A Clinical Practice Guideline for Staphylococcus aureus Decolonization in Select Surgical Outpatients

Abigale A. Celotto

University of Maryland School of Nursing

DNP Scholarly Project
Abstract

**Long Title:** A Clinical Practice Guideline for *Staphylococcus aureus* Decolonization in Select Surgical Outpatients

**Short Title:** The Decolonization of Surgical Outpatients

Surgical site infections (SSI) are among the most prevalent types of hospital-acquired infections, causing substantial negative consequences for patients and health care systems, including increased morbidity and mortality rates, and higher costs to hospitals and insurers. Preoperative nasal colonization with *Staphylococcus aureus* (*S. aureus*) is an independent risk factor for the development of an SSI. Decolonization bundles that include combined use of nasal *S. aureus* colonization screening, targeted nasal decolonization, and preoperative Chlorhexidine gluconate (CHG) bathing are an effective means of SSI prevention.

The purpose of this DNP scholarly project was to develop and evaluate an institutional clinical practice guideline (CPG) for the decolonization of *S. aureus* in adult, non-emergent cardiac surgery and total hip and/or knee arthroplasties. This manuscript focuses on the CHG recommendations within the larger decolonization bundle. The setting for this project was an ambulatory, Patient Readiness and Evaluation Center within a tertiary, mid-Atlantic medical center. It was anticipated that the guideline would be evaluated and graded as high quality and be considered reasonable and practical for implementation.

Guided by Steven’s *Stevens Star Model of Knowledge Transformation*, the CPG was developed and evaluated in three phases. Prior to Phase One, a thorough evidence review and first draft of the CPG were completed. Phase One involved introductory meetings with stakeholders while Phases Two and Three were evaluation and revision phases. Two samples
were utilized to evaluate the quality of the CPG. The first sample included seven subject-matter-experts (SMEs) within key departments who evaluated the CPG for quality utilizing the Appraisal of Guidelines for Research & Evaluation (AGREE II) Tool. The second sample consisted of eight end-users who assessed the CPG for applicability and sustainability utilizing the Practitioner Feedback Questionnaire.

All six domains within the AGREE II tool scored greater than the targeted 80% agreement. The highest scoring domain was *Editorial Independence* with 94% agreement, while the lowest scoring domain was *Applicability* scoring 82% agreement. The final item, *Overall Assessment of the Guideline*, scored 90% agreement all SMEs stating they would recommend use of the guideline. Components that scored close to 80% were revised before Phase Three commenced. Of the four factors within the Practitioner Feedback Questionnaire, *quality* scored the highest with 93.75% favorable responses, while *applicability of recommendations* scored the lowest with 35.5% positive responses. Overall the CPG was found to be of high quality and practical for implementation with all SMEs and end-users stating they would use the CPG if it were implemented at their facility.

The overarching goals of the CPG to standardize practice and minimize patient morbidity aligned with the institutional missions to deliver superior health care and discover ways to improve health outcomes. If the CPG were implemented as standard institutional practice, it is anticipated that the number of SSIs, specifically *S. aureus* infections, would decrease, reducing the targeted medical center’s healthcare costs and improving patient outcomes.
A Clinical Practice Guideline for *Staphylococcus aureus* Decolonization in Select Surgical Outpatients

Surgical site infections (SSI) are among the most prevalent types of hospital-acquired infections, causing substantial negative consequences for patients and health care systems, including increased morbidity and mortality rates, and higher costs to hospitals and insurers (Klevens et al., 2007). Hospital costs increased an estimated ten to twenty-five thousand dollars per infection in 2005, and the costs are likely to further increase as figures are adjusted for inflation (Anderson et al., 2005; Stone, Braccia, & Larson, 2002). The extra costs can be attributed to increased length of hospital stay, additional medications and therapies, readmission costs, and further charges accrued through increased morbidity related to SSIs (Chlebicki, Safdar, O’Horo, & Maki, 2013). In 2012, the number of national SSIs occurring for ten procedures specifically tracked by the Centers for Medicare and Medicaid Services (CMS) was over 13,770 annually, and the SSI rate at the targeted institution has been increasing over the past several years (Centers for Disease Control and Prevention (CDC), 2015; CDC, 2016). Adding to accumulating financial challenges, CMS no longer reimburses hospitals for SSIs, leaving hospitals saddled with the excess debt (CMS, 2015).

The CDC defines SSIs as infections that occur within 30 days of an operation and involve either purulent drainage, isolated organisms obtained from a culture, and/or clinical signs and symptoms of infection such as erythema or edema (Mangram, Horan, Pearson, Silver, & Jarvis, 1999). SSIs are classified by location and depth of the infection. The infections may be superficial, involving the skin or subcutaneous tissue; deep incisional, involving soft tissue and/or fascia; or organ/space, including any other part of the patient’s surgically manipulated anatomy (Mangram et al., 1999). Although all SSIs are concerning, deep and/or organ/space
infections are particularly worrisome if they involve cardiac or orthopedic procedures, are caused by *Staphylococcus aureus* (*S. aureus*), and/or incorporate artificial hardware (Thompson & Houston, 2013).

The intent of many perioperative interventions is to decrease bacterial colonization and transient flora on surrounding skin, and to prevent contamination of the surgical wound (Chlebicki et al., 2013). Interventions can include application of prophylactic antimicrobials, nasal and skin antiseptic techniques, and surgical techniques (Edmiston, Okoli, Graham, Sinski, & Seabrook, 2010). Chlorhexidine gluconate (CHG), an antiseptic agent, has been used for years but has recently gained popularity for its unique ability to suppress microbial growth for up to six hours post-application with a cumulative antimicrobial effect after repeated applications (Edmiston et al., 2010). CHG does not undergo inactivation in response to contact with blood and is effective against gram-negative and gram-positive non-spore-forming bacteria, as well as enveloped viruses such as HIV (Edmiston, Seabrook, Johnson, Paulson, & Beausoleil, 2007; McDonnell & Russell, 1999; Veiga et al., 2009). Although CHG decreases cutaneous bacterial load, preoperative CHG baths have not been proven to decrease the rate of SSIs (Webster & Osborne, 2015). Due to the lack of definitive evidence linking CHG to decreased SSI rates, national guidelines and accrediting organizations cannot require preoperative CHG baths. However, significant evidence does suggest that CHG decreases the incidence of *S. aureus* colonization and infections; therefore, use of CHG is still recommended in patient-care guidelines (Berrios-Torres, 2014; Mangram et al., 1999; Webster & Osborne, 2015).

The targeted medical center has chosen CHG as the skin antisepsis product of choice for their elective surgical patients who are medically evaluated through the outpatient Patient Readiness and Evaluation Program (PREP) Center. Providers at the PREP center prescribe CHG
preoperative skin antisepsis products for outpatient, elective surgical patients. However, the preoperative orders are not consistent across all providers and patients for identical surgical procedures. For adult, non-emergent cardiac surgery and adult orthopedic total arthroplasties of the hip and knee, patients can be medically cleared for surgery in one of three ways: at their surgeon’s office, at the ambulatory PREP Center, or over the phone by PREP Center Nurse Practitioners. The choice of medical clearance is dependent on the patient’s comorbidities and the provider’s preference. The medical center purchases preoperative CHG-cloth-kits as part of the normal perioperative budget, with the intent of distributing these kits to all patients at the time of their preoperative medical clearance appointment. Unfortunately, based on information obtained from staff at the surgeons’ offices and the PREP Center, the CHG-cloth-kits are not consistently distributed to all patients for these specific procedures.

This quality improvement (QI) project was designed to address the inconsistent ordering, distribution, and use of the CHG-cloth-kits, as well as the increased SSI rates at this center. The purpose of this DNP scholarly project was to develop, implement, and evaluate an institutional clinical practice guideline (CPG) for the decolonization of *S. aureus* in adult, non-emergent cardiac surgery and total hip and/or knee arthroplasties. This manuscript focuses primarily on the CHG bathing aspects of the larger decolonization bundle outlined within the guideline.

By creating a uniform, standard of practice using CHG, it is expected that post implementation all providers would prescribe the appropriate CHG skin prep regimen for preoperative patients via the electronic health record, all patients would receive the same CHG-cloth-kits at the time of their medical clearance appointment, and all patients would receive consistent education on proper use of the CHG-cloth-kits. In developing an evidence-based guideline for CHG use within a larger decolonization bundle, it was anticipated that the guideline
would be evaluated and graded as high-quality and be considered reasonable and practical for implementation

**Theoretical Framework**

The *Stevens Star Model of Knowledge Transformation*, developed by Stevens (2015), is a five-step practice-level model for the implementation of evidence-based practice; the preoperative CHG CPG was developed using this model (See appendix A). Each component of the model addresses an aspect of knowledge integration and presents common barriers to successful progression. The steps are sequential in order and include: (a) knowledge discovery, (b) evidence summary, (c) translation to guidelines, (d) practice integration, and (e) process outcome evaluation. Stevens explains that a plethora of scientific knowledge is available and emphasizes that this knowledge must be translated into evidence-based guidelines and policies to guide clinical interventions.

According to Stevens, data and new knowledge is developed through research, and that data is then synthesized via literature reviews, meta-analyses, and systematic reviews. The summarized knowledge is then delivered to providers in a form that is suitable to time, cost, and standard of care, usually in the form of clinical practice guidelines. Through formal and informal education, knowledge is integrated into practice. The effects of knowledge and the new interventions are evaluated and modifications to current practice policies can be established (Stevens, 2015). This five-step process is constant, fluid, and circular. By utilizing *Stevens’ Star Model of Knowledge Transformation*, evidence-based literature supporting preoperative CHG use as part of a larger preoperative care bundle was translated into an institutional CPG. This guideline was vetted through the targeted facility using validated usability tools and adjustments were made according to these evaluations.
Literature Review

The focus of this literature review is the use of preoperative bathing with CHG as a means to decrease cutaneous bacterial colonization and SSIs (See Appendix B). The impact of CHG bathing on SSI rates and the evidence supporting CHG’s ability to decrease *S. aureus* SSIs will be analyzed. The discussion will also differentiate between Methicillin-resistant *Staphylococcus aureus* (MRSA) and Methicillin-sensitive *Staphylococcus aureus* (MSSA) in regards to the differences identified in SSI rates. Finally, the review will conclude with current evidence surrounding the role of CHG in preoperative antiseptic and decolonization bundles.

Multiple studies have been completed to determine if preoperative CHG bathing decreases infection rates; however, the results have been mixed, and a definite and direct relationship between the two has not been confirmed. Rotter et al. (1988) compared patients who bathed preoperatively with CHG solution compared to patients who used a placebo solution in a large, multicenter trial. Rotter et al. (1988) found no statistically significant difference in the infection rates of the two groups. Overall, SSI rates were 2.62% in the CHG treatment arm compared to 2.36% in the placebo arm. The study’s findings were strengthened by a large multi-center sample, low attrition, and a standardized method for CHG bathing. Unfortunately, Rotter et al. used subjective assessments of infection instead of a validated tool and inconsistent perioperative antibiotics, creating the concern for confounding variables and decreased internal validity. Rotter et al.’s (1988) results were supported in another seminal study by Byrne, Napier, & Cuschieri (1992), who reported a 14.7% SSI infection rate in patients who showered with a CHG solution preoperatively compared to an SSI rate of 15.8% in patients who showered with a placebo agent. This study had a sufficient sample size based on a power calculation, was blinded and randomized, and used a validated wound grading tool for SSI assessments. In 2015,
the Cochran Library published a fourth update of the systematic review evaluating preoperative bathing to prevent SSI. Over 10,000 participants from randomized controlled trials (RCT) published between 1983-2009 were evaluated. No clear evidence could be found to support the claim that washing with CHG solution preoperatively decreased the incidence of SSIs (Webster & Osborne, 2015). Many of the included studies’ designs lacked the means to prove patient adherence to consistent bathing protocols, used varying definitions of SSIs, and had small sample sizes. The varying SSI definitions created challenges for inter-study comparisons, and weakened the internal validity of the included studies. Similar to the Cochran Review, Schweizer et al. (2015) reported no statistically significant decrease in overall rates of SSIs using a preoperative antiseptic bundle that included CHG preoperative bathing as one of the interventions. They used a heterogeneous patient population that closely mimicked true clinical situations, which strengthened the external validity of the study (Schweizer et al., 2015).

Given the varying quality of published studies, it is not possible to state there is a direct relationship between CHG pre-op bathing and subsequent SSI rates. However, other research has shown encouraging trends related to CHG use and reduced rates of *S. aureus* infections. Colling, Statz, Glover, Banton & Beilman (2015) reviewed all patients between January 2010 through June 2012 who underwent hip and knee arthroplasties at two affiliated hospitals, during which only one of the hospitals used a preoperative CHG regimen. No significant difference was found between the CHG group and the non-CHG group regarding overall hospital SSI rates (*p*=1.0). However, Colling et al. did report a statistically significant difference (*p*=0.03) in rates of SSIs caused by *S. aureus* between the two hospitals (17% vs. 61%). These results suggest that CHG does not reduce the overall rate of SSIs, but does decrease the incidence of SSIs being caused by *S. aureus*. A standardized decolonization protocol was used throughout. Unfortunately, this
research was based on patient self-reporting and the data collection was incomplete. Schweizer et al. (2015) screened preoperative patients for \textit{S. aureus} colonization and treated positive patients with a decolonization bundle consisting of mupirocin intranasal ointment, CHG baths, and patient-specific perioperative antibiotics. Implementation of the decolonization bundle showed significant reduction in complex and deep wound \textit{S. aureus} SSIs (odds ratio, 0.60 [95\% CI, 0.37-0.98]). The research also identified a statistically significant increase in the number of months that passed without any complex SSI diagnoses for the hospital (\(p=0.006\)).

Based on the evidence at this time, the greatest impact on SSI outcomes is found when CHG preoperative bathing is incorporated into a preoperative decolonization bundle. As previously stated, Schweizer et al. decreased \textit{S. aureus} SSIs with the implementation of a decolonization bundle. In 2009, Pofahl et al. examined the impact of MRSA screening and subsequent prescribing of a decolonization bundle preoperatively at a tertiary care hospital. The rate of MRSA SSIs in patients undergoing orthopedic procedures decreased significantly between pre and post-bundle implementation (\(p=0.04\)). The rate of MSSA SSI did not change significantly, but trends toward statistical significance were noted. Another finding in the study showed that the four patients who screened positive for MRSA preoperatively, but did not complete the decolonization protocol, subsequently developed MRSA SSI\_s. This data suggests that the preoperative bundle offered effective protection for the patients who followed the protocol. Similar to Pofahl et al., Thompson and Houston (2013) reported a significant decrease in MRSA SSI rates for two consecutive years after a preoperative bundle using mupirocin and CHG cloths was implemented for their cardiac, orthopedic, neurosurgery, and vascular patients (year one \(p=0.016\), year two \(p=0.003\)). Interestingly, the hospital’s MRSA SSI rate increased in
the populations not included in the bundle implementation, supporting the effectiveness of the bundle.

The validity of the three patient-bundle studies highlighted in this review was strengthened due to large sample sizes, and their alignment with national SSI standards for assessment and tracking. As stated previously, CMS tracks SSI rates based on CDC definitions; studies that use primary outcomes and definitions different from CDC and CMS standards weaken their internal and external validity. It should be noted, however, that preoperative asepsis campaigns had been initiated at several of the sites used in the study, and this may have affected the results noted herein.

There is mounting evidence that CHG applied pre-operatively may work best as part of a bundled approach, especially since CHG efficacy is cumulative with repeated application over several days (Edmiston et al., 2013) Standardized, multi-day, preoperative decolonization bundles may optimize cutaneous concentrations of CHG, but the optimal number of applications is unknown (Edmiston et al., 2013). Bailey et al. (2011) used an analytic computer simulation model and determined that home-based preoperative bathing with CHG is cost-effective across a wide range of antimicrobial cloth efficacy and patient compliance scenarios. For example, Bailey et al. (2011) ran scenarios with 10%, 25%, 50% and 75% cloth efficacy paired with 25%, 50%, 75%, 100%, 150%, and 200% baseline patient compliance to understand the significance of multiple product and patient variables. Using over one million simulations with multiple patient scenario combinations, the researchers suggest patient compliance may not be as important as originally thought. The simulations showed that CHG is one cost-effective component of a preoperative decolonization bundle to decrease infection rates.
The literature reviewed herein suggests that CHG bathing, as part of a preoperative decolonization bundle that also includes MRSA colonization screening, targeted mupirocin intranasal ointment for colonized patients, and patient-specific perioperative antibiotics may significantly decrease the incidence of SSI caused by *S. aureus* (Pofahl et al., 2009; Schweizer et al., 2015; Thompson and Houston, 2013) Although CHG is not proven to decrease overall SSI rates, the benefit of its cumulative and persistent effects on decreasing bacterial colonization, especially *S. aureus*, is documented and allows for widely accepted preoperative CHG use (Colling et al., 2015; Mangram et al., 1999; Veiga et al., 2009). MRSA is independently associated with increased morbidity and mortality; therefore, economical and effective infection prevention strategies continue to be a major focus for health care institutions (Bailey et al., 2011; Edmiston et al., 2013; Thompson & Houston, 2013).

**Methods**

**Study Design, Setting, and Sample**

As stated previously, this QI project involved the development of an institutional CPG for CHG bathing as part of a larger decolonization bundle. The setting for this CPG was an ambulatory, PREP Center within an urban, tertiary, mid-Atlantic medical center. Two samples were utilized to appraise the quality of the CPG. The first sample included seven subject-matter-experts (SMEs) representing primary and secondary stakeholders within key departments. The identified SMEs included the Clinical Assistant Professor of Anesthesiology, the Nurse Manager for the PREP Center and Ambulatory Surgical Care Unit, the Division Head of Health Care Outcomes Research, the Medical Director of Infection Prevention and Hospital Epidemiology, the lead Nurse Practitioner from the PREP Center, a member of the Department of Infection Prevention and Epidemiology, and the Director of Infection Prevention and Hospital
Epidemiology. The second sample included eight end-users such as nurse practitioners, staff nurses, clinical infectious-disease pharmacists, and other direct patient care professionals in the perioperative departments.

**Procedures**

This QI project was divided into three phases, as described below. The three student members of the DNP committee who focused on the development and evaluation of the CPG participated in all phases, and specific duties were determined based on need, clinical expertise, and availability within the timeline. The site coordinator facilitated stakeholder meetings, offered guidance when professional obstacles arose, reviewed the CPG rough draft, and reminded stakeholders and end-users to submit their feedback. A full timeline for this project is provided in Appendix C.

**Phase One.** Phase One involved conducting introductory meetings with primary and secondary stakeholders to address an overview of the project, desired outcomes, and recommendations for the PREP Center. Visual aids such as summaries of literature, project objectives, and a skeleton draft of the CPG were used to focus the meetings. The *Stevens Star Model of Knowledge Transformation* (Stevens, 2015) was incorporated into the CPG presentations to illustrate the model’s utility throughout the development, implementation, and evaluation of the CPG. The summaries of project goals and skeleton drafts of the CPG were made available to stakeholders.

Desired outcomes included decreasing surgical patients’ *S. aureus* SSI infections, decreasing overall SSI rates, and decreasing or eliminating patient care inconsistencies within the perioperative system. See Appendix F for detailed desired outcomes and recommendations included within the CPG.
After the introductory meetings with the stakeholders were completed, the skeleton of the CPG was edited into a first draft incorporating preliminary input from the stakeholders, the institution’s vision, and current evidence of best practices. See Appendix B for details regarding current literature. This CPG first draft was e-mailed to the SMEs for their review and/or comments, and follow-up meetings occurred to clarify their feedback. Appropriate SME feedback was incorporated into the second draft of the CPG. Additionally, at these second meetings, SMEs received a guided overview and copy of the Appraisal of Guidelines for Research & Evaluation (AGREE) II tool and a rapid-read tip sheet so that they could familiarize themselves with the tool before Phase Two began (Brouwers et al., 2010) (see References for a link to the AGREE II tool). Between Phases One and Two, the edited CPG was reviewed with the DNP committee before it was redistributed to the SMEs for AGREE II appraisal.

**Phase Two.** The SMEs were contacted to review and appraise the updated guideline. Utilizing the AGREE II tool, six domains were evaluated: CPG Scope and Purpose, Stakeholder Involvement, Rigor of development, Clarity of Presentation, Applicability, Editorial Independence and Overall Guideline Assessment (Brouwers et al., 2010) (see Appendix D). SMEs were given three weeks to appraise the CPG before their feedback was collected through the password-protected My AGREE PLUS platform provided by The AGREE II Trust. SME scores and feedback obtained through the AGREE PLUS platform was used to revise the CPG before it was distributed to end-users.

**Phase Three.** In Phase Three, the revised CPG was presented to the end-users to evaluate the guideline for acceptability, usefulness, and sustainability. The Practitioner Feedback Questionnaire (Brouwers, Graham, Hanna, Cameron, and Browman, 2004) was utilized to assess and obtain end-user data (see Appendix E). The Practitioner Feedback
Questionnaire collects data across four factors: *quality of the practice guideline and rigor of its development, acceptability of the recommendations, applicability of the recommendations, and value of the new recommendations compared to current practice* (Brouwers et al., 2004).

Incorporating end-user feedback regarding these four factors is imperative to translating evidence and knowledge into realistic practice, a critical step highlighted in the *Stevens Star Model of Knowledge Transformation* (Stevens, 2015). Using the Practitioner Feedback Questionnaire data, the CPG was revised again. The updated CPG and the corresponding CHG-cloth-kit patient instructions were reviewed with the DNP committee and final revisions were completed. The results of Phase Two and Three were disseminated to the PREP Center Nurse Practitioner Group and the Department of Infection Prevention and Hospital Epidemiology. Both groups were presented with the final CPG and the patient instructions (Appendix F, G, I) and the CPG was submitted to the Director of Infection Prevention and Hospital Epidemiology for future implementation.

**Data Collection**

Several methods of data collection were utilized throughout the three phases of this QI project. During meetings with stakeholders, records were kept and referenced throughout the drafting and revision processes. The AGREE II tool was utilized to assess CPG quality. This tool was developed to assess clinical guidelines, offer strategic guidance for the development of guidelines, and provide a universal structure and format for guidelines (Brouwers et al., 2010). The data obtained from the AGREE II tool was reported on a Likert scale with scores ranging from one (strongly disagree) to seven (strongly agree). Total domain scores were calculated according to the methods outlined within the tool and overall scores were analyzed to interpret the quality of the CPG. CPG recommendations with less than 80% agreement between SMEs
were considered for amendments or removal from the guideline. The *My AGREE PLUS* platform documented and organized all obtained data according to domain during Phase Two.

As stated, the Practitioner Feedback Questionnaire collects data across four factors. The reported reliability of the questionnaire ranges from 0.75 to 0.85 (Brouwers et al., 2004). The factors’ ordinal data was collected using a Likert-type scale with three fixed choice responses: agree, neither agree nor disagree, and disagree. In addition to the questionnaire data, each volunteer’s professional role within the perioperative departments was collected for data analysis and inter-role comparisons. The online platform documented and organized all data collected during Phase Three. During each data collection period, participants had over 21 days to submit their feedback. The 21-day timeline was reassessed throughout both phases and extended to allow for optimal participation.

**Protection of Human Rights**

Leading up to Phase One, an Institutional Review Board (IRB) query for a nonhuman subjects’ research determination was submitted to the University of Maryland Baltimore IRB committee as well the institution’s IRB committee (see Appendix H). Once this determination was made, Phase One began. All participants were volunteers, and all data was de-identified, with the exception of professional job title, to protect the participants. Data from the AGREE II tool and the Practitioner Feedback Questionnaire was collected through password-protected digital services including The AGREE II Tool’s *My AGREE PLUS* platform and an online survey service. Furthermore, throughout this QI project, no overt changes in practice took place. Rather, the focus was to eliminate inconsistencies within the PREP Center’s current practice by developing a CPG. The CPG was not implemented for patient use during this DNP project;
implementation was operationalized through the AGREE II tool and the Practitioner Feedback Questionnaire.

**Results**

The sample for Phase Two consisted of seven SMEs. There was 100% completion of the AGREE II tool by all seven participants. All six domains scored greater than the targeted 80% agreement. The highest scoring domain was *Editorial Independence* with 94% agreement, while the lowest scoring domain was *Applicability* scoring 82% agreement. Additionally, the final item of *Overall Assessment of the Guideline* scored 90% agreement with six SMEs stating they would recommend use of the guideline and one SME stating he or she would recommend use of the guideline with modifications.

In Phase Three, the sample consisted of eight end-users who completed the Practitioner Feedback Questionnaire. These end-users consisted of four providers, two clinical pharmacists, and two registered nurses. As described earlier, the Practitioner Feedback Questionnaire responses are categorized into four factors: *Quality, acceptance of recommendations, applicability of recommendations*, and *comparative value*. *Quality* scored the highest with 93.75% favorable responses, 6.25% neutral responses and 0% negative responses. *Applicability of recommendations* scored the lowest with 35.5% positive responses, 45.2% neutral responses, and 19.4% negative responses. Within the *applicability of recommendations* factor, there was one participant who did not respond to one item. This was the only missing data for both phases. The final two items within the questionnaire, which assessed end-users’ overall approval and likelihood to use the CPG, scored 100% favorable responses. Refer to Tables A and B, and Figure 1 for details regarding all AGREE II domains and Practitioner Feedback Questionnaire factors.
Discussion

In response to increasing SSI rates and lack of standardization for peri-operative practices at the target facility, The Clinical Practice Guideline for the Decolonization of *Staphylococcus aureus* in Elective Cardiac Surgery and Total Hip and Knee Arthroplasty was developed and evaluated utilizing two validated tools. Applying the AGREE II Tool, the guideline scored above the target 80% agreement for all six domains. The seven SMEs judged the guideline to be of high quality; high quality means that the CPG was developed by appropriate stakeholders and represents the views of intended users, was created from rigorous evidence synthesis, was clear and structurally logical, addressed facilitators and barriers to implementation, and was unbiased and without competing interests (Brouwers et al., 2010). The guideline scored lowest within the Applicability domain with 82% agreement. Although this was the lowest score, it remained above the target goal of 80% agreement. To improve the quality of this domain, recommendations for barriers, facilitators, intervention monitoring, and timelines for implementation were addressed in the CPG revision. In addition to these added recommendations, comments made by the SMEs were incorporated or amended within the CPG. As outlined by the Stevens Star Model (Stevens, 2015), the process of CPG development, evaluation, amendment, and re-evaluation is critical for the successful translation of knowledge into practice. The model’s concepts were operationalized through a thorough literature review followed by a systematic development, evaluation, revision, and re-evaluation process by SMEs and this DNP committee. Overall, the SMEs would recommend use of the guideline for the intended population.

Following the process outlined by the Stevens Star Model, the revised CPG was given to
end-users for further evaluation. The majority of end-user feedback in Phase Three was favorable. The CPG scored lowest in the *applicability of the recommendations* factor. This is not surprising since this CPG did not focus on, or explicitly outline operationalization within the institution; the revised recommendations for barriers, facilitators and monitoring were general so that the institution may apply the guidelines in a manner that was cohesive with their staff and ancillary resources. Accordingly, within the *applicability of recommendations* factor, 50% of the end-users reported that to apply the CPG recommendations would require reorganization of services and care. Under the circumstances, this reorganization of services and care is not necessarily a negative event. Before Phase One commenced, the PREP center environment was assessed for causes of the inconsistencies in practice. Inconsistencies in process, education, and patient management were highlighted and became one of the focuses of this CPG. Therefore, perioperative processes can be re-examined with the CPG in mind, and possibly streamlined or standardized. Tasks may need to be reassigned to different professional roles to improve workflow, standardization, and patient satisfaction. When the end-users were asked how technically challenging the CPG implementation would be, 79% of responses were neutral, while only 14.29% believed the CPG would be too challenging to apply. This enforces that although changes in flow will be necessary, these changes are reasonable. Sixty-two percent of end-users felt that the draft recommendations were not overly rigid for individual patients and 75% stated they felt the CPG would produce benefits for their patients.

**Limitations**

There are several limitations within the development of this CPG stemming from difficulties gaining access to stakeholders early and often. Lead surgeons from both the Cardiac Surgery and Orthopedic Services were not accessed until Phase Three. This significantly limited
primary stakeholder involvement during the guideline development. Lack of surgeon input created potential for resistance, anger, and decreased buy-in during the evaluation phase and future implementation. Late access to the surgeons and their service’s Nurse Practitioners prohibited this committee from assessing their perceptions of the problem, any past attempts to rectify these problems, and their readiness for change within their pre-operative process. Since the surgeons were not accessed until late in Phase Three, they did not participate in evaluating the CPG utilizing a validated tool. Instead, their informal individual feedback was considered during final revision of the CPG. In addition to late access to surgeons, limited access to end-users prohibited a robust group of end-users. The small sample of eight end-users did not allow for variance analysis of usability between roles.

Accessing the system and contacting stakeholders and SMEs proved to be the most difficult barrier to overcome throughout this process. Despite having points of contact within the facility, feedback from the contacts was minimal unless prefaced with an introduction from a colleague. This barrier emphasizes the need for a solid network and proper management of stakeholders within a health care system in order to make QI a reality.

**Future Direction**

Looking forward, an interdisciplinary task force must be formed; this task force will devise the implementation strategy necessary to translate the CPG into a working bundle. The barriers identified in the CPG as well as those outlined by the Practitioner Feedback Questionnaire must be addressed and planned for utilizing a translational theory to guide implementation, buy-in, and staff education. Although the selected *Stevens Star Model* is a practice-level model, it is not an implementation model and therefore, will be too vague for the task force to use regarding techniques for overcoming barriers and achieving staff buy-in.
Instead, a literature review for translational research and a performance improvement model should be utilized for implementation to identify specific process redundancies and techniques for overcoming the identified barriers to implementation. The literature review should focus on specific methods for successful and sustainable incorporation of the CPG recommendations into PREP Center workflow. Although many of the barriers to successful incorporation were briefly discussed within the CPG, operationalization was not outlined to the detail required for smooth patient implementation.

During implementation of practice changes, the culture of an institution bears significant weight compared to evidence-based interventions; therefore creating policy from an evidence-based CPG is not without its own challenges. Brownson, Chriqui, and Stamatakis (2009) state that research evidence may hold equal or less importance than other factors when creating health policy. The Institute of Healthcare Improvement states that on average, there is a 17-year lag for new evidence-based findings to reach clinical practice (Balas & Boren, 2000). Competing priorities, stakeholder mismanagement, mismatched time horizons, research being isolated from those in charge of policymaking, and lack of value placed on prevention of specific outcomes are several examples given for why health policy and scientific evidence do not consistently align (Brownson et al, 2009). Furthermore, institutions that hold traditional, hierarchal leadership pyramids often require top down delegations of power to initiate change. In one meeting with stakeholders, it was mentioned that a senior mandate would be required to implement this CPG. This comment suggests that the target facility has a top-down management structure with less center-out innovation, collaboration, or quantum leadership (Fewster-Thuente & Velsor-Friedrich, 2008).

Many of these barriers will affect successful implementation of this CPG at the PREP
Center or within the associated service lines. Some of these barriers to implementation were proactively managed during the development and evaluation stages of this CPG. All the SMEs and end users agreed that the CPG is of high quality and would be useful if implemented. Although it was late, buy-in from cardiac surgery, orthopedic surgery, infection prevention, and PREP center providers was achieved. It may prove prudent to pilot implementation within one surgical service line that directly feeds into the PREP Center, such as Cardiac Surgery. Multiple Cardiac Surgery nurse practitioners participated in the Practitioner Feedback Questionnaire, and there was approval by one of the lead cardiac surgeons. Additionally, there is a dedicated member of the Infection Prevention Department who acts as a liaison between the two departments. The level of buy-in from this service, and the direct connection to the Infection Prevention Department, suggests this service line may be the most receptive and prepared for implementation congruently with the PREP center. A strong translation theory, specific implementation strategies, and a dedicated task force will be essential for successful implementation despite identified barriers.

**Conclusion**

According to the Stevens Stare Model of Knowledge Transformation, knowledge is created through research but remains isolated unless it can be successfully translated into something usable. Volumes of data regarding SSIs and decolonization strategies exist, however this information remains in silo from current infection prevention guidelines and therefore, remains unusable for institutions struggling with increasing SSI rates. To address the inconsistent perioperative decolonization practices, as well as the increased SSI rates at the targeted medical center, a QI project to develop an institutional CPG for CHG bathing as part of a larger decolonization bundle was completed. The CPG was evaluated for quality utilizing the AGREE
II Tool and assessed for applicability and usability utilizing the Practitioner Feedback Questionnaire. The CPG was found to be of high quality and all end-users agreed they would use the CPG if it were implemented at their facility. The Stevens Star Model of Knowledge Transformation facilitated the organized process for translating the evidence into the guideline, followed by systematic evaluation and revision phases utilizing valid and reliable tools. The cyclical, constant evaluation of data, and the interaction with clinical experts, allowed the recommendations to evolve into a high quality guideline, and made the aforementioned isolated knowledge into something meaningful and useful. The goals of the CPG to standardize practice and minimize patient morbidity align with institutional missions to deliver superior health care and discover ways to improve health outcomes. If the guideline were implemented as standard institutional practice, it is anticipated that the number of SSIs, specifically S. aureus infections, would decrease, reducing the targeted medical center’s healthcare costs and improving patient outcomes.
References


Edmiston, C.E., Seabrook, G.R., Johnson, C.P., Paulson, D.S., & Beausoleil, C.M. (2007). Comparative of a new and innovative 2% chlorhexidine gluconate-impregnated cloth with 4% chlorhexidine gluconate as topical antiseptic for preparation of the skin prior to


STAPHYLOCOCCUS DECOLONIZATION

Tables

Table A

AGREE II Tool Data and Target Agreement

<table>
<thead>
<tr>
<th>Domain</th>
<th>Scope and Purpose</th>
<th>Stakeholder Involvement</th>
<th>Rigor of Development</th>
<th>Clarity of Presentation</th>
<th>Applicability</th>
<th>Editorial Independence</th>
<th>Overall Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Agreement to item</td>
<td>91%</td>
<td>87%</td>
<td>89%</td>
<td>90%</td>
<td>82%</td>
<td>94%</td>
<td>90%</td>
</tr>
<tr>
<td>Target Agreement</td>
<td>80.00%</td>
<td>80.00%</td>
<td>80.00%</td>
<td>80.00%</td>
<td>80.00%</td>
<td>80.00%</td>
<td>80.00%</td>
</tr>
<tr>
<td>Would you use this Guideline</td>
<td>Yes</td>
<td>No</td>
<td>Yes with Modifications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>0</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: n=7
Table B

Practitioner Feedback Questionnaire Data

<table>
<thead>
<tr>
<th>Factor</th>
<th>Favorable Responses</th>
<th>Percent Favorable Responses</th>
<th>Neutral Responses</th>
<th>Percent Neutral Responses</th>
<th>Negative Responses</th>
<th>Percent Negative Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>45/48</td>
<td>93.75%</td>
<td>3/48</td>
<td>6.25%</td>
<td>0/48</td>
<td>0%</td>
</tr>
<tr>
<td>Acceptance of Recommendations</td>
<td>38/48</td>
<td>79.2%</td>
<td>10/48</td>
<td>20.8%</td>
<td>0/48</td>
<td>0%</td>
</tr>
<tr>
<td>Applicability of Recommendations</td>
<td>11/31</td>
<td>35.5%</td>
<td>14/31</td>
<td>45.2%</td>
<td>6/31</td>
<td>19.4%</td>
</tr>
<tr>
<td>Comparative Value</td>
<td>13/16</td>
<td>81.25%</td>
<td>3/16</td>
<td>18.75%</td>
<td>0/16</td>
<td>0%</td>
</tr>
<tr>
<td>Overall Outcomes</td>
<td>32/32</td>
<td>100%</td>
<td>0/32</td>
<td>0%</td>
<td>0/32</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Note: n=8*
Results from the AGREE II appraisal, presented as percent agreement. The data obtained from the AGREE II tool were reported on a Likert scale with scores ranging from one (strongly disagree) to seven (strongly agree). Domain scores were calculated by the equations: 

\[
\frac{\text{Obtained score} - \text{Minimum Possible Score}}{\text{Maximum Possible Score} - \text{Minimum Possible Score}} \times 100
\]

Domain scores were as follows: Scope and Purpose 91%, Stakeholder Involvement 87%, Rigour of Development 89%, Clarity of Presentation 90%, Applicability 82%, Editorial Independence 94%, and Overall Guideline Assessment 90%. Target Agreement, as defined by the AGREE II Trust, is 80%.

Figure 1. n=7. Results from the AGREE II appraisal, presented as percent agreement. The data obtained from the AGREE II tool were reported on a Likert scale with scores ranging from one (strongly disagree) to seven (strongly agree). Domain scores were calculated by the equations: 

\[
\frac{\text{Obtained score} - \text{Minimum Possible Score}}{\text{Maximum Possible Score} - \text{Minimum Possible Score}} \times 100
\]

Domain scores were as follows: Scope and Purpose 91%, Stakeholder Involvement 87%, Rigour of Development 89%, Clarity of Presentation 90%, Applicability 82%, Editorial Independence 94%, and Overall Guideline Assessment 90%. Target Agreement, as defined by the AGREE II Trust, is 80%.
Appendix A

Stevens Star Model of Knowledge Transformation

Note: Adapted from Stevens (2015). Five-step practice-level model for the implementation of evidence-based practice.
Appendix B

Evidence Rating Table Supporting and Disputing Use of Chlorhexidine Preoperative Bathing

<table>
<thead>
<tr>
<th>#</th>
<th>Author(s), year</th>
<th>Objective</th>
<th>Design and Sample size (n)</th>
<th>Outcomes Studied/ Results</th>
<th>Strengths (.) &amp; Limitations (-)</th>
<th>Rating (Strength / Quality)</th>
</tr>
</thead>
</table>
| 1 | Bailey, Stuckey, Norman, Duggan, Bacon, Connor, Lee, Muder, & Lee (2011) | • Determine, from the perspective of the hospital, the economic value of preoperative CHG-cloth bathing for orthopedic patients | • Computer simulation model  
• Stochastic decision-analytic computer simulation model depicting the decision of whether to distribute a CHG-cloth-kit to patients for home-based preoperative bathing.  
• 1,000,000 simulated trials. | • Measured effectiveness of bathing with CHG cloth in “quality of adjusted life-years” (QALY)  
• Incremental cost-effectiveness ratio (ICER)  
• ICER less than $50,000 per QALY is considered cost-effective.  
• Home-based preoperative bathing with CHG is cost-effective across a wide range of antimicrobial efficacy and patient compliance scenarios.  
• Model suggests that concerns about patient compliance and cloth efficacy may not be as crucial as previously thought in relevant literature. | • Simulated pre, intra, and post-operation care/variables were protocolized in both the treatment and control arms increasing internal validity.  
• Created a range of scenarios to mimic true hospital perspectives.  
• The literature used to create simulations was assessed for robustness of the results.  
- Computer simulation models are simplifications of clinical situations.  
- Models based on literature that examined CHG cloth use for SSI prevention- literature may have been biased. | 3A |
<table>
<thead>
<tr>
<th></th>
<th>Authors</th>
<th>Study Details</th>
<th>Methods</th>
<th>Results</th>
<th>Conclusions</th>
</tr>
</thead>
</table>
| 2 | Byrne, Napier, & Cuschieri (1992) | • Impact of CHG whole body washing on wound infection rates | • Randomized Controlled Trial (RCT)  
• Prospective, Experimental  
• Placebo-controlled  
• *n* = 3,489 | **SEMINAL STUDY**  
• Wound score  
• Length of stay  
• Timing of wound infection  
• Patient demographics  
• 257/1745 (14.7%) in CHG arm vs. 271/1721 (15.8%) in the control arm scored as having postoperative infections. | **Power calculation performed and sample large enough**  
**Blinded, randomized protocol**  
**Validated wound grading tool.**  
**Low attrition**  
**Low risk for bias**  
**Included level I and II wounds** |
| 3 | Colling, Statz, Glover, Banton & Beilman (2015) | • Determine if preoperative antiseptic showers or baths decrease the rate of SSI | • Retrospective review of all patients who underwent hip and knee arthroplasties at two affiliated hospitals between January 2010 through June 2012.  
• CHG preoperative bathing at the medical center vs. no specified pre-operative CHG bathing the affiliated regional hospital  
• Convenience sample  
• *n* = 4,042 | **Patient demographics**  
**Type of procedure and related anesthesia**  
**American Society of Anesthesiologists score**  
**Wound class**  
**Surgical infection rate compiled from reports, surveys, diagnostic coding, and surveillance software**  
**Wound cultures from identified SSI**  
**No statistically significant difference between hospitals’ SSI rates**  
• 1.96% vs. 1.95% (p=1.0)  
• Statistically significant difference of SSI caused | **Same hospital system; obtaining patient data is consistent**  
**All patients had the same intraoperative skin antiseptic procedures decreasing variables and increasing internal validity**  
**Prophylactic antibiotics were protocolized decreasing variables increasing internal validity.**  
**Captured wound assessment data in many ways; decreased chance for missing wound data**  
- Regional hospital
by MSSA/MRSA between the two hospitals
  ○ 17% vs. 61%  
    (p=0.03)
- CHG does not reduce the overall rate of SSI however it does decrease the morbidity related to SSI caused by *S. aureus*
- *S aureus* infections cause significant morbidity and increase hospital cost compared to other pathogens.

| performs approximately half the number of cases compared to the medical center. The volume of patients seen is not equal. Decreases interval validity |
| - Patient showers were completed at home. Unable to verify technique and therefore unable to verify consistency and compliance. Weakens internal validity. |
| - Only 75% of patients had documentation addressing pre-operative bathing. |
| - Limited data on shower compliance before 2012. |
| - Compliance documented per patient report and subject to bias. Bias and missing data decreases internal validity |
| - Electronic charting changed for the regional hospital in 2011. Authors unable to acquire patient demographic data on patients who did not get an SSI. Missing data |
|   | Address the evidence that CHG has a broad safe range of application when used in as an adjunct intervention to prevent SSI. | Literature Review | CHG efficacy is cumulative with repeated application. Standardized protocols and patient compliance may optimize cutaneous concentrations of CHG. CHG cloths may work best as part of a bundled approach to SSI prevention. Optimal number of applications pre-operation is undetermined. CHG reduces skin flora more effectively than alcohol/iodine agents or combinations of these two agents Low incidence of hypersensitivity to CHG | Decreases internal validity and causes undue bias. Multiple brands of CHG were used in the medical center. Confounding variables |
|---|---|---|---|
| 4 | Edmiston, Bruden, Rucinksi, Henen, Graham, Lewis (2013) | • Not a systematic review • Opinion of individual based on research evidence | 5B |
| 5 | Pofahl, Goettler, Ramsey, Cochran, Nobles, & Rotondo (2009) | • Examine impact of MRSA screening and preoperative eradication bundle • Quasi-experimental • Prospective intervention arm compared to historical control arm. n=5,094 patients • Statistically significant decrease in rate of MRSA SSI in patients undergoing orthopedic procedures. (p=0.04) • Four patients who screened (+) for MRSA did not go through eradication per protocol and subsequently developed an MRSA SSI. Rate of MSSA SSI did not change significantly however trended toward statistically significant. | - Surgical subgroups aligned with national surveillance initiatives and therefore are very accurately tracked. - Standardized protocol for MRSA screening and eradication - Peri-operative antibiotic regimens changes during the intervention timeframe. - Retroactive data | 2B |
|   | Rotter, Larsen, Cooke, Dankert, Daschner, Greco, Gronroos, Jepsen, Lystad, & Nystrom (1988) | The effect of preoperative whole-body bathing on two occasions with a detergent containing CHG | Prospective, Randomized, double-blind, placebo-controlled experimental | CHG solution baths the day before surgery and the morning of surgery vs. placebo baths following the same schedule | 27 surgical departments in 6 countries | level 1 wounds/operation | n=2,813 | (1,413-CHG; 1,400-placebo) | **SEMINAL STUDY** | Patient demographics | Types of operation | Use of Prophylactic antibiotics | Type of organism cultured from the wound | No statistically significant difference between treatment groups regarding the rate of post operation infection | **2.62% in CHG arm vs. 2.36 in the control arm.** | Large sample from multiple centers | Low attrition rate | Low risk for bias | Standardized method for cleansing both instructed and written for patients | 1B | - No power calculation | - Did not follow patients for full 30 days post operation | - Unable to determine if patients were consistent with cleansing practices |
### Subjective definition of infection:
- No validated tool
- Relied on surgeons to turn in data regarding their patient outcomes.
- Inconsistent use of prophylactic antibiotics

- 20 hospitals affiliated with Hospital Corporation of America Research  
- n= 38,049 patients and 42,534 operations.  
- Prospective interventional group compared to pre-intervention measurements with time-series evaluation.  
- Rolling implementation of bundle June 1, 2012 through October 1, 2012  
  o MSSA/MRSA (+) Patients received Mupirocin ointment and CHG application daily for five days pre-surgery  
  o MSSA/MRSA (-) Patients received CHG bathing for five days pre-surgery  
- Intra-operative antibiotics | Pre-intervention observational measurements March 1, 2009 through until that specific hospital rolled out their bundle initiate.  
- Preoperative screening for MRSA and MSSA.  
- Degree of bundle adherence by patient  
- Degree of antibiotic adherence by surgeon  
- Wound surveillance according to CDC definition of SSI for 90 days post-operation.  
- Patient variables obtained from corporate data warehouse  
- Susceptibility testing on cultured organisms.  
- Rates of SSI, types of organisms, level of wound complexity, and readmission rates | Susceptibilities of organism isolates all tested in the same lab with the same techniques increasing internal validity.  
- Infection subgroup stratification decided \textit{a priori}.  
- Power calculation performed: Need 8,905 operations to reach 70% power to detect a 30% relative reduction ratio.  
- Heterogeneous patient population closely represented a true clinical situation increasing external validity.  
- Stratified level of bundle adherence for more concise data collection and clinical meaningfulness.  
- Rolling bundle |
were tailored to MRSA/MSSA screen results.
- Patients 18 years of age or older who underwent scheduled, urgent, or emergent primary hip or knee arthroplasty, or primary cardiac operation through median sternotomy incision with no preexisting surgical site infection.
- Audits monthly for assessment of adherence to bundle elements.

- Associated with the infections.
- **Statistically significant decrease in overall complex MRSA/MSSA SSI rates**
  - Odds ratio 0.60 [95% CI, 0.37-0.98]
- **Statistically significant increase in months without complex SSI**
  - \( p=0.006 \)
- **Overall SSI rates did not statistically significantly decrease.**
- Rates of complex MRSA/MSSA SSI did not decrease as significantly in the urgent/emergent subgroups suggesting that multiple applications of mupirocin and CHG are more efficacious.

8 Thompson Houston (2013)

- Investigate the success of an anti-MRSA mupirocin/CHG preoperative bundle previously implemented at one hospital
- Case-control examination pre and post bundle implementation in 2007.
- Five-day course of intranasal mupirocin and 2% CHG cloths.
- \( n=9,976 \) procedures control arm (pre-implementation) vs.
- Retrospective chart review
- MRSA SSI rates per 100 procedures
- MRSA isolates cultured from SSI wounds
- Statistically significant decrease in MRSA SSI rates in four populations for two consecutive years

- Standard, nationally recognized definitions for SSI and MRSA SSI used
- Target populations most at risk for substantial morbidity by MRSA infections included.
- Analyzed non-included populations for additional implementation decreases risk for seasonal maturation.
- Identified statistically significant confounding patient characteristics may have lead to biased results.
- No randomization-susceptible to bias.
- Full bundle adherence rate was 39%.
- Specifics of surveillance were inconsistent between the participating hospitals weakening internal validity.
|   | Facility. | 10,068 procedures treatment arm (post-implementation) | after bundle implementation.  
  o  p=0.016 in 2007  
  o  p=0.003 in 2008  
  • All 31 patients who contracted a MRSA SSI in 2008 had incomplete compliance to the bundle.  
  • Incidence in MRSA SSI infections statistically significantly increased in non-study populations during the same time frame. Adds support to usefulness of the bundle.  
  • Estimated savings of $2,745,000 dollars, 6 deaths prevented, and 1000 less hospital days. | comparison  
  - Both inpatient and outpatient patients  
  - Not all patients routed through the preoperative surgery center, decreasing compliance.  
  - Historical controls may introduce confounding variables and missed data.  
  - Also reviewed central-line MRSA infections (not a specific concern for this literature review) |
|---|---|---|---|
| 9 | Veiga, Damasceno, Veiga-Filho, Figueras, Vierira, Garcia, Silva, Novo, & Ferreira (2009) | • Assess the effect of preoperative CHG showers on skin colonization and surgical site infection rates. | • Randomized, prospective, experimental trial  
  • CHG vs. placebo vs. control arms  
  • Convenience sample from one facility  
  • n= 150  
  • Patient demographics  
  • Cultures pre and post operation on all patients  
  • Wound assessments weekly for four weeks  
  • 1.3% of all patients developed SSI; 1 patient in the placebo arm and 1 patient in the CHG arm (p=0.6)  
  • No statistically significant difference in surgical site infection rates | Randomly assigned patients  
  • Specific bathing instructions given to patients to help decrease variation  
  • Used the CDC definition of SSI  
  • Followed patients for a full 30 days  
  - No statistically significant difference in |
| 10 | Webster & Osborne (2015) | • To review the evidence for preoperative bathing or showering with antiseptics for preventing hospital-acquired surgical site infections. | • Systematic review of randomized controlled trials.  
• Six trials from nine citations  
• 26 year period of evidence (1983-2009)  
• 10,007 participants | • Primary outcome of rates of SSI  
• Secondary outcomes of mortality, allergic reactions, antibiotic use, length of stay, readmission rates, cost, and other serious infections or infectious complications.  
• No clear evidence that washing with CHG preoperatively decreases incidence of SSI. | • Only used RCTs  
• Large sample of participants  
• Twenty six year time frame  
• Evidence is supported by at least two other evidence reviews (meta-analysis and systematic review)  
• Did not include CHG cloths consistently in the reviewed studies.  
• Many low quality studies available to review | 1A |

- Statistically significant difference in bacterial culture counts between control and placebo groups vs. the CHG group ($p<0.001$).

SSI rates between treatment arms, however the authors still concluded that the CHG showers should be utilized in all patients.
- Recommendations are inconsistent with results.
- Used bacterial counts to justify recommendations despite this not being their definition of SSI.
- Small sample with no power calculation. Unable to determine if sample was large enough.
| | | | - Inconsistent definitions used among studies included for primary outcome measurement.  
- Heterogeneous populations creates difficulties for parallel study analysis |

## Appendix C

### Overview of Implementation Plan and Timeline

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit proposal to committee members by 4/25/16</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submit to University of Maryland and Medical Center IRB committee by 4/20/16</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present proposal to committee members by 5/12/16</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase One</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Introductory Meeting- first week of September</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distribution of CPG first draft to SMEs- second week of September</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Second meeting with SMEs to discuss CPG first draft and introduce AGREE II tool- fourth week of September</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revise first draft of CPG and review with DNP committee- first and second week of October.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase Two</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email AGREEII tool and 2nd draft CPG to SMEs- second to third week of October</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collect feedback from Stakeholders- fourth week of October through first week of November.</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase Three</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revise CPG based on AGREE II feedback and meet with DNP committee- second and third week of November</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email CPG to end-users- third week of November</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collect questionnaire feedback- third through fourth week of November. Consider extending to first week of December.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revise to final CPG form- December</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submit to administration- no later than December 20, 2016</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analyze AGREE II and Practitioner’s Feedback Questionnaire data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present final scholarly project manuscript to committee for review</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present final scholarly project to committee</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. CPG=Clinical Practice Guideline; IRB= Internal Review Board
Appendix D

AGREE II Tool

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Total Responses for each Domain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Domain 1: Scope and Purpose

<table>
<thead>
<tr>
<th>Likert Scale Responses</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>The overall objective(s) of the guideline is (are) specifically described.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The health question(s) covered by the guideline is (are) specifically described.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Domain 2: Stakeholder Involvement
The guideline development group includes individuals from all the relevant professional groups.

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

The target users of the guideline are clearly defined.

### Domain 3: Rigor of Development

Systematic methods were used to search for evidence.

The criteria for selecting the evidence are clearly described.

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

The methods for formulating the recommendations are clearly described.

The health benefits, side effects, and risks have been considered in formulating...
There is an explicit link between the recommendations and the supporting evidence.

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

A procedure for updating the guideline is provided.

### Domain 4: Clarity of Presentation

<table>
<thead>
<tr>
<th>Likert Scale Responses</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>The recommendations are specific and unambiguous.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The different options for management of the condition or health issue are clearly presented.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Key recommendations are easily identifiable.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Domain 5: Applicability

<table>
<thead>
<tr>
<th>Likert Scale Responses</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>The guideline provides advice and/or tools on how the recommendations can be put into practice.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The potential resource implications of applying the recommendations have been considered.

The guideline presents monitoring and/or auditing criteria.

### Domain 6: Editorial Independence

<table>
<thead>
<tr>
<th>Likert Scale Responses</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>The views of the funding body have not influenced the content of the guideline.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competing interests of guideline development group members have been recorded and addressed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Overall Guideline Assessment

<table>
<thead>
<tr>
<th>Likert Scale Responses</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Quality of the Guideline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| I would recommend this guideline for use | Yes: | Yes with modifications: | No: |
Appendix E

Practitioner Feedback Questionnaire

For each item, please check off the box that most adequately reflects your opinion

1. Are you responsible for the care of patients for whom this draft guideline report is relevant? This may include the referral, diagnosis, treatment, or follow-up of patients.
   - Yes ☐
   - No ☐
   - Unsure ☐

If you answered “No” or “Unsure”, there is no need to answer or return this questionnaire. If you answered “Yes”, please answer the questions below and return to [enter expected destination of Questionnaires].

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Neither agree or disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. The rationale for developing a guideline is clear.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. There is a need for a guideline on this topic.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. The literature search is relevant and complete (e.g., no key evidence was missed nor any included that should not have been) in this draft guideline.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. I agree with the methodology used to summarize the evidence included in this draft guideline.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. The results of the evidence described in this draft guideline are interpreted according to my understanding of the evidence.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7. The draft recommendations in this report are clear.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8. I agree with the draft recommendations as stated.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9. The draft recommendations are suitable for the patients for whom they are intended.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10. The draft recommendations are too rigid to apply to individual patients.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>11. When applied, the draft recommendations will produce more benefits for patients than harms.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>12. The draft guideline presents options that will be acceptable to patients.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13. To apply the draft recommendations will require reorganization of services/care in my practice setting.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>14. To apply the draft guideline recommendations will be technically challenging.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
15. The draft guideline recommendations are too expensive to apply. | ☐ | ☐ | ☐  
16. The draft guideline recommendations are likely to be supported by a majority of my colleagues. | ☐ | ☐ | ☐  
17. If I follow the draft guideline recommendations, the expected effects on patient outcomes will be obvious. | ☐ | ☐ | ☐  
18. The draft guideline recommendations reflect a more effective approach for improving patient outcomes than is current usual practice. (If they are the same as current practice, please tick NA). NA ☐  
19. When applied, the draft guideline recommendations will result in better use of resources than current usual practice. (If they are the same as current practice, please tick NA). NA ☐  
20. I would feel comfortable if my patients received the care recommended in the draft guideline. | ☐ | ☐ | ☐  
21. This draft guideline should be approved as a practice guideline. | ☐ | ☐ | ☐  
22. If this draft guideline were to be approved as a practice guideline, I would use it in my own practice. | ☐ | ☐ | ☐  
23. If this draft guideline were to be approved as a practice guideline, I would apply the recommendations to my patients. | ☐ | ☐ | ☐
Appendix F

Clinical Practice Guideline for the Decolonization of *Staphylococcus aureus* in Elective Cardiac Surgery and Total Hip and Knee Arthroplasty

Abigale Celotto, BSN, RN, CCRN
Susanne Lara, BSN, RN, CCRN
Ashifa Moledina, BSN, RN, CCRN

University of Maryland School of Nursing
Table of Contents

Scope and Purpose ........................................................................................................ 4
  Purpose
  Scope
  Intervention
  Background
  Expected Outcomes
  Responsibilities

Stakeholder Involvement ............................................................................................. 6

Methods ....................................................................................................................... 7
  Rating Scheme for Strength of Evidence and Recommendations

Recommendations ........................................................................................................ 9
  Medical Pre-Procedure Evaluation
  Chlorhexidine Gluconate Cloth Kit Application
  Universal Decolonization Bundle
  Targeted Decolonization Bundle

Guideline Utilization .................................................................................................. 13

References .................................................................................................................... 15

Evidence Supporting the Recommendations ............................................................. 22
  Clinical Practice Guideline Table 1

Utilization Tools ......................................................................................................... 39
  Appendix G
  Appendix I
Disclaimer

The views and recommendations of this guideline do not necessarily reflect the views and recommendations of the University Of Maryland School Of Nursing or the target medial system. No funding source was utilized in the development of this clinical practice guideline. There are no conflicts of interests to report.

Acknowledgements

Joan Davenport, PhD, RN
- Associate Professor, Vice Chair, Department of Organizational Systems and Adult Health, University of Maryland School of Nursing
- Project chair

Shannon Idzik, DNP, MS, CRNP, FAANP
- Associate Professor and Associate Dean, University of Maryland School of Nursing
- Project co-chair

Deborah Schofield, DNP, CRNP, FAANP
- Director of Quality and Safety
- Systems navigator

We would like to thank Dr. Joan Davenport, Dr. Shannon Idzik, and Dr. Deborah Schofield for their support and mentorship throughout this process.
Clinical Practice Guideline for the Decolonization of *Staphylococcus aureus* in Elective Cardiac Surgery and Total Hip and Knee Arthroplasty

**Scope and Purpose**

I. **Purpose:** To provide a guideline for screening and decolonization of surgical outpatients.
   a. Recommendations of the guideline are intended to standardize and streamline the decolonization process to satisfy the needs of the target surgical population.

II. **Scope:** Applicable to adult, non-emergent, elective, surgical outpatients within the Preoperative Readiness Evaluation and Preparation (PREP) Center to include:
   a. Cardiac Surgery
      i. Adult cardiac surgery patients scheduled for non-emergent surgical procedures, who will receive pre-procedure evaluation for surgery through the PREP Center.
   b. Orthopedic Total Arthroplasty of the Hip and Knee
      i. Adult patients scheduled for non-emergent total hip or knee arthroplasty, who will receive pre-procedure evaluation for surgery through the PREP Center.

III. **Intervention**
   a. **Nasal screening for the identification of Methicillin Sensitive *Staphylococcus aureus* (MSSA) and Methicillin Resistant *Staphylococcus aureus* (MRSA) colonization.**
   b. **Universal Decolonization Bundle:** For those who screen negative for MSSA and MRSA nasal colonization, the following interventions will be applied: standard precautions, standardized chlorhexidine gluconate (CHG) cloth kit application, standardized patient instructions for pre-operative application, and antimicrobial prophylaxis per institutional protocol.
   c. **Targeted Decolonization Bundle:**
      i. For those who screen positive for MSSA nasal colonization, the targeted bundle includes: standard precautions, standardized CHG cloth kit application, standardized patient instructions for pre-operative CHG application, *administration of intranasal mupirocin for 5 days*, and antimicrobial prophylaxis per institutional protocol.
      ii. For those who screen positive for MRSA nasal colonization, a targeted bundle includes: contact precautions, standardized CHG cloth kit application, standardized patient instructions for pre-operative CHG application, *administration of intranasal mupirocin for 5 days*, and the *addition of vancomycin to the institutional antimicrobial prophylaxis protocol.*
IV. Background:

a. Rationale: Surgical site infections (SSIs) have been deemed preventable; if an SSI occurs in particular patient populations, reimbursement is withheld for portions of their care (CMS, 2015). Despite increased surveillance and institution of prevention measures, SSIs continue to burden the United States health care system with over 150,000 cases in 2011 from a ten state survey (Magill et al., 2014). This led the CDC to report SSIs as the most prevalent healthcare associated infection to date (CDC, 2015). SSIs are associated with adverse patient outcomes and increased length of hospital stay and reflect a decreased quality of care. SSIs also lead to greater patient and hospital expenses, as the care of patients who develop an SSI can cost anywhere from 10 to 26 thousand dollars (Scott, 2009). The state of Maryland was found to have SSI rates up to 13% higher than the national average (Anderson et al., 2014; Magill et al., 2014). Preoperative nasal colonization with Staphylococcus aureus (S. aureus) has been identified as a significant risk factor for the development of an SSI (Bode et al., 2010; Gupta et al., 2011; Sasi et al., 2015; Yano et al., 2009).

S. aureus SSIs are associated with significant morbidity, and increase hospital and patient costs compared to other pathogens (Colling et al., 2015). Standardized targeted decolonization bundles have shown to reduce overall S. aureus infections by up to 60% when compared to placebo (Bode et al., 2010). Furthermore, non-bundled care, or non-standardized care had statistically significant increases in the development of MRSA SSIs (Bode et al., 2010; Kapadia et al., 2012; Pofahl et al., 2009; Pofahl et al., 2011; Schweizer et al., 2015; Thompson & Houston, 2013). Utilization of a standardized targeted bundled decolonization has been reported to save over 2.7 million dollars, six deaths, and 1,000 hospital days over two years in a single institution (Thompson & Houston, 2013).

b. Definitions:

Surgical Site Infection: The CDC defines SSIs as infections at or near the sight of surgical manipulation occurring within 30 days of an operation and includes either purulent drainage, isolated organisms obtained from a culture, and/or clinical signs and symptoms of infection such as erythema or edema (Mangram et al., 1999). SSIs are classified by location and depth of the infection. The infections may be superficial, involving the skin or subcutaneous tissue; deep incisional, involving soft tissue and/or fascia; or organ/space, including any other part of the patient’s surgically manipulated anatomy (Mangram et al., 1999).

Bundle: A standardized set of evidence-based practices applied to a specific patient population, with the intent to optimize patient outcomes.
**CHG Cloth Kit:** Kits are composed of three packages. Each disposable, single-use package consists of two, 2% CHG impregnated polyester cloths. Therefore, each kit contains a total of six CHG cloths. One kit is used for each application.

V. **Expected Outcomes**
   a. Timely identification of patients colonized with MRSA/MSSA prior to surgery.
   b. Application of indicated treatments for patients colonized with MRSA/MSSA.
   c. Elimination of patient care inconsistencies within the perioperative process.
   d. Decreased rates of *S. aureus* SSIs in the target population.
   e. Decreased overall rate of SSIs in the target population.

VI. **Responsibility:** It is the responsibility of all providers to follow these guidelines as appropriate for the target population’s perioperative care.
   a. **Intended Users**
      i. Advanced Practice Nurses, Registered Nurses (RN), Patient Care Technicians, Physicians, Physician Assistants, Anesthesia Providers

**Stakeholder Involvement**

I. **Guideline Panel**
   Subject Matter Expert 1, MD
   - Clinical Assistant Professor of Anesthesiology
   - Anesthesiologist perspective of perioperative interventions
   - External Reviewer

Subject Matter Expert 2, MS, BSN, RN, CCRN
   - Nurse Manager for the PREP Center and Ambulatory Surgical Care Unit
   - External Reviewer

Subject Matter Expert 3, MD, MPH
   - Professor and Division Head of Health Care Outcomes Research
   - Epidemiology & Public Health
   - External Reviewer

Subject Matter Expert 4, BSN, RN, CIC
   - Director of Infection Prevention and Hospital Epidemiology
   - Nursing expert in infection prevention
   - External reviewer
Methods

I. Methods for Evidence Collection and Selection
A literature review was completed to analyze the evidence that pertains to the reduction of SSIs in cardiac surgery and hip and knee arthroplasty patients. Searches were conducted utilizing PubMed, CINAHL, EMBASE, the Cochrane Database, and review of federal health agency recommendations.

II. Descriptions of Methods Used for Evidence Collection and Selection
Reviewers conducted a thorough literature search of the databases and evidence was rated utilizing the Johns Hopkins Nursing Evidence Based Practice Rating Scale (Dearholt & Dang, 2012) and using the following inclusion criteria: Cardiac Surgery, Orthopedic Surgery, Arthroplasty, Inpatients and Ambulatory Care Settings, Surgical Site Infections, Prevention, Methicillin Resistant Staphylococcus aureus, Decolonization, Preoperative Decolonization, Chlorhexidine Gluconate, Preoperative Bathing, Asepsis Techniques, Povidone-Iodine, Intranasal Povidone-Iodine, Preoperative Asepsis, Decolonization Bundles, Targeted Decolonization Bundle, Hospital Acquired Infections, Mupirocin, Nasal Methicillin Resistant Staphylococcus aureus Colonization, Mupirocin Resistance; Adults; in English; accessible for retrieval; Systematic Review, Randomized Control Trials, Meta-Analysis, Clinical Practice Guidelines, higher-quality quantitative research studies. Exclusion criteria were as
follows: low quality evidence, literature published in languages other than English, if the abstracts did not answer the following questions:

- What are risk factors for the development of a surgical site infection?
- What is, if any, the best agent for preoperative bathing?
- What is the evidence surrounding CHG application method for preoperative bathing?
- Does preoperative MSSA and MRSA colonization status affect the development of surgical site infections?
- In patients undergoing cardiac surgery and total arthroplasty of the hip or knee, is mupirocin or intranasal povidone-iodine best supported for MSSA and MRSA decolonization?
- Does perioperative antibiotic administration need to be tailored for MSSA or MRSA positive patients?

III. Rating Scheme for Strength of Evidence and Recommendations

Johns Hopkins Nursing Evidence Based Practice Rating Scale (Dearholt & Dang, 2012)

**Design:**

I: Experimental study/randomized controlled trial (RCT) or meta-analysis of RCT
II: Quasi-experimental study
III: Non-experimental study, qualitative study, or meta-synthesis
IV: Opinion of nationally recognized experts based on research evidence or expert consensus panel (systematic review, clinical practice guidelines)
V: Opinion of individual expert based on non-research evidence. (Includes case studies; literature review; organizational experience e.g., quality improvement and financial data; clinical expertise, or personal experience)

**Quality:**

A: High

**Research:** consistent results with sufficient sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence

**Summative Reviews:** well-defined, reproducible search strategies; consistent results with sufficient numbers of well-defined studies; criteria-based evaluation of overall scientific strength and quality of included studies; definitive conclusions

**Organizational:** well-defined methods using a rigorous approach; consistent results with sufficient sample size; use of reliable and valid measures

**Expert Opinion:** expertise is clearly evident
B: Good

**Research**: reasonably consistent results, sufficient sample size, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence

**Summative Reviews**: reasonably thorough and appropriate search; reasonably consistent results with sufficient numbers of well-defined studies; evaluation of strengths and limitations of included studies; fairly definitive conclusions

**Organizational**: Well-defined methods; reasonably consistent results with sufficient numbers; use of reliable and valid measures; reasonably consistent recommendations

**Expert Opinion**: expertise appears to be credible

C: Low Quality or Major Flaws:

**Research**: little evidence with inconsistent results, insufficient sample size, and conclusions cannot be drawn

**Summative Reviews**: undefined, poorly defined, or limited search strategies; insufficient evidence with inconsistent results; conclusions cannot be drawn

**Organizational**: Undefined, or poorly defined methods; insufficient sample size; inconsistent results; undefined, poorly defined or measures that lack adequate reliability or validity

**Expert Opinion**: expertise is not discernable or is dubious

Please see attached Table 1 for details regarding literature utilized, strengths and limitations, and evidence rating.

IV. Methods Used to Formulate the Recommendation

- Expert consensus based on available body of evidence.

**Recommendations**

I. Procedures

a. Medical Pre-Procedure Evaluation

i. Cardiac surgery and hip and knee arthroplasty surgical outpatients should receive on-site pre-operative evaluation at the PREP Center. Evaluation should occur a minimum of seven days before the scheduled procedure to allow time for full decolonization if necessary.

- Risk: Funnelling patients through the PREP Center may potentially delay medical evaluation and surgical procedures.
Benefit: Maximizing the use of the PREP Center for the pre-operative evaluation of the targeted population allows for identification of a larger volume of patient at risk for SSIs and facilitates that standardized decolonization, clearance, and education.

ii. Cardiac surgery and hip and knee arthroplasty surgical outpatients should be screened for MSSA and MRSA nasal colonization: (Bode et al., 2010; Bratzler et al., 2013; Sasi et al., 2015, Schweizer et al., 2015; Pofahl et al., 2009; Pofahl et al., 2011; Yano et al., 2009).

Risk: Increased cost related to increased screening.

Benefit: Identifying patients within the target population who have a significant risk factor for developing an SSI, to allow for improved quality of care and cost avoidance. Active surveillance for the identification of patients who are colonized with MSSA or MRSA has been proven as an effective way to tailor SSI prevention therapy (Bode et al., 2010, Pofahl et al., 2009; Pofahl et al., 2011; Schweizer et al., 2015). Utilization of chromogenic agar as opposed to PCR testing provides similar sensitivity and specificity, but at a lower cost (Wassenberg et al., 2010).

1. A swab of bilateral nasal vestibule, the anterior portion of bilateral nares, will be conducted in the PREP Center.

2. Rapid testing for MSSA and MRSA will be completed according institutional lab standards.

iii. Institutional pre-operative materials, including education and CHG cloth kits will be distributed. (Colling, Statz, Glover, Banton & Beilman, 2015; Schweizer et al., 2015; Pofahl et al., 2009; Thompson and Houston, 2013; Edmiston, 2008; Edmiston, 2013)

Risk: Distributing materials that are not utilized, resulting in increased cost.

Benefit: Guarantees patients receive necessary supplies, prescriptions, and pre-operative education while decreasing financial barriers for patients.

b. Chlorhexidine Gluconate Cloth Kit Application

i. All patients should receive preoperative skin decolonization with CHG (Colling, Statz, Glover, Banton & Beilman, 2015; Pofahl et al., 2009; Schweizer et al., 2015).

Risk: No high quality evidence supporting reduction of overall SSI rates with CHG use.
Benefit: Results in a statistically significant decrease in SSIs caused by MSSA and MRSA (Colling et al., 2015, Edmiston et al., 2008, Jakobsson et al., 2011).

ii. During the PREP Center evaluation, patients will receive 2 CHG cloth kits. Kits are composed of three packages. Each disposable, single-use package consists of two 2% CHG impregnated polyester cloths. Therefore, each kit contains a total of six CHG cloths. One kit is used for each application. (Edmiston, 2008; Karki and Cheng, 2012; Afonso, Llaurado, and Gallart, 2013; Pofahl et al., 2009; Thompson and Houston, 2013)

- Risk: Individual packages are more expensive than bulk solution.
- Benefit: Cloth kits have a standardized concentration of CHG allowing for even distribution and easy application. Polyester’s exfoliating properties, coupled with the scrubbing action during application, allows for efficient CHG deposition (Edmiston, 2008; Afonso, Llaurado, and Gallart, 2013). CHG cloths do not require reconstitution or rinsing, removing potential environmental barriers such as absence of running water.


1. All patient instructions will be presented in a clear and simple format.
2. Patients will be provided with written instructions for appropriate CHG cloth kit use. (Please see Appendix G).
3. Patients will be verbally instructed during their pre-operative evaluation about correct CHG regimen and application.

- Risk: Education provided is above the level of the patient’s health literacy.
- Benefit: In order to meet the views and preferences of the target population education is reinforced through various forms and simplified to a fourth grade reading level. All instructions are given at the time of medical evaluation. Written and visual instructions can be taken home and referenced by the patients at their convenience. Standardized education optimizes the potential for proper CHG application and bundle adherence.

iv. It is expected that patients will perform two full applications of CHG at home. The first application is done the night before surgery and the second the morning of surgery (Kapadia et al., 2013).
1. Adherence to this regimen of CHG application should be discussed and documented during the patient intake assessment on the day of surgery.

v. Patients will receive a third application of CHG in the perioperative area on the day of surgery prior to donning a clean hospital gown. (Edmiston, 2008; Jakobsson, Perlkvist, and Wann-Hansson, 2011; McDonnell & Russell, 1999; Paulson, 2003).

1. Documentation of this process in the pre-operative checklist.
   - Risk: Optimal number of CHG applications is inconclusive in current literature.
   - Benefit: CHG use results in a statistically significant decrease in SSIs caused by MSSA and MRSA (Colling et al., 2015, Edmiston et al., 2008, Jakobsson et al., 2011). The efficacy of CHG is dependent on skin surface concentration; the concentration accumulates with each application and is bactericidal (Edmiston et al. 2013; McDonnell & Russell, 1999). The third application performed in the perioperative area guarantees at least one CHG application prior to donning a clean patient gown.

c. Universal Decolonization Bundle
   i. To be applied to the aforementioned surgical population who screen negative for MSSA or MRSA nasal colonization.
   ii. Use of standardized CHG cloth kits as described above.
   iii. Initiate standard precautions for all patients.
   iv. Patients to receive institutional antimicrobial prophylaxis.
      - Risk: Potential for allergic reaction or skin irritation to CHG, or inappropriate application of CHG.
      - Benefit: Reduction of overall bacterial load and reduced risk of S. aureus SSIs.

d. Targeted Decolonization Bundle
   i. To be applied ONLY to cardiac and hip or knee arthroplasty surgery patients who screen POSITIVE for MSSA or MRSA nasal colonization. (Bode et al.,2010; Bratzler et al., 2013; Pofahl et al., 2009; Pofahl et al., 2011; Sasi et al., 2015, Schweizer et al., 2015; Yano et al., 2009).
   ii. MSSA Positive Targeted Decolonization Bundle
      1. Use of standardized CHG cloth kits as described above.
      2. Patient to receive prescription for mupirocin upon return of positive culture.
         a. Treatment should occur for 5 days leading up to surgery.
      3. Initiate standard precautions.
4. Patient to receive institutional antimicrobial prophylaxis.

   iii. MRSA Positive Targeted Decolonization Bundle
      1. Use of standardized CHG cloth kits as described above.
      2. Patient to receive prescription for mupirocin upon return of positive culture.
         a. Treatment should occur for 5 days leading up to surgery.
      3. Contact precautions should be implemented upon entrance to the healthcare facility.
      4. Inclusion of weight-based dosing of vancomycin in addition to the institutional antimicrobial prophylaxis.
         a. Consider alternative MRSA coverage in the presence of vancomycin contraindication.
            ➢ Risk: Potential to miss patients due to false negative. Risk for potential medication adverse effects due to increased exposure to antimicrobials. Risk for increasing resistance to vancomycin due to increased exposure, as it is not part of standard antimicrobial prophylaxis.
            ➢ Benefit: Decolonization of identified patients would be completed pre-operatively. Patients who may not have been decolonized due to mupirocin resistance or break in bundle compliance, should be treated with a perioperative antibiotic that covers MRSA. Given the emergence of mupirocin and vancomycin resistance, antimicrobial stewardship is indicated and supported (Bratzler et al., 2013). The use of vancomycin in only patients who are colonized limits the overall population exposure and reduces the risk of adverse effects related to vancomycin therapy.
      iv. It is recommended that intranasal 5% povidone-iodine solution not be used in place of mupirocin within this targeted bundle.
         1. The use of intranasal 5% povidone-iodine was considered as an alternative to mupirocin use, but was not found to be superior to mupirocin (Anderson et al., 2014; Bebko et al., 2015; Phillips et al., 2014).

   e. Refer to Appendix I for Decolonization Algorithm

Guideline Utilization

I. Barriers and Facilitators
   • Barrier: Time allotted for pre-procedure medical evaluation is currently less than 7 days.
- **Facilitators:** It is the suggestion of this committee that cardiac and arthroplasty patients be screened through the PREP center and scheduled for surgery at least 7 days from the date of medical evaluation to allow for culture maturation and 5 days of decolonization. For those patients who require more rapid surgical scheduling, *S. aureus* screening can be performed at the surgical clinic/surgeon’s office, which will allow screening results to be available at the time of medical evaluation and immediate prescription of mupirocin. It should be noted that by screening at the PREP center, the cost of the MRSA culture will be incurred by the PREP center budget and not the surgical specialty’s budget. Current practice requires all cardiac surgery patients to receive medical clearance by the anesthesia department in the PREP center. Therefore, the decolonization bundle algorithm does not significantly change practice regarding location of clearance, but does change timeline, and screening and decolonization practices.

Increasing the amount of time allotted for pre-procedure evaluation creates an opportunity for: 1) complete decolonization prior to surgery, as recommended by the IDSA, 2) time for enhanced patient and family involvement in education and planning for the postoperative phase, and 3) an opportunity for transitional care coordination.

- **Barrier:** Mupirocin will be not be prescribed until receipt of the positive MSSA or MRSA culture. Patients will no longer be able to depart from the PREP Center to the in-house pharmacy to obtain their prescription. Patients will now be required to retrieve their prescription at a later time.

- **Facilitator:** Through e-prescription patients will be able to select their preferred pharmacy.

- **Barrier:** PREP Center staff will have to follow up on cultures, release the mupirocin e-prescription, and contact the patient to inform them of their colonization status.

- **Facilitator:** The current process requires providers to follow-up on pre-operative diagnostic test results. There will not be a complete change in practice, rather an adjustment in the follow-up timeline.

- **Barrier:** Change in practice regarding the addition of vancomycin for select patients creates risk for inappropriate antimicrobial usage by the operative team.

- **Facilitator:** Weight-based vancomycin can be electronically ordered and placed on hold until the *S. aureus* cultures results are obtained. If the cultures are positive for MRSA the provider must release the order, which can be done at the same time the mupirocin order is released. Vancomycin can be obtained in the preoperative area and, will then be sent with the patient to the operating room to be administered.
• Operationalization of recommendations regarding microbiology testing, microbiology result review, facilitation of mupirocin and antibiotic prescription, intra-facility communication, and altering patients of MRSA status should occur in accordance to resources and provider utilization within each institution.
  o Monitoring points to be considered by the institution during implementation include but are not limited to the following outcomes measures
    ▪ SSI rates and causative organism, where an SSI is defined per national standards.
    ▪ Adherence to all aspects of the appropriate bundle.
    ▪ Retrospective chart audits are suggested to measure institution specific aspects of individual bundle implementation process.

• It is the recommendation of this committee that during the initial implementation phase, additional time be considered to allow for the third CHG application and acquisition of the vancomycin dose from pharmacy if appropriate. Once the staff has adapted to the new workflow, the perioperative department can modify day-of-surgery timing.

• Feedback from stakeholders indicates that current mupirocin is prescribed in tube form which costs approximately 10 to 30 US dollars. Intranasal 5% povidone-iodine costs approximately 35 US dollars. It is the suggestion of this committee that all patients be prescribed mupirocin and that the e-prescription be sent to the patient’s pharmacy of choice. The in-house pharmacy is available for e-prescriptions however, patients should be consulted on which pharmacy they are most likely/most easily able to visit if their culture returns positive.

II. Tools for Implementation:
• See appendix G for educational handouts
• See appendix I for summary and algorithm for each bundle

III. Guideline Update
  a. The content owners of this institutional clinical practice guideline will reach out to the Director of Infection Prevention and Hospital Epidemiology, the Medical Director of Infection Prevention and Hospital Epidemiology, the Division Head of Health Care Outcomes Research, and the lead Nurse Practitioner from the PREP Center for periodic updating of this clinical practice guideline according to institutional revision standards.

  b. Current recommendations support the use of mupirocin for intranasal use in the decolonization of MSSA and MRSA patients. The use of intranasal 5% povidone-iodine was considered as an alternative to mupirocin use, but was not found to be
superior to mupirocin. Current literature is underpowered and lacked internal and external validity (Bebko, Green, & Awad, 2015; Phillips, Rosenberg, Shospin, Cuff, Skeete, Foti, Kraemer, Inglima, Press, & Basco, 2014). Therefore, the current body of evidence regarding intranasal 5% povidone-iodine is not robust enough to endorse its use over mupirocin. Future versions of this guideline should address this product and consider its use as new, high-quality evidence emerges.

IV. Evidence Supporting the Recommendations
- Refer to Clinical Practice Guideline Table 1
References


Edmiston, C.E., Okoli, O., Graham, M.B., Sinski, S., & Seabrook, G.R. (2010). Evidence for using chlorhexidine gluconate preoperative cleansing to reduce the risk of surgical site


carriage after decolonization: A case-control study. *Clinical Infectious Disease, 52*(12), 1422-1430. doi: 10.1093/cid/cir233


Positive nasal culture of Methicillin-resistant staphylococcus aureus (MRSA) is a risk factor for surgical site infection in orthopedics. *Acta Orthopaedica, 80*(4), doi: 10.3109/17453670903110675
Clinical Practice Guideline Table 1

Additional Evidence

<table>
<thead>
<tr>
<th>Author &amp; Date</th>
<th>Study Design &amp; Sample</th>
<th>Results</th>
<th>Limitations</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afonso, Llaurado, &amp; Gallart (2013)</td>
<td>Systematic Review 15 studies including 9 RTCs</td>
<td>• 64% reduction in pathogen transmission in hospitalized patients  • Decreased bacterial colonization in pre-surgical patients  • Recommend 2% CHG wipes to decrease bacterial colonization and spread of pathogens in healthcare and pre surgical settings  • Recommend patient education for pre-surgical use of CHG.</td>
<td>• Various research methods included in review  • Varying CHG concentrations and application methods across reviewed studies  • Various patient populations and patient settings included in study</td>
<td>IV-A</td>
</tr>
<tr>
<td>Anderson, Podgorny, Berrios-Torres, Bratzler, Dellinger, Greene, Nyquist, Saiman, Yokoe, Maragakis, &amp; Kaye (2014)</td>
<td>Practice Recommendations (SHEA/ IDSA)</td>
<td>• Patients undergoing cardiac and some orthopedic arthroplasty procedures should be screened for S. Aureus and decolonized with intranasal mupirocin preoperatively  • Routine preoperative decolonization using mupirocin without screening is not recommended as mupirocin resistance has</td>
<td></td>
<td>VI-A</td>
</tr>
</tbody>
</table>
Antimicrobial prophylaxis should be weight based and administered within 1 hour of incision to maximize tissue concentration - administer within 2 hours of incision if administering fluoroquinolones or vancomycin.

Overall SSI rates have been shown to be significantly lower with use of Chlorhexidine-alcohol antiseptic agents when compared to povidone-iodine agents.

Patients and families should be provided with SSI information and education along with instruction on SSI prevention techniques preoperatively. Printed instructions and education should also be provided.

Preoperative screening for *S. aureus* bundled with decolonization of patients with documented *S. aureus* and Chlorhexidine bathing preoperatively has shown to be effective in reducing SSIs.

<p>| Bailey, Stochastic decision-analytic | Home-based preoperative | Computer simulation models | III-A |</p>
<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Study Type</th>
<th>Sample Size</th>
<th>Findings</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stuckey, Norman, Duggan, Bacon, Connor, Lee, Muder, &amp; Lee (2011)</td>
<td>Computer simulation model</td>
<td>1,000,000 simulated trials.</td>
<td>bathing with CHG is cost-effective across a wide range of antimicrobial efficacy and patient compliance scenarios. Model suggests that concerns about patient compliance and cloth efficacy may not be as crucial as previously thought in relevant literature.</td>
<td>Models based on literature that examined CHG cloth use for SSI prevention - literature may have been biased.</td>
</tr>
<tr>
<td>Bebko, Green, &amp; Awad (2015)</td>
<td>Prospective Quasi-experimental</td>
<td>N= 709</td>
<td>13 SSIs in the control group vs. 4 SSIs in the intervention group (p=0.02).</td>
<td>Single-center trial with risk of selection bias (non-randomized sample) No power reported Did not give and operational definition of usual care to compare to intervention group. Claimed 100% adherence, but did not report methods of data collection. Claimed significance of MRSA carrier status, however investigators did not collect pre-operative samples. Intranasal application of povidone-iodine is not consistent with manufacturer’s instructions. Potential for bias due to confounder. Measurement occurred during the bundle implementation period, as opposed to when the bundle II-C</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>--------</td>
<td>---------</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Bode, Kluytmans, Werheim, Bogaers, Vandenbrouke-Grauls, Roosendaal, Troelstra, Box, Voss, van der Tweel, van Belkum, Verbrugh, & Vos (2010) | Randomized, double-blinded, placebo-control trial Randomized Sample n= 917 | ● Overall hospital acquired infections (HAI) was lower in the mupirocin/chlorhexidine group than in the placebo.  
● Most frequent infection was deep surgical site infection  
● Mupirocin/chlorhexidine 0.9% vs. placebo 4.4% RR 0.21 95% CI 0.07-0.62  
● No difference in all cause mortality.  
● Close to 60% reduction in overall staph aureus infections.  
● Use of rapid PCR screening for detection of staph aureus colonization is an effective tool for identification and targeted decolonization. |
| Bratzler, D., Dellinger, E., Olsen, K., Perl, T., Auwaerter, P., Bolon, M., | Clinical Practice Guideline | ● Supports the use of active surveillance for pre-operative *Staph Aureus* nasal colonization, and treatment of only those who are identified |
| | | ● Power was recalculated for change in incidence rates reported at one of the facilities involved in the study. Statistics were re-run and power was redefined mid study. This threatens the internal validity of the study, as the design was altered after the study was started.  
● Details how those who were administering decolonization treatment were blinded, but not if those collecting data were blinded.  
● MRSA not represented as there was a low incidence in the population.  
● Mortality was calculated as all cause with no differentiation to mortality due to staph aureus. |

**Notes:**
- I-A: Level of evidence I-A
- IV-A: Level of evidence IV-A
<table>
<thead>
<tr>
<th>Study Authors</th>
<th>Study Type</th>
<th>Study Details</th>
<th>Findings and Implications</th>
</tr>
</thead>
</table>
| Fish, D., Napolitano, L., Sawyer, R., Slain, D., Steinberg, J., & Weinstein, R. (2013) | | as positive.  
● Addresses the emergence of *Staph Aureus* resistance to mupirocin by suggesting only those who are nasally colonized be treated, as opposed to universal use. | |
| Byrne, Napier, & Cuschieri (1992) | Randomized Controlled Trial (RCT)  
Prospective, Experimental  
Placebo-controlled  
n= 3,489 | CHG vs. placebo  
257/1745 (14.7%) in CHG arm vs. 271/1721 (15.8%) in the control arm scored as having postoperative infections. | Data were extracted from 3 papers reporting results from the one study (Lynch 1992 & Byrne 1994). There were minor discrepancies in numbers reported between the 3 studies. The version reported is the definitive study.  
I-B |
● Convenience sample  
n= 4,042 | No statistically significant difference between hospitals’ SSI rates  
1.96% vs. 1.95% (p=1.0)  
Statistically significant difference of SSI caused by MSSA/MRSA between the two hospitals  
17% vs. 61% (p=0.03)  
CHG does not reduce the overall rate of SSI however it does decrease the morbidity related to SSI caused by *S. aureus*  
*S. aureus* infections cause significant morbidity and  
Regional hospital performs approximately half the number of cases compared to the medical center. The volume of patients seen is not equal. Decreases interval validity  
Patient showers were completed at home. Unable to verify technique and therefore unable to verify consistency and compliance. Weakens internal validity.  
Only 75% of patients had documentation addressing pre-operative bathing.  
Limited data on shower | III-B |
increase hospital cost compared to other pathogens.

- Compliance documented per patient report and subject to bias. Bias and missing data decreases internal validity
- Electronic charting changed for the regional hospital in 2011. Authors unable to acquire patient demographic data on patients who did not get an SSI. Missing data decreases internal validity and causes undue bias
- Multiple brands of CHG were used in the medical center. Confounding variables

| Edmiston, Krepel, Seabrook, Lewis, Brown, & Towne (2008) | Randomized Control Trial n= 60 | Greater CHG skin concentrations observed with two applications when compared to one (p<0.05)  
CHC efficacy is based on a cumulative effect on the skin and time frame of application  
CHG 2% wipes produce higher skin surface concentration – 12.7-27% greater than 4% bathing solution  
Standardized cleansing technique must be used  
CHG should be left on to air dry and not wiped off.  
Pre-surgical cleansing at least | Small sample size  
No power analysis completed  
Randomization method unclear  
Study funded by Sage company | I-B |
<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Type</th>
<th>Findings</th>
<th>Methodological Limitations</th>
</tr>
</thead>
</table>
| Edmiston, Bruden, Rucinski, Henen, Graham, & Lewis (2013) | Literature Review | - CHG efficacy is cumulative with repeated application. Standardized protocols and patient compliance may optimize cutaneous concentrations of CHG.  
- CHG cloths may work best as part of a bundled approach to SSI prevention.  
- Optimal number of applications pre-operation is undetermined.  
- CHG reduces skin flora more effectively than alcohol/iodine agents or combinations of these two agents  
Low incidence of hypersensitivity to CHG | - Not a systematic review  
- Opinion of individual based on research evidence |
| Gupta, Strymish, Abi-Haidar, Williams, & Itani (2011) | Retrospective cohort study  
Non-randomized n= 4,238 | - Pre-operative MRSA colonization status is associated with MRSA SSI (p=0.01), a positive MRSA culture (p<0.001), and post-operative MRSA infection (p<0.01)  
- Significant risk of surgical site infection when vancomycin is used as the only prophylactic antibiotic | - Retrospective and non-randomized design  
- Power is not reported.  
- Lowered internal validity due to lack of definition of how data was collected and reviewed for accuracy  
- Poor external validity as it was a single-site study done in a very specific patient population |
<table>
<thead>
<tr>
<th>Jakobsson, Perlkvist, &amp; Wann-Hansson (2011)</th>
<th>Systematic Review</th>
<th>Each study reviewed showed a sharp reduction in skin flora after CHG application</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 studies</td>
<td>Studies including 3 or more CHG applications showed highest efficacy for bacterial decolonization</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Efficacy of CHG bathing is based on a cumulative effect</td>
</tr>
</tbody>
</table>

- OR 3.43 CI 1.62-7.24  
- Increased likelihood of contracting MRSA with OR 1.32 CI 0.68-2.56  
  ● Conclusion is that there is benefit to active MRSA surveillance in the inpatient population.  

- Conducted at a Veterans affairs hospital.  
  ● External validity threatened due to the sample being 90% male.  
  ● Lack of transparency as no table of demographics was included.  
  ● Possibility of selection bias due to retrospective design.  
  ● Internal validity decreased as there is no true control group.  
  ● Historical threat exists due to the retrospective design and no definition of other measures which may have occurred in the 2 year time period that may have changed MRSA rates or SSI rates further diminishing internal validity  
  ● Concluding statement of the study does not reflect the initial purpose and outcomes  

- Studies including 3 or more CHG applications showed highest efficacy for bacterial decolonization  
- Efficacy of CHG bathing is based on a cumulative effect  
- Inability to merge study results due to diverse interventions, study design, and study endpoints  
- Several studies in review are >10 years old  
- IV-B
<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>N or Number of Studies</th>
<th>Findings</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| Kapadia, Johnson, Daley, Issa, & Mont (2012) | Retrospective cohort             | N=2,458                | - Lower number of SSIs in the group that used a CHG preoperative protocol of 2, at-home applications of CHG prior to surgery (p<0.05)  
- Patient education and direction for proper CHG use is important in compliance and maximum effect | - Lack of randomization  
- Poor patient and surgeon compliance to CHG protocol  
- Patient factors created heterogeneous comparison groups decreasing statistical significance |
| Karki & Cheng (2012)                | Systematic Review                 | 16 studies and 4 abstracts | - No rinse CHG was associated with decreased the risk of SSIs  
- Reduction > 50% in MRSA and VRE colonization with CHG application | - Mostly observational studies reviewed with inclusion of only 2 RCT  
- No statistically significant reduction of MRSA or VRE infection  
- Publication bias noted in some of the studies reviewed  
- Poorly reported co-founding variables in studies reviewed |
| Lee, Macedo-Vinas, Francois, Renzi, Schrenzel, Vernaz, Pittet, | Retrospective Case Control Non-randomized | n= 150                 | Case patients were those who were not decolonized, and the control patients were those who were successfully decolonized.  
- Mupirocin resistance was observed in 64% of case | - Single center trial decreases external validity.  
- Retrospective design confines the study to only the available data. May have led to selection bias. |
| & Harbath (2011) | patients and 35% of control patients (p<0.001).  
• Chlorhexidine resistance was observed in 91% of case patients and 68% of control patients (p<0.001)  
• Persistent nasal colonization of MRSA was associated with both mupirocin and chlorhexidine resistance. (OR 3.4, 95% CI 1.3-7.2; p=0.01). | ● Selection bias decreases the internal validity of the study.  
• During 12 month follow-up of patients who underwent decolonization therapy, patients who were decolonized may have been included in the case group due to re-colonization in the public. This could have skewed the eradication rates. |
n= 1539 | ● 5 deep SSIs developed in the mupirocin group vs. 0 in the iodine group.  
● Mupirocin Group: 92% remained decolonized post-operatively compared to 54% in the iodine group (p=0.03). | ● Single center trial.  
• Did not meet power.  
• Only measured deep SSIs, neglecting superficial SSIs.  
• Only accounts for orthopedic surgery patients.  
• No report of adherence.  
• True SSI rate may not have been identified as potential admissions to other institutions were not followed. |
| Pofahl, Goettler, Ramsey, Cochran, Nobles, & Rotondo (2009) | Retrospective cohort design  
n=5,094 patients | ● Overall reduction of MRSA SSI from 0.23 per 100 procedures to 0.09 per 100 procedures. This was not statistically significant.  
● Reduction in MRSA SSI in knee and hip joint replacements was 0.3 per 100 | ● 75% compliance in MRSA screening with inconsistencies  
• Peri-operative antibiotic regimens changes during the intervention timeframe.  
• Retroactive data collection is susceptible to historical bias and missing data. |
<table>
<thead>
<tr>
<th>Authors</th>
<th>Study Design</th>
<th>Participants</th>
<th>Findings</th>
</tr>
</thead>
</table>
| Pofahl, Ramsey, Nobles, Cochran, & Goettler (2011) | Retrospective cohort design Non-randomized n=8,980 | | to 0 (p=0.04).  
- Researchers concluded that given other studies of high quality along with the success in MRSA SSI reduction in their institution active surveillance is effective for targeted treatment and decolonization.  
- Screening/eradication bundle was part of a larger asepsis campaign, increasing compounding variables and altering internal validity.  
- Looked only at the SSI outcomes of patients undergoing procedures that are tracked by CMS, excluding some surgical populations and decreases external and internal validity.  
- Pofahl, Ramsey, Nobles, Cochran, & Goettler (2011) Retrospective cohort design Non-randomized n=8,980  
- Further investigates 2009 study listed above.  
- Identified 11 patients who underwent a SCIP procedure and developed an MRSA SSI.  
- 5 of the 11 were found to be MRSA nasal carriers.  
- Only 1 of the 5 who were nasally colonized with MRSA pre-operatively was appropriately treated. None of the 5 received Vancomycin as a part of their surgical prophylaxis.  
- 6 of the 11 were negative on their pre-operative nasal screen.  
- Overall study showed a reduction in both MRSA and MSSA SSI infections from || Peri-operative antibiotic regimens changes during the intervention timeframe.  
- Retroactive data collection is susceptible to historical bias and missing data.  
- Screening/eradication bundle was part of a larger asepsis campaign, increasing compounding variables and altering internal validity.  
- Evaluated only SSI outcomes of patients undergoing procedures that are tracked by CMS, excluding some surgical populations, and decreasing external and internal validity.  
- All baseline information and care information was not accessible for those who |
<table>
<thead>
<tr>
<th>Study Authors (Year)</th>
<th>Study Design</th>
<th>n</th>
<th>Key Findings</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotter, Larsen, Cooke, Dankert, Daschner, Greco, Gronroos, Jepsen, Lystad, &amp; Nystrom (1988)</td>
<td>International, Prospective, Randomized, double-blind, placebo-controlled experimental</td>
<td>2,813</td>
<td>CHG vs. control</td>
<td>No statistically significant difference between treatment groups regarding the rate of post operation infection. 2.62% in CHG arm vs. 2.36 in the control arm.</td>
</tr>
<tr>
<td>Sasi, Sistla, Sistla, Karthikeyan, Mahalakshmy, Ali, &amp; Vijayaraghavan (2015)</td>
<td>Quasi-Experimental</td>
<td>602</td>
<td>Patients undergoing groin surgery had the highest rate of surgical site infections (66.7%). Those who were colonized with MRSA in the groin had a significantly higher likelihood of infection (p=0.008). 7.8% of SSIs were due to MRSA. A positive pre-operative</td>
<td>Groups are not randomized, Lower external validity as this was a single center trial, Possibility of selection bias as the trial was not randomized, Lacks standardization in the implementation of the intervention, Compliance of MRSA decolonization practices was assessed by 1 researcher through personal interview, but</td>
</tr>
</tbody>
</table>
| Schweizer, Chiang, Septimus, Moody, Braun, Jafner, Ward, Hickok, Perencevich Diekema, Richards, Cavanaugh, Perlin, & | Quasi-experimental | MRSA screening was found to be significant when compared to the development of a surgical site infection (p=0.0414).
- Rates of surgical site infections were not reduced when patients who were colonized with MRSA pre-operatively were treated with mupirocin and chlorhexidine for decolonization (p=0.493).
- Surgeries longer than 120 minutes had a significant increase in SSI development (p<0.001).
- Pre-operative MRSA status has no effect on the development of other nosocomial infections despite decolonization (p=0.638).

- Statistically significant decrease in overall complex MRSA/MSSA SSI rates
  - Odds ratio 0.60[95%CI, 0.37-0.98]
- Statistically significant increase in months without complex SSI
  - p=0.006
- Overall SSI rates did not statistically significantly decrease

there was no mention of standardization leading to low intra-rater reliability.
- Tables showing statistical test results from where many of the conclusions are being drawn were not included.

- No true control group due to the quasi-experimental design.
- Standard care prior to implementation of the bundle is not fully defined.
- Convenience sampling may have led to selection bias.
- Bundle adherence was only 83% so the full impact of the bundle may not have been achieved.

II-A
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herwaldt (2015)</td>
<td>Rates of complex MRSA/MSSA SSI did not decrease as significantly in the urgent/emergent subgroups suggesting that multiple applications of mupirocin and CHG are more efficacious.</td>
<td></td>
</tr>
<tr>
<td>No single definition of an SSI existed among the hospitals and hospitals tracked the rates at differing time intervals. This may have resulted in an incomplete data set in regard to the total number of SSI and in the effect of the bundle.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergent surgery patients did not receive the full bundle but infection rates were calculated in data.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Thompson & Houston (2013) | Case-control n= 20,044 procedures | Statistically significant decrease in MRSA SSI rates in four populations for two consecutive years after bundle implementation. |
| | | - p=0.016 in 2007 |
| | | - p=0.003 in 2008 |
| | | All 31 patients who contracted a MRSA SSI in 2008 had incomplete compliance to the bundle. |
| | | Incidence in MRSA SSI infections statistically significantly increased in non-study populations during the same time-frame. Adds support to usefulness of the bundle. |
| | | Both inpatient and outpatient patients |
| | | Not all patients routed through the preoperative surgery center, decreasing compliance. |
| | | Historical controls may introduce confounding variables and missed data. |

II-B
<table>
<thead>
<tr>
<th>Study</th>
<th>Study Design</th>
<th>Key Findings</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Veiga, Damasceno, Veiga-Filho, Figueras, Vierira, Garcia, Silva, Novo, &amp; Ferreira (2009)</td>
<td>Randomized Control Trial n= 150</td>
<td>- Estimated savings of $2,745,000 dollars, 6 deaths prevented, and 1000 less hospital days.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 1.3% of all patients developed SSI; 1 patient in the placebo arm and 1 patient in the CHG arm ($p=0.6$)</td>
<td>- No statistically significant difference in surgical site infection rates</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- No statistically significant difference in bacterial culture counts between control and placebo groups vs. the CHG group ($p&lt;0.001$).</td>
<td>- Statistically significant difference in bacterial culture counts between control and placebo groups vs. the CHG group ($p&lt;0.001$).</td>
</tr>
<tr>
<td>Wassenberg, Kluytmans, Box, Bosboom, Buiting, van Elzakker, Melchers, van Rijen, Thijsen, Troelstra, Vandenburgroek e-Grauls, Visser, Voss, Wolffs, Wulf,</td>
<td>Prospective Multicenter Quasi-experimental Non-randomized n= 1764</td>
<td>- Analyzed effectiveness and cost considerations in the use of different mediums for identification of patients colonized with MRSA.</td>
<td>- Lacks a true control group</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Included the swabbing of the anterior portion of the nares.</td>
<td>- Not randomized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Compared PCR and chromogenic agar results to the conventional microbiologic cultures.</td>
<td>- Selection bias due to different portions of the study being run at varying times over the 2-year study period.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Using the results of</td>
<td></td>
</tr>
</tbody>
</table>
van Zwet, de Wit, & Bonten (2010)

| conventional cultures as a reference, sensitivity, specificity and positive and negative predictive values for detecting MRSA at the patient level were 85.2%, 96.5%, 44.2% and 99.5% for BD GeneOhm MRSA PCR; 75.0%, 94.5%, 33.3% and 99.1% for the Xpert MRSA assay; and 85.7%, 96.6%, 46.2% and 99.5% for chromogenic agar testing, respectively |
| - No significant difference in the result time between PCR and chromogenic agar. |
| - Chromogenic agar was identified as more cost effective, as the test is significantly cheaper to run and the results very similar to PCR. |

Webster & Osborne (2015)

| Systematic review of randomized controlled trials. n= 10,007 |
| - No clear evidence that washing with CHG pre-operatively decreases incidence of overall SSI. |
| - Did not include CHG cloths consistently in the reviewed studies. |
| - Many low quality studies available to review |
| - Inconsistent definitions used among studies included for primary outcome measurement. |
| - Heterogeneous populations |

I-A
| Yano, Minoda, Sakawa, Kuwano, Kondo, Fukushima, & Tada (2009) | Prospective observational cohort study n= 2,423 | ● Total of 0.6% of patients in the study developed an MRSA SSI.  
● Patients who were identified as pre-operative nasal MRSA carriers had a higher incidence of SSI than those who were not (6% vs. 0.5%; p<0.001)  
● Pre-operative culture positive of nasal MRSA is associated with a significant increased risk of SSI (OR 11; 95% CI 3-37). | creates difficulties for parallel study analysis  
● Convenience sampling may lead to sampling bias.  
● Single center trial, decreases external validity due to homogenous sample.  
● Homogeneity of the sample is even further increased due being focused only on orthopedic patients. | II-B |
Appendix G

How to Use Chlorhexidine Cloths Before Your Surgery

Use one wipe for each numbered circle

1. Neck, chest, and belly
2. Right arm front and back, hand, fingers, shoulder, and armpit
3. Left arm front and back, hand, fingers, shoulder and armpit
4. Right leg front and back including feet, toes, and right groin
5. Left leg front and back including feet, toes, and left groin
6. Back, back of neck, buttocks

Your skin may feel sticky after using the wipes.
Let your skin air dry. Do not use a towel.
Do not use cream or lotion after using the wipes.
How to Use Chlorhexidine Cloths Before Your Surgery

**Do:**

- Use one set (6 cloths) the night before your surgery and the other set the morning of your surgery.
- Shower and dry your skin. Then use the chlorhexidine wipes.
- Use one cloth for each part of your body as shown in the picture.
- Lightly scrub your skin with the cloths.
- Let your skin air dry after using the chlorhexidine wipes.

**Do NOT:**

- Do not use the Chlorhexidine wipes on your face, eyes, ears, penis or vagina.
- Do not put the wipes in the microwave.
- Do not put the wipes in water before using them.
- Do not dry or rinse off your skin after using the wipes.
- Do not use powders, deodorant, creams or lotion after using the wipes.
Appendix H

IRB Approval

University of Maryland, Baltimore
Institutional Review Board
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: hrpo@umaryland.edu

NOT HUMAN RESEARCH DETERMINATION

Date: July 6, 2016

To: Joan Davenport
RE: HP-00070148
Name: A Clinical Practice Guideline for the Decolonization of Surgical Outpatients

This letter is to acknowledge that the UMB IRB reviewed the information provided and has determined that the submission does not require IRB review. This determination has been made with the understanding that the proposed project does not involve a systematic investigation designed to develop or contribute to generalizable knowledge OR a human participant (see definitions below).

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are human subject research in which the organization is engaged, please submit a new request to the IRB for a determination.

Definitions –

**Human Research:** Any activity that either:
- Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
- Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

**Research as Defined by DHHS:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Research as Defined by FDA:** Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:
- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

**Human Subject as Defined by DHHS:** A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:
• Intervention means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
• Interaction means communication or interpersonal contact between investigator and subject.
• Private Information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
• Identifiable Information means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

**Human Subject as Defined by FDA:** An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Please keep a copy of this letter for future reference. If you have any questions, please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@umaryland.edu.
Appendix I
Decolonization Algorithm

Adult outpatient referred for cardiac or hip/knee arthroplasty

- Yes
  - Patient will receive medical evaluation on-site in the PREP Center

- Nasal Swab performed **

** S. aureus screening can be performed at the surgeon’s office preceding medical evaluation to facilitate rapid scheduling.

MSSA/MRSA (-)

- MSSA (+)
- MRSA (+)

MSSA TARGETED BUNDLE
- Standardized CHG cloth kit application
- E-prescription for 5-day course of mupirocin
- Initiate standard precautions
- Institutional perioperative antimicrobial prophylaxis

MRSA TARGETED BUNDLE
- Standardized CHG cloth kit application
- E-prescription for 5-day course of mupirocin
- Initiate contact precautions
- Weight-based vancomycin in addition to institutional perioperative antimicrobial prophylaxis

UNIVERSAL BUNDLE
- Standardized CHG cloth kit application
- Initiate Standard Precautions
- Institutional peri-operative antimicrobial prophylaxis