

## Distribution Agreement

In presenting this thesis or dissertation as a partial fulfillment of the requirements for an advanced degree from Emory University, I hereby grant to Emory University and its agents the non-exclusive license to archive, make accessible, and display my thesis or dissertation in whole or in part in all forms of media, now or hereafter known, including display on the world wide web. I understand that I may select some access restrictions as part of the online submission of this thesis or dissertation. I retain all ownership rights to the copyright of the thesis or dissertation. I also retain the right to use in future works (such as articles or books) all or part of this thesis or dissertation.

Signature:

---

Ian Charpie

---

Date

Development of Interventions for Reducing Surgical Site Infection in Pediatric Cardiac Surgery:  
A Case Study of Michigan Medicine

By

Ian Charpie

Degree to be awarded: Master of Public Health

Hubert Department of Global Health

---

Monique Hennink, Ph.D.

Committee Chair

---

Scott Fridkin, MD

Committee Member

Development of Interventions for Reducing Surgical Site Infection in Pediatric Cardiac Surgery:  
A Case Study of Michigan Medicine

By

Ian Charpie

B.S.

University of Michigan, USA

2015

Thesis Committee Chair: Monique Hennink, Ph.D.

An abstract of  
a thesis submitted to the Faculty of the  
Rollins School of Public Health of Emory University  
in partial fulfillment of the requirements for the degree of  
Master of Public Health  
in Hubert Department of Global Health  
2020

## Abstract

### Development of Interventions for Reducing Surgical Site Infection in Pediatric Cardiac Surgery: A Case Study of Michigan Medicine

By Ian Charpie

**Background:** Hospital acquired infections (HAI) contribute to significant morbidity, mortality, and healthcare-associated costs. Among HAI, surgical site infections (SSI) are the most difficult to manage, especially in children. Children's immune systems are still developing and pediatric patients undergoing cardiac surgery are a particularly vulnerable subpopulation. There is a need to develop SSI prevention recommendations targeted for pediatric patient populations that are adaptable for individual patient and surgical contexts. **Purpose:** This case study, aimed to: 1) document the process of developing a bundle of interventions for SSI prevention for pediatric surgery patients and 2) evaluate the impact of this intervention bundle on SSI rates among pediatric surgery patients at C.S. Mott Children's Hospital. **Method:** The development of interventions involved 5 steps: 1) forming an expert panel, 2) developing a process map outlining the current state of care and identify gaps leading to SSI, 3) developing an impact-effort matrix and prioritizing areas for intervention, 4) developing a root cause analysis that identifies the underlying causes of SSI and 5) developing and implementing a bundle of interventions to reduce SSI. A process evaluation was conducted to evaluate if process measure targets were met and measure the overall change in SSI rates. An evaluation of adherence to the bundle of interventions was conducted at 1 month and 6 months post-implementation, to determine the efficacy of the developed intervention bundle. **Results:** This case study documents the process of developing and implementing a bundle of 17 interventions. High fidelity to the interventions was shown with 100% of process measure targets with 86% adherence measures met. For SSI rates, a 47% decrease was observed relative to pre-intervention baseline SSI rates. **Discussion:** This case study demonstrates the feasibility of the process of intervention development for other clinical areas of hospitals or target populations (pediatric, adult, underserved etc.). Aspects of the development process can also be used to manage resource allocation and prioritization of interventions, which is important with increasing healthcare costs. **Conclusion:** This study documents the successful development and implementation of a bundle of interventions targeted at attenuating SSI rates in pediatric cardiology patients at CS Mott Children's Hospital. Future work should be done to further evaluate the efficacy of interventions as well as applying the intervention development process to other clinical settings.

Development of Interventions for Reducing Surgical Site Infection in Pediatric Cardiac Surgery:  
A Case Study of Michigan Medicine

By

Ian Charpie

B.S.

University of Michigan, USA

2015

Thesis Committee Chair: Monique Hennink, Ph.D.

A thesis submitted to the Faculty of the  
Rollins School of Public Health of Emory University  
in partial fulfillment of the requirements for the degree of  
Master of Public Health  
in Hubert Department of Global Health

2020

## **Acknowledgement**

I would like to acknowledge everyone who had a role in helping to make this thesis possible. I am deeply grateful to Dr. Monique Hennink and Julia Sobolik for their unwavering support and patience throughout this thesis writing process. You both have been instrumental in helping make this thesis a reality, as well as helping me keep my sanity during this COVID-19 pandemic. Further recognition lies with Dr. Scott Fridkin as without his expertise and dedication to the attenuation of hospital acquired infections the inspiration for this thesis project would not have been possible.

Special thanks goes out to the University of Michigan C.S. Mott Children Hospital who offered an enlightening summer practicum experience in a friendly and informative environment. From that institution I would like to offer my most sincere gratitude to Christine LaJeunesse, Jamie MacLaren, and Mandy McKay for all their guidance and help throughout my practicum experience. Without all your support and dedication, I would not have had the opportunity to make it this far.

Thank you to Flavia Traven, my Rollins ADAP, for your organizational skills and advice that have helped me manage the complexities of this thesis project alongside the larger goal of achieving a Masters in Public Health.

Finally, I want to thank my family for all their support, motivational talks, and for believing that this was all possible. Your belief in me has pushed me to achieve goals I never before thought were possible and afforded me the courage and confidence to pursue those goals.

## Table of Contents

Table of Contents.....	7
List of Figures.....	8
List of Acronyms.....	8
1. Background.....	9
2. Current Recommendations to Prevent SSI.....	11
2.1 Preoperative Period.....	12
2.2 Intraoperative Period.....	12
2.3 Postoperative Period.....	13
3. Case Study Site: Michigan Medicine.....	14
4. Statement of Purpose.....	15
5. Documentation of Intervention Development Process.....	15
5.1 Step I: Creating an Expert Panel.....	16
5.2 Step II: Developing a Process Map.....	16
5.3 Step III: Ranking Critical Areas for Intervention via Impact-Effort Matrix.....	20
5.4 Step IV: Root Cause Analysis.....	21
5.5 Step V: Development of Interventions.....	23
5.6 Implementation of Interventions.....	24
5.7 Assessing Efficacy of Interventions.....	25
5.8 Evaluation of Intervention Bundle.....	25
6. Discussion.....	27
7. Conclusion.....	34
References.....	35

## List of Figures

Figure 1: Process of Patient Care from Pre-Operation to Discharge.....	18
Figure 2: Impact-Effort Matrix and Expert Panel Votes.....	21
Figure 3: Root Causes of SSI at Michigan Medicine.....	22
Figure 4: Description of Bundle of Interventions.....	24
Figure 5: Surgical Adherence Tracking Tool.....	27

## List of Acronyms

Acronym	Definition
AR	antibiotic resistant (resistance)
CAUTI	catheter-associated urinary tract infections
CDC	Center for Disease Control
CDIT	Clinical Design and Innovation Team
C. diff	Clostridioides difficile
CHG	chlorhexidine gluconate
CLABSI	central line-associated bloodstream infections
CMS	Centers for Medicaid and Medicare Services
CPNB	Continuous peripheral nerve blockade
CSMCH	CS Mott Children’s Hospital
EMR	Electronic Medical Record
FDA	Food and Drug Administration
FiO <sub>2</sub>	fraction of inspired oxygen
HAI	hospital acquired infections
HHS	Health and Human Services
ICU	intensive care unit
IRB	Institutional Review Board
IPC	infection prevention and control
MRSA	methicillin resistant Staphylococcus aureus
NHSN	National Healthcare Safety Network
NQF	National Quality Forum
OR	operating room
PrEP	Pre-exposure Prophylaxis
QI	Quality Improvement
SENIC	Study on the Efficacy of Nosocomial Infection Control
SOC	Standard of care
SSI	surgical site infection
US	United States
VAP	ventilator-associated pneumonias
VRSA	vancomycin resistant Staphylococcus aureus
WHO	World Health Organization



Development of Interventions for Reducing Surgical Site Infection in Pediatric Cardiac Surgery:  
A Case Study of Michigan Medicine

**Background**

Hospital-acquired (or nosocomial) infections (HAI) are generally defined as infections that are diagnosed between 48 hours after hospital admission and 3 days after hospital discharge, or within 30 days following an invasive procedure<sup>1-3</sup>. Greater than 90% of all HAI fall into one of five distinct categories: central line-associated bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), surgical site infections (SSI), ventilator-associated pneumonias (VAP), or specific antibiotic resistant bacterial infections. Antibiotic resistant bacterial infections are most commonly found with methicillin/vancomycin resistant *Staphylococcus aureus* (MRSA/VRSA) and *Clostridioides difficile* (C. diff)<sup>2-4</sup>. HAI, and other healthcare-acquired conditions, have recently garnered the attention of clinicians and hospital administrators due to their links with excess morbidity and mortality among patients and the significant increased healthcare costs from treating HAI.

Globally, HAI occur in 7% of hospital patients in developed countries and 10% of patients in developing countries<sup>3,5</sup>. Developing countries face three times the morbidity attributable to HAI than developed nations. In these underserved regions the patient population with intensive care unit (ICU) acquired infections reaches over 80%<sup>3</sup>. Children and newborns are at the greatest risk of HAI, with infection rates 3-20 times greater in developing countries than in developed regions<sup>3</sup>. Although it is difficult to attribute HAI to specific causes of death, it is estimated that 4% to 56% of all neonatal deaths in developing countries are associated with HAI<sup>3</sup>. In the United States, the best estimates of HAI are extrapolated from the CDC's Study on the Efficacy of Nosocomial Infection Control (SENIC) from the 1970s, and from National Healthcare Safety Network (NHSN) statistics. Recent estimates for the total HAI burden in the US are between 1.5 to 2 million cases each year<sup>6</sup>.

In addition to increased morbidity and mortality, global estimates of HAI healthcare costs are staggering. Globally, while difficult to estimate, the direct costs of HAI to hospitals and healthcare centers total in the hundreds of billions of dollars per year<sup>3,5</sup>. In the United States, cost estimates are even more staggering, ranging from \$9.8 billion<sup>7</sup> to \$46.8 billion<sup>8</sup> each year. The lower range of cost estimates are direct hospital costs from Centers for Medicare and Medicaid

Services reimbursement data<sup>7</sup> and do not take into consideration lost work time, psychological toll, and long term health complications from HAI. The estimate of \$46.8 billion, on the high end, is adjusted for those indirect costs and loss of income potential that typically fall onto the patient<sup>8</sup>.

Among HAI, SSI are associated with the highest hospital costs, disproportionately affecting populations in resource limited settings and patients who are immunocompromised. SSI are defined as infections that occur at the site of a surgery within 30 days after the surgery<sup>9</sup>. SSI fall into three categories, depending on the initial location of infection:

1. **Superficial incisional infections** refer to an infection on or around the skin where the incision was made<sup>9</sup>.
2. **Deep incisional** infections occur just below the incision area, typically in the muscle and its surrounding tissues<sup>9</sup>.
3. **Organ or space infections** refer to any infections not described in 1 or 2, and typically include infection of parts of organs or highly disseminated between organs<sup>9</sup>.

Although mortality rates from SSI are low at approximately 3% of all mortality attributable to HAI, SSI account for more than a third of annual US hospital costs attributable to HAI<sup>13,14</sup>. This equates to \$3.3 billion in funding and an additional 1 million inpatient-days annually<sup>13,14</sup>. Advances in hospital infection control practices, such as sterilization techniques and antimicrobial prophylaxis, have somewhat attenuated national rates of SSI, but high risk populations remain untargeted by these large scale interventions. In the US, SSI are a significant contributor to mortality, accounting for 90,000 deaths in 2009<sup>8</sup>.

The National Quality Forum (NQF) in conjunction with the Food and Drug Administration (FDA) approve more new surgical procedures each year compared with those that are retired from practice. Compounding this increase in surgical procedures are data from healthcare centers suggesting a greater volume of surgeries performed than ever before<sup>10</sup>. In 2010, the NQF reported that over 50 million inpatient procedures were performed in non-federal US hospitals. Although the CDC reports attenuated rates of HAI, SSI rates have remained largely unaffected despite various targeted interventions<sup>11</sup>. The WHO, CDC, Centers for Medicaid and Medicare Services (CMS), and the US Department of Health and Human Services (HHS) have all declared that urgent action is needed to prevent the acquisition and spread of HAI –

specifically antibiotic resistant (AR) organisms<sup>6</sup>. These organizations released guidelines outlining the core components of infection prevention and control (IPC) and an evidence-based list of recommendations to reduce HAI that IPC teams could focus on implementing in healthcare contexts. Together, SSI are the most difficult type of HAI to manage due to a range of highly variable procedures – in location, complexity, and invasiveness – that can result in differential probability of contracting a particular SSI. Despite these clear challenges, there is no single set of guidelines or list of interventions designed to reduce SSI in every hospital setting.

Children are particularly vulnerable to SSI. Children with heart problems typically require multiple highly invasive procedures while already immune compromised and are therefore especially susceptible to infection. Pediatric surgical cases account for 8-10% of the ~36 million US hospital admissions each year<sup>15</sup> and nearly 20% involve surgical intervention, there are hundreds of thousands of children each year potentially exposed to SSI in the US. Importantly, pediatric patients have differential susceptibility to SSI compared to adult patients. Pediatric patients have largely underdeveloped immune systems due to the transition period for carryover of maternal antibodies and the time it takes to supplement it through natural acquisition<sup>16</sup>. Children also have more sensitive organ systems than adults, with underlying conditions and treatment side effects being more severe than in adults<sup>17</sup>. Pediatric patients undergoing multiple or more invasive procedures are at an even increased risk for infection, with multiple deep exposures for long periods and likely exacerbated immune suppression being major risk factors. Furthermore, the current standard of care recommendations for SSI prevention are for adult patients as there is no consensus on how to handle pediatric SSI.

### **Current Recommendations to Prevent SSI**

The CDC, WHO, CMS, and HHS have developed joint recommendations for an ideal standard of care package for SSI prevention. Recommendations are tailored to the three periods of patient care that present risk for SSI: the pre-operative, intra-operative, and post-operative periods.

The *preoperative period* consists of activities to reduce SSI between the patient, clinical and support staff, and the surgical team up to the moment the patient enters the operating room. These SSI prevention activities include:

1. Patient showers with an antimicrobial wash or plain soap prior to surgery, which reduces potential exposure of the incision site to skin microbiome that can cause SSI.
2. Clinical staff apply 2% mupirocin nasal decolonization for known *Staphylococcus aureus* carriers – an expansion of skin decolonization for a commonly AR organism.
3. Clinical staff only remove necessary hair for surgery using clippers, NOT a razor – which reduces the likelihood of skin nicks that can lead to infection.
4. Surgical prophylaxis is given within 2 hours of incision, which is operation and antibiotic dependent.
5. Surgical staff scrub-in with proper technique and suitable antimicrobial soap or with alcohol-based hand rub.
6. For adult colorectal surgery, carry out mechanical bowel preparation and administer preoperative antibiotics.
7. For underweight patients, consider administering oral/enteral nutrient-enhanced formulas.
8. Do not discontinue immunosuppressive medication.
9. Sterilize surgical instruments and other equipment.
10. Clean and prepare the OR environment.

Activities 1 to 4 have research-based evidence supporting their direct link to reducing SSI, while activities 5 to 10 are not targeted at managing SSI exposure specifically but represent best practice for infection control. Activities 5 to 10 represent updates to the standard of care, which may reduce overall rates of SSI by better maintaining the sterile field, however there is little scientific evidence attributable SSI attenuation.

The *intraoperative period* includes recommendations for activities by the surgical team to reduce SSI that target surgery-specific SSI risks mentioned above. These interventions consist mostly of room configuration and situational recommendations that are based on less scientific evidence. The recommended activities at this stage include:

1. Use chlorhexidine gluconate (CHG) for skin preparation – skin decolonization that attenuates risk of infection from skin microbiome.

2. Use sterile drapes and surgical gowns.
3. Maintain asepsis and discipline in OR – following entry/exit protocols for staff during operation can reduce potential contaminated air flow and fomite transmission.
4. Consider using warming device to help maintain normothermia.
5. Consider intensive blood glucose control.
6. Consider using goal-directed therapy.
7. Consider irrigating incisional wound with an aqueous povidone iodine (PI) solution before closure.
8. Consider using wound protector devices.
9. Consider triclosan-coated sutures.
10. Consider prophylactic negative pressure wound therapy.
11. DO NOT use laminar airflow ventilation systems, as it can circulate contaminated air to OR.
12. DO NOT use plastic adhesive incise drapes.
13. DO NOT use antimicrobial sealants after surgical site skin preparation.
14. DO NOT perform antibiotic wound irrigation.
15. If patient is an adult AND intubated, administer 80% fraction of inspired oxygen (FiO<sub>2</sub>).

Recommendations with the phrase ‘consider’ are noted by the WHO as having positive results although there is limited scientific evidence to support a conclusive decision on their utility for SSI prevention.

The *postoperative period* consists of activities between the surgical team, clinical staff, and the patient. These recommendations largely depend on the continued involvement of the patient as there can only be follow-up for the recommended 30-day observation window after a patient is discharged and with their continued involvement. Recommendations to reduce SSI during the post-operative period include:

1. Administer 80% FiO<sub>2</sub> for 2-6 hours post-operatively.
2. Evaluate and manage wound appropriately given wound situation including cleansing, dressing, and care.
3. DO NOT prolong surgical antibiotic prophylaxis in the postoperative period.
4. DO NOT use advanced dressings of any sort.

5. DO NOT continue surgical antibiotic prophylaxis due to the presence of a drain – remove wound drain when clinically indicated.

There are numerous caveats to these recommendations, most notably the lack of focus on what happens to the patient after discharge. SSI are still indicated within 30 days post-operation, which extends well beyond the average length of hospital stay, yet there are no recommendations for SSI management or surveillance during this period. This is a significant gap in patient care that follow-up visits often fail to adequately cover. Notably these guidelines are targeted at specific surgeries and nearly all are recommended for adults. This highlights a need for specific guidelines for pediatric populations and more evidence-based care relating to the prevention of SSI in pediatric patients.

Considerations for pediatric patients would likely require modification to most of the prior adult recommendations. For instance, strict glycemic control to regulate blood glucose, while beneficial in adults, can become more complex and volatile in pediatric patients. Additionally, enriched oxygen (FiO<sub>2</sub>), becomes a potential hazard for children if used for extended periods, requiring tight control to recover/maintain normoxia and adaptations for the specific pediatric context. In babies and infants, aspects of normothermia are even harder to maintain as the ideal zone is narrower with greater potential for severe fluctuations. Moreover, irrigation is rarely possible in smaller children, and sparse available data suggest it is potentially dangerous in younger pediatric patients. Local shaving often needs to be done pre-operatively but is neglected or otherwise ‘not done’ – particularly in male pediatric patients. Regarding nutrition, specific blends of nutrient enriched feeding are required for pediatric patients as standard components are more difficult for children to digest. Clear context and population specific guidelines are needed for pediatric populations undergoing surgeries for SSI prevention.

### **Case Study Site: Michigan Medicine**

One healthcare institution is focusing on SSI prevention for pediatric patients. Michigan Medicine healthcare system, operating partially under the University of Michigan, is a premier institution in the US with regards to pediatric patient care and cardiac surgery. In 2018 their most recent data indicated that Michigan Medicine’s rate of SSI – 1% deep and 2% superficial SSI –

was 3 to 4 times greater than the average of all participating institutions (0.33% and 0.52% respectively). Recognizing the current state of SSI and the vulnerability of their patient population, the Director of Pediatric Cardiology and the Administrative Director of CS Mott Children’s Hospital (CSMCH) sent out a request to the Clinical Design and Innovation Team (CDIT) for support preventing SSI in Congenital Heart Center (CHC) patients – specifically pediatrics. Given the current state of SSI prevention at this institution, Michigan Medicine healthcare system was identified as an effective site for this case study on designing SSI prevention interventions in pediatric cardiology patients.

### **Statement of Purpose**

There is a need to develop recommendations for SSI prevention targeted at the pediatric patient population, and preferably adaptable for each patient and surgical context. The purpose of this case study is to a) document the process of developing a bundle of interventions for SSI prevention for pediatric surgery patients and b) assess the impact of this bundle of interventions on SSI rates among pediatric surgery patients at CSMCH, and discuss the broader public health implications of this case study. Recommendations for expansion to all healthcare institutions within Michigan Medicine system will be proposed if intervention successfully reduces SSI rates.

### **Documentation of Intervention Development Process**

Qualitative methods were used by CDIT to develop contextually specific interventions to reduce SSI amongst pediatric patients at Michigan Medicine. The process of intervention development is described here. In summary, it involved creating a panel of local experts and tasking them with creation of a) a process map outlining the current state of care, b) an impact-effort matrix to determine the most effective areas for intervention, c) a root cause analysis that identifies the underlying problems within each area to intervene on and d) the development of the intervention bundle itself. Each of these stages of intervention development is documented below.

### *Step I: Creating an Expert panel*

The process began with creating an expert panel to guide the intervention development. An interdisciplinary collaborative panel was formed, comprising Ann Arbor based hospital staff at CSMCH with direct pediatric patient contact and specific experience treating SSI. The expert panel consisted of doctors, nurses, and surgeons at various levels of care because these staff most frequently interacted with pediatric patients. In addition, members of CSMCH who had indirect contact with pediatric patients were also included on the expert panel. They were included because of their experience in fomite (surfaces, inanimate objects) transmission, which is a common vector for contracting SSI. These members comprised of staff from environmental services, Child Life, and various technicians who either shared spaces with patients or came into contact with items that patients use. Finally, executive sponsors (physicians designated to take over the program when CDIT moves onto the next project), and department heads tasked with ensuring adherence to changes were added to the expert panel to advise on resource allocation for the intervention design. The expert panel comprised of 26 individuals representing every department within CSMCH who could have contact with pediatric patients or equipment and facilities used by these patients.

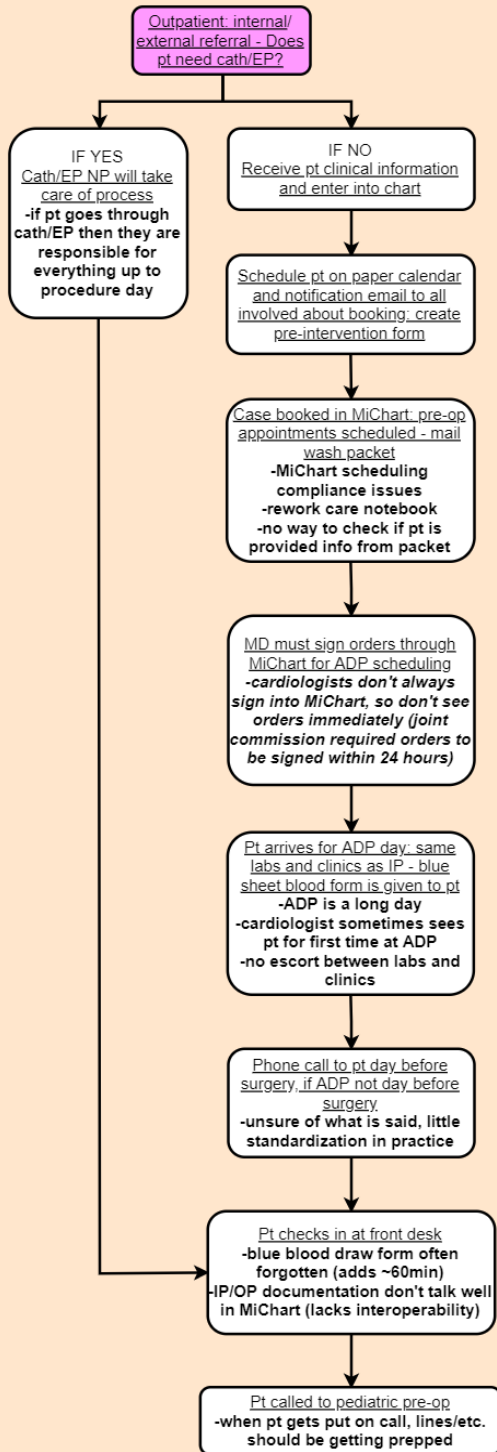
### *Step II: Developing a Process Map*

The first task of the expert panel was to identify the current process of pediatric surgical patient care. This involved developing a timeline of patient care activities from patient admission to surgery, recovery, and discharge, then through outpatient follow-up. The expert panel met three times, for two hours each session, over the course of one month. They used the process of ‘swim lane’ mapping to visually distinguish procedures and responsibilities<sup>12</sup> in the process of pediatric surgical patient care. The goal was to prepare a flowchart of the pediatric surgery process, that reflected reality from the experience of experts from each department, and the current gaps in care they regularly face. This process map (shown in Figure 1) was then divided into nine stages to reflect the pediatric surgical patient care process. The nine stages of care included: Surgical Scheduling, Pre-Operation Readiness for Inpatients, Outpatient Pre-Operation Readiness, Day of Procedure – start to incision, Day of Procedure – incision to handoff, Patient/Family Education, 48hr Post-Operation, Post 48hr Care Through Discharge, and

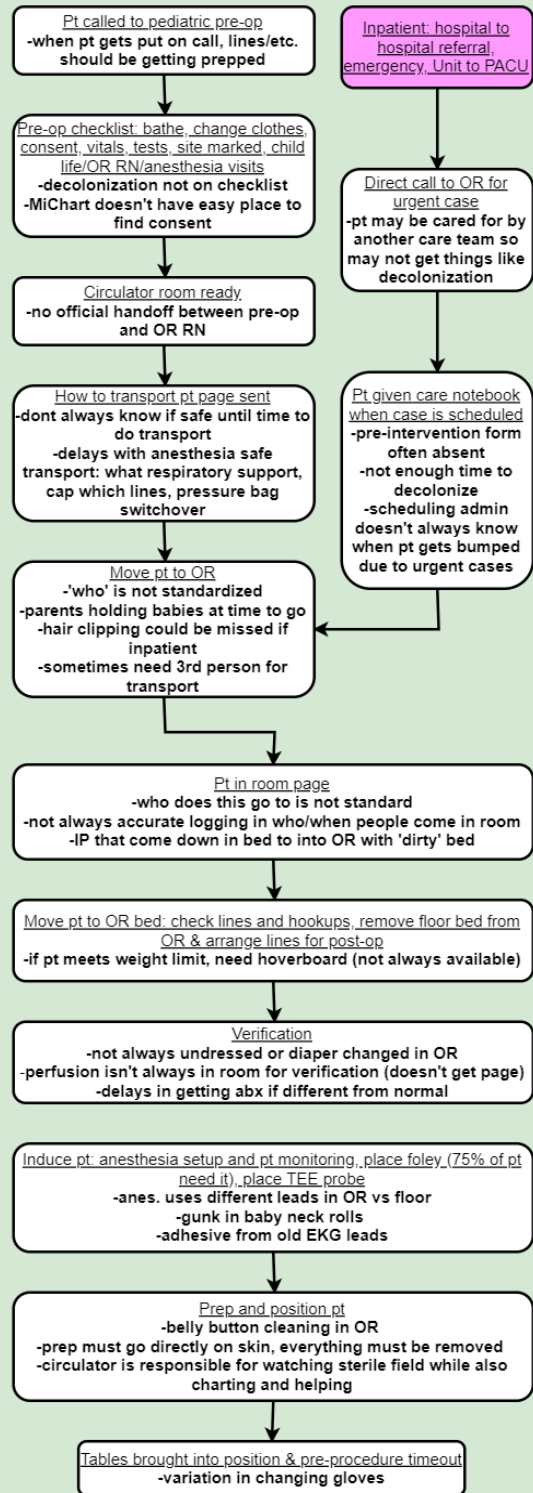


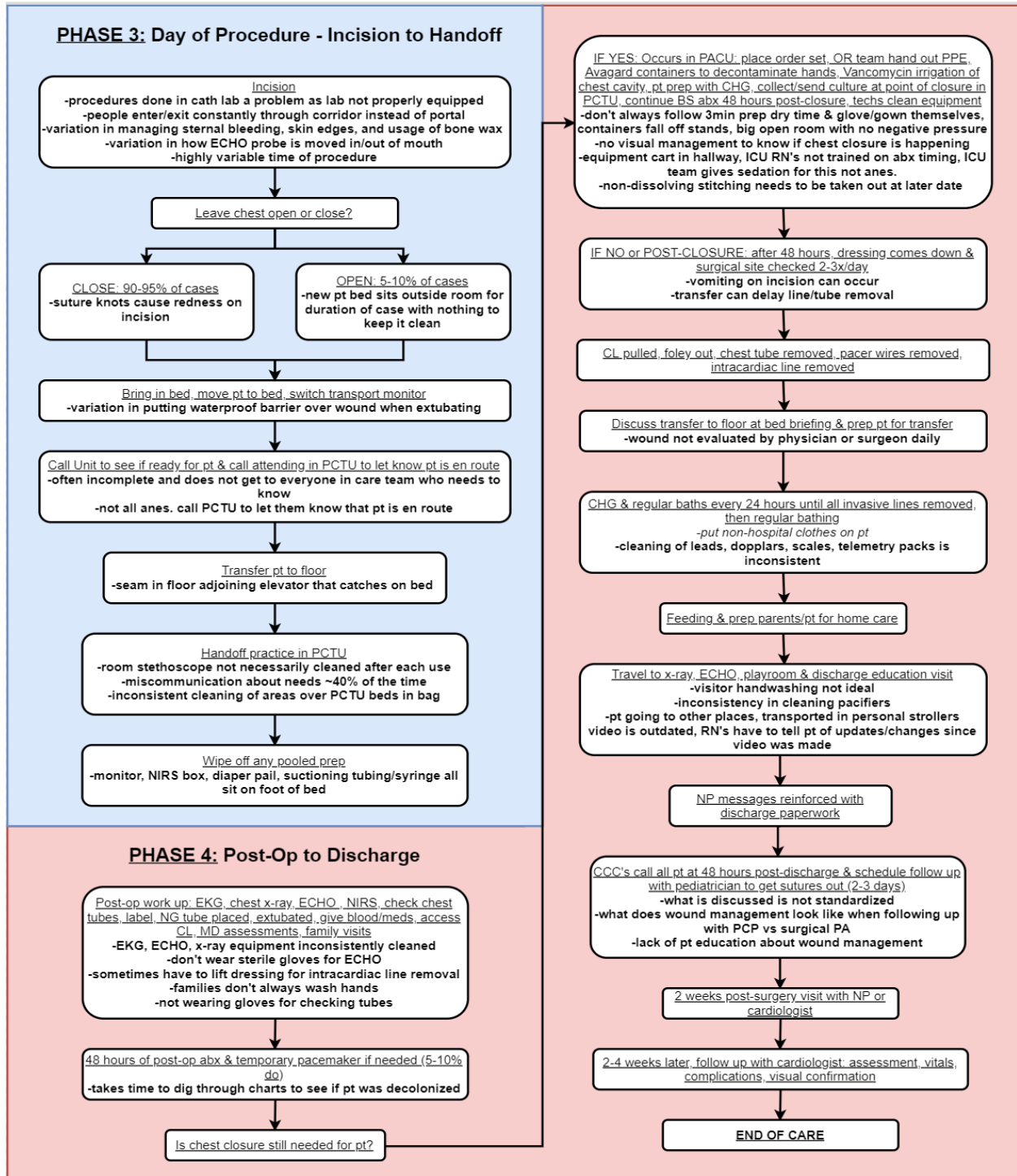
Outpatient Wound Management. Subsequent meetings added detail and refinements to each stage by listing the steps taken to prevent HAI at each stage and noting any gaps in care. Identified gaps in care are shown in **bold** in Figure 1. These gaps in care typically related to the lack standardization of practices across departments. Two members from CDIT worked with a data analyst from the Quality Improvement (QI) department to prepare a new iteration of the process map after each meeting. This was performed utilizing a Microsoft diagramming and vector graphics application, Visio, to condense the new comments with the initial ‘swim lane’ map to produce the new diagram. With limited resources available to address all 9 stages of care, it was necessary to prioritize each stage by their potential impact on SSI reduction and the feasibility of implementing the intervention. An impact effort matrix was used to determine which stages of care to prioritize for the interventions, which is described below.

## PHASE 1: Outpatient Pre-Op Readiness



## PHASE 2: Day of Procedure - Pre-Op to Incision





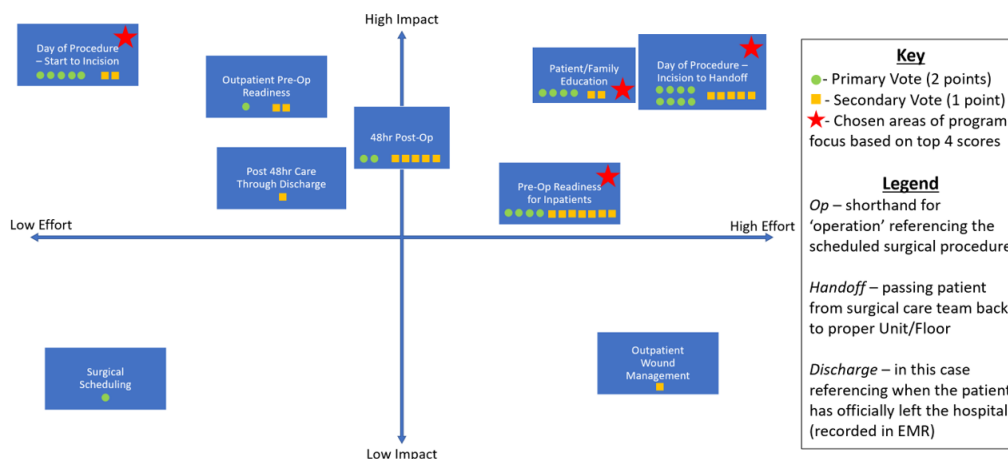
**Figure 1.** Process of Patient Care from pre-Operation to Discharge

**Notes:** pt = patient ; cath = cardiac catheterization ; EP = electrophysiology ; NP = nurse practitioner ; MiChart = medical record database with integrated orders/tracking ; op = operation ; MD = medical doctor ; IP = inpatient ; OP = outpatient ; PACU = pediatric acute care unit ; RN = resident nurse ; OR = operating room ; abx = antibiotics ; TEE = transesophageal echocardiography ; EKG = electrocardiogram ; PCTU = pediatric cardio-thoracic intensive care unit ; NIRS = near-infrared spectroscopy ; NG = nasogastric ; CL = central line ; PPE = personal protective equipment ; ICU = intensive care unit ; CHG = chlorhexidine gluconate ; CCC = child care coordinator ; PCP = primary care physician ; PA = physician assistant.

### *Step III: Ranking of Critical Areas for Intervention via Impact Effort Matrix*

The next step was to develop an impact effort matrix and have the expert panel vote on it to determine the most critical stages of care on which to focus the interventions. CDIT met multiple times with department heads and hospital administrators (external to the expert panel) to identify the most important criteria by which to rank these nine stages of care. An impact-effort matrix was used, whereby potential impact of an intervention relates to the degree to which it can attenuate SSI and effort comprised the estimated draw on hospital resources, effort and time involved in addressing gaps at each stage of care. Collectively, these four metrics (impact, resources, effort, and time) were used to place each of the nine stages of care onto an impact-effort matrix. For example, as shown in Figure 2, the stage “Day of Procedure – incision to handoff” was deemed to be a high impact intervention due to most SSI being directly attributed to surgical procedures and high in effort because reworking a surgical suite is a costly endeavor involving the whole surgical team. In contrast, the “Day of Procedure – start to incision” was also deemed as a high impact intervention, but would be low effort to implement because many identified gaps in care falling under this category can be addressed with little resource allocation. The stages of care in this quadrant of the impact-effort matrix would likely receive priority for implementation. A matrix utilizing the four criteria, summarized as ‘impact’ and ‘effort’, was produced by QI and again shared with the expert panel.

Each expert was then asked to identify which two stages of care in the impact effort matrix would have the greatest potential for SSI reduction. Each expert was also asked to rank the two stages of care they selected by attaching a primary vote (2 points) and a secondary vote (1 point). For example, the stage “Day of Procedure – incision to handoff” received eight primary votes (totaling 16 points) and five secondary points (totaling 5 points), giving it a total of 21 points and thereby the highest point total of any stage. All voting was blinded from other experts. The results of the voting process are summarized in Figure 2. At the end of voting, four stages of care were identified as having potential for significant reduction to SSI were deemed to be the focal areas for intervention, these were: Pre-Operation Readiness for Inpatients, Day of Procedure – start to incision, Day of Procedure – incision to handoff, and Patient/Family Education.

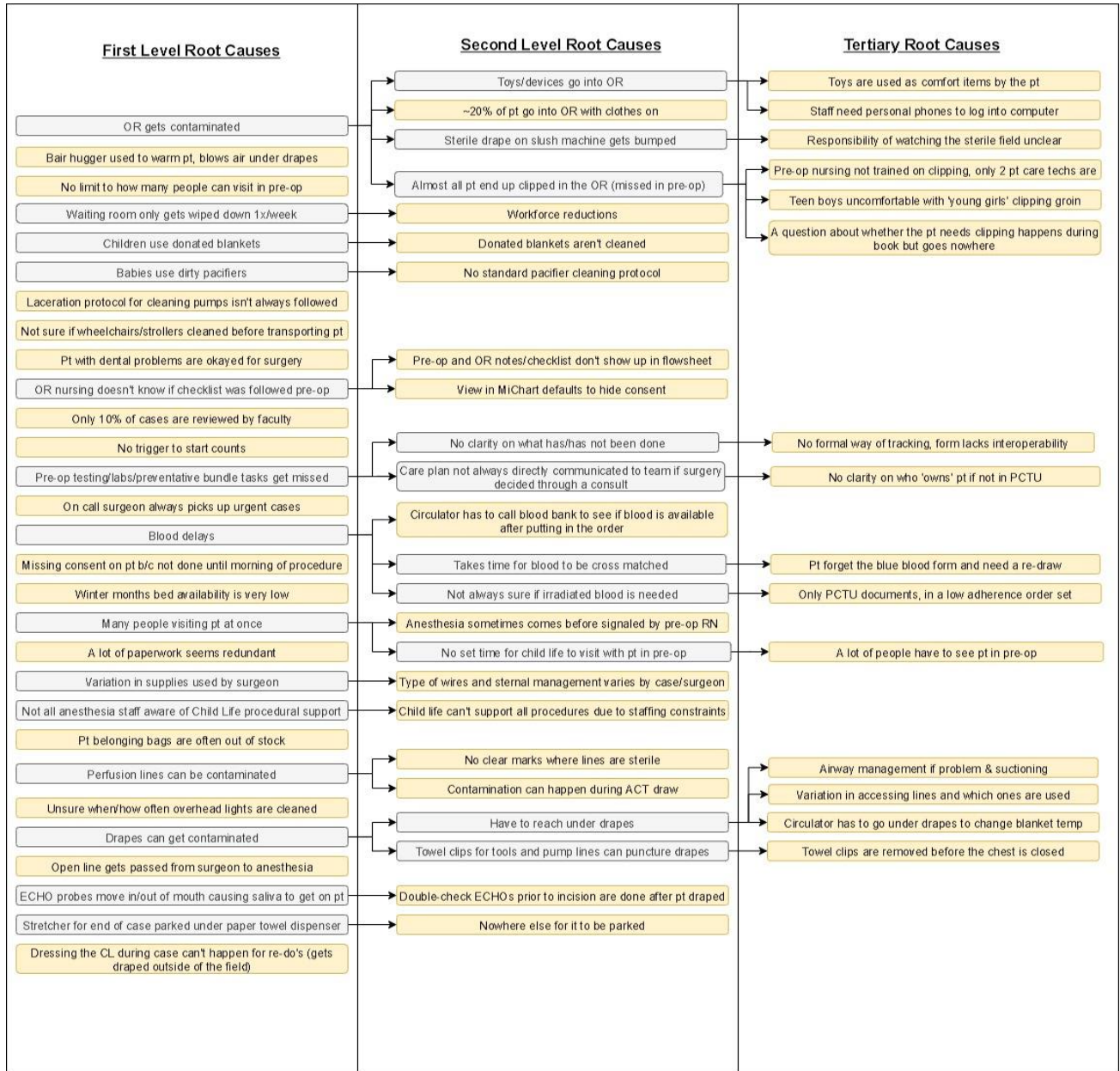


**Figure 2.** Impact-Effort Matrix and Expert Panel Votes

#### Step IV: Root Cause Analysis

The next step was to explore root causes of the gaps identified in each of the four stages of care such that interventions could be targeted to those causes. To achieve this, the expert panel was divided into working groups based on their experience in each identified category. For example, surgical staff were encouraged to identify root causes for the “Day of Procedure – incision to handoff” stage of care as they were most instrumental in identifying current gaps within this category. Each working group met separately with CDIT to identify the root causes and prepare a root cause analysis for each category. A root cause analysis is used to help understand the vectors causing the identified gap and involves thinking critically about the most basic causes of a particular problem. The end goal of a root cause analysis is to find the most basic level at which to intervene to address the upstream cause. For example, within the stage “Day of Procedure – incision to handoff”, one gap identified by experts was that there were variations in the surgical equipment supplies used by surgeons for the same procedures. The root causes of this gap relate to surgeon’s preference to use specific tools on different patients despite them having the same procedure. This practice can lead to differences in patient recovery ability and the risk of SSI. The group who identified this gap suggested that standardizing the practices and supplies for a particular procedure and patient type may reduce this variability. All root cause analyses are summarized in Figure 3, with highlighted components representing the end root causes that interventions should address. After identifying the root causes of the most significant gaps in the current state of care, each was discussed among the expert panel. This was

done to determine feasible measures to track efficacy of potential interventions at attenuating each end root cause.



**Figure 3.** Root Causes of SSI at Michigan Medicine

Notes: pt = patient ; OR = operating room ; op = operation ; b/c = because ; ECHO = echocardiogram ; MiChart = Michigan Medicine's electronic medical record system ; RN = resident nurse ; ACT = activated clotting time

### *Step V: Development of Interventions*

The next step was to develop interventions which addressed each of the end root causes identified in the root cause analysis. A descriptive statistic was identified for each end root cause which related to an adherence target for that end root cause. An example of this is standardization of handoff practices between units. These descriptive statistics and associated adherence targets were used as a starting point for discussion of interventions – what kind of intervention could address this end root cause, via the specified descriptive statistic, to achieve the associated adherence target. CDIT worked together with the expert panel to identify interventions which would be practically implementable within CSMCH, achieve the objectives derived from the root causes, and be measurable via the process measures. This process of developing interventions was largely achieved through discussion between experts on the panel and reviewing current scientific literature and recommended guidelines. A complete bundle of 17 interventions was derived from this discussion. These are summarized in Figure 4 alongside a justification for their selection. The complete bundle of interventions was derived in two ways, either from discussion based on the experiences of the expert panel (expert consensus) or based in published scientific evidence (evidence based). This bundle can be broken down into three major categories of interventions, a) standardization of practices, b) sterilization updates and consistency, and c) OR/recovery room configuration.



Interventions	Justification
<i>Expert Consensus</i>	
Positioning OR bed closer to perfusion	Lines less likely to get tangled, provides better environment for controlled flow of blood, affords more space to move other tables and get around in OR
Removing x-ray gown rack from OR	Affords more space to move other tables and get around in OR, helps reduce traffic in/out of OR for staff needing an x-ray gown since racks are shared between OR's
Standardizing anesthesia line setup	Using alcohol impregnated caps on lines reduces ports for infection, clustering lines away from ECHO probe (to pt left) reduces risk of contaminating probe which moves in/out of pt
Changing sterile table setup configuration	Extra space for surgeons to move while maintaining sterile field, back not to instrument table ensures nothing bumped by turning around for instruments (maintains sterility)
Draping solution warmer after patient	If pt enters with inadequate decolonization or contaminated object the solution warmer can become contaminated and impact the sterility of anything it warms during the operation
Using sterile cassette drape for trash	Reduces potential for contact transferral of organism from non-sterile cassette drape to pt or surgical team
Getting smaller tables behind nurses' computer	Affords more space to move other tables and get around in OR
Using gown table for scrub only	Ensures scrub process is sterile, reduces chance for contamination from scrub-in, reduces chance of other cross-contamination
Positioning blanket machine in front/to side of overhead table	Not having to reach underneath the sterile field to change blanket warmer temperature reduces chances of unintentional breach of field
Covering patient's stretcher with impervious drape	Prevents potentially dirty water from staff hand washing from getting onto stretcher as it has to be positioned under the paper towel dispenser just outside of the OR
Keeping bypass lines on sterile field until ready to remove drapes/chest closed	Prevents sterile field disruption, reduces chance of potentially contaminated line coming into contact with open chest
Stocking patient belonging bags in OR for support items	Support items for pediatric patients are not sterile upon entering OR and require sterile storage during operation to ensure minimal opportunity for cross-contamination
<i>Evidence Based</i>	
Establishing expectation of using core door	Reduced OR traffic correlates with lower SSI rates, maintains negative pressure during surgery so airflow doesn't carry in organisms while chest is open
Changing to a wall mount Surgiscanner	Wall mount conserves space, hanging pockets for gauze/sponges removes need to use separate table to scan and count, system use improves accountability and reduces errors
Prepping neck line and applying Sorbaview dressing	Best results for preventing infections around site of line while still being able to view the line
Using gelfoam instead of bone wax for sternal closure	Gelfoam for sternal management associated with attenuated SSI rates compared to bone wax
Patient decolonization protocol	Disrupts skin and nasal microbiome by killing organisms that could otherwise cause disease if exposed to incision site (or deeper), abx can achieve this for the intestinal microbiome too

**Figure 4.** Description of Bundle of Interventions

### *Implementation of Interventions*

Following the development of the intervention bundle, a total of 17 interventions were implemented across the hospital departments and specialties. These 17 interventions were packaged as a bundle, which was disseminated to each Department Chair who would be responsible for intervention implementation in their department. Fifteen of the seventeen interventions were minor adjustments to the current standard of care practices. Examples of these minor modifications include: standardizing cleaning services, reconfiguring patient rooms/operating rooms, and modifying surgical equipment setup. The two remaining interventions underwent a piloting stage prior to implementation to ensure their acceptability and feasibility. These two interventions were revisions to the CSMCH's electronic medical record system (MiChart) case request order form and hardcopy SSI informational sheets which are provided pre-operation to patients and their family.



There were several steps involved in piloting of the new EMR case request forms and the SSI informational sheet. For the EMR case request order form, initial changes to the form were proposed during individual department meetings, such as adding required fields for whether hair clipping was indicated. Once these additions were made, the EMR form were piloted for one week followed by full-scale implementation. For the revised SSI information sheet, a prior CSMCH factsheet on preventing SSI peri-operatively was used as a template and adapted for use with pediatric populations. This was also condensed to two-pages for ease in provider-patient communication. Once revised, piloting of this SSI informational sheet involved multiple iterations in department meetings for optimal clarity in wording for pre-operation readiness to reduce SSI risk. These informational sheets were also revised to address current gaps in recommendations for wound maintenance post-discharge.

### *Assessing Efficacy of Intervention*

Following implementation of the interventions, the next step involved collecting data to determine the efficacy and adherence to the interventions. Data on process measures and change in overall SSI were collected to evaluate the efficacy of the intervention bundle. These process measure data were abstracted from medical records by CDIT while the overall change in SSI were collected by the IPE team. These data were collected at one month and six months post-implementation to determine the level of adherence to the individual interventions within the bundle. Adherence data were collected through observation of surgical procedures. All data were then de-identified and analyzed by QI specialists to generate three summary statistics (process measures met [%], adherence rate [%], and reduction in SSI rates [%]) which were used to assess the efficacy of the intervention bundles. No additional analysis was conducted on these composite, de-identified summary statistics, which were then used to evaluate the impact of the interventions on SSI rates.

### *Evaluation of the Intervention Bundle*

Data on process measures were collected at baseline and post-implementation of the intervention bundle to determine how well the interventions were implemented (both the

intervention delivery and adherence) and whether these interventions effectively attenuated SSI rates. An intervention evaluation was performed using these data. The intervention evaluation involved tracking whether identified process measure targets for each component of the intervention bundle had been met. The tracked process measures were as follows: decolonization compliance (%), patients receiving appropriate pre-operation testing (%), compliance with pre-operative preventative bundle (%), time from admission to surgery (minutes), antibiotic timing compliance (% and when administered), patient cleaning compliance (%), PrEP compliance (%), hair clipping pre-operation (%), operating room traffic (# of times hall door and core door opened), hand hygiene compliance (%), glove changing compliance (%), and education material dissemination (%). Overall percent reduction in SSI was also quantified as part of the evaluation process.

Adherence to the intervention procedures was also assessed, to ensure intervention components had been integrated into regular care. The evaluation of adherence was conducted in 2 phases. Phase I was conducted 1 month post-implementation and the phase II was conducted at 6 months post-implementation. To assess adherence to the intervention, an observation form was developed to determine whether specific procedures were conducted to reduce SSI in the operating room. Figure 5 shows the observation form which lists 15 surgical interventions that were observed (referred to as ‘countermeasures’) and allows tracking of operating room traffic during various stages of the procedure. This observational tracking form also noted any variations that occurred and the context of these. The observation form allowed tracking of adherence to 15 of the 17 interventions in the SSI prevention bundle. Adherence data for the remaining two interventions was not collected through the observation form, use of the electronic case request form and dissemination of the SSI informational sheet were assessed directly by department heads and quantified for stakeholder reporting.

All interventions in the bundle were implemented successfully with good adherence. For example, at 1 month post-intervention the average adherence rate was 92%, and at the 6 month follow-up the adherence rate was 86%. Furthermore, all process measure targets related to the implemented interventions were met. Since the implementation of the SSI prevention bundle there has been an average 47% reduction in SSI rates, with deep SSI rates at 0.55% (baseline deep SSI rate = 1.07%) and superficial SSI rates at 1.1% (baseline superficial SSI rate = 2.01%)

during 2019. Although this change in SSI rates cannot be directly attributed to the intervention bundle, this provides sufficient evidence to demonstrate the efficacy of this process.

**CDI CHC Program Improvement Sustainment Tracking**

Date: \_\_\_\_\_ Patient In Time: \_\_\_\_\_ Incision Time: \_\_\_\_\_ Closure Time: \_\_\_\_\_ Patient Out Time: \_\_\_\_\_

Track the number of times the doors are opened between Incision and Closure with tally marks

	Pre-incision	Intra-op	
Hall Door Opened:	↓	↓	
Core Door Opened:	↓	↓	
<b>Countermeasure</b>			<b>Circle One</b>
If applicable, Hair Clipped in OR?			Yes No
X-Ray Gown Rack positioned outside OR?			Yes No
Stretcher waiting outside OR for after case is covered with white plastic drape?			Yes No
Antibiotics present in room at start of case?			Yes No
Blanket warmer positioned out from under the scrub table?			Yes No
Scrub table set up in "L" configuration?			Yes No
If applicable, patient personal belongings (stuffed animal, etc.) placed in patient belonging bag?			Yes No
Anesthesia used standard line set up? (see and compare to picture diagram in OR)			Yes No
Slush/solution warmer machine draped AFTER patient draped?			Yes No
Sorbaview dressing applied when prepping neck line?			Yes No
Same Day Type and Screen blood draw performed in OR on patient?			Yes No
Gown table used for Scrub only (not surgeons, fellows, etc.)?			Yes No
Gelfoam used for sternal management?			Yes No
Perfusion pump lines were left on OR bed until chest was closed?			Yes No
Anesthesia used green caps on lines?			Yes No
<b>Case Details</b>			
Circulator: _____	Anesthesiologist: _____	Perfusionist: _____	OR# _____ Age _____ M/F _____ Primary Procedure _____

**Figure 5.** Surgical Adherence Tracking Tool

**Discussion**

The purpose of this case study was to document the process of developing an intervention bundle for SSI prevention for pediatric surgery patients and to assess the impact of these interventions on SSI rates among pediatric surgery patients at CSMCH. Through this case study a process for identifying and implementing targeted interventions was documented, key steps included: a) creating a panel of local experts, b) developing a process map outlining the current state of care with the expert panel, c) developing and voting on an impact-effort matrix with the expert panel to determine the most effective areas for intervention, d) developing a root cause analysis with the expert panel that identifies the underlying problems within each area to

intervene on, and e) developing the intervention bundle itself. Assessment of adherence to the interventions showed high fidelity to the bundle of interventions and a 47% decrease in SSI rates.

In this case study, a comprehensive process for identifying and developing interventions was documented. To our knowledge this is the first documentation of an intervention development process that includes local knowledge to develop a process map, conduct an impact-effort matrix, and a root cause analysis. This case study began with the creation of a panel of experts, namely employees of CSMCH who had experience with SSI and/or pediatric cardiac surgery alongside department heads. Their long-term goal was to develop interventions to reduce SSI burden from pediatric cardiac surgeries within CSMCH. A similar study by Vitale *et. al.* compiled a panel of experts to develop best practice guidelines for SSI prevention in pediatric spine surgery<sup>18</sup>. This expert panel successfully developed and agreed on fourteen guidelines for preventing pediatric SSI from spinal surgery<sup>18</sup>. Notably some recommendations from Vitale *et. al.* align with interventions identified through the process outlined in this case study, such as providing SSI information materials to the patient/family and standardizing hair clipping protocols, but many of the recommendations of Vitale are specific to spinal surgery.

In this case study, a process map was developed and used to identify the gaps and employee experiences surrounding pediatric surgical patient care. A process map methodology was also used by Newton *et. al.* to develop quality improvement (QI) measures to reduce pre-operative pediatric clear fluid fasting times. Through this process they identified knowledge gaps relating to confusion around fasting start times and the standardized protocol<sup>19</sup>. They successfully identified and developed interventions which reduced mean fasting times in children admitted to this hospital from 6.3 hours to 3.1 hours<sup>19</sup>. Although for a different indication, the success of Newton's study indicates the benefits of using a process map methodology and how it can translate to effective interventions within a specified context.

The use of an impact-effort matrix has been applied to studies in different contexts. For example, Fieldston *et. al.* used an impact-effort in an evaluation at a children's hospital to rank ideas for improvements from an interdisciplinary team and found that inclusion of an impact-effort matrix allowed prioritization of ideas while managing resource allocation<sup>20</sup>. In regard to the root cause analysis, this strategy was successfully utilized to identify points for interventions to be developed and added to the standard of care in this case study. Similarly, Nadja *et. al.*

looked at use of continuous peripheral nerve blockade (CPNB) to control pain in children undergoing pectus excavatum repair<sup>21</sup>. Through use of a root cause analysis they found catheter proximity to wound, implanted hardware and delayed utilization were resulting in the ten-fold increase in SSI that had been noted since CPNB introduction<sup>21</sup>. Although these other studies did not use all of the approaches for intervention development outlined in this case study, the process used is based on multiple effective processes utilized in these other studies which together lead to sustainable, targeted intervention development.

Through the process outlined in this paper 17 interventions were compiled into a bundle. One intervention of note was pre-operation hair clipping. Similar to this case study, a meta-analysis by Woodings *et. al.* evaluated pre-operative hair removal to reduce adult SSI and found that use of a razor over clippers significantly increased risk of SSI (RR = 2.02, 95% CI 1.21 – 3.36)<sup>22</sup>. While this is a different population, this significant risk reduction in SSI through use of clippers supports results of this interventions development study. The rigor of this process for intervention development facilitated creation of a uniquely tailored bundle, which met stakeholder targets, was readily integrated into the SOC, and effectively reduced SSI rates in the pediatric cardiology patient population at CSMCH.

Evaluation of the implementation process involved assessing whether individual interventions had met their targets and the level of adherence to the interventions. This evaluation found that 100% of process measures were met, and adherence measures averaged 86% at 6 months post-implementation. A similar study by Vandenberg *et. al.* looked at implementation of a comprehensive antibiotic protocol in pediatric spinal surgery patients and found an 85% adherence rate to their intervention<sup>23</sup>. While their adherence rates are slightly lower than noted for this study, they are comparable to what was found utilizing the intervention development process outlined in this paper. This indicates that the process for intervention development outlined in this paper leads to effective interventions, which can be implemented with relative ease, and can be integrated well enough into the standard of care for surgical patients to be used continuously in future. A secondary outcome of this case study was to assess the impact of the interventions on the reduction of SSI. This assessment found that SSI rates were reduced by nearly 50% from pre-intervention baseline data. A similar study by Schaffzin *et. al.* looked at attenuating SSI in three high risk procedures (cardiothoracic, neurosurgical shunt,

and spinal fusion) among pediatric patients and found a reduction in SSI by 21% (from 2.5 SSI per 100 procedures to 1.8 SSI per 100 procedures)<sup>24</sup>. While their reduction in SSI rates was significantly smaller than noted for this study, they are comparable to what was found utilizing the intervention development process outlined in this paper. This indicates that the process for intervention development outlined in this paper leads to interventions which can be more effective than their evidence-based counterparts when working with a similar population.

### *Strengths of Intervention Development Process*

There are several strengths associated with the intervention development process and implemented interventions. First, the intervention development process documented here is executed in a bottom-up fashion – involves community engagement, and inclusion of those who will implement and benefit from the interventions, in the development process. The benefit of this bottom-up approach is that it affords researchers the opportunity to consider cultural, institutional, and/or regional sensitivities while developing the intervention(s). A study by Ndum explored the efficacy of bottom-up intervention development for solid waste management in African LMIC, compared to the traditional top-down approach to this issue that is typically present<sup>25</sup>. Although this study focuses on another issue in a different population, the benefits achieved through use of bottom-up intervention development and integration over top-down include sensitivity and sustainability. Ndum notes that the top-down approach fails to consider the concerns and opinions of those directly affected by the intervention in the context of local public attitudes and behaviors<sup>25</sup>. Furthermore, Ndum sites the sustainability of the bottom-up waste management intervention being much longer than the top-down interventions which were not appropriately adapted to the local context<sup>25</sup>.

The second strength relates to the ability of this intervention development process to target rare groups, whether this is defined as rare diseases, risk factors, or underserved populations. This is because the intervention development process can be targeted to specific needs using qualitative research methodology. At its most basic level this involves collecting and analyzing, through thematic analysis, the perspectives of a population of interest to inform development of a theory, which could then be intervened upon or used to inform intervention development. The feasibility of this concept is demonstrated in a mixed-methods randomized

controlled trial by Rooshenas *et. al.* who used semi-structured interviews, with patients and clinical professionals, to inform abdominal wound dressing interventions to prevent SSI<sup>26</sup>.

The third strength lies in the built-in evaluation of resource allocation through development and use of an impact-effort matrix. A study by Kashani *et. al.* looking at QI training for fellows used an impact-effort matrix to prioritize which projects would be selected for the fellows to address in order to optimize time, schedules, and hospital financial resources<sup>27</sup>. Curriculum projects were chosen based on their potential to improve patient care with the least difficulty or draw on resources<sup>27</sup>. They selected five projects, which by the end of the study had all been completed and showed positive impacts on patient care. This is like the process for prioritizing intervention categories outlined in this paper and had similarly positive implementation and results. It is especially important to address the allocation of resources when looking at SSI, which have direct hospital costs in the US totaling \$3.3 billion annually<sup>13,14</sup>. In this study, use of an impact-effort matrix assisted in optimizing time, personnel allocation, and hospital financial resources to achieve the greatest potential reduction in SSI rates. Greater reductions in SSI correlate with greater reductions in direct hospital costs attributable to SSI, which, if expanded, can significantly reduce the annual cost of SSI in the US.

A final strength of this intervention development process is the high fidelity to the implemented interventions. This relates to all of the process measure targets for the implementation evaluation being met, indicating that each intervention was delivered as intended. A study by Breitenstein *et. al.* looking at implementation fidelity in community-based interventions found that higher fidelity is generally observed with bottom-up, or community-based, interventions<sup>28</sup>. This finding by Breitenstein *et. al.* is comparable to the high fidelity demonstrated by the documented intervention development process outlined in this paper, further bolstered by the high adherence rates noted.

### *Limitations of Intervention Development Process*

There were several limitations identified in this study pertaining to the adherence evaluation and the implemented interventions. As part of the adherence evaluation, less than complete adherence to the intervention bundle was noted (86%). Upon investigation the surgical

staff explained that certain interventions were not applicable to every pediatric cardiology case coming through the operating room. For example, hair clipping is a pre-operation intervention which was implemented as a required field in the new case request order set. The goal was to prevent clipping intra-operatively to reduce the risk of skin nicks potentially becoming infected, but some patients were too young for clipping to be necessary, so it was not done. The limitation identified was inadequate piloting of the surgical adherence tracking forms. With no N/A option, simply a Yes/No choice, additional piloting could have been done to ensure capturing of this discord as it artificially lowered the adherence rates.

Another limitation was identified through informal discussion with surgical staff post-intervention. The new operating room table and equipment configurations as part of the intervention forced the biohazard bins to be pushed into a corner where an air vent was located. This caused disruptions to air flow within the OR, increasing temperature more than normal (by ~2 degrees F) and potentially interfering with air scrubbing. Future work on OR set-up should consider pilot testing multiple configurations to achieve a balance with air circulation.

Finally, the current intervention bundle for attenuating SSI rates in pediatric cardiology patients at CSMCH may not be generalizable to other populations or medical institutes. This is likely because other institutes may have different standard of care processes to which the intervention bundle would not directly be compatible with. Additionally, this case study focused exclusively on pediatric populations. While possible, substantial process development and piloting will be needed to expand these interventions to adult or non-cardiac surgery divisions. While decreased SSI rates were detected, due to the study design this rate reduction cannot be attributed specifically to the intervention bundle. Future studies would benefit from a standard of care control group to create a randomized controlled trial such that resultant changes can be attributed to the interventions developed.

### *Public Health Implications*

Through the use of the intervention development process outlined in this case study, a bundle of interventions for pediatric SSI prevention was successfully developed and implemented at CSMCH. There are several public health implications of this study. First, there is



the potential for expansion of the intervention bundle developed to populations outside the study population. Although interventions developed during this study have been demonstrated effective in reducing SSI in pediatric cardiology patients, there are still no policy guidelines for SSI prevention in all pediatric patients. Given the success of the bundle of interventions and its lack of cardiac surgery specific components, it may also be applicable to all pediatric surgical cases, including adult surgical cases within that healthcare system. This appears to be moving forward at Michigan Medicine with the integration of these interventions into all pediatric surgical care settings within the healthcare network, not just CSMCH. Although these interventions were developed to address SSI rates, there may also be applicability to other indications as well. EMR updates, operating room configuration and surgical tool set-up standardization represent the bulk of implemented interventions. These are changes to the system which can reduce likelihood of exposure to more than just SSI, including other infections. This could be achieved through improvements to standard sterile practice, such as reduced operating room traffic or using alcohol impregnated caps on lines, and can even help reduce redundancies or lapses in general care.

There are also potential policy implications arising from this work. These recommendations for pediatric SSI prevention could inform new guidelines tailored to the whole pediatric patient population, that may be adopted by policy organizations such as the CDC or State Health Departments. Future studies may further support CDC guidelines which can inform new federal policy on blanket updates to the SOC relating to SSI prevention and general patient safety improvements across multiple surgical procedures.

Another implication of this study involves expanding the use of this intervention development process to other rare or underserved populations. The demonstrated rigor, fidelity, and bottom-up design of this process lends itself to exploring other areas where there has previously been little research or intervention. This is due to the lack of reliance on an evidence base to develop the interventions as this process emphasizes local engagement at each stage of development. Future studies would benefit from consideration of this method for intervention development when research is lacking or the population/indication of interest are uniquely structured such that the typical top-down approach is impractical for sustained, efficacious intervention.

A further implication of this study relates to the method used for resource allocation, or rather the importance of considering available resources when developing interventions. Integrating use of an impact-effort matrix during intervention design can optimize cost savings and health benefits in low resource or rural settings. On a global scale, this method for allocating resources can be valuable for prioritizing projects and ensuring that the most necessary infrastructure for implementation is present, particularly in low and middle income countries. Future studies would benefit from use of an impact-effort matrix to evaluate how to allocate available resources when encountering low resource/rural settings or high level program management requiring prioritization of components.

The final implication of this study is that it provides data to inform the design of rigorous clinical trials. A limitation of this study was the inability to absolutely attribute the SSI reduction to the bundle of interventions that was implemented, which was due to the lack of a control group for comparison. However, the viability of the intervention development method was successfully demonstrated. Future studies may be able to use the outlined process to perform a clinical trial or randomized controlled trial to determine the causal pathway and attribute the changes noted to the developed interventions.

## **Conclusion**

Through use of this process a bundle of interventions targeted at a high risk population (pediatric cardiology patients), within a unique institutional environment (CSMCH), to address a relatively rare infection (SSI) was successfully developed and implemented. The success of this case study indicates that high risk populations, rare risk factors and diseases, and unique cultural /institutional /regional considerations can all be addressed utilizing the outlined method for intervention development. In this way, community and workers can be involved such that they remain engaged enough to continue with the interventions without outside influence. Future studies to test efficacy of this intervention development process would benefit from extensive piloting of interventions and inclusion of a control group who does not receive the interventions. In this way the noted changes could be further attributed to the interventions delivered, and onward to the intervention development process itself.

## **References**

1. Inweregbu, K., Jayshree, D., Pittard, A. (2005). Nosocomial infections, *Continuing Education in Anaesthesia Critical Care & Pain*, Volume 5, Issue 1, February 2005, Pages 14–17, <https://doi.org/10.1093/bjaceaccp/mki006>
2. CDC. (2015). Types of Healthcare-associated Infections. Retrieved from <https://www.cdc.gov/hai/infectiontypes.html>
3. WHO. (2011). Health Care-Associated Infections. Retrieved from <https://health.gov/our-work/health-care-quality/health-care-associated-infections>
4. U.S. Department of Health and Human Services. (2020). Health Care-Associated Infections. Retrieved from <https://health.gov/our-work/health-care-quality/health-care-associated-infections>
5. WHO. (2017). Health Care-Associated Infections. Retrieved from [https://www.who.int/infection-prevention/publications/burden\\_hcai/en/](https://www.who.int/infection-prevention/publications/burden_hcai/en/)
6. CDC. (2018). Current HAI Progress Report. Retrieved from <https://www.cdc.gov/hai/data/portal/progress-report.html>
7. Zimlichman E, Henderson D, Tamir O, et al. (2013). Health Care–Associated Infections: A Meta-analysis of Costs and Financial Impact on the US Health Care System. *JAMA Intern Med.* 2013;173(22):2039–2046. doi:10.1001/jamainternmed.2013.9763
8. Stone P. W. (2009). Economic burden of healthcare-associated infections: an American perspective. *Expert review of pharmacoeconomics & outcomes research*, 9(5), 417–422. <https://doi.org/10.1586/erp.09.53>
9. CDC. (2020). Surgical Site Infection (SSI) Event. Retrieved from <https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscscsscurrent.pdf>
10. NDF. (2017). Surgery 2015-2017 Final Report. Retrieved from [http://www.qualityforum.org/Publications/2017/04/Surgery\\_2015-2017\\_Final\\_Report.aspx](http://www.qualityforum.org/Publications/2017/04/Surgery_2015-2017_Final_Report.aspx)
11. CDC. (2019). 2018 National and State Healthcare-Associated Infections Progress Report. Retrieved from <https://www.cdc.gov/hai/pdfs/progress-report/2018-Progress-Report-Executive-Summary-H.pdf>
12. Knox L, Brach C. Primary Care Practice Facilitation Curriculum (Module 10). AHRQ Publication No. 15-0060-EF, Rockville, MD: Agency for Healthcare Research and Quality; September 2015.
13. Zimlichman, E., et al., "Health Care-Associated Infections. A Meta-analysis of Costs and Financial Impact on the US Health Care System". *JAMA Intern Med*, 173(22): (2013): 2039-46.
14. de Lissovoy, G., et al., "Surgical site infection: Incidence and impact on hospital utilization and treatment costs". *Am J Infect Control*, 37(5): (2009): 387-97.
15. AHA. Fast Facts on U.S. Hospitals, 2019. (2019). Retrieved from <https://www.aha.org/statistics/2020-01-07-archived-fast-facts-us-hospitals-2019>
16. Niewiesk S. (2014). Maternal antibodies: clinical significance, mechanism of interference with immune responses, and possible vaccination strategies. *Frontiers in immunology*, 5, 446. <https://doi.org/10.3389/fimmu.2014.00446>

17. Simon, A. K., Hollander, G. A., & McMichael, A. (2015). Evolution of the immune system in humans from infancy to old age. *Proceedings. Biological sciences*, 282(1821), 20143085. <https://doi.org/10.1098/rspb.2014.3085>
18. Vitale, Michael G., Riedel, Matthew D., Glotzbecker, Michael P., Matsumoto, Hiroko., Roye, David P., Akbarnia, Behrooz A., Anderson, Richard C.E., Brockmeyer, Douglas L., Emans, John B., Erickson, Mark, Flynn, John M., Lenke, Lawrence G., Lewis, Stephen J., Luhmann, Scott J., McLeod, Lisa M., Newton, Peter O., Nyquist, Ann-Christine, Richards, B. Stephens III., Shah, Suken A., Skaggs, David L., Smith, John T., Sponseller, Paul D., Sucato, Daniel J., Zeller, Reinhard D., Saiman, Lisa. Building Consensus: Development of a Best Practice Guideline (BPG) for Surgical Site Infection (SSI) Prevention in High-risk Pediatric Spine Surgery, *Journal of Pediatric Orthopaedics*: July/August 2013 - Volume 33 - Issue 5 - p 471-478 doi: 10.1097/BPO.0b013e3182840de2
19. Newton, RJG, Stuart, GM, Willdridge, DJ, Thomas, M, Kurth, D. Using quality improvement methods to reduce clear fluid fasting times in children on a preoperative ward. *Pediatr Anesth*. 2017; 27: 793– 800. <https://doi.org/10.1111/pan.13174>
20. Fieldston, E. S., Jonas, J. A., Lederman, V. A., Zahm, A. J., Xiao, R., DiMichele, C. M., Tracy, E., Kurbjun, K., Tenney-Soeiro, R., Geiger, D. L., Hogan, A., & Apkon, M. (2016). Developing the Capacity for Rapid-Cycle Improvement at a Large Freestanding Children's Hospital. *Hospital pediatrics*, 6(8), 441–448.
21. Apelt, N., Schaffzin, J., Bates, C., Brown, R. L., Mecoli, M., Sadhasivam, S., & Garcia, V. (2017). Surgical site infection related to use of elastomeric pumps in pectus excavatum repair. Lessons learned from root cause analysis. *Journal of pediatric surgery*, 52(8), 1292–1295.
22. Tanner, J., Woodings, D., & Moncaster, K. (2006). Preoperative hair removal to reduce surgical site infection. *The Cochrane database of systematic reviews*, (2), CD004122. <https://doi.org/10.1002/14651858.CD004122.pub2>
23. Vandenberg, C., Niswander, C., Carry, P., Bloch, N., Pan, Z., Erickson, M., & Garg, S. (2018). Compliance with a Comprehensive Antibiotic Protocol Improves Infection Incidence in Pediatric Spine Surgery. *Journal of pediatric orthopedics*, 38(5), 287–292. <https://doi.org/10.1097/BPO.0000000000000812>
24. Schaffzin, J., Harte, L., Marquette, S., Zieker, K., Wooton, S., Walsh, K., Newland, J. (2015). Surgical Site Infection Reduction by the Solutions for patient Safety Hospital Engagement Network. *Pediatrics*, 136 (5) e1353-e1360. <https://doi.org/10.1542/peds.2015-0580>
25. Ndum, A. (2013). Bottom-Up Approach to Sustainable Solid Waste Management in African Countries. Accessed at [https://www.researchgate.net/publication/283378695\\_Bottom-Up\\_approach\\_to\\_sustainable\\_solid\\_waste\\_management\\_in\\_African\\_countries](https://www.researchgate.net/publication/283378695_Bottom-Up_approach_to_sustainable_solid_waste_management_in_African_countries)
26. Rooshenas, L., Bluebelle Study Group, Severn and Peninsula Audit and Research Collaborative for Surgeons, & West Midlands Research Collaborative (2016). Bluebelle study (phase A): a mixed-methods feasibility study to inform an RCT of surgical wound

dressings strategies. *BMJ open*, 6(9), e012635. <https://doi.org/10.1136/bmjopen-2016-012635>

27. Kashani, K. B., Ramar, K., Farmer, J. C., Lim, K. G., Moreno-Franco, P., Morgenthaler, T. I., Dankbar, G. C., & Hale, C. W. (2014). Quality improvement education incorporated as an integral part of critical care fellows training at the Mayo Clinic. *Academic medicine: journal of the Association of American Medical Colleges*, 89(10), 1362–1365. <https://doi.org/10.1097/ACM.0000000000000398>
28. Breitenstein, S. M., Gross, D., Garvey, C. A., Hill, C., Fogg, L., & Resnick, B. (2010). Implementation fidelity in community-based interventions. *Research in nursing & health*, 33(2), 164–173. <https://doi.org/10.1002/nur.20373>