant surgery. The risk of an SSI may be reduced for an older person having joint replacement surgery if decolonization is successful in the presence of these variables. Buhlmann et al. (2008) reported decolonization was “highly effective” when patients completed the entire course of treatment. Completion of

decolonization treatment may be more easily accomplished within the hospital setting where it is essentially a directly observed therapy.

Results. There was a significant decrease in SSI rates with decolonization in the studies conducted by Kim et al. (2010), Gupta et al. (2011) and Hadley et al. (2010). Kim et al. (2010) found the SSI rate during study period lower than in control period (59% reduction rate, $p=0.009$). Gupta et al. (2011) found a positive pre-op MRSA culture significant for positive post-op culture ($p<0.001$), for a MRSA SSI ($p=0.01$), and for other post-op infections ($p<0.01$) unadjusted. Yano et al. (2009) found one is 11 times more likely to have an MRSA SSI if prescreening was positive (adjusted OR 11.0, 95% CI (3.0-37), $p<0.001$). Lee et al. (2011) found age, combined mupirocin and CHG resistance, hospitalization within two years, wounds/ulcers, MRSA inactive antibiotic use, and central lines to be independent risk factors associated with persistent colonization and decolonization failure. The study by Price et al. (2008) revealed 30.3% subjects (86/284) to be colonized with *S. aureus*, five of which were MRSA (6%). Of the 284 patients screened in two years, 1.8% were colonized with MRSA. Buehlmann et al. (2008) found decolonization completed in 87% (54/62) patients with a mean of 2.1 and a SD±1.8.

Validity is a question in the study by Hadley et al. (2010). From the results section (Hadley et al., 2010, p.2) in the article:

> During the study period, 2058 patients were included in the study. There was complete follow-up in this retrospective study of prospectively collected data. The total number of treatment patients was 1644 patients (80%) and 414 (20%) in the control group. At the onset of the study the proportion of the preadmission testing (PAT) treatment group was roughly equal. However as the study progressed the protocol was quickly adopted by all surgeons and the non-PAT patients decreased significantly.

The treatment group had approximately four times the number of patients as the control group. Only deep SSIs were reported in the outcome data, superficial and organ/space (joint) infections

were not. The reported 13% decrease in deep SSIs in the treatment group versus the control group was not significant at the reported p value of 0.809, but does represent a favorable trend. There was no discussion about adjusting statistically for the confounder of surgeons adopting the protocol outside of the study parameters.

Synthesis of the Evidence Related to the Clinical Question.

These studies have clinical significance because MRSA decolonization in adult patients undergoing total hip and total knee arthroplasty may reduce SSIs when compared to the standard of care. Decolonization has not been recommended in the past except in outbreak situations or for use with specific populations, in this case adults scheduled for elective joint replacement.

The articles assembled in the literature review contain evidence suggesting that prescreening and eradication of nasal MRSA is a practical action to consider. It has been previously stated that SSIs increase morbidity and mortality. Yet, SSIs are preventable and one approach may be prescreening and decolonization. All articles that discussed decolonization favored it. Five of the seven articles reviewed were specifically written to address decolonization and SSI prevention in patients scheduled for orthopedic surgery. Completing the full treatment course was noted to make decolonization "highly effective" by Buehlmann et al. (2008, p. 501), although the article was not written related to orthopedic surgery, but to overall hospital admits.

The study by Lee et al. (2011) cautioned against widespread use of the antimicrobial and skin disinfectants. The authors found resistance to those products significantly increased the risk for persistent nasal MRSA colonization following treatment to eradicate it. It is noted in the article that the study site had been using mupirocin and CHG to decolonize patients since 1994 (Lee et al., 2011, p. 1423). Antimicrobial stewardship is a large part of the mission of the

Infectious Disease Section and an Antimicrobial Subcommittee at the facility where the project was implemented. Decolonization and resistance always merits close monitoring.

In spite of the inconsistencies noted above there is sufficient evidence in the literature reviewed for this paper to attempt prescreening and decolonization for adult patients undergoing total hip and total knee arthroplasty. Prescreening and decolonization can be an effective prevention strategy that may be adopted as a change in institutional protocol, and thus a change in a system in the population served by this project. Surgeries involving implants are high risk surgeries. Surveillance cultures for MRSA are collected on admission, transfer, discharge and death under an existing directive at this facility. Decolonization and monitoring of infection is more easily done because of this. MRSA decolonization as a part of a pre-operative protocol could increase positive post-operative outcomes and assist in decreasing the MRSA burden hospital wide.

Additional Evidence

National practice guideline review. The National Guideline Clearinghouse, Cochrane Reviews, and the Association of Professionals in Epidemiology and Infection Control (APIC) were accessed online in the search process. Search terms used included MRSA infection and preventing surgical site infection as topics or diseases. Three related documents were found: Clinical Practice Guidelines by the Infectious Diseases Society of America for the Treatment of Methicillin-Resistant *Staphylococcus Aureus* Infections in Adults and Children (Liu et al., 2011), Guide to the Elimination of Methicillin-Resistant *Staphylococcus aureus* (MRSA) Transmission in Hospital Settings (APIC, 2010), and the Guide to the Elimination of Orthopedic Surgical Site Infections (APIC, 2010). Guideline documents selected for this literature review are included in the attached Table 2 (Appendix C).

The Guide to the Elimination of Methicillin-resistant *Staphylococcus aureus* (MRSA) Transmission in Hospital Settings (APIC, 2010) addressed nasal decolonization. Decolonization is not routinely recommended; but indicated for certain situations such as in an outbreak setting, or to eradicate carriage in patients with recurrent infections, and in colonized MRSA patients undergoing a surgical procedure identified as high risk for a MRSA SSI (APIC, 2010). Decolonization was described as:

> The use of a variation of the following regimen for adults: Nasal decolonization with 2% mupirocin ointment applied to the nares twice a day for five days; AND, Skin antisepsis with chlorhexidine or hexachlorophene for 5 days applied per manufacturer's instructions (APIC, 2010, p. 62).

The document reports decolonization may be indicated for patients undergoing surgeries with implants including cardiac, orthopedic, vascular and neurosurgical procedures (APIC, 2010).

The Guide to Elimination of Orthopedic Surgical Site Infections (APIC, 2010) reports, "*Staphylococcus aureus*, particularly MRSA, remains a significant pathogen in postoperative orthopedic SSIs (APIC, 2010, p. 39). Decolonization is discussed as an option for orthopedic surgery patients. The authors urge that decolonization strategies and protocols be standardized, and suggest order sets and pathways as two potential ways of achieving this end (APIC, 2010).

The Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA) for the Treatment of Methicillin-Resistant *Staphylococcus Aureus* Infections in Adults and Children (Liu et al., 2011) is an evidence-based guideline providing recommendations for management of MRSA infections in adult and pediatric patients. Multiple clinical syndromes are discussed including bone and joint infections. Decolonization was not addressed related to management of bone and joint infections. It was discussed concerning skin and soft tissues infection. The authors report an association between mupirocin and a decrease in hospital-

acquired *S. aureus* infections in patients undergoing surgical procedures or receiving dialysis (Liu et al., 2011). The guideline lists recommendations for decolonization followed by a summary of the evidence.

The IDSA guideline was appraised using the AGREE II online tool (Brouwers et al., 2010) [Appendix D]. The document is succinct with clearly written definitions, and based on evidence of best practice. A standard procedure was used by the IDSA panel to grade the recommendations and weigh the quality of evidence used in the development of the guideline. There was an external peer review of the draft document which was reviewed and approved by multiple professional organizations These steps contribute to the validity and reliability of the document and it's applicability to the practice setting. Options and alternative treatments are discussed demonstrating clinical flexibility.

There are some limitations to the IDSA guidelines. Although the domain of Rigour of Development received the highest score at 46 points, PubMed was the only computerized database searched for literature and the search was limited to English-language only. The domain Stakeholder Involvement scored the lowest at 11 points. Patients and providers are identified as the target population however no statement is included as to whether the views and preferences of patients/public were considered while the document was being developed. It is unclear whether multiple disciplines were involved in developing the document as the author's titles are not identified. No plans were offered for future review and update.

This guideline is recommended for providers. Guideline sections begin with a clinical practice question followed by graded recommendations and a weighted quality rating. A summary of recent evidence supporting the recommendation completes the discussion of each question. Clinical applicability and patient-centered care are addressed throughout the

document. There is also a statement about voluntary adherence to the guidelines. Providers are encouraged to consider individual patients and specific clinical situations, recognizing that this guideline is not the only option for providing quality patient care. Further, antimicrobial use is not the only intervention that is recommended. Prevention education messages about personal hygiene and wound care are included as suggested strategies. There is discussion about not sharing or reusing personal items. Environmental hygiene measures are also described as effective interventions for patients. At the close of the document a section on Research Gaps examines areas of limited or conflicting data, and the need for additional research on certain topics. The guideline is worth referencing when managing MRSA infections in adults and children. It is valid, reliable and applicable to many practice settings.

Systematic reviews. Two systematic reviews will be addressed in this section: (McGinigle, Gourlay, & Buchanan, 2008; van Rijen, Bonten & Kluytmans, 2008). These are included in Table 3 (Appendix E). McGinigle et al. (2008), found evidence from several studies that collecting ASCs decreases the incidence of MRSA infection. However, the authors concluded that the evidence was of poor quality and reported no definitive clinical recommendations could be made.

The objective of a review by van Rijen et al. (2011) was to determine whether the use of mupirocin nasal ointment in patients identified with *S. aureus* nasal carriage reduced *S. aureus* infection rates. In this review an extensive literature search focused on RCTs regardless of language or publication status (Table 3, Appendix E). Nine RCTs were selected. Patient population, interventions and outcomes are described in detail. Seven of the nine studies were double-blind RCTs with four of the seven rated high quality for including blinding, intention-to-treat, and report of loss to follow-up in addition to the double-blind. Bias was well controlled for

in the study designs. The use of mupirocin in nasal carriers resulted in a statistically significant decrease in *S. aureus* infections (van Rijen et al., 2008). Two studies were deemed low quality. Outcomes were examined individually and combined across the studies when appropriate (Table 3, Appendix E). Applicability to clinical practice is articulated throughout this article, most strongly in the authors' conclusions. Their conclusions were reported as implications for practice and implications for research. The practice implications concluded by the reviewers are that in confirmed nasal carriers, mupirocin use should be considered in hospitalized patients undergoing surgery or dialysis, and that limited use of mupirocin does not appear to be associated with antimicrobial resistance (van Rijen et al., 2008). The research implication gleaned from this systematic review is that the effectiveness of mupirocin is related to carriers alone. Rapid tests to confirm and differentiate MRSA and Methicillin-Sensitive *S. aureus* (MSSA) were discussed. These important diagnostic tools will enable providers to treat carriers in real time, within hours as opposed to days using standard culture technique. Rapid tests also influence proper antibiotic selection for patients (van Rijen et al., 2008).

Ranking and type/level of evidence. Three clinical guidelines, two systematic reviews and three original research articles were ranked by level of evidence and quality. Level of evidence criteria are taken from Melnyk & Finehout-Overholt (2011, p.12), and are listed below Table 4 (Appendix F). Criteria used to assess quality are derived from the United States Preventive Services Task Force (2008) which are also noted in Appendix F.

All documents examined MRSA colonization in one or more of four ways: identification (screening), preventing, treating and eliminating (decolonizing). Discussion of decolonization was common to all articles. While none of the authors supported routine decolonization, all discussed it as part of an intervention program. Intervention programs are indicated for MRSA

outbreaks or for certain at-risk populations (APIC, 2010; APIC, 2010; Liu et al., 2011, van Rijen et al., 2008). The strength of the evidence for pre-screening and decolonization is low to moderate and of fair quality (Table 1, Appendix B; Table 2 Appendix C; Table 3, Appendix E). In part this is related to the lack of RCTs, a standardized decolonization protocol, concerns about possible resistance to mupirocin, and lack of outcome data about reduction of infection rates (Liu et al., 2011). Further research is needed to add to the body of evidence and address these concerns.

Integration of literature review. MRSA decolonization in adult patients undergoing total joint replacement may reduce SSIs. Recent studies (Kim et al., 2010; Yano et al., 2009; Hadley et al., 2010; Price et al., 2008) favor prescreening and decolonization as a preventive measure for patients scheduled for orthopedic surgery (Table 1, Appendix B). According to the APIC Guide to the Elimination of Methicillin-resistant *Staphylococcus aureus* (MRSA) Transmission in Hospital Settings (2010, p. 61), "Decolonization regimens may be indicated for both nasal MRSA and *S. aureus* colonization in patients undergoing vascular surgery with placement of a graft, total joint arthroplasty, and neurosurgical procedures with implantation of hardware as well as other surgical procedures."

The IDSA Clinical Practice Guidelines for the Treatment of Methicillin-Resistant *Staphylococcus Aureus* Infections in Adults and Children do not offer recommendations for decolonization related to orthopedic surgery or bone and joint infections, but do for MRSA skin and soft tissue infections. The recommendation suggests decolonization with mupirocin twice daily for 5-10 days as a strategy, and that it is offered with education and reminders about hygiene (Liu et al., 2011). It is disappointing that the recommendation has a CIII rating which is defined as "poor evidence to support a recommendation for or against use" as the "evidence is

from opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees" (Liu et al., 2011, p.52). This is of interest as the literature review and analysis section for the IDSA document states: "There were few randomized clinical trials; many recommendations were developed from observational studies or small case series, combined with the opinion of expert panel members" (Liu et al., 2011). The basis for the IDSA document is exactly what was identified as not supporting evidence-based practice.

In a Cochrane review, van Rijen et al. (2008) concluded that decolonization with mupirocin in *S.aureus* nasal carriers resulted in a significant reduction in *S. aureus* infections. This systematic review also found a significant reduction in infection rates in surgical and dialysis patients in a subgroup analysis. However, when SSIs were analyzed as the primary outcome the result was not statistically significant (van Rijen et al., 2008).

An additional finding of van Rijen et al. (2008) was that mupirocin resistance should not be an issue following short-term intranasal use for surgical or dialysis patients. Caution is still recommended related to this as Lee et al. (2011) reported genotypic CHG resistance alone did not predict persistent MRSA carriage. CHG and mupirocin are often used simultaneously to decolonize or eradicate MRSA. This suggests that a combination of low-level mupirocin and CHG resistance may be required to result in failure to eradicate MRSA. Persistent colonization was also discussed by Buehlmann et al. (2008). This group determined their standard decolonization protocol was highly effective when the full treatment course was completed. Their treatment regimen was complex, including intranasal mupirocin ointment, CHG mouth rinse and CHG full-body washes, all applied for five days (Buehlmann et al., 2008).

Researchers continue to investigate MRSA decolonization. Many favor this approach for certain patient populations. Prescreening and decolonization is a prevention strategy that could

be easily implemented for orthopedic patients scheduled for total joint replacement. Reducing MRSA SSIs is an important goal. Decolonization is an intervention to consider.

Summary of recommendations from the literature review. The summary recommendation is: there is sufficient evidence in the literature to implement prescreening and decolonization of MRSA in adult patients undergoing joint replacement surgery. Recent studies (Kim et al., 2010; Yano et al., 2009; Hadley et al., 2010; Price et al., 2008) favor prescreening and decolonization as a preventive measure for patients scheduled for orthopedic surgery (Table 1, Appendix B). Intervention programs are indicated for MRSA outbreaks or for certain at-risk populations (APIC, 2010; APIC, 2010; Liu et al., 2011, van Rijen et al., 2008). A Cochrane systematic review and APIC Guideline documents (Table 2, Appendix C) define orthopedic surgery patients as at-risk populations for MRSA infection if colonized preoperatively (van Rijen et al., 2008; APIC, 2010; APIC, 2010).

Implementation of the summary recommendation requires the following steps: 1) collection of an admission nares swab to screen for MRSA (Appendix G); 2) the lab notifies the anesthesia workroom (Appendix H); 3) appropriate antibiotic prophylaxis is administered (vancomycin instead of cefazolin); 4) first dose of mupirocin is administered in the OR; 5) postoperative mupirocin and vancomycin are ordered. Step 1) is required at the facility where the project was implemented under an established policy. Step 2) is referenced in the system review by van Rijen et al, "Recent technological advances in rapid diagnostics have provided the ability to detect nasal carriage of *S. aureus* within hours rather than days which makes it possible to treat nasal carriers rapidly" (2008, p. 14). Step 3) is referenced in the Guide to Elimination of Methicillin-Resistant *Staphylococcus aureus* (MRSA) Transmission in Hospital Settings, "The use of systemic antimicrobials for MRSA decolonization may be considered by the patient's

healthcare provider if deemed clinically appropriate" (APIC, 2010, p.62). Gupta et al. (2011) reported the risk of vancomycin administration preoperatively in nares positive patients was protective, but additionally state an association for this subgroup is not conclusive given the wide confidence intervals for this variable.

Step 4) Successful decolonization beginning on the day of surgery as opposed to five days preoperatively is being implemented. Liu et al. (2011) reported, "While awaiting guidance from ongoing clinical trials, the Panel suggests mupirocin alone or a combined strategy of mupirocin and topical antiseptics (e.g., chlorhexidine and diluted bleach baths) if decolonization is being considered. The optimal dosage and duration of such regimens is unknown; suggested dosages are based on several ongoing clinical trials" (2011, p. 18). Step 5) is supported by the evidence from the literature addressed under Step 3).

Methicillin-Resistant *Staphylococcus aureus* SSIs have been identified as a risk to patients colonized with MRSA, and planning joint replacement surgery (Kim et al., 2010; Yano et al., 2009; Hadley et al., 2010; Price et al., 2008). This postoperative complication impacts health outcomes for patients in terms of morbidity and mortality (Gupta et al., 2011). Methicillin-Resistant *Staphylococcus aureus* SSIs also contribute to increased length of stay and rising costs in health care (Anderson et al., 2009). Decolonization may be an additional strategy to make total joint replacement surgery safer for patients.

Conclusion. The literature supports a systems change project that will implement a program to preoperatively screen the nares of orthopedic patients presenting for joint replacement surgery at the facility. Admission screening will identify the presence of MRSA. Those patients with positive results will be decolonized prior to or at the time of surgery, because they are at an increased risk of surgical site infections with a permanent implant. Mupirocin

ointment will be the drug used for decolonization, and intravenous vancomycin will be the drug given as preoperative antibiotic prophylaxis.

Chapter 3

Project Design and Methodology

This SCP implemented a program to preoperatively screen the nares of patients presenting for TKA or THA surgery at a Midwest teaching hospital. Screening identified whether MRSA colonization was present or not. Those patients with positive results were decolonized at the time of surgery, because they were at an increased risk of SSI as they were undergoing surgery for a permanently implanted prosthetic device. The data was analyzed to determine the differences between the two groups. Cases were compared to controls who underwent the same procedure but who were not decolonized for MRSA, to determine whether decolonization was a factor in preventing SSIs at 90 days postoperatively.

Data handling and record keeping. A proposal for this project was reviewed and approved by the facility IRB. The St. Catherine University IRB reviewed the facility IRB file and granted approval as well. A waiver for informed consent was obtained from the facility IRB as part of the approval process. Since the project was a retrospective chart review it was not possible to contact all the subjects to obtain consent. Chart review presented a minimal risk of loss of confidentiality and an adequate plan was developed to protect identifiers.

Compliance with HIPPA regulations was met. Lists of subjects were coded. The links for the coded lists were maintained in a locked cabinet in a double locked office available only to the research team. Data was entered into a spreadsheet stored on a personal drive on a secure computer. The computer was accessed with a personal identity verification card and password. The facility's firewall and all other security measures applied to the computer. When data was shared with research staff a secure share drive was used. No conflict of interest was identified

for anyone on the research team. When the data collection was completed and entered into the spreadsheet, the identifying link to the subjects was destroyed.

Selection of subjects. The project was a retrospective case-control study of patients at the facility who were MRSA screen positive preoperatively, began decolonization on the day of surgery, and underwent total hip or total knee surgery from May 1, 2012 through May 1, 2013. Cases were identified from a convenience sample of 299 patients undergoing THA or TKA surgery during the same time period. The controls were selected from patients undergoing THA or TKA surgery at the facility from May 1, 2009 through September 1, 2011. Controls were matched by age (+/- three years), gender (M/F), type of procedure (THA/TKA), and location of the surgery (right/left side of the body). Age inclusion criterion for cases and controls was that patient be 18 years of age or older. While randomization of subjects was not directly applied in this project, the historical controls were selected from a database that does utilize a randomization process.

Project intervention. Admission nares swabs were submitted to the Microbiology lab. Analysis was performed utilizing Polymerase Chain Reaction (PCR). PCR analysis is only utilized for admission nares swabs at the facility unless specifically ordered otherwise. Specimens were collected using Copan swabs. The Cepheid GeneXpert® Infinity-80 System is the analyzer that will be employed by laboratory staff to determine the results of the nares swabs.

Mupirocin ointment was the drug used for decolonization, and intravenous vancomycin was the drug given for pre-operative antibiotic prophylaxis. Mupirocin was applied twice a day to the patient's nares for a total of five days. The initial dose was applied by a certified registered nurse anesthetist (CRNA) in the operating room. Nursing staff or patients themselves applied the mupirocin twice a day for the three days on average that the patient was hospitalized.

The patients continued applying the mupirocin two times daily for the remaining two days at home to complete the total of five days.

Observations and definitions. Chart review was used for data collection. Data collection included demographics, details of antibiotic use, surgery type and conditions, laboratory results, comorbidities and type of surgical site infection. Secure facility approved computer access was used to review the electronic medical record. Patient data were identified by a coded number to protect confidentiality.

SSIs were identified using definitions and criteria from the CDC NHSN, "Surgical Site Infection (SSI) Event" portion of the "Procedure-associated Events" section of the National Healthcare Safety Network (NHSN) Manual Patient Safety Component (CDC NHSN, 2013). Definitions from the Veterans Affairs Surgical Quality Improvement Project (VASQIP) were used with permission as criteria for all other variables (Mark A. Wilson, MD, personal communication, July 7, 2012).

Subject population for analysis. The estimate for enrollment size was based on the number of total hip and total knee surgeries seen per month in fiscal year 2011. The projected number was predicted to be between 300 and 330 patients. Case subjects were compared to control subjects undergoing the same procedure, but who were not decolonized for MRSA. The study was terminated following the collection and analysis of the data.

Statistical analysis. Characteristics of cases and controls were compared on categorical variables using Chi-square statistics. Fisher Exact tests were used when expected cell frequencies are less than 5. For continuous variables, independent group t-tests were be used for comparisons. Evaluation of change in infection rates pre to post surgery was done using the

Wilcoxon test. For those cases or controls with colonization pre surgery, Chi-squared tests, and logistic regression, when possible, were used to examine predictors of infection postoperatively.

Introduction of an unforeseen confounder. A confounding factor was introduced four months prior to the completion of the project. Another study was implemented using the same patient population, patients undergoing THAs and TKAs, but with a different intervention. This may have introduced potential for bias, although it is unlikely.

Evidence-based Project Implementation Plan

Timeline. The timeline for the project was May 1, 2012 through May 1, 2013. Case data was collected retrospectively following those dates using chart review for known MRSA positive or patients positive for MRSA on admission and undergoing THA or TKA surgery during that period of time. Control data was collected using retrospective chart review of patients undergoing THA or TKA who were not MRSA positive preoperatively from May 1, 2009 through September 1, 2011. IRB approval for the project lasts for one year from the initial date of approval until February 14, 2014.

Resources—personnel, technology, budget, return on investment (ROI). Quality health care is of vital concern to individuals in the United States (U.S.) and to the country's economy. In 2008, per capita health care costs were $7,681, compared with individual costs of $356 in 1970 (Weisfeld, 2011). During that same year the total cost of U.S. health care was $2.3 trillion, with payments coming from multiple sources such as private insurance, payment out of pocket; and public funding from federal, state and local entitlement programs (Weisfeld, 2011). Stone (2010, p. 30) reports: "In fact, healthcare spending is growing at a faster rate than that of our economy overall."

An important source of health care expenditures is surgical site infection (SSI) following total hip arthroplasty (THA) or total knee arthroplasty (TKA). Courville et al. (2012) documented the cost of a total joint revision surgery related to a deep infection as being about $100,000; 3-4 times the cost of an initial THA or TKA. Lentino (2003) reported the cost of a THA or TKA SSI at approximately $50,000.

According to Lee et al. (2010), around 35% of Americans are carriers of *Staphylococcus aureus*. The authors note colonization rates of Methicillin-resistant *Staphylococcus aureus* (MRSA) of 0.4% to 20.6% have been reported in the literature and that orthopedic surgery patients are at risk for MRSA SSIs (Lee et al., 2010). Decolonization is an existing strategy to provide/supply THA and TKA surgery with a decreased risk of MRSA SSIs.

Kurtz, Lau, Watson, Schmier, and Parvizi (2012) note that in 2010, it was expected that approximately 8,136 infections related to hip prostheses and 17,781 infections related to knee prostheses would occur. Projections for 2020, suggest 16,584 infections related to THAs and 48,971 related to TKAs may develop (Kurtz et al., 2012). These figures translate into an estimated cost to U.S. hospitals of nearly $1.62 billion in 2020 and an estimated cost of nearly $1 billion by 2014 (Kurtz et al., 2012). The trend has been that each year individuals, private and public health care organizations and insurers face scarcer resources. In addition, the Patient Protection and Affordable Care Act (PPACA) will result in 32 million more Americans having health insurance (Knickman, 2011).

An expectation is that more Americans with health insurance will create an increased demand for health services overall, two of which may be THA and TKA surgeries. This effect would demonstrate moral hazard, electing to have a surgery one may not have had in the past

when uninsured. If having health insurance is viewed as a type of income increase, the demand for surgical services will likely increase as well.

The goal of this systems change project was to determine the short term success of MRSA decolonization beginning on the day of surgery, and to determine whether decolonization at the time of surgery was effective in reducing the rate of SSIs for patients having THA or TKA surgery at a Midwest hospital as a quality improvement project. The nares of patients admitted for THAs or TKAs at the facility were swabbed to identify the presence of MRSA. This screening was not a new expense as it has been done for all facility patients on admission, transfer, discharge and death since 2006. Patients with newly positive MRSA results and known positive patients were decolonized at the time of surgery because they were at increased risk of a MRSA SSI by undergoing surgery resulting in a permanent implant. Mupirocin ointment was the drug used for decolonization and intravenous vancomycin was the drug given for preoperative antibiotic prophylaxis. The patients' nares were also swabbed at discharge, again, not a new expense as done for all discharges since 2006. The results of the swabs were compared to determine temporary decolonization. Surveillance for THA and TKA SSIs was done for 90 days postoperatively.

The market for this project consisted of patients electing to undergo THA or TKA surgery at the facility (buyers) and the interdisciplinary group of health care providers involved in orthopedic surgery at the facility (sellers). Decolonization was not "new" technology per se, but could be viewed as a supply shifter related to increasing the quality outcomes associated with THA/TKA surgery. More positive outcomes would likely increase the supply of these surgeries.

Fixed costs associated with this project were the number of patients having THA/TKA surgery (which does not change greatly from year to year), utility costs, and software used

related to the electronic health record. Some variable costs include medical supplies for lab work, drugs and the cost THA/TKA prostheses. The need to quarantine instrumentation was a variable cost. Vendors may or may not be on a tight schedule providing instrumentation to multiple hospitals.

THA/TKA surgery has associated direct medical costs including imaging and prosthetic devices, and direct nonmedical costs such as copays and other out of pocket expenses. There are also intangible costs to the patient such as anxiety, localized pain, deconditioning and decreased mobility related to the procedure. There are indirect costs such as lost work and family time.

Project costs are listed in Table 5, the cost spreadsheet (Appendix I). Included are the costs of developing the protocol and templates for the project, staff education (such as time for employee attendance and for the educator), and initial administrative costs. There were no program material costs, room rental costs, or travel and lodging costs. Project benefits are measured in terms of avoided costs: admission and discharge labs (Appendix J) are routinely collected at the facility; and averted costs: the estimated cost of a single THA/TKA SSI. An explanation of the ROI calculation, which was favorable, is found in Appendix K. Generally, if the calculated ROI of a project is greater than zero it is considered reasonable to proceed with the project.

A present value calculation was not discussed with stakeholders during the project development process but was examined for this paper. Appendix L contains a representation of present value over a five year time period assuming the medical cost avoided is $50,000, if one SSI is prevented. This would amount to $216,473.83 in savings in present value terms.

Continuous quality improvement was well served by the implementation of this project. Patients colonized with MRSA received a more appropriate prophylactic antibiotic and were

attempted to be temporarily decolonized during the perioperative and immediate postoperative period when the risk of SSI is the greatest. Decolonization of MRSA positive THA/TKA patients not only decreased the risk of SSI for the project patients but decreased the MRSA burden in the hospital overall as well with temporary decolonization.

Preventing infection is about quality of care and patient safety. It can also be about costs avoided/averted, loss reduction (e.g., decreased length of stay) and even profit. Decisions are made about projects such as this one and strategies are implemented. Outcome evaluation data determines whether expectations are met. This cost benefit analysis is an attempt at making a business as well as a clinical case for preventing SSIs through the use of screening and decolonization.

Support from site. The facility had the resources to support the decolonization project. However, although the hospital epidemiologist, the chief of surgery, and the chief of orthopedics were in favor of the project, a limitation was that the residents rotate approximately every two months which impacted continuity of the project. The chief of orthopedics and the orthopedic nurse coordinator included education about this protocol during the resident orientation and emphasized the importance of adherence to the protocol. The protocol itself was added to the orthopedic resident handbook. This action added to the project's feasibility. The scalability of the project involved the orthopedic team, one nursing unit pre and postoperatively and the operating room staff assigned to THA/TKA surgeries.

This project was considered a pilot study. It has been continued beyond the pilot phase as there is an increasing body of evidenced-based literature to support preoperative MRSA decolonization (van Rijen et al., 2008; Lonneke et al., 2010; Courville et al., 2012; Lee et al.,

2010). Costs should not expand greatly beyond increases for drugs and lab related to those described in Appendices I, J, and K.

Ethical considerations. Universal screening was implemented to determine the MRSA status of patients. In order to meet a standard informed consent, patients were allowed to make the choice about whether or not to consent to a treatment or procedure. This applied to MRSA screening on admission. The universal screening strategy was implemented under an existing directive, which ensured the risks and benefits of the screening procedure were discussed with every patient on admission. This discussion included how the results of the swabs were used, and how the results when positive affect patient care, for example, contact precautions were implemented. The MRSA screening program promoted the principle of the greatest good for the greatest number of people as one part of a bundled approach to decrease the MRSA burden facility-wide and thus decrease the risk of transmission for patients who were not MRSA colonized. Careful consideration of these measures established safe, quality patient care within the practice of active MRSA surveillance.

Conclusion. Many of the human and financial assets required for this project were already in place at the facility. Positive outcomes from this project should conserve existing resources. Reductions in length of stay may occur, related to a decrease in SSIs. The overall facility burden of MRSA should decrease. Mortality may decline as well. Successful decolonization has the potential to result in improved patient-centered quality care and a favorable return on investment.

Chapter 4

Data Analysis.

During the study period 299 patients underwent THA or TKA procedures. Ten (3.5%) of 299 patients were positive on admission for MRSA. Four historical controls were selected for each case for a total of 40 controls. Controls were matched by age, gender, type of surgery, and location of surgery. Only one control was MRSA positive on admission.

Project Evaluation: Evidence-based Methodology and Analysis. Comparisons were made between the 10 cases who underwent decolonization for MRSA and 40 control subjects who did not. By definition all 10 of the cases were positive for MRSA prior to surgery. One of the control subjects was positive for MRSA on admission. The remaining 39 controls were not. All subjects were male and were operated on during the day of admission. None had acute renal failure, were on dialysis, or had chronic obstructive pulmonary disease (COPD). The mean age was 62.9 and mean body mass index (BMI) was 31.9 (Appendix M).

Chi-squared tests were used to compare the two groups on surgery type, surgery side, duration of surgery, ASA score, length of pre-operative stay, type of pre and post-operative antibiotic used, use of mupirocin, diabetic condition, tobacco use, preoperative albumin level, use of tranexamic acid, history of MRSA infection/colonization, MRSA colonization at discharge, SSI identified at $\leq$ 30 days from surgery, and at $\leq$ 90 days from surgery (Appendix N).

Findings (Appendix O) showed that case patients were significantly more likely than the control patients to have a history of MRSA colonization/infection prior to admission for surgery (Fisher's Exact=.001), and no MRSA colonization at discharge (Fisher's Exact=.022). There was a significant difference in pre-operative antibiotic use, with 85% of control patients receiving cefazolin and 70% of case patients receiving vancomycin ($X^2(2)=32.8$, $p<.001$). Use

of mupirocin was also significantly higher in case subjects at 70% compared with no use in control patients ($X^2(1)=32.6.p<.001$). Only case patients received tranexamic acid (40%), while none of the control subjects did (Fisher's Exact=.001). Finally, 80% of the control subjects were receiving no treatment for diabetes where 80% of cases were receiving either dietary or medicinal treatment for diabetes ($X^2(3)=15.0$, $p<.002$). No other significant differences were observed. Analyses of variance found no difference in age or BMI across the groups.

MRSA colonization in the cases was reduced from 100% to 30% pre to post surgery (Wilcoxon Signed Ranks Z=2.65, p=.008). The impact of tranexamic acid on postoperative colonization was also examined. No significant difference was found with use of tranexamic acid among those colonized postoperatively and those not colonized. Observation of site infection at 30 and 90 days postoperatively found only two patients, both controls, with a SSI. One SSI was revealed at postoperative day 10 and one at postoperative day 82. Different pathogens were identified.

Conclusion. Of the 11 patients with pre-operative MRSA colonization various predictors of postoperative infection were examined. However, the small sample size precluded meaningful inferential statistical tests related to these variables. Descriptively, two of the three patients with MRSA colonization on discharge had knee surgery lasting over two hours. Two of the three patients remaining colonized on discharge also received cefazolin rather than vancomycin postoperatively. Only one of the three patients remaining colonized on discharge received mupirocin. Two of the three colonized on discharge received tranexamic acid in the perioperative period.

Chapter 5

Discussion of Findings and Outcomes

Nasal colonization of MRSA may increase the risk of SSI in patients undergoing total joint replacement surgery such as THA or TKA. A growing body of literature exists related to the topic of MRSA and SSI as a complication of Orthopedic surgery (Kim et al., 2010; Gupta et al., 2011; Yano et al., 2009; Hadley et al., 2010; Buelmann et al., 2008). There is evidence in the literature supporting preoperative decolonization for patients planning to undergo surgery with a permanent implant.

While there is evidence favoring preoperative decolonization, no standard protocol exists. Much of the literature describes beginning the decolonization process at five days before surgery. This project sought to determine whether patients scheduled to undergo THA or TKA surgery could be temporarily decolonized by implementing a protocol beginning on the day of surgery. The project also examined whether patients were identified with a SSI within the postoperative period as defined by the NHSN. Demographic data, procedure-related data, and other risk factor data potentially associated with SSIs were also examined.

Some difference between the cases and controls varied widely when considering particular variables. While 50% (5/10) of the cases had a history of MRSA infection/colonization prior to admission for surgery, none of the controls (0/40) did. Because historical controls were used, only eligible case patients received tranexamic acid in the perioperative period. Eighty percent of the cases were found to use dietary restrictions, oral medications, or insulin injections to control diabetes; while 80% of the controls did not as they did not have a diagnosis of diabetes. No SSIs were identified from 0 to 90 days in the cases. Two SSIs were identified from 0 to 90 days in the control group.

There was no difference in mean age (62.9 years) between the cases and controls as matching age within three years was one of the selection criteria for controls. BMI data was very similar for both groups with the mean BMI for the cases at 33.19 kg/m², and at 31.67 kg/m² for the controls. There were no odds ratios to examine because the small number of observations prohibited a regression analysis. An additional factor of interest that was not significant, yet emerged from the analysis was that 100% (10) of the cases had an ASA score of 3, while only two-thirds of the controls 67.5% (27) of the controls were assigned an ASA score of 3.

The findings of this pilot project suggest that beginning decolonization on the day of surgery may be a reasonable approach given that 7 of the 10 cases had negative MRSA swabs at discharge. Project results also demonstrate the need for further research about the benefits of MRSA decolonization related to THA and TKA surgery and preventing SSI. In addition, the findings lend support to the preliminary work and outcomes of other researchers such as Buehlmann et al. (2008), who found that MRSA decolonization was successful when individuals completed the full treatment course. It may be that beginning decolonization on the day of surgery and continuing the process while the patient is hospitalized creates a supportive environment that assists the patient in obtaining a positive outcome.

The results of this project are also consistent with those of Kim et al. (2010), who found that it is feasible to implement a facility-wide prescreening program to identify and eliminate MRSA colonization in patients undergoing orthopedic surgery. In addition the authors found a significant decrease in SSIs. That finding was not demonstrated with this SCP as the limited number of subjects prohibited such a statistical analysis.

Methodological issues must be addressed to guide similar projects about decolonization in the future. Since the convenience sample was limited to only one Midwestern teaching

hospital, the findings are not generalizable to patients in all hospital settings. A possible solution would be for multiple hospitals from different regions to participate in a similar study to assist in overcoming this limitation. Access to a larger sample size would also make a significant contribution towards obtaining meaningful results.

Another factor to consider when developing a future proposal would be to include a screening swab at a three or four month postoperative appointment to determine the sustainability of the temporary decolonization. This knowledge is of importance to Infection Preventionists as NHSN SSI surveillance for THA and TKA procedures now extends for 90 days rather than the previous one year following a procedure (CDC, 2013). With large enough sample sizes it may be possible in the future to examine whether there is an association between decolonization and prevention of MRSA SSIs.

While no effect was demonstrated statistically related to this project, the concurrent study with the same patient population must be addressed as an unforeseen confounding factor. Communication among investigators about other active or proposed studies is critical in avoiding the addition of such a confounding factor. Close inter-relationships may result in both variables appearing weaker and unnecessarily compromising results.

Conclusions

Patient safety and satisfaction, evidence-based quality care outcomes, costs of an SSI, and making good use of scarce resources were the driving forces for change with this project. The system change of decolonizing THA and TKA patients on the day of surgery appears to have been successful although the number of cases was small. A multidisciplinary group led by nursing was required to establish, implement, and support the change. The protocol continues to be used and was included in the handbook that is distributed to orthopedic residents at the

facility. Despite the limitations encountered with this project, the results may be useful in stimulating other hypotheses for future research.

Recommendations

DNP as a consultant. A doctoral prepared nurse has the ability to define and propose changes to administrators within the organization. This recommendation should enhance the consultation role within organizations in various clinical areas, with a critical eye toward scrutinizing standards of care. One example is forming and leading multidisciplinary teams to revise protocols and policies such as the MRSA decolonization project for patients undergoing THA and TKA procedures. The evidence-based change in practice of MRSA decolonization better serves the patient, potentially leads to both a quality and cost beneficial health care outcome by reducing the MRSA burden in the facility and possibly preventing SSIs. Activities such as this not only demonstrate the DNP's skill at collaboration, but create an opportunity to advance the field of nursing by sharing and gaining new knowledge from colleagues in other disciplines.

It is also recommended that DNPs in a consultative role continue to not only maintain, but augment skills related to information technology and virtual environments. These essential skills for searching and reviewing literature, mining data, performing statistical analyses, performing evaluations, providing health education, and for communication in general call for lifelong learning. Utilizing health informatics increases opportunities for telemedicine contact with patients and web-based conferencing, education, and mentoring opportunities for nurses as well.

A final recommendation for DNP nurses in a consultative role is to remain aware of politics, policy making, and of the importance of forming partnerships when planning a systems

change. Depending on one's practice location communications may need to involve additional key stakeholders as partners in the planning to ensure that implementation proceeds effortlessly and efficiently. For example, providing a proposal to labor representatives for review and comment prior to overall group planning sessions may alleviate unnecessary future controversy. Labor representatives can provide another voice for frontline staff during future discussions involving the proposed change, and members may be inclined to speak more directly about concerns with their representative.

Potential transferability of project findings. The findings from the project itself are transferable to some extent. Three initial issues should be considered. First it is important to consider this as a pilot project because the anticipated number of cases was not observed, resulting in a limited number of cases. Second, the facility interested in a similar study should know the prevalence of MRSA in the institution prior to beginning an investigation. This would assist the researcher to a more accurate estimate of the number of expected cases and in determining the number of historical controls to choose. Third, this was a convenience sample, not a randomized one. Randomization may create difficulty obtaining sufficient numbers of cases and controls depending on the criteria identified for matching. This would also increase the length of time that the study would be implemented.

Assuming further interest in a similar project, the first requirement would be that the facility had the capability to perform PCR analysis of the nares swabs. Without the forty-five minute to one hour turnaround time PCR analysis offers it would not be possible to begin decolonization at the time of the surgical procedure. Cultures require twenty-four to forty-eight hours for results of swabs collected from patients arriving on the day of surgery. A similar project would not be possible in a facility without MRSA PCR analysis capabilities.

If a facility has the ability to perform PCR analysis of the nares swabs it would be prudent to align with other sites to implement a multisite project in order to increase the sample size overall which would improve the likelihood of identifying more cases. This would contribute to the generalizability of the study results. Greater numbers would also permit a regression analysis and would result in odds ratios that could be examined. Finally, the timeline for the study should be extended to greater than the one year implemented for this pilot project. This would assist in determining an association between decolonization and a decrease in SSI rates.

The skills required by the nurse investigator for this project are transferable to other system change projects. Knowledge of evidence-based practice, nursing and change theory, organizational culture, negotiation skills, and multidisciplinary collaboration all have far-reaching application.

Dissemination plan. The initial dissemination of the project results will be in a public presentation at the university where the investigator is enrolled in the DNP program. There are numerous other potential options for disseminating the results. One is to present the findings at the project site's nursing grand rounds. This will be in addition to presenting at staff meetings for the operating room nurses, CRNAs, microbiology lab, pharmacy, and to nurses on the surgical unit. The results will also be presented at the operating room committee and at the onsite orthopedic surgery subspecialty meeting. In addition, there are two poster presentation opportunities in the site facility. One is during research week and the other during nurse's week. The onsite nurse newsletter has requested an article about the project.

Externally, a submission for a poster presentation to peers in infection prevention and control at the annual state APIC conference will be completed. A regional group of nurses who

collect surgical quality improvement data have requested a web-conference presentation. It is possible to present to a similar regional group of infection preventionists. Finally, the possibility exists to submit an article to a nursing journal.

The project as a foundation for future scholarship. This project provides a foundation for future nursing scholarship. It may directly impact scholarship relative to MRSA decolonization if the investigator expands the pilot project. Indirectly, the project affects scholarship because the skills demonstrated by the nurse investigator are generic to any project where evidence-based practice is applied to improve quality health outcomes, and the results of the applied research are disseminated to address issues in clinical practice. Doctoral prepared nurses are willing and ready to examine and revise existing nursing practice to produce improved outcomes and patient satisfaction. They are nurse leaders who have designed and implemented a project beginning with developing the research question to disseminating the practice innovation. Confidence is gained or increased by completing such a project. This is empowering, which is valuable because it can be challenging to change clinical practice.

American colleges of nursing essentials. A DNP project must be scholarly. It should be developed with the intent of translating research findings into practice. This project implemented a change in the standard of care in the clinical setting of total hip and total knee joint replacement surgery as a strategy to temporarily decolonize patients beginning on the day of surgery, and potentially prevent SSIs in this patient population.

The project was in keeping with the American Association of Colleges of Nursing (AACN) *Essentials of Doctoral Education for Advanced Nursing Practice* (2006). Related to Essential I, Scientific Underpinnings for Practice, the nurse investigator formed a multidisciplinary group to plan and implement the project that included: pharmacy, the

orthopedic nurse coordinator, CRNAs, the clinical microbiology laboratory, two nurse managers, the chief of orthopedic surgery, and the hospital epidemiologist. Concepts and principles from all disciplines were discussed and integrated into the protocol. The group determined decolonization to be a significant strategy to enhance health care delivery. Implementing decolonization was a new practice approach for the facility.

Essential II, Organizational and Systems Leadership for Quality Improvement and Systems Thinking (2006), was also addressed by the project. Business principles were applied in discussion with pharmacy and informatics staff. The investigator negotiated with pharmacy concerning the use of a small unit dose tube of ointment by the CRNAs in the operating room, and the use of a multi-dose tube of ointment for use on the surgical unit and for patient use during the two days following discharge. When considering cost benefit, the use of unit dose tubes were more efficient and less wasteful for the CRNAs in the operating room who were administering the initial dose of ointment. When this was determined informatics staff became involved to build the pre and postoperative order sets.

The above is an example of a small portion of this pilot project, which following implementation offered support for the hypothesis that beginning decolonization on the day of surgery in a supportive environment can result in temporary decolonization. This may improve post-operative health outcomes, and avoid the expenses that may be incurred with an extended hospitalization associated with a SSI.

The project was also in keeping with Essential III, Clinical Scholarship and Analytical Methods for Evidence-Based Practice (2006). Gaps in practice were identified with review of the first patients who participated in the decolonization protocol. The outcomes were evaluated at the facility locally, but indirectly had implications for practice at the regional level as the

facility was and is a referral site for THA and TKA surgeries. Practice guidelines were formalized again and resident staff re-educated. The protocol was then included in the handbook provided to all residents in the Orthopedic Surgery Subspecialty.

Essential IV, Information Systems/Technology and Patient Care Technology for the Improvement of Health Care (2006), was addressed as well during the project. Order sets for the protocol were developed by the nurse investigator and a clinical applications coordinator. Data was abstracted from the electronic medical record and entered into a spreadsheet for analysis. Knowledge gained from continuous review of the overall process was summarized and added to the protocol entered into the handbook described above.

Implementing the project further developed knowledge and skills for the nurse investigator related to Essential V, Health Care Policy for Advocacy in Health Care (2006). An issue, no existing standard of care for decolonization of patients undergoing THA or TKA surgery, was identified and action was taken to change practice. The process required a multi-disciplinary approach and consensus building. As stated earlier, the protocol is unique to the facility where the project was implemented, but influences a regional patient population through referrals made by other facilities for THA and TKA surgery.

Essential VI, Inter-professional Collaboration for Improving Patient and Population Health Outcomes (2006), suggests that the DNP use communication and collaboration skills to develop and implement practice guidelines. The nurse investigator was the leader in planning and implementing the pilot project. Partners from other disciplines were invaluable in developing a project that offers support for a decolonization protocol beginning on the day of surgery.

The decolonization pilot project met Essential VII, Clinical Prevention and Population Health for Improving the Nation's Health (2006). Project findings suggest that this is a clinical prevention strategy that may result in temporary decolonization in the perioperative period, which may contribute to decreased morbidity by reducing the number of SSIs. Patients receiving total hip or total knee implants were the population served. Healthy People 2010 included Developmental Objective 2-6: Eliminate racial disparities in the rate of total knee replacements. This project did not directly address racial disparities and joint replacement, but was in keeping with a history of studying orthopedic implants related to a population-based health outcome.

Finally, regarding Essential VIII, Advanced Nursing Practice (2006), the nurse investigator leading the project met these components as the project evolved. The nurse designed, implemented and evaluated the decolonization pilot. Although therapeutic relationships were not established with the patient population, professional relationships with other disciplines were enhanced by developing a new intervention and changing practice. This project demonstrates leadership and independence in nursing practice, in advancing interdisciplinary partnerships, and in influencing patient health outcomes through a systems change.

Closing. This project has implications for DNPs and other health professionals who are involved in providing care during the perioperative period for patients undergoing THA and TKA surgery. Methicillin-Resistant *Staphylococcus aureus* prevalence will vary by facility, and thus the risk of colonization, transmission, and potential for SSI. Continued attention must be directed toward developing evidence-based protocols that will reduce the above risks and result in quality health care outcomes along with patient satisfaction. Adherence to protocol as in the case of this project will rely not only on the health professionals, but also on the patients. This

pilot project suggests that identifying existing nasal MRSA and beginning decolonization on the day of surgery for patients undergoing THA or TKA surgery may effectively result in temporary decolonization during the perioperative period and may potentially prevent a MRSA SSI.

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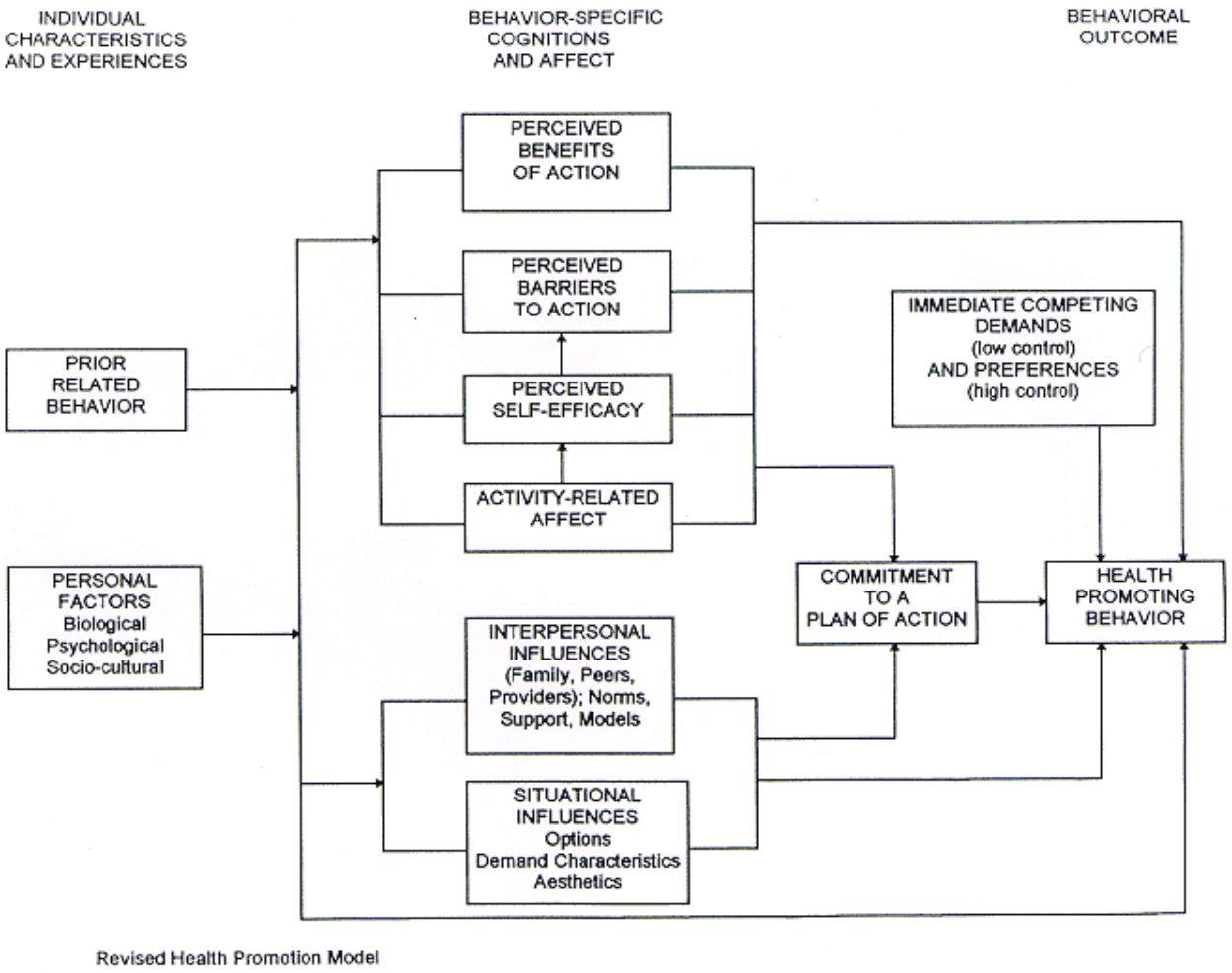
Appendix A: Nola J. Pender (1996) Health Promotion Model Diagram, www.http://hdl.handle.net/2027.42/85351 [used with permission]



Revised Health Promotion Model

Appendix B TABLE OF STUDY CHARACTERISTICS – Quantitative (Table 1)

Study (Author, Year)	**Purpose**	**Population/ Sample**	**Research Design**	**Intervention**	**Comparison**	**Outcome Measures/ Scales**	**Results**
Kim, D. et al, 2010	Evaluate MRSA screening and eradication in elective Orthopedic surgery patients	7019/7338 convenience sample	Prospective cohort (7/2006-9/2007) with historic control period (10/2005-7/2006)	Mupriocin ointment bid x 5 days and CHG shower daily x 5days if MRSA positive nares screen	Primary: rates of SSI during study period and control period Secondary: rates of SSI between MRSA/MSSA carriers and non-carriers during the study period	Carrier status Rates of SSI	SSI rate during study period lower than in control period (59% reduction rate, p=0.009), Higher SSI rate in MRSA carriers compared with non-carriers (p=0.016) during study period
Gupta, K. et al, 2011	Determine if MRSA nares carriage is predictor of SSI	4238/5200 convenience sample in VA hospital with routine admission nasal swabs	Retrospective cohort with nares screening within 31 days of clean or clean contaminated surgery from 10/1/2008-9/30/2009	None	Post-op outcomes in MRSA positive and MRSA negative patients and the impact of pre-op vancomycin	Associations between positive pre-op MRSA swab and poor post-op outcomes	Positive pre-op MRSA culture significant for positive post-op culture ($p<0.001$), MRSA SSI ($p=0.01$), and other post-op infection ($p<0.01$) unadjusted.

Study (Author, Year)	Purpose	Population/ Sample	Research Design	Intervention	Comparison	Outcome Measures/ Scales	Results
Yano, K. et al, 2009	Examine the relationship between pre-op nares MRSA colonization and post-op SSI	Convenience sample of 63/2432 with positive MRSA nares screens who had orthopedic surgery	Prospective cohort from 4/1/2003-6/30/2005	None	Relationship of positive nares pre-op and subsequent SSI	OR for MRSA SSI with pre-op positive nares	+ nares and develop MRSA SSI crude OR= 15 (4.5-47), p<0.001; + nares and develop MRSA SSI adjusted OR= 11 (3.0-37), p<0.001; negative nares and develop MRSA SSI crude and adjusted OR =1
Hadley, S. et al, 2010	Compare the rates of SSIs in THA and TKA patients completing an MRSA decolonize-tion protocol to patients not following the protocol	1644/2058 (treatment group) adhered to routine decolonize-tion protocol (selected by attending admit nares screening clinic), 414 non-adherent (control group) did not attend clinic	Prospective cohort from 11/2007-6/2009	Patients screened for MRSA given mupirocin ointment x 5 days and CHG shower x1. If nares + on day of surgery Vancomycin as pre-op antibiotic	Compare SSI rates in patients adhering to protocol with non-adherent	Descriptive statistics for SSI rate between protocol adherent and non-adherent	

Study (Author, Year)	**Purpose**	**Population/ Sample**	**Research Design**	**Intervention**	**Comparison**	**Outcome Measures/ Scales**	**Results**
Price, C. et al., 2008	Determine the prevalence of pre-op *S. aureus* nasal colonization in Orthopedic patients, assess trends in methicillin resistance with time, ascertain risk factors for nasal colonization, and to correlate SSI to nasal colonization status and procedure	284 patient nares swabs collected, patients screened x 1 2 weeks prior to scheduled surgery	Cross sectional sample 9/19/2003-9/26/2005	None	None with primary objective (% colonized), 2° objective: correlate SSI to colonization status and procedure	Percent colonized, correlation between carriage, SSI or surgical procedure	86/284 colonized, 81 with methicillin sensitive *S. aureus* and 5 with MRSA, number of MRSA carriers did not increase from 2003-2005; no correlation between MRSA carriage, demographic data, SSI, or surgical procedure

Study (Author, Year)	Purpose	Population/ Sample	Research Design	Intervention	Comparison	Outcome Measures/ Scales	Results
Buelhmann M. et al., 2008	Evaluate efficacy of decolonization and identify factors influencing failure	62/94 convenience sample of consecutive hospitalized patients	Prospective cohort from 1/1/2002-4/30/2007	Mupirocin BID x 5 days, Oral rinsing with 2% CHG TID, 4% CHG daily body wash, antimicrobial (oral) once or twice daily for urogenital or gastrointes-tinal colonization	Percent colonized on admit, percent colonized after decolonizatio n cycle	Percent decolonized after completing full decolonization cycle	Decolonization completed in 87% (54/62) with a mean of 2.1, SD $\pm$ 1.8. MRSA sites: nose 68% (42/62), throat 53% 33/62, perianal 53% 33/62, rectal 58% (36/62), inguinal 49% (30/62). 65% required oral antibiotic treatment to decolonize

Study (Author, Year)	**Purpose**	**Population/ Sample**	**Research Design**	**Intervention**	**Comparison**	**Outcome Measures/ Scales**	**Results**
Lee, A. et al, 2011	Determine whether resistance to mupirocin and CHG increases the risk of persistent MRSA carriage after decolonization	Hospitalized patients: 75 case patients and 75 controls	Case control	None	Characteris-tics of cases and controls	Identify factors associated with failure to decolonize	Independent risk factors associated with decolonization failure (adjusted ORs): combined mupirocin and CHG resistance OR=3.4, 95% CI (1.5-7.8), p=0.004; age/1yr increment OR=1.04, 95% CI (1.02-1.1), p=0.001; hospital within 2 yrs OR=2.4, 95% CI (1.1-5.7), p=0.04; wound/ulcer OR=5.7, 95%CI (1.8-17.6), p=0.003; MRSA inactive antibiotic use OR=3.1, 95% CI (1.3-7.2), p=0.01; central line OR=5.7, 95% CI (1.4-23.9), p=0.02

Appendix C: Table Ranking the Evidence for Clinical Practice Guidelines and Systematic Reviews (Table 2)

Study Author	**Purpose**	**Population**	**Results**	**Practice Applicability**	**Risk/Benefit**	**Level/Quality**
APIC, 2010	Eliminate MRSA in hospital setting	Patients and providers in hospital setting	Strategies: surveillance, hand hygiene, contact precautions, environmental hygiene, education, cultural transformation, antimicrobial stewardship, decolonization	Clinical setting & patients similar to those in guideline	Benefit: temporary decolonization during perioperative period; Risk: possible mupirocin resistance	Level 5 (observational, some case-control/cohort studies & many opinion/committee reports) Good
APIC, 2010	Eliminate orthopedic SSIs	Patients, surgeons, perioperative personnel	Strategies to prevent orthopedic SSIs related to modifiable and non-modifiable risk factors	Clinical setting & patients similar to guideline	Benefit: decreased SSI rate; Risk: may decrease other hospital-acquired infection but not necessarily SSI	Level 5 (observational, some case-contol/cohort studies & many opinion/committee reports) Good
Liu, 2011	Treatment of MRSA infections	Patients (adults & children) and providers	Recommendations for management of MRSA clinical syndromes associated with MRSA	Clinical setting & adult patients similar to guideline	Benefit: Standardized treatment protocol; Risk: consideration of patient values & preferences, possible resistance issues	Level 3 (clinical practice guideline, evidence from well-designed RCTs, is an opinion of authorities on an expert panel) Good

McGinigle, 2008	Use of active surveillance cultures (ASC) to reduce MRSA	Patients in MICU or SICU	Existing evidence favors use of ASCs, as evidence is poor recommendations can't be made	ASC required by VA Directive in clinical setting	Benefit: control increasing numbers of infections; Risk: < staff contact with isolation, > financial cost with isolation	Level 5 (systematic review) Review itself was good although negative as studies of poor quality. Good
van Reijen, 2011	Determine if nasal mupirocin in patients with MRSA/MSSA reduces *S.aureus* infection rates	Surgical & dialysis patients, non-surgical MRSA nares colonized patients	Use of mupirocin in nasal *S. aureus* carriers is associated with a decrease in *S. aureus* infections	Clinical setting similar to those in guideline	Benefit: reduction in rate of hospital-acquired infections; Risk: possible mupirocin resistance	Level 1 (systematic review) Based on 9 RCTs. Four were considered high quality. Good

APPENDIX D: AGREE II Online Appraisal Tool

A critical appraisal of:
Clinical Practice Guidelines by the Infectious Diseases Society of America for the Treatment of Methicillin-Resistant *Staphylococcus Aureus* Infections in Adults and Children
using the AGREE II Instrument

Created with the AGREE II Online Guideline Appraisal Tool.

No endorsement of the content of this document by the AGREE Research Trust should be implied.

Appraiser: Laurel Chelstrom

Date: 12 May 2012

Email: ljchelstrom@stkate.edu

URL of this appraisal: **http://www.agreetrust.org/view-appraisal/?doc=2294**

Overall Assessment

Title: Clinical Practice Guidelines by the Infectious Diseases Society of America for the Treatment of Methicillin-Resistant Staphylococcus Aureus Infections in Adults and Children

Citation:

Overall quality of this guideline: 6/7

Guideline recommended for use? Yes

Notes

Guideline sections begin with a question followed by quantified recommendations with a summary of recent evidence supporting the recommendation. There is a research gaps section which discusses areas of limited/conflicting data or the need for additional research.

Domain	Total
1 - Scope and Purpose	21
2 - Stakeholder Involvement	11
3 - Rigour of Development	46
4 - Clarity of Presentation	21
5 - Applicability	19
6 - Editorial Independence	14

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1. Scope and Purpose

1. The overall objective(s) of the guideline is (are) specifically described.

Rating: 7 Strongly Agree

Yes, in the brief executive summary.

2. The health question(s) covered by the guideline is (are) specifically described.

Rating: 7 Strongly Agree

Yes, expressed in question form and specific responses for adult or pediatric patients.

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Rating: 7 Strongly Agree

Yes, adults and children with MRSA infections.

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2. Stakeholder Involvement

4. The guideline development group includes individuals from all relevant professional groups.

Rating: 2

Reviewer was unable to determine. Organizations are specified for the individuals, not their titles or roles. All authors/panelists are considered infectious disease experts in management of MRSA.

5. The views and preferences of the target population (patients, public, etc.) have been sought.

Rating: 2

External peer review feedback of the draft is reported in the document. No report of comments from patients or the public concerning the development of the document.

6. The target users of the guideline are clearly defined.

Rating: 7 Strongly Agree

Yes, practitioners and patients.

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3. Rigour of Development

7. Systematic methods were used to search for evidence.

Rating: 3

The search identified PubMed as the database. A limit was English-language only. Years searched were from 1961-2010. Search terms used were "methicillin-resistant *Staphylococcus aureus*" or "MRSA." The focus was on human studies however some experimental animal studies, in vitro data, and abstracts from national meetings were included. The authors reported many recommendations were developed from observational studies or small case series studies combined with the opinion of expert panel members.

8. The criteria for selecting the evidence are clearly described.

Rating: 7 Strongly Agree

Yes, an A (good evidence to support a recommendation for or against use), B Moderate evidence to support a recommendation for or against use), C (Poor evidence to support a recommendation) scale was used to rate the strength of recommendations.

A scale for quality of evidence was scored as: I (evidence from ≥ 1 properly randomized controlled trial); II (evidence from ≥ 1 well designed clinical trial, without randomization from cohort or case-controlled analytic studies, preferably from > 1center; from multiple time-series, or from dramatic results from uncontrolled experiments); and III (evidence from opinions of

respected authorities based on clinical experience, descriptive studies or reports of expert committees).

9. The strengths and limitations of the body of evidence are clearly described.

Rating: 7 Strongly Agree

Yes, detailed narrative descriptions are included for each question.

10. The methods for formulating the recommendations are clearly described.

Rating: 7 Strongly Agree

Yes, use of teleconference and annual meetings of all members. All members participated in preparation and review of the draft guideline. Feedback from external peer reviewers was obtained. Guideline was endorsed by Pediatric Infectious Diseases Society, American College of Emergency Physicians, and American Academy of Pediatrics. The guideline was reviewed and approved by IDSA Standards and Practice Guidelines Committee and the IDSA Board of Directors.

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

Rating: 7 Strongly Agree

Discussions and recommendations are detailed and decisions are clear and succinct.

12. There is an explicit link between the recommendations and the supporting evidence.

Rating: 7 Strongly Agree

Yes, evidence-based literature is referenced throughout the document.

13. The guideline has been externally reviewed by experts prior to its publication.

Rating: 7 Strongly Agree

Yes, reviewer commented on this earlier in #10 under Rigour of Development.

14. A procedure for updating the guideline is provided.

Rating: 1 Strongly Disagree

Reviewer did not see a procedure in place for this.

4. Clarity of Presentation

15. The recommendations are specific and unambiguous.

Rating: 7 Strongly Agree

The recommendations are clearly detailed and followed with an evidence summary.

16. The different options for management of the condition or health issue are clearly presented.

Rating: 7 Strongly Agree

Yes, alternatives are presented (see decolonization for example) and are stratified by adult and child.

17. Key recommendations are easily identifiable.

Rating: 7 Strongly Agree

Yes, some key recommendations are identified in the executive summary and some are identified as performance measures on the concluding page of the document.

---

5. Applicability

18. The guideline describes facilitators and barriers to its application.

Rating: 4

Not clearly labeled as facilitators or barriers, or stated in a particular section. Caution and controversy are noted appropriately.

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

Rating: 7 Strongly Agree

Yes, throughout the document.

20. The potential resource implications of applying the recommendations have been considered.

Rating: 7 Strongly Agree

Yes, for example personal and environmental hygiene and wound care in the home are discussed.

21. The guideline presents monitoring and/or auditing criteria.

Rating: 1 Strongly Disagree

Implied in some areas but not defined.

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6. Editorial Independence

22. The views of the funding body have not influenced the content of the guideline.

Rating: 7 Strongly Agree

All panel members complied with IDSA policy including actual, potential or apparent conflict of interest. Panel members were asked to identify links to companies developing products that may be influenced by dissemination of the guideline. Information was requested regarding employment, consulting, stock ownership, honoraria, research funding, expert testimony, or participation on company advisory committees.

23. Competing interests of guideline development group members have been recorded and addressed.

Rating: 7 Strongly Agree

Potential conflicts of interest were listed in the Acknowledgement section.

Appendix E: Table Ranking the Evidence for Systematic Reviews (Table 3)

Study Author	**Purpose**	**Population**	**Results**	**Practice Applicability**	**Risk/Benefit**	**Level/Quality**
McGinigle, 2008	Use of active surveillance cultures (ASC) to reduce MRSA	Patients in MICU or SICU	Existing evidence favors use of ASCs, as evidence is poor recommendations can't be made	ASC required by VA Directive in clinical setting	Benefit: control increasing numbers of infections; Risk: < staff contact with isolation, > financial cost with isolation	Level 5 (systematic review) Review itself was good although negative as studies of poor quality.
van Reijen, 2011	Determine if nasal mupirocin in patients with MRSA/MSSA reduces *S.aureus* infection rates	Surgical & dialysis patients, non-surgical MRSA nares colonized patients	Use of mupirocin in nasal *S. aureus* carriers is associated with a decrease in *S. aureus* infections	Clinical setting similar to those in guideline	Benefit: reduction in rate of hospital-acquired infections; Risk: possible mupirocin resistance	Level 1 (systematic review) Good

Appendix F: Ranking the Evidence (Table 4)

Literature	Level Ranking	Quality Ranking
APIC, 2010 (MRSA guideline)	Level 5	Good
APIC, 2010 (Orthopedic guideline)	Level 5	Good
Liu, C, et al, 2011 (IDSA guideline)	Level 3	Good
McGinigle, K, 2008 (systematic review)	Level 5	Poor
van Rijen, M, 2011 (systematic review)	Level 1	Good
Gupta, K. et al, 2011 (original article)	Level 4 (retrospective cohort)	Good
Kim, D. et al, 2010 (original article)	Level 4 (prospective cohort)	Good
Yano, K. et al, 2009 (original article)	Level 4 (prospective cohort)	Good

Rating System for the Hierarchy of Evidence for Intervention/Treatment Questions:

Level 1: Systematic review or meta-analysis of all relevant randomized controlled trials (RCTs), or evidence-based clinical practice guidelines based on systematic reviews of RCTs
Level 2: Evidence from at least one well-designed RCT
Level 3: Evidence from a well-designed controlled trial without randomization
Level 4: Evidence from well-designed case-control and cohort studies
Level 5: Evidence from systematic reviews of descriptive and qualitative studies
Level 6: Evidence from a single descriptive or qualitative study
Level 7: Evidence from the opinion of authorities and/or reports of expert committees

(Melnyk, & Fineout-Overholt, 2011, p. 12). Modified from Guyatt, G., & Rennie, D. (2002). Users' guides to the medical literature. Chicago, IL: American Medical Association; Harris, R. P., Hefland, M., Woolf, S. H., Lohr, K. N., Mulrow, C. D., Teutsch, S. M., et al. (2001). Current methods of the U. S. Preventive Services Task Force: A review of the process. American Journal of Preventive Medicine, 20, 21-35.

Quality Criteria:

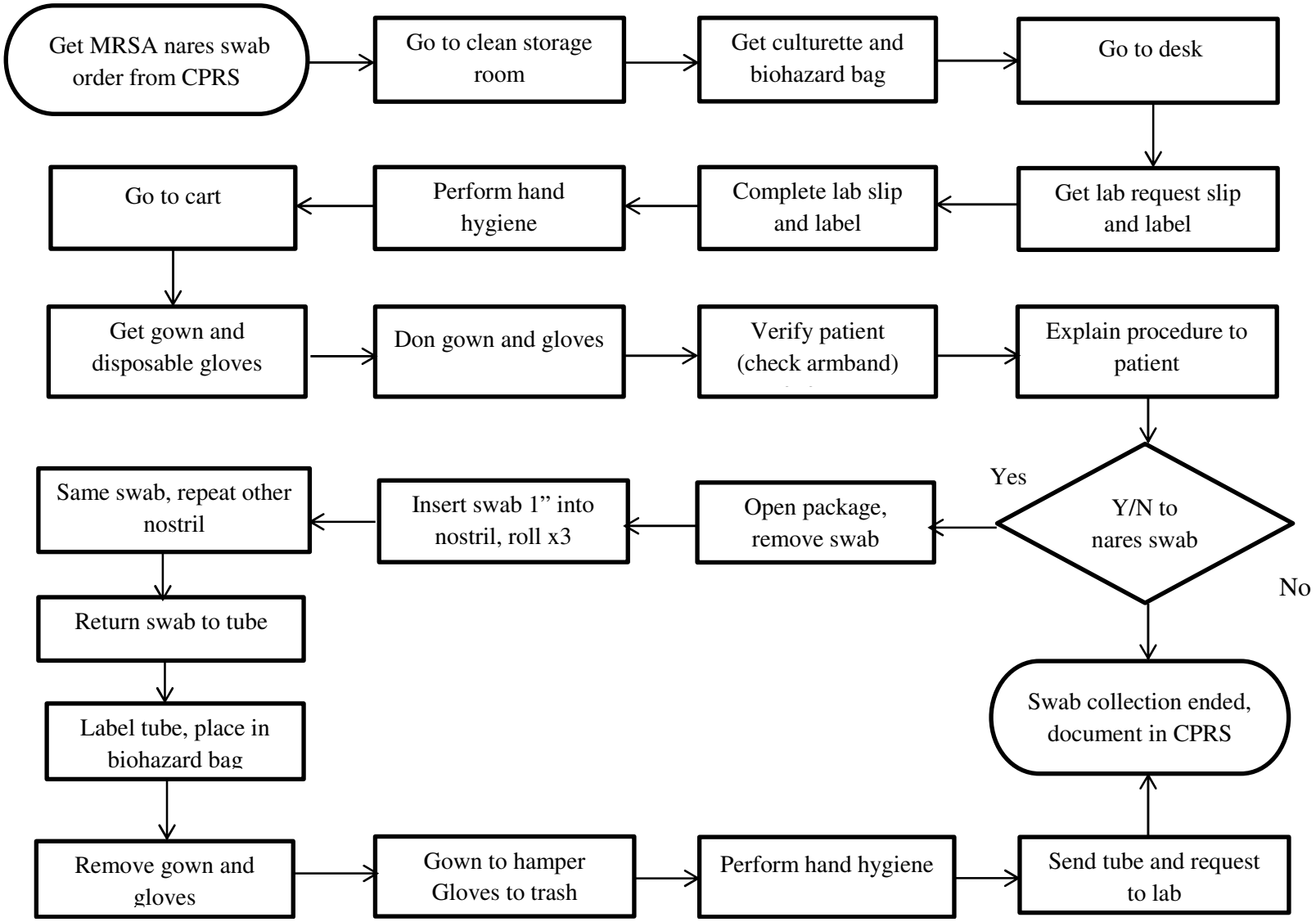
Good: Evidence includes consistent results from well-designed, well-conducted studies in populations that directly assess effects on health outcomes. (Quality Criteria continue on the next page)

Fair: Evidence is sufficient to determine the effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

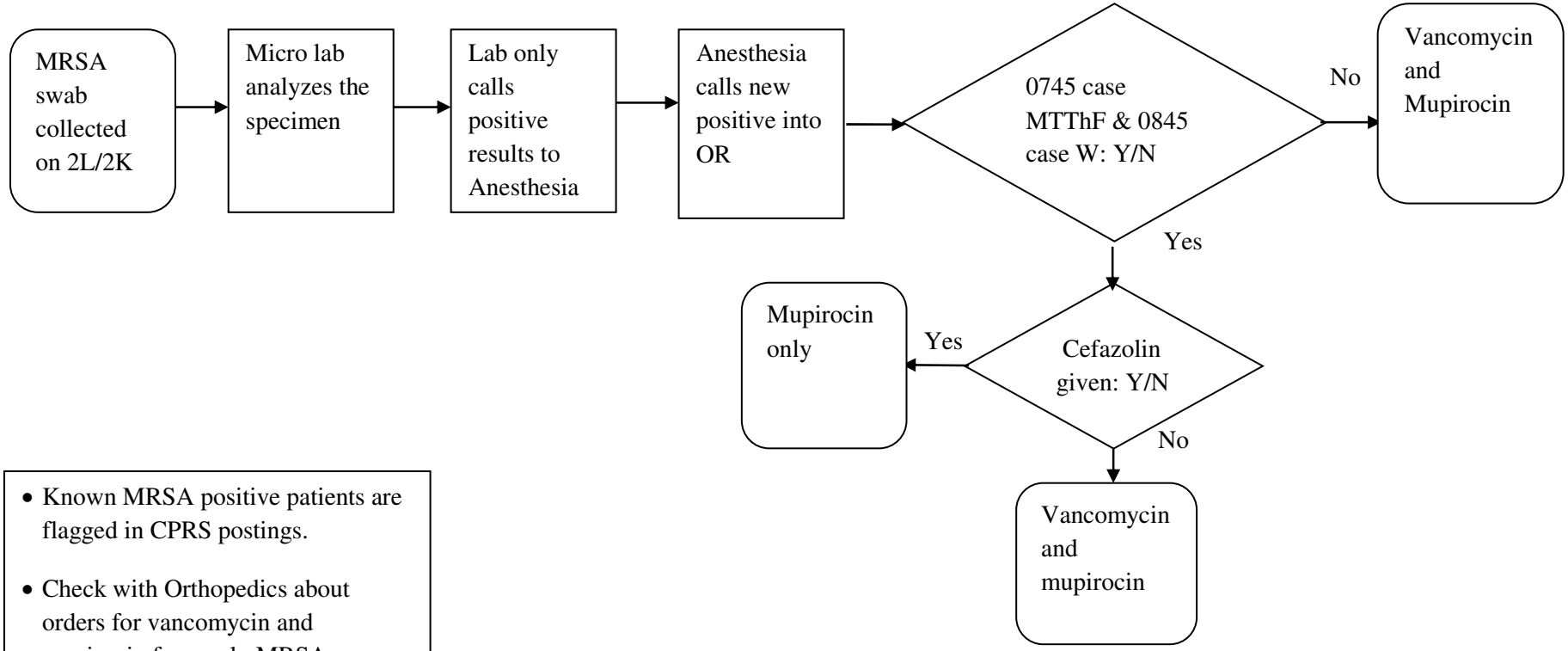
Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

U. S. Preventive Services Task Force (USPSTF) [May 2008] grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor).

Appendix G: Flowchart: Collection of Nasal Swab for MRSA Surveillance



Appendix H: Anesthesia workflow diagram for decolonization of MRSA positive THA and TKA patients



- Known MRSA positive patients are flagged in CPRS postings.
- Check with Orthopedics about orders for vancomycin and mupirocin for newly MRSA positive patients
- Orthopedics is responsible for writing orders for known MRSA positive patients

Instructions for opening and applying Bactroban nasal (Mupirocin calcium ointment 2%) from the 1 X 1.0 gram single-use tube are found on the back of the package.

Appendix I: Table 5, Cost Spreadsheet Based on 30 THA and TKA Surgeries/Month

(Costs highlighted in yellow are annual repeating costs based on a 10% facility prevalence of MRSA, assuming 3 THA or TKA patients/month will be either newly or known MRSA positive)

Supplies/other variable	New Cost	Avoided Cost	Averted Cost
1 THA/TKA SSI			‡$50,000.00
2 Admit PCR assay		$51.00(3)(12)=$1836.00	
3 Discharge Agar plate		$14.00(3)(12)=$504.00	
4 Vancomycin x 24 hours	$7.00(3)(12)=$252.00		
5 Ancef x 24 hours	$3.00(3)(12)=$108.00		
6 Mupirocin unit dose	$5.00(3)(12)=$180.00		
7 Mupirocin multidose	$5.00(3)(12)=$180.00		
8 Staff education by IP*			
8a 2nd floor RNs** by IP	$100.00 (4x30") IP RN $800.00 (rounds x 4) for 8 nurses		
8b CRNAs*** by IP	$25.00 (1x30") IP RN $800.00 (staff mtg x1) for 32 CRNAs		
8c Lab staff† by IP	$13.00 (1x15") IP RN $200.00 (staff mtg x1) for 12 lab personnel		
8d Pharmacy†† by IP	$50.00 (1x60") IP RN $50.00 (1x60") PharmC		
9 Mtgs w/Ortho Chief & IP†††	$150.00 (3x60") IP RN $375.00 (3x60") OrthC		
10 Mtgs w/Ortho RN & IP (Administration)	$250.00 (5x60") IP RN $250.00 (5x60") OrthRN		
11 Computer template, CAC• & IP	$150.00 (3x60") CAC		
12 SubTotals (Yellow):	$720.00	$2340.00	
13 Totals:	$3933.00	$2340.00	$50,000.00

All salaries below are hypothetical. All amounts above were rounded for ease of calculation.

Drug costs were estimated by Pharmacy. Pharmacy tech time is included, thus true drug cost to VA may vary from above amounts if actual tech grade and step data is considered.

*Infection Prevention RN salary=$50.00/hour
**2nd floor RN salary=$50.00/hour
***CRNA salary=$50.00/hour Orthopedics Chief salary=$125.00/hour
†Lab personnel salary=$16.00/hour
††Pharmacy assistant chief salary=$50.00/hour
†††Chief of Orthopedics salary=$125.00/hour
•Computer applications coordinator (CAC) salary=$50.00/hour
‡2003 article quoted cost of a THA/TKA SSI as approximately $50,000.00. This amount appears more often in the literature than the $100,000.00 amount quoted in the 2012 article.

Appendix J: Lab Costs for MRSA Nasal Swab Surveillance

PCR assay costs (admission*):

Tech accessioning time=2 minutes=$3.60
PCR consumables=$35.14
Setup time=3 minutes=$5.40
Tech time to read and report out=2 minutes=$3.60

Materials needed to process:
1 ten part label=$0.01
2 staples=$0.01
1 card stock (workcard)=$0.02
1 pair nitrile gloves per specimen=$1.75
1 COPAN swab=$0.80
Bleach and alcohol to countertop after setup per specimen=$0.10

Total=$50.43 per PCR specimen

Agar plating costs (discharge):
Tech accessioning time=2 minutes=$3.60
Agar plate cost=$2.33
Plating time=1 minute=$1.80
Tech time to read and report out=2 minutes=$3.60

Materials needed to process:
1 ten part label=$0.01 2 staples=$0.01
1 card stock (workcard)=$0.02
1 pair nitrile gloves per specimen=$1.75
1 COPAN swab=$0.80

Total=$13.92 per agar specimen

*Admission lab is more costly to process as results are available in 45 minutes to 1 hour, so patients can be placed in isolation precautions more quickly. The discharge swab is plated and less expensive because results are not available for 24-48 hours. Isolation precautions are no longer critical once the patient is discharged.

Appendix K: Cost Benefit Summary Calculations

Total decolonization costs for initial year: $3933.00

Total averted cost if one THA/TKA SSI is averted: $50,000.00

Total avoided annual cost for admission and discharge labs: $2340.00

Total benefits: $52,340.00

Benefit Cost Ratio = Total benefits/Total costs = $52,340/$3933 = 13.3

Return on investment (ROI) = Total benefits – Total costs/Total costs x 100 =

($52,340 - $3933)/$3933 x 100 =
($48,407/$3933) x 100 = 1230 = ROI

ROI figure is greater than zero it is worthwhile to consider investing in this project. A limitation is possible development of Mupirocin resistance. Decolonization should be limited to high risk and high volume surgical procedures such as those with permanent implants like THAs and TKAs.

Appendix L: Present Value Calculation

Assume medical cost avoided for 1 THA/TKA SSI = $50,000
Assume 5% interest

Present Value of 5 years avoided medical cost of 1 SSI assuming a 5% interest rate:

PV savings in year 1: $50,000/$1.05=$47,619.05
PV savings in year 2: $50,000/$(1.05)^2$=$45,351.47
PV savings in year 3: $50,000/$(1.05)^3$=$43,191.88
PV savings in year 4: $50,000/$(1.05)_4$=$41,135.12
PV savings in year 5: $50,000/$(1.05)_5$=$39,176.31

$47,619.05+$45,351.47+$43,191.88+41,135.47+$39,176.31=$216,473.83

Total: $216,473.83 = Savings in present value terms

Appendix M: Table 6

Descriptive statistics

Variable	Statistic	Subjects
Gender	Percentage (Number)	
Female		0% (0)
Male		100% (50)
Age	Mean (Std. Dev.)	
Cases		62.90 yrs. (6.226 yrs.)
Controls		62.90 yrs. (5.991 yrs.)
BMI	Mean (Std. Dev.)	
Cases		33.19 lbs. (6.006 lbs.)
Controls		31.67 lbs. (6.349 lbs.)

Appendix N: Table 7

Variables in the Project

MRSA positive on admission
MRSA positive history
MRSA positive on discharge
Gender
ASA score
Length of preoperative stay
Type of surgery
Location of surgery
Duration of surgery
Wound class
Preoperative antibiotic
Mupriocin administered
Postoperative antibiotic
Diabetic chronic
Tobacco use
Albumin level within 90 days
Acute renal failure
Current dialysis
Chronic obstructive pulmonary disease
Tranexamic acid administered
SSI within 30 days
SSI within 90 days
Postoperative day of infection
Depth of SSI
Site cultured
Pathogen

Appendix O: Table 8

Case and Control Result Summary

Variable	Cases	Controls	Overall	X^2	p value
MRSA admit +	100% (10)	2.5% (1)	22% (11)	44.318 □	.000
MRSA hx +	50% (5)	2.5% (1)	12% (6)	17.093 □	.001
MRSA d/c +	30% (3)	2.5% (1)	8% (4)	8.220 □	.022
ASA score					
1	0% (0)	2.5% (1)	2.0% (1)		
2	0% (0)	27.5% (11)	22% (11)		
3	100% (10)	67.5% (27)	74.0% (37)		
4	0% (0)	2.5% (1)	2.0% (1)	4.392 □	.222
Pre-op stay	100% (10)	100% (40)	100% (50)	□	
Surgery type					
THA	50% (5)	50% (20)	50% (25)		
TKA	50% (5)	50% (20)	50% (25)	.000	.637
Surgery side					
Right	70% (7)	70% (28)	70% (35)		
Left	30% (3)	30% (12)	30% (15)	.000 □	.659
Surgery length					
1 to<2hrs	30% (3)	42.5% (17)	40% (20)		
2 to>2hrs	70% (7)	57.5% (23)	60% (30)	.521	.365
Wound class	100% (10)	100% (40)	100% (50)	□	
Preop abx					
Cefazolin	30% (3)	85% (34)	74% (37)		
Vancomycin	70% (7)	0% (0)	14% (7)		
Clindamycin	0% (0)	15% (6)	12% (6)	32.770 □	.000
Mupirocin	70% (7)	0% (0)	14% (7)	32.558 □	.000
Postop abx					
Cefazolin	30% (3)	82.5% (33)	72% (36)		
Vancomycin	70% (7)	5% (2)	18% (9)		
Clindamycin	0% (0)	10% (4)	8% (4)	23.090 □	.000

DM chronic					
No	20% (2)	80% (32)	68% (34)		
Diet	20% (2)	2.5% (1)	6.0% (3)		
Oral	40% (4)	7.5% (3)	14% (7)		
Insulin	20% (2)	10% (4)	12% (6)	15.021 □	.002
Tobacco use					
Never	10% (1)	0% (0)	2% (1)		
w/in 2 weeks	20% (2)	22.5% (9)	2% (11)		
w/out > 12 mo.	70% (7)	77.5% (31)	76% (38)	4.082 □	.130
Albumin w/in 90d	100% (10)	90% (36)	92% (46)	1.087 □	.397
Acute renal failure	100% (10)	100% (40)	100% (50)	□	
Current dialysis	100% (10)	100% (40)	100% (50)	□	
COPD	10% (1)	10% (4)	10% (5)	.000 □	.742
Tranexamic acid	40% (4)	0% (0)	8% (4)	17.391 □	.001
SSI<30d	0% (0)	2.5% (1)	2% (1)	.255 □	.800
SSI 30-90d	0% (0)	2.5% (1)	2.0% (1)	.255 □	.800
POD of SSI					
<30d	0	pod 10		□	
30-90d	0	pod 82		□	
Depth of SSI					
Superficial	0	0		□	
Deep	0	0		□	
Organ/space (joint)	0	2		□	
Site cultured					
Right	0	2		□	
Left	0	0		□	
Pathogen	none	CNS (1)			
		Group B beta streptococcus (1)		□	

a. Cell count <5, computed for 2x2 table only.
b. No statistics are computed, variable is a constant.