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Reducing the Risks of Wrong Site Surgery Using the Joint Commission's Targeted Solutions Tool for Safe Surgery

Stephanie Kelly Parks
The University of Southern Mississippi

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The University of Southern Mississippi

REDUCING THE RISKS OF WRONG SITE SURGERY
USING THE JOINT COMMISSION'S TARGETED SOLUTIONS
TOOL FOR SAFE SURGERY

by

Stephanie Kelly Parks

Abstract of a Capstone Project
Submitted to the Graduate School
of The University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

May 2015

ABSTRACT
REDUCING THE RISKS OF WRONG SITE SURGERY
USING THE JOINT COMMISSION'S TARGETED SOLUTIONS
TOOL FOR SAFE SURGERY

by Stephanie Kelly Parks

May 2015

The purpose of this project was to utilize the Institute for HealthCare Improvement's Model of Improvement as a consultation framework to facilitate improvement in core processes for the prevention of wrong site surgery (WSS) using The Joint Commission Targeted Solutions Tool for Safe Surgery© Program at a surgery center in Mississippi. The TST Program was conducted across 6 months and had 6 phases: 1) Getting Started, 2) Training Data Collectors, 3) Measuring Risk Factors, 4) Analyzing Data, 5) Implementing Solutions, and 6) Sustaining the Gains. A convenience sample of 47 surgical staff participated and 8 data collectors observed behaviors. The nurse consultant, using the TST program, assisted staff in reducing the risk of WSS from 16% to 9% in surgical booking, 86% to 53% in pre-op/holding, and 73% to 25% in the OR, and empowered them to make 9 practice decisions (just-in-time coaching; improved communication between scheduling and pre-admissions; OR schedule fax back; primary documents within 48 hours before surgery; standardized patient verification; set up regional block time-out (TO) and role-based TO; standardized surgical site marking and adoption of a surgical checklist). Nurse consultants play a powerful role in enabling surgical staff to reexamine existing practice, change behavior, and create a culture of safety in reducing the risks of WSS and promoting patient safety.

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A Capstone Project
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Approved:

Dr. Mary L. Coyne
Committee Chair

Dr. Patsy L. Anderson

Dr. Karen S. Coats
Dean of the Graduate School

May 2015

DEDICATION

I dedicate this work to my family. A special feeling of gratitude to my parents and partner, whose words of encouragement and unconditional love were felt in every step of this achievement.

Finally, I dedicate this work to my Heavenly Father for answering all of my prayers for strength and seeing this work through.

ACKNOWLEDGMENTS

I offer great appreciation to my committee chair, Dr. Mary Coyne, for encouraging my writing and being a tremendous mentor. You taught my first research course in my baccalaureate program and your partnership with this project made this educational journey complete. Your advice on writing and ‘pushing the envelope’ have been priceless. I would also like to thank Dr. Patsy Anderson for serving as my committee member and the entire DNP faculty for the support and education.

I would like to acknowledge and thank the facility that gave me permission and support to conduct this project. Your employees are the finest example of patient advocates and guardians of patient safety.

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LIST OF ABBREVIATIONS

AORN	Association of periOperative Registered Nurses
ASC	Ambulatory Surgery Center
CITI	Collaborative Institutional Training Initiative
CRNA	Certified Registered Nurse Anesthetists
CTH	Center for Transforming Health
CMS	Centers for Medicare and Medicaid Services
IHI	Institute for HealthCare Improvement
IOM	Institute of Medicine
JIT	Just-In-Time
OR	Operating Room
PDSA	Plan-Do-Study-Act
QIP	Quality Improvement Program
RN	Registered Nurse
RPI	Robust Product Improvement
TO	Time Out
TST	Targeted Solutions Tool
UP	Universal Protocol
WHO	World Health Organization
WSS	Wrong Site Surgery
WWII	World War II

CHAPTER I

INTRODUCTION

Mr. King, a 51-year-old male with a history of type 2 diabetes and chronic ulcerations of both lower extremities went to his physician because both heels were badly inflamed with the left showing signs of slow improvement while the right heel showed signs of infection. Upon examination, his physician informed him that he required a right below-the-knee amputation as soon as possible due to the extent of the infection and presence of wet gangrene extending above his ankle. Mr. King agreed to the surgery and prior to his departure, the office staff scheduled the surgery with the surgeon and surgical service. Mr. King was admitted through the emergency department for an amputation of his right leg.

Immediately, the surgeon called ahead with orders and request to obtain a signed surgical consent from the patient. Upon arrival on the surgical service, Mr. King signed the surgical consent form and was prepped for the amputation. By the time the surgeon arrived in the operating room (OR), the patient was intubated, asleep, and the procedure was ready to begin. The surgeon made the incisions cutting through the major nerves and arteries of the left leg. Several minutes later, an anxious circulating nurse called out to the surgical team that the surgical consent was for the right leg. Well past the point of return, the amputation was performed on Mr. King's less infected and improving left leg (Agrawal, 2014).

Medical Errors

In the United States, medical errors are the eighth leading cause of death, exceeding the annual number associated with motor vehicle accidents (Institute of

Medicine [IOM], 1999). Approximately, 44,000 to 98,000 people die due to medical-related errors on an annual basis (IOM, 1999).

The Joint Commission, the primary accreditation group for many healthcare organizations in the United States, has identified a set of critical health and medical errors, referred to as ‘sentinel events,’ that compromise patient safety and which must be immediately addressed. A sentinel event is defined as “an event that is unexpected and involves death, serious physical or psychological injury, or the risk thereof” (Joint Commission, 2014, p. 1). Wrong site surgery (WSS) is classified as a sentinel event according to the Joint Commission.

Incidence of Wrong Site Surgery

The Joint Commission defines WSS as surgery on the wrong organ, wrong person, or the wrong surgical site (Joint Commission, 2013), and states the problem is worsening. In 2005, it was ranked the second most frequently reported sentinel event to the Joint Commission, while it ranked number one in 2014 (Joint Commission, 2014). Every year, approximately 2,000 patients or 40 patients per week are victimized by WSS (Center for Transforming Health [CTH], 2011). Medical errors involving wrong-site, wrong-procedure, or wrong-patient surgery have been estimated to potentially impact at least one patient per year in a 300-bed hospital (Kelly, 2012).

Failure of Site Verification in WSS

There are a myriad of human and system failures contributing to WSS. The Institute of Medicine (IOM) notes that WSS is due to “faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them” (IOM, 1999, p. 2). At the core of these errors are communication failures. Examples of poor communication related to WSS include, but are not limited to, the surgeon providing wrong site information via phone to the surgical scheduler or the surgical scheduler incorrectly transposing right from left sided procedures. Examples of incomplete patient assessments are x-ray films accidentally reversed or patients that are not physically examined by the surgeon immediately prior to transport to the operating room. An example of an error in judgment may be when surgery was intended for the left leg but staff prepped and draped the right leg.

In the case of Mr. King, analysis reveals a series of system and communication failures leading to the wrong leg amputated and, subsequently, the need for bilateral leg amputations. The surgeon did not obtain surgical consent and site verification with the patient but was instead obtained by surgery personnel; the wrong procedure was placed on the surgical schedule; the operative site was not marked by the surgeon; the incorrect leg was prepped and draped prior to the surgeon’s arrival to the OR; and there was no ‘Time-Out’ site verification performed by the surgical team prior to the first incision.

Financial and Personal cost of WSS

WSS is avoidable; however, when it occurs it has financial consequences for patients, providers, and health care facilities and an immeasurable impact on the quality of life of patients. The severity and extent of damage related to the WSS determines the personal and financial costs associated with the WSS.

The personal cost of WSS may have devastating emotional, physical, and economic consequences for patients and their families, including but not limited to loss of employment, income, mobility, and inability to engage in activities of daily living and those activities that bring meaning to the patient. In the case of Mr. King, the state authorities fined the surgeon \$10,000 and suspended the surgeon's license for a 6-month period. The hospital paid Mr. King \$900,000 and the surgeon paid an additional \$250,000 directly to Mr. King (Agrawal, 2014).

The professional cost of WSS results in a negative impact on the surgical team. Healthcare providers can become the 'second victims' when their patients are victimized by adverse clinical events such as WSS. This phenomenon causes providers to question their clinical skills, medical knowledge, and possibly their choice of career (Agrawal, 2014).

State licensure boards are imposing penalties on surgeons for WSS. Some insurers have decided to no longer pay providers for WSS or wrong-person surgery, or for leaving a foreign object in a patient's body after surgery. Surgery performed on the wrong site or wrong person has often been held compensable under malpractice claims. In fact, "84% of wrong-site orthopedic and 79% of wrong-site eye surgery claims resulted in malpractice awards" (Mulloy & Hughes, 2008, p. 381).

The organizational cost of WSS is also costly. Loss of public trust in the healthcare system and its providers occurs after negative media attention resulting from a WSS event. Defending these types of errors is nearly impossible and those involved usually pay a significant financial, professional, and emotional price for the event.

Efforts to Reduce WSS

In 1995, the Joint Commission required mandatory reporting of every WSS event. According to the Agency for Healthcare Research and Quality (2015), the Joint Commission developed and implemented The Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery in 2004, also referred to as the Universal Protocol (UP-Appendix A).

The three principal components of the UP included a pre-procedure verification, site marking, and a time out (Joint Commission, 2015b). Since 2006, all hospitals, ambulatory care facilities, and office-based surgery programs accredited by the Joint Commission are required to use the UP and all insurance companies require adherence to the UP for reimbursement.

The Centers for Medicare and Medicaid Services (CMS) mandate that in order to receive reimbursement, medical facilities must use a safe surgery checklist that reflects the steps found in the UP. Beginning in 2015, the CMS have mandated that every health care facility conducting surgical procedures must use a safe surgery checklist in order to receive reimbursement. The checklist must demonstrate effective communication and safe practices during three perioperative periods: prior to anesthesia, prior to skin incision, and prior to the patient leaving the procedure area. While there is no one specific mandated checklist, several exist to include one developed by the Universal

Protocol established by the Joint Commission (Appendix A), the Surgical Safety Checklist established by the World Health Organization (WHO-Appendix B), and the Comprehensive Surgical Checklist established by the Association of periOperative Registered Nurses (AORN-Appendix C).

In order to maximize patient safety, reduce the risks of WSS, and optimize quality patient care and outcomes, the Joint Commission’s Center for Transforming Health developed the Targeted Solutions Tool for Safe Surgery© Quality Improvement Program (TST) to reduce the risk of WSS. The TST Program consists of a six-phase process guiding health care organizations through a “step-by-step” process to accurately assess their organization’s true performance, identify their barriers to performance excellence, and facilitate them to proven solutions that specifically address their particular obstacles (Center For Transforming Health [CTH], 2011). The phases progress from 1) Getting Started, 2) Training Data Collectors, 3) Measuring Risk Factors, 4) Analyzing Data, 5) Implementing Solutions, to 6) Sustaining the Gains. In the pilot test of the TST Program, the 7 participating hospitals and ambulatory centers “were able to reduce the number of cases with risks by 46 percent in the scheduling area, by 63 percent in pre-operative (pre-op), and by 51 percent in the OR” (Joint Commission, 2013, p. 2).

Statement of the Purpose

The purpose of this capstone project was to utilize the ‘Institute for HealthCare Improvement’s (IHI) Model of Improvement (Langley, Nolan, Nolan, Norman, & Provost, 2009) as a consultation framework to facilitate organizational improvement in core processes for the prevention of wrong site surgery, i.e., wrong patient, organ, site, procedure using The Joint Commission Targeted Solutions Tool for Safe Surgery©

Quality Improvement Program among a surgical team (schedulers, pre-op personnel, perioperative personnel, and surgeons) at one ambulatory surgery center in South Mississippi. The primary purposes of using the TST Program were to: 1) identify breakdowns in patient care, 2) discover the underlying causes of the breakdown, and 3) generate solutions that are organization-specific to the causes of wrong-site surgeries.

Consultation Framework - IHI “Model of Improvement”

The IHI ‘Model of Improvement’ (Langley et al., 2009) was used to facilitate organizational improvement in core processes for the prevention of WSS using the TST Program among a surgical team at one ambulatory surgery center in South Mississippi. Fundamental concepts and steps of this change model are based on ‘Plan-Do-Study-Act’ (PDSA) cycle proposed by The Deming Institute (2013). The anticipated and achieved outcome of this process was that the surgical team at one surgical center came to value and incorporate the TST Program as the standard and best practices approach to reduce the incidence of WSS.

Application of the IHI and TST Cycles for Sustained WSS Improvement

For this capstone project, concepts of the IHI ‘Plan-Do-Study-Act’ (PDSA) Model of Improvement’ and TST cycles for sustained WSS improvement were utilized in order to evoke a change in practice. The application of these processes is described below and is illustrated in Figure 1.

- During the ‘IHI Planning Phase’, the consultant facilitated change by engaging several key players from the surgical team and organization in the Getting Started TST Phase. By the end of this phase, the consultant assessed

their buy-in and readiness to take action to adopt a safe surgery checklist for reducing the risk of WSS at their facility (Joint Commission, 2014).

- During the 'IHI Doing Phase', the consultant facilitated change by 1) enabling the team to identify the specific types of data to be collected in each surgical area using the appropriate forms, i.e., The Surgical Booking Process Audit Tool, The Pre-op Holding Process Audit Tool and the Operating Audit Tool, 2) conducting the training of data collectors, and 3) assuring that data collectors measured compliance with accuracy and a high level of inter-rater reliability. This phase coincided with the TST phases of 'Training Data Collectors' and 'Measuring Risk Factors.' The consultant was responsible solely for entering all data into the secure Joint Commission Connect extranet and generating findings.
- During the 'IHI Studying Phase', the consultant presented the evidence-based findings to the entire surgical team and facilitated a dialogue on analyzing data that contribute to safe care and risk of errors by generating solutions for improvement at the surgical center. This phase coincided with the TST phase 'Analyzing Data.'
- During the 'IHI Acting Phase', the consultant led the team to 1) implement their solutions and 2) confirm a continuous quality improvement plan for on-going measurement of compliance, sustaining positive changes evoked from the process across over time, and educating new staff to this process. This final phase coincided with the TST phases 'Implementing Solutions' and 'Sustaining the Gains.'

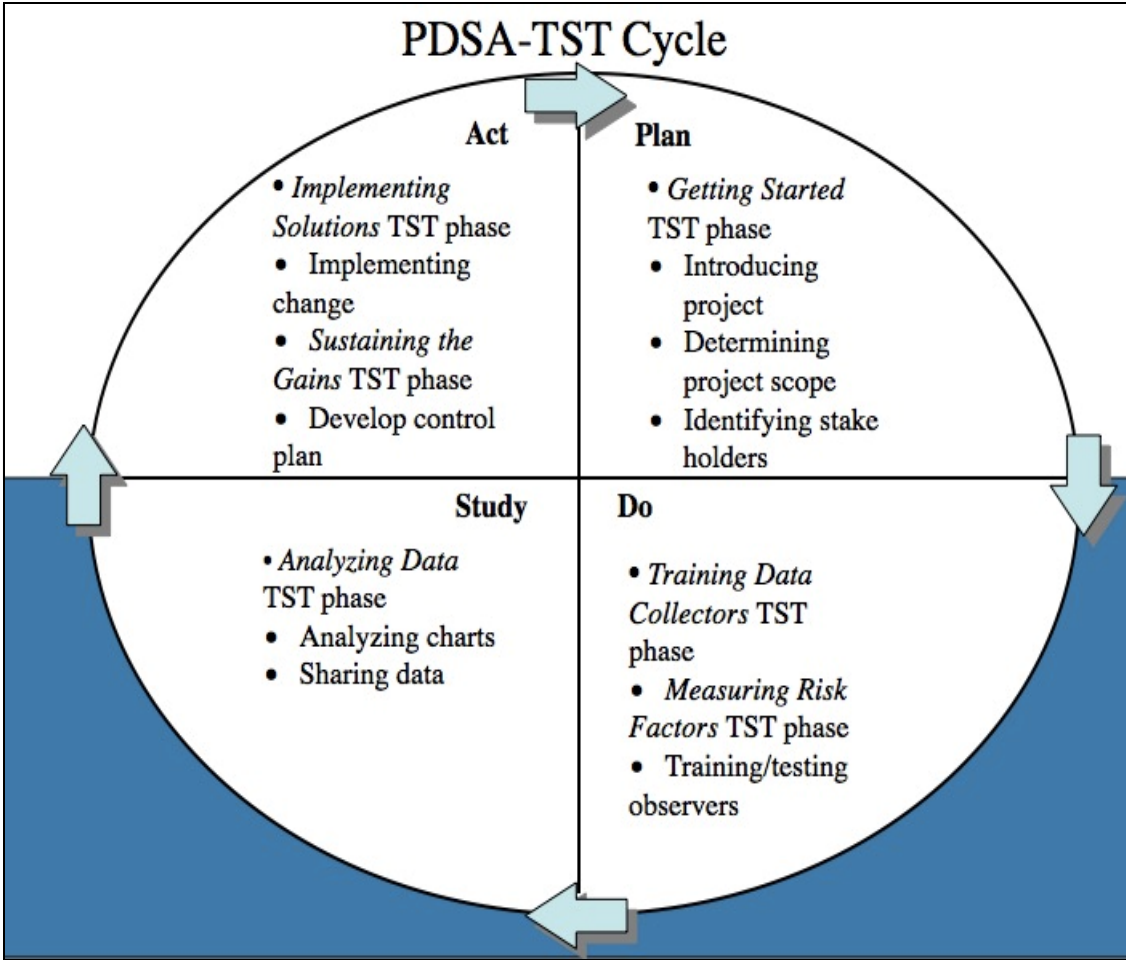


Figure 1. IHI PDSA-Joint Commission Safe Surgery Program.

Significance of this Project

WSS is an avoidable event. Patient safety must be the core, overriding value of every decision made by health professionals. To enact patient safety, we must not only 'Do Good and Do No Harm' but must create a culture of safety, challenging one another to examine the prevalence, causes, and potential solutions for medical errors. The overall aim of this project was to serve as an advanced practice nurse consultant empowering surgical staff to reexamine existing practice, change behaviors as needed, and create a culture of safety in reducing the risks of WSS and promoting patient safety.

Review of Literature

The following databases were used to investigate WSS and related topics: Cochrane, PubMed of the National Library of Medicine, Cumulative Index of Nursing and Allied Health Literature (CINAHL), and Google Scholar.

Human and System Failures Contributing to WSS

There is consensus (DeVine, Chutkan, Norvell, & Dettori, 2010; Dunn, 2006; Hempel et al., 2013; Mulloy, 2008) in the reporting of evidence related to human and system failures contributing to WSS. Communication is the leading error contributing to WSS. In a systematic review, Hempel et al. (2013) identified 125 empirical studies and four clinical practice guidelines published from 2004 through 2013 that reported causes of WSS. Their analysis revealed that primary root causes of wrong-site surgery were due to 1) communication problems such as incorrect information and misperceptions of information, 2) not following policies, 3) not performing safety procedures in a meaningful way, 4) inadequate policies, and 5) the lack of procedural standardization contributed to WSS events. As an outcome of this evidence synthesis, the researchers

recommended that a standardized protocol to prevent WSS be developed for all health care facilities conducting surgeries.

By 2005, communication was cited as the major cause of WSS accounting for 70% of WSS, followed by “deficits of procedural compliance (64%), leadership (46%), competency and credentialing (29%), availability of information (28%), organizational culture (23%), orientation and training (20%), patient assessment (18%), care planning (17%), staffing (10%), environmental safety/security (10%), and continuum of care (5%)” (Joint Commission, 2013, p. 5). Mulloy (2008) found similar results when examining the efficacy of the ‘AORN Correct Site Surgery Tool Kit’ (Appendix C) and the UP (Appendix A) among 519 registered nurses and 325 non-registered nurse-surgical technician respondents. A root cause analysis of WSS was conducted and revealed three recurring communication risk situations: 1) communication failures with the patient and among members of the surgical team, 2) communication failures during the preoperative assessment of the patient, and 3) communication failures when verifying the correct operative site. Mulloy (2008) found that 91% of registered nurses and 73% of non-registered nurse--surgical technicians reported the AORN toolkit was helpful.

Dunn (2006) analyzed 455 WSS records and found that in 80% of the cases, inadequate communication was the root cause of the event. Stahel et al. (2010) found that out of 27,370 self-reported adverse occurrences, 85% of WSS events were due to errors in judgment while 72% were due to failure to perform a surgical ‘time-out’ prior to incision.

Surgical errors take a variety of forms. DeVine et al., (2010) conducted a systematic review of 433,528 spinal surgical cases in Pennsylvania to determine the

incidence of surgical errors. There were 427 incidences of WSS with 70% related to wrong-side surgeries, 56% to 'near-misses', 14% to wrong location/level surgeries, 9% to wrong procedures, and 8% to the wrong patient. The findings showed that WSS is the result of breakdowns in communication related to incorrect surgical site verification and incorrect communication between the surgical team. It also showed that WSS resulted from failure to verify patient information prior to surgery. The clinical recommendations of this systematic review suggest that the use of the Joint Commission UP alone is insufficient to prevent WSS. From this review, the clinical recommendations posit that in addition to the Joint Commission UP there be intraoperative images taken after the surgical site is visualized. Preoperative images are then compared to these images in the room to ensure the correct level of spinal surgery.

Use of the IHI 'Model of Improvement' in Health Care Organizations by the Consultant

The Plan-Do-Study-Act (PDSA) model for improvement is a helpful tool used to rapidly change the way an organization operates in the health care industry. It was originally developed by the Associates in Process Improvement then later adopted by the Institute for Healthcare Improvement (IHI) to conduct rapid cycle research focused on quality improvement in health care agencies.

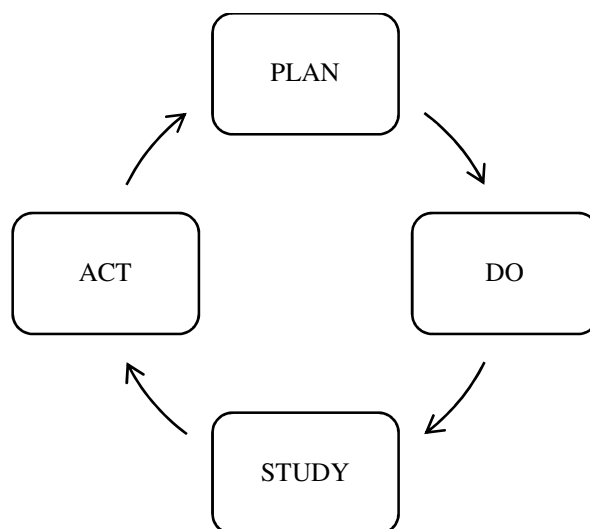


Figure 2. IHI PDSA Model of Change (How to Improve section, para. 2).

The IHI describes the phases as follows. During the ‘Plan Phase’, the consultant guides the process by facilitating: 1) recruitment of team members, 2) drafting a purpose statement, and 3) describing the problem, and identifying the causes of the problem.

During the ‘Do Phase’, the consultant aids the team in: 1) starting to implement action plan for change and 2) collecting data pertinent to change topic. During the ‘Study Phase’, the consultant guides the team in using the purpose statement from ‘Plan Phase’ and data gathered in ‘Do Phase’ in order to discern if 1) an improvement was made as result of the plan selected, 2) if the plan was worth the investment, and 3) if there were any unintended side effects. During the ‘Act Phase’, the consultant helps the team 1) reflect on their plan and outcomes, 2) acknowledge their improvement and processes learned, 3) verbalize successes to internal and external stakeholders, and 4) set in place guidelines to preserve gains and sustain achievements.

Program in Health Care Organizations by the Consultant

The Center for Transforming Healthcare (CTH) created the TST Program to assist health care organizations through a step-by-step process to identify, quantify, and reduce

risks of WSS. The TST was first used in 2009 as a result of the Joint Commission’s systematic approach of “Robust Process Improvement (RPI)” to analyze specific breakdowns in care, discover their underlying causes, and develop solutions that are targeted to the causes of wrong-site surgeries (Joint Commission, 2015c). The TST Program focuses on minimizing risks across the surgical areas, including surgical booking area, pre-op area, and the operating room. The TST Program addresses routine surgeries only and excludes procedures done outside of the main operating room area, such as, cystoscopies, endoscopies, surgical procedures coming from the emergency department, and multiple procedures that occur during the same operative case that are performed by different surgeons.

The TST Program is designed to be readily used by an organization’s surgical team without requiring any additional resources to implement the program. Each of the six steps outlines key action items that must be completed before the subsequent step is initiated. The TST Program enables the surgical team to examine specific causes that could result in a WSS event within their organization and provides them with a targeted solution implementation plan for process improvement to reduce the risk of WSS. Fundamental to the program is the use of Lean Six Sigma to enable the surgical team from scheduler through incision to realize the causes of WSS and stop the chain of events that result in the breakdown of patient care.

The six phases of TST Program are 1) ‘Getting Started’, 2) ‘Training Data Collectors’, 3) ‘Measuring Risk Factors’, 4) ‘Analyzing Data’, 5) ‘Implementing Solutions’, and 6) ‘Sustaining the Gains.’ Each of these phases is described on the

website designed to assist organizations in the implementation of the tool (Joint Commission, 2015d).

The 'Getting Started Phase' consists of defining the scope of the project and gathering the surgical team and stakeholders to assess their buy-in and readiness to change. During this phase, the consultant guides the process by facilitating 1) discussion about safe surgery with surgical staff and 2) the identification of committed team members and stakeholders.

The 'Training Data Collectors Phase', the consultant focuses on educating observers to gain a clear picture of what is to be observed in three key surgical areas: 1) the surgical booking area, 2) the pre-op holding area, and 3) the operating room. Data collectors undergo specific training by watching area-specific videos, learning how to correctly complete data collection audit tools, and must successfully complete a written the "Safe Surgery" post-test with a 90% or higher score. Further, the data collectors are trained to provide the observers in each area with 'Just-in-Time' coaching strategies when near misses are anticipated.

During the 'Measuring Risk Factors Phase', the trained observers begin direct observation of how procedures are performed in each of the three areas. Findings are recorded on the data collection audit tools specific for each area. These baseline observations are the basis for future comparisons of performance and improvements. The TST Program recommends that baseline data be collected across a two-week time period resulting in a minimum of 50-100 samples for each observation area. The consultant enters the data into the secure Joint Commission CONNECT extranet and findings are generated providing charts and statistical analyses of the data.

During the ‘Analyzing Data Phase’, the consultant presents evidence-based findings to the surgical team for discussion of factors contributing to safe and risky care. Collectively, the surgical team generates solutions for immediate and long-term improvement. Noteworthy is that many organizations are surprised to find vast inconsistencies in practice discovered during this phase.

During the ‘Implementing Solutions Phase’, the consultant empowers staff to 1) implement prioritized solutions generated from the previous phase and 2) identify at least one just-in-time (JIT) coach, such as a manager, nurse, technician and/or surgeon to serve as an informal change agent and reinforce new actions or behaviors in the surgical booking area, pre-op holding area, and the operating room. All solutions must be implemented to make the greatest impact of reducing the risk of WSS and creating a culture of safety. This is a critical decision-making time for the team, that is, they either change identified problems or resume old patterns that increase their risk of WSS.

The hallmark of the ‘Sustaining the Gains Phase’ is that quality improvement has occurred and is demonstrated in fewer errors/defects and/or greater adherence with best practices in reducing the risks of WSS. In this phase, the consultant helps the team 1) reflect on their plan and outcomes, 2) acknowledge their improvement and processes learned, 3) verbalize successes to internal and external stakeholders, and 4) set in place guidelines to preserve gains and sustain achievements. Several solutions to sustain gains are to train new WSS observers, perform monthly observations for continued compliance, and continuance of JIT coach training.

There is a paucity of research evidence related to the effectiveness of the TST Program on reducing WSS. The Joint Commission (Health Research & Educational

Trust and Joint Commission Center for Transforming Healthcare, 2014) conducted a pilot test of the effectiveness of the TST Program in reducing WSS was conducted among 8 participating hospitals and ambulatory centers. The pretest analysis of WSS-related errors was classified according to the location of where the error occurred, i.e., the scheduling area, the preoperative holding area or the operating room. The errors in the scheduling, area included but were not limited to unverified booking documents, verbal requests for surgical booking, illegible handwriting and unapproved abbreviations. Errors in the pre-operative holding area included but were not limited to missing primary documents, unresolved preoperative paperwork, inconsistent use of site marking, and rushing during patient verification. Errors in the operating room included but were not limited to lack of site verification, distractions during Time-Out, omitted Time-Out, or Time-Out performed without full surgical team participation.

Role of the Nurse Consultant in Facilitating Change in Health Care Organizations

The role of the nurse consultant is to empower health care providers and organizations with the knowledge and skills necessary to provide quality-based, safe and cost-effective patient care. Manley (2001) identified six core skills and qualities required of a nurse consultant:

- 1) Apply the practice of nursing to a specific client group,
- 2) Have leadership and strategic vision for the organization,
- 3) Use evidence of literature that focuses on day-to day issues in nursing practice,
- 4) Facilitate practice development and structural,
- 5) Create a learning culture, one that enables all members of the interdisciplinary team to learn and develop their potential, and
- 6) Provide a continuum of consultation from the individual at the clinical level to the managers

and directors at the organizational level in terms of the provision of patient-centered services. (p. 30)

Hicks, James, Hill, and Vanterpool (2012) discovered that patients who received care at clinics led by nurse consultants reported significantly positive medical outcomes when compared to clinics without nurse consultants. In this study, participants reported a feeling of partnership with the nurse consultant and this partnership instilled a feeling of confidence in the patient's ability to better control their diabetes. In another study, Manley (2000) reported that nurse consultants provided clear direction and vision to patients and staff, motivated others to use their clinical skills, and helped develop evidence-based practice.

CHAPTER II

METHODOLOGY

The purpose of this capstone project was to utilize the ‘Institute for HealthCare Improvement’s (IHI) Model of Improvement (Langley et al., 2009) as a consultation framework to facilitate organizational improvement in core processes for the prevention of wrong site surgery, i.e., wrong patient, organ, site, procedure using the TST Program among a surgical team (schedulers, preoperative personnel, perioperative personnel, and surgeons) at one ambulatory surgery center in South Mississippi. The methodology is organized as follows: 1) Design; 2) Setting, 3) Population and Sampling Plan, 4) Treatment, 5) Measurement Tools, 6) Training Observers/Data Collectors, 7) Procedures, 8) Protection of Human Subjects, 9) Limitations, and 10) Proposed Data Analysis.

Design

This capstone project was focused on quality improvement and used a quasi-experimental design with a prediction and control approach.

Setting

The setting for this project was one ambulatory surgery center (ASC) with four (4) operating rooms in south Mississippi. ASCs are “modern health care facilities that provide same-day surgical care to include but not limited to diagnostic and preventive procedures” (“What is an ASC?” 2014, para. 2). These health care facilities offer patients an alternative to hospital-based procedures in a convenient, patient-centered experience. This 100% physician-owned ASC provides care for the following specialties: ear-nose-throat (ENT), gastroenterology, general surgery, ophthalmology, orthopedic, pain management, and plastic surgery.

Population and Sampling Plan

The subjects/participants for this capstone project were the surgical and support staff of one surgical center in South Mississippi. The forty-seven (47) member staff worked in the following areas: Surgical Booking Area (n=2 Registered Nurses[RN]); Pre-op Holding Area (n=6 RNs); and Surgical Areas (n=8 RNs, n=9 Surgical Technicians, n=5 Certified Registered Nurse Anesthetists [CRNAs], n=5 Anesthesiologists, and n=12 Surgeons). All participants were either full-time or part-time employees at the surgical center and were licensed in their respective specialty areas. All staff were eligible for participation in this project based on employment in the surgical center. A convenience-sampling plan was used to select the surgery center. There was no random selection from the population or random assignment to either an experimental or control group.

Treatment

The independent variable was The Joint Commission Targeted Solutions Tool for Safe Surgery© Quality Improvement Program (TST Program) and the dependent variable was risk of wrong site surgery. All surgical procedures were eligible for observation in this project with the exception of endoscopies and multiple procedures that occurred during the same operative case that were performed by different surgeons.

Measurement Tools

The capstone project utilized three tools to measure risks associated with WSS. The tools were the audit forms for the three specific areas of observation: scheduling, pre-op holding, and operating room developed and tested by The Joint Commission. No information was provided regarding the validity and reliability of the tools.

Audit Observation Forms

The “Surgical Booking Process Audit Tool” (Appendix D) was comprised of six items and was used to record: 1) Specialty (Surgical) Type, 2) How booking was received, 3) Receipt of Forms Defects, 4) Booking Form Defect and 5) Coaching if necessary. A trained observer who was an RN who has worked in this area for 7 years completed this tool.

The “Pre-Op Holding Process Audit Tool” (Appendix E) was comprised of eight items and was used to record: 1) Specialty (Surgical) Type, 2) Primary Document Verification, 3) Patient Verification, 4) Rushing Elements, 5) Time-Out Elements, 6) Regional Block Elements, and 6) Coaching if necessary. A trained observer who was a RN who has worked in this area for 12 months or longer completed this tool.

The “Operating Room Audit Tool” (Appendix F) was comprised of sixteen items and was used to record: 1) Specialty (Surgical) Type, 2) Consent Elements, 3) Rushing Elements, 4) Site Marking Elements, 5) Time-Out Elements, and 6) Coaching if necessary. This tool was completed by 5 trained observers who were CRNAs who have worked in this area for 5 years or longer.

Training Observers/Data Collectors

During *Phase II: Training Data Collectors*, eight (8) data collectors were trained to observe specific events in their respective locations using standardized video training materials provided by The Joint Commission TST Program. Training was conducted by the nurse consultant and the method for training the eight data collectors consisted of having each observer view a 30-minute video produced by the Joint Commission that explained the use of the TST Program and the location-specific observation form (Appendix D-F) for each of the three areas. After viewing the instructional video, the participant was required to pass the Joint Commission provided 14-item exam with a 90% or higher. If potential errors were anticipated, then observers were instructed to move into the 'Just-in-Time' coaching role to prevent an error. Prior to training, all observers provided written informed consent to participate in the project.

Procedures

The procedure utilized in the capstone project was as follows:

1. The student, chair, and committee members of the doctoral capstone project have successfully completed the Common Course at The University of Southern Mississippi and obtained Institutional Review Board approval prior to the conduction of the QIP. The Univeristy of Southern Mississippi IRB approval letter is displayed in Appendix H.
2. Obtained written approval to conduct the quality improvement program (QIP) from key stakeholders of the Surgical Center, including the Director and Board of Directors (*Phase I: Getting Started*).

3. Posted informational flyers in strategic areas of the center to alert staff to an explanatory meeting about the quality improvement study.
4. At the beginning of the program, the student serving in the role of consultant provided participants with information about conditions of participation:
 - a. Participation: Participants may choose to participate and/or not participate in the QIP program. Note: Participants are observed only and do not complete any questionnaires.
 - b. Program Benefits: The potential benefits of the QIP is that the risks of WSS are reduced and that the center is able to 1) identify breakdowns in patient care, 2) discover the underlying causes of the breakdown, and 3) generate solutions that are organization-specific to the causes of wrong-site surgeries.
 - c. Program Risks: There are no identified bio-psycho-social risks, discomforts, and/or inconveniences associated with participation in the QIP.
 - d. Confidentiality and Anonymity: No participant will complete any questionnaire associated with this study. No participant will be identified by name in any audit tool associated with this QIP. On each of the three audit tools, numeric codes will be used to identify surgeons and the last four digits of a patient's record for case identification. No participant will be identified by name in any report or publication associated with the QIP. No individual data will be shared about any staff member with the administration of the surgical center. Only the student will examine, have access to, and enter completed audits into software program for data analysis. Electronic data will be password protected and physical data will be

locked in a file drawer. All completed audits will be shredded within three months following the analysis of data.

5. Conducted *Phase II: Training Data Collectors* – See Training Observers/Data Collectors. This phase was accomplished in 2 days.
6. Conducted *Phase III: Measuring Risk Factors*. Trained observers recorded practices in the Surgical Booking area, Pre-op/Holding area, and Surgical Areas until 50-100 observations were completed. If potential errors occurred, then the observer moved into the ‘Just-in-Time’ coaching role to prevent the error. This phase was accomplished in 2 weeks. Methods to control for threats to validity were executed during this phase, that is, the first two days of observations were discarded to minimize the Hawthorne effect (Campbell, J., Maxey, V., & Watson, W.,1995).
7. The consultant entered all data collected into the TST data analysis program via the secured Joint Commission Connect Extranet. The TST Data Analysis Program is in Excel© format and provides data entry and analysis in numeric and graphic format. This program was used by the consultant only.
8. Conducted *Phase IV: Analyzing Data*. During this phase, the consultant presented evidence-based findings to the surgical team for discussion of factors contributing to safe and risky care. Collectively, the surgical team generated solutions for immediate and long-term improvement. This phase was accomplished in 5 days.
9. Conduct *Phase V: Implementing Solutions*. During this phase, the consultant empowered staff to 1) implement prioritized solutions generated from the previous phase and 2) identify at least one just-in-time (JIT) coach, such as a manager, nurse, technician and/or surgeon to serve as an informal change agent and reinforce new

- actions or behaviors in the surgical booking area, pre-op holding area, and the operating room. This phase was accomplished in 2 weeks.
10. Conduct *Phase VI: Sustaining the Gains*. In this phase, the consultant helped the team 1) reflect on their plan and outcomes, 2) acknowledge their improvement and processes learned, 3) verbalize successes to internal and external stakeholders, and 4) set in place guidelines to preserve gains and sustain achievements. This phase was presented in 1 day but is an on-going process.
11. Will destroy completed audits by shredding within three months following the analysis of data and no later than one month after graduation.

Protection of Human Subjects

In order to ensure the protection of human subjects, the student, chair and committee members of the doctoral capstone project successfully completed the CITI Common Course at The University of Southern Mississippi and sought Institutional Review Board approval prior to the conduct of the QIP. Written approval to conduct the quality improvement program (QIP) from key stakeholders of the Surgical Center, including the Director and Board of Directors was completed during the first phase, *Getting Started*, of the QIP. At the beginning of the program, the student serving in the role of consultant provided participants with information about conditions of participation. Participants chose to participate or not participate in the QIP program. Participants were observed and did not complete any questionnaires.

The potential benefits of the QIP is that the risks of WSS are reduced and that the center is able to 1) identify breakdowns in patient care, 2) discover the underlying causes of the breakdown, and 3) generate solutions that are organization-specific to the

causes of wrong-site surgeries. There were no identified bio-psycho-social risks, discomforts, and/or inconveniences associated with participation in the QIP.

No participant was identified by name in any audit tool associated with this QIP. On each of the three audit tools, numeric codes were used to identify surgeons and the last four digits of a patient's record for case identification. No participant was identified by name in any report or publication associated with the QIP. No individual data was shared about any staff member with the administration of the surgical center. Only the student examined, had access to and entered completed audits into software program for data analysis. Electronic data was password protected and physical data was locked in a file drawer. All completed audits will be shredded within three months following the analysis of data.

Limitations

A limitation of this QIP was that only one ASC was used and the facility is small when compared to a freestanding hospital. When compared to other surgery centers, the ASC used in this study was classified as "medium", having 3-4 operating rooms (Fields, 2011, p. 1). The number of observations recommended by the Joint Commission is 100 for each of the three areas: scheduling, pre-op holding, and operating room. Observations totaling less than this number could result in a misrepresentation sample and therefore render the pretest data inaccurate or misleading.

Proposed Data Analysis

Descriptive statistics, that is, frequency distributions and measures of central tendency were used to analyze the data. A comparative analysis of differences in mean compliance scores between '*Measuring Risk Factors Phase*' and '*Implementing*

Solutions Phase’ was conducted using the TST Data software developed by The Joint Commission. The TST Data Software was used to: 1) Enter data from the three audit tools, 2) Generate charts based on the data, and 3) Analyze and interpret the data. The rate of defective case charts are defined and displayed in Appendix G.

CHAPTER III

ANALYSIS OF DATA

The purpose of this capstone project was to utilize the ‘Institute for HealthCare Improvement’s (IHI) Model of Improvement (Langley et al., 2009) as a consultation framework to facilitate organizational improvement in core processes for the prevention of wrong site surgery, i.e., wrong patient, organ, site, procedure using The Joint Commission Targeted Solutions Tool for Safe Surgery© Quality Improvement Program among a surgical team (schedulers, preoperative personnel, perioperative personnel, and surgeons) at one ambulatory surgery center in South Mississippi. The analysis of data is organized as follows: 1) Rate of Defect Defined, 2) Presentation of Findings, and 3) the Implementation of Targeted Solutions.

Rate of Defect Defined

The TST Program (Defect Defined, 2015, p. 4) defined a defect in any of the three areas of observation as “a risk point for wrong site surgery...referring to a process that is or could be inconsistent with organization policy...a single operative case may have multiple defects”. The findings from this study revealed that there were defects in each of the three areas of observation.

Presentation of Findings

The project was conducted in one ‘medium-sized’, physician-owned, ambulatory surgical center in south Mississippi across a six-month time period. A convenience sample of forty-seven (47) staff including RNs, surgical technicians, CRNAs, anesthesiologists and surgeons participated in the study. Eight observers were trained to collect data in the surgical booking, pre-op holding, and operating room.

Baseline data was collected by trained observers during *Phase III: Measuring Risk Factors* and are reported according to the three areas of observation: surgical booking, pre-op holding, and operating room. Improvement data was collected by trained observers during *Phase IV: Implementing Solutions* and are reported according to the three areas of observation: surgical booking, pre-op holding, and operating room.

Surgical Booking Findings

Baseline findings revealed that there were 63 observations made in the Surgical booking area. The rate of defective cases in this area was 16% (Figure 3). The most common errors were 1) surgical form not received within 48 hours (83%, n=5 observations) and 2) date and time of procedure missing (25%, n=2 observations). No 'Just-in-Time' coaching were provided during this time frame.

Improvement findings revealed that there were 64 observations made in the Surgical booking area. The rate of defective cases chart shows improvement from 16% to 9% (Figure 3). The most common errors were 1) surgical form not received within 48 hours (n=5 observations) and 2) date and time of procedure missing (n=1 observations). No 'Just-in-Time' coaching events were provided during this time frame.

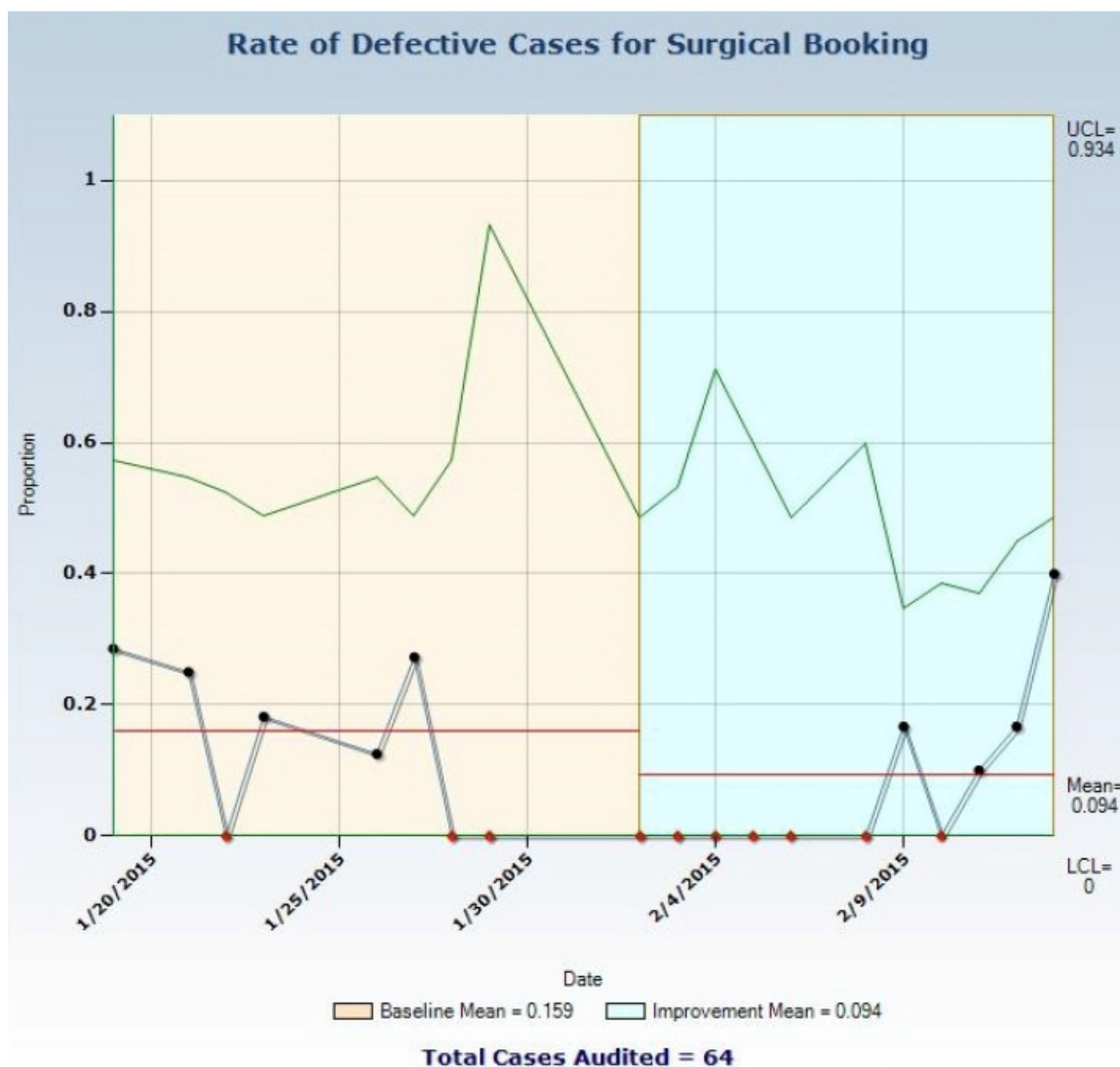


Figure 3. Line graph for baseline and improvement rate of defective cases in surgical booking based on days observed that show a defective rate improvement from 16% to 9% based on 64 post-test observations.

Pre-op Holding Findings

Baseline findings revealed that there were 95 observations made in the Pre-op Holding area. The rate of defective cases in this area was 87% (Figure 4). The most common errors were 1) errors on primary document verification (41%, n=78 observations), 2) errors in patient verification (38%, n=67 observations), 3) errors in

elements of 'Time-Out' (15%, n= 26 observations), and 4) elements of 'rushing' (3%, n=6 observations). One 'Just-in-Time' coaching event was provided during this time frame.

Improvement findings revealed that there were 98 observations made in the Pre-op Holding area. The rate of defective cases in this area improved from 87% to 53% (Figure 4). The most common errors were 1) errors in patient verification (54%, n=48 observations), 2) errors on primary document verification (32%, n=20 observations), 3) errors in elements of 'Time-Out' (15%, n= 13 observations). There were no errors in rushing observed during this time period. There were no 'Just-in-Time' coaching events provided during this time frame.

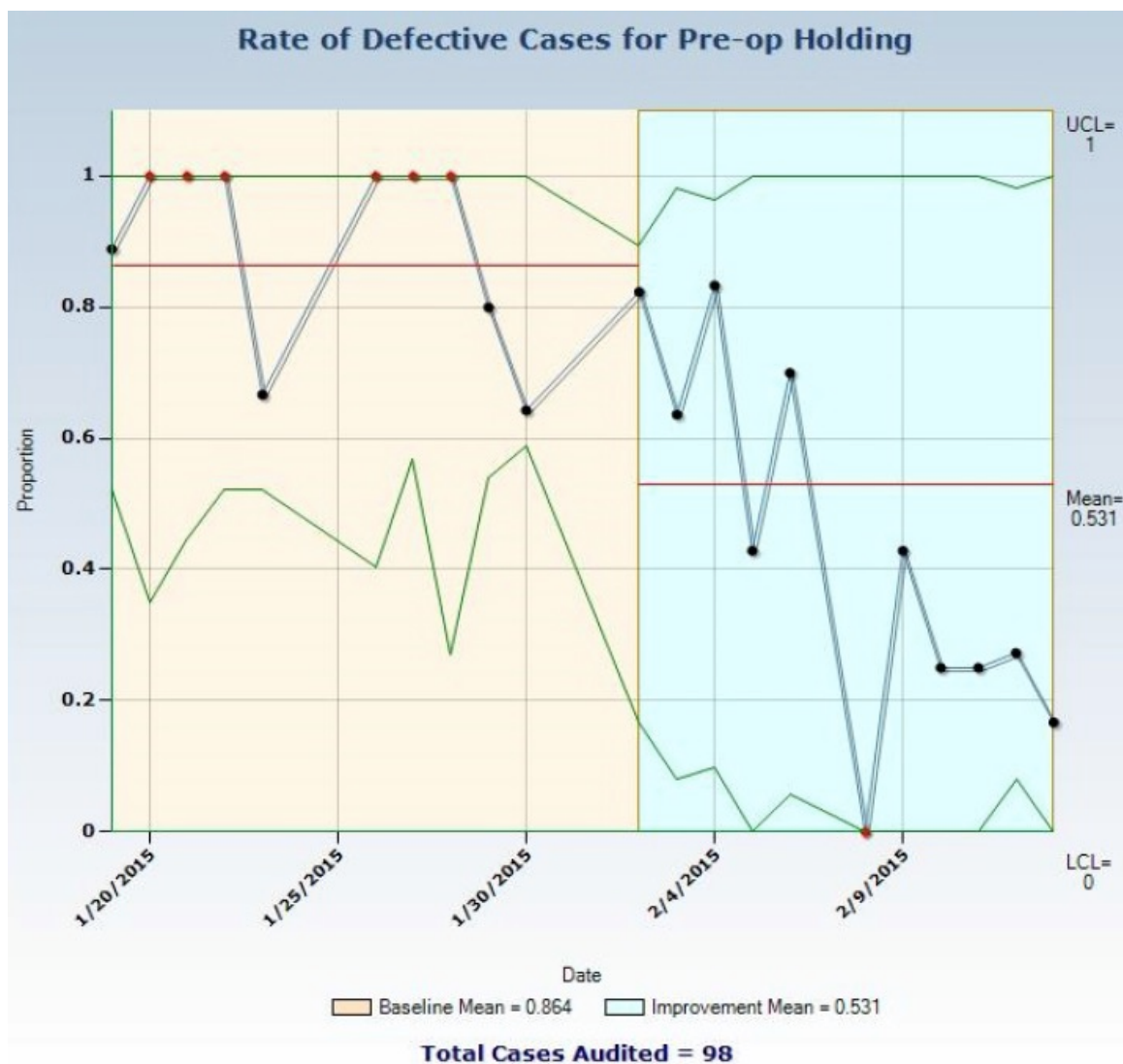


Figure 4. Line graph comparison between the baseline data to the improvement data of defective cases in pre-op holding based on days observed. The defective case rate improved from 86% to 53% based on 98 observations.

Operating Room Findings

Baseline findings revealed that there were 56 observations made in the Operating Room area. The rate of defective cases in this area was 73% (Figure 5). The most common errors were 1) errors in elements of 'Time-Out' (90%, n=83 observations), 2) errors in consent elements (5%, n=5 observations), and 3) errors in site marking elements (4%, n= 4 observations). There were no 'Just-in-Time' coaching events provided during this time frame.

Improvement findings revealed that there were 68 observations made in the Operating Room area. The rate of defective cases in this area improved from 73% to 25% (Figure 5). The most common and only error was in elements of 'Time-Out' (n=18 observations). There were no 'Just-in-Time' coaching events provided during this time frame.

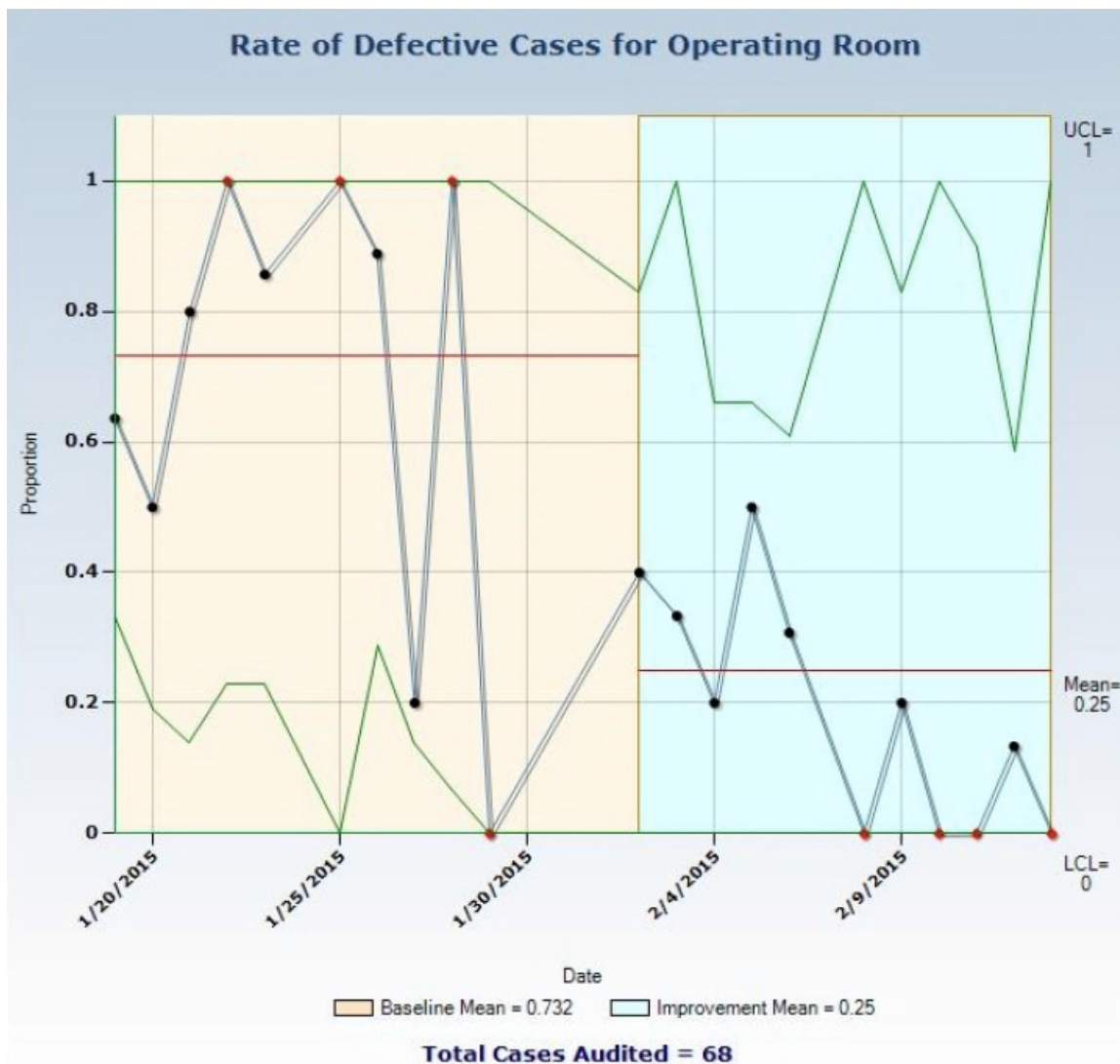


Figure 5. Line graph for baseline and improvement rate of defective cases in surgical booking based on days observed that show that the improvement phase defective case rate improved from 73% to 25% when compared to the baseline phase.

The Implementation of Targeted Solutions

Once the baseline data was collected, the results were analyzed during Phase IV: Analyzing Data in order to identify and prioritize targeted solutions to reduce the risk of WSS. During Phase V: Implementing Solutions, the consultant collaborated with staff to 1) implement prioritized solutions generated from the previous phase and 2) identify at least one just-in-time (JIT) coach, such as a manager, nurse, technician and/or surgeon to serve as an informal change agent and reinforce new actions or behaviors in the surgical booking area, pre-op holding area, and the operating room. The Targeted Solutions chosen and implemented by the surgical team are presented below in the following order: surgical booking, pre-op holding, and operating room.

Surgical Booking Area

The targeted solutions chosen by staff for implementation in the surgical booking area to reduce the risk of WSS in their area were: 1) to improve communication between scheduling and pre-admissions departments and 2) to establish an OR schedule fax back. Each strategy is described below.

In order to improve communication between the scheduling and pre-admissions department, the staff adopted two best practices strategies. Strategy one consisted of the following: If booking documents are not compared between departments and changes communicated before the day of surgery, inconsistencies are forced to be resolved the day of surgery resulting in confusion and elements of rushing in attempts to stay on time. This could cause the patient to have a negative perception or lack of trust if asked to confirm inaccurate information the day of surgery. In order to improve communication between scheduling and pre-admissions department, the pre-admission staff will compare

the history and physical examination (H&P) and consent forms with the operative schedule to ensure information is complete and consistent. The following flow sheet (Figure 6) demonstrates the pre-admission verification process.

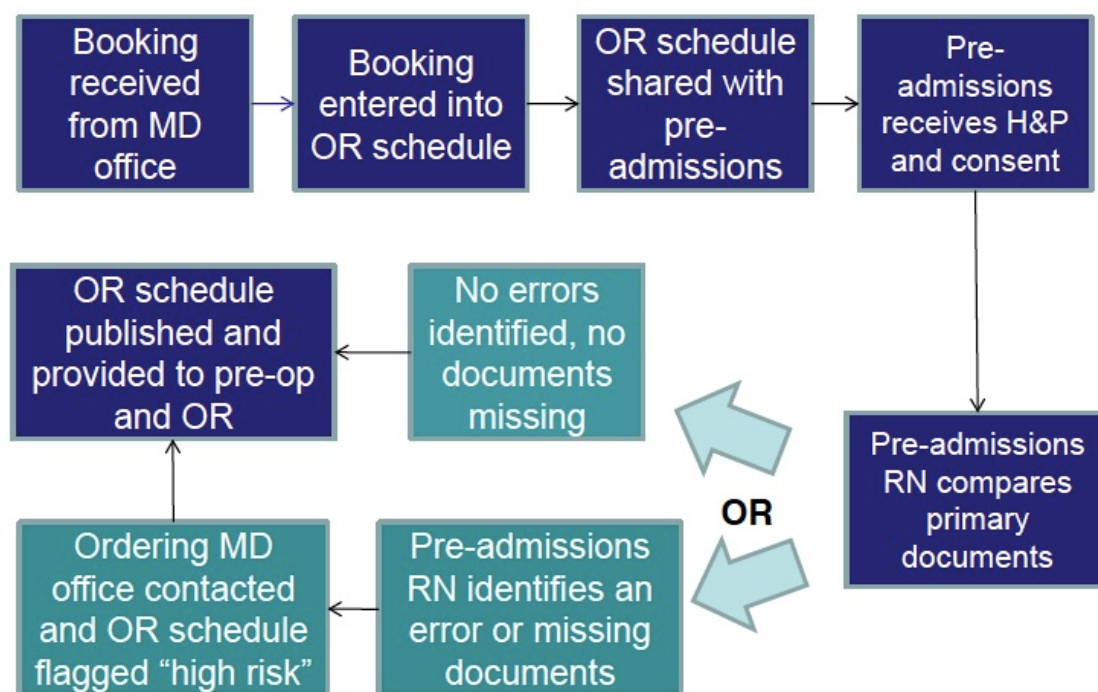


Figure 6. Visual map documenting the improved flow of information between the scheduling and pre-admissions department.

The second strategy adopted was the OR schedule fax back. Incorrect OR schedules lead to the need to correct the OR schedule and primary documents producing possible delays in surgery start times. The OR schedule is confirmed with the physician's office the day before surgery but this call can occur at an inconvenient time, resulting in missed or incorrect information regarding details of the procedure. In order to reduce the risk of incorrect information, the OR schedule will be faxed to the physician's office by 5 p.m. the day prior to surgery and included in the fax will be a deadline for the office to fax back the schedule with any changes.

Pre-op/holding Area

The following targeted solutions were chosen by staff for implementation in the pre-op/holding area in order to reduce the risk of WSS in their area: 1) Assure that primary documents are available 48 hours before surgery, 2) Establish a standardized patient verification process, and 3) Implement a regional block Time Out (TO).

In order to assure that primary documents are available 48 hours before surgery, the staff adopted three best practices strategies. Primary documents that arrive at the surgery center prior to surgery may contain errors. Failing to verify information on the primary documents and continuing to communicate misinformation can increase the risk of WSS. Each organization establishes their guidelines of how far in advance a surgical consent can be signed by the physician. One requirement that is universal is there must be a physician signature and date on the consent. In order to eliminate the occurrence of missing or incomplete primary documents, the preadmissions personnel will compare the information on the consent to that on the H&P and OR schedule. When inconsistencies are discovered, the physician's office will be contacted before the day of surgery so that corrections can be made.

A standardized patient verification process is the first line of defense in reducing the risk of WSS. There exists the perception that patients will be irritated by the need to repeat requests to identify themselves. However, the risk of WSS far outweighs the decision to omit the patient verification process. In order to improve the patient verification process, all members of the surgical team will verify patient information in the pre-op/holding area.

A common surgical error is that regional blocks, such as retrobulbar block for

cataract surgery are being conducted without a Time Out. These surgical procedures are often performed in the pre-op/holding area and not in an OR. The incidence of block procedures is increasing and so is the incidence of related errors. The staff confirmed that prior to starting a regional block regardless of setting, i.e., the pre-op/holding area or OR: 1) a regional block TO will be performed and verified by a team member and 2) the correct procedure site and side will be verified by a team member.

Operating Room Area

The following targeted solutions were chosen by staff for implementation in the operating room area in order to reduce the risk of WSS in their area: 1) Role-based TO, and 2) Standardize surgical site marking. Each strategy is described below.

In most organizations, the TO is conducted by a single individual who reads the required information, i.e., name of patient, second patient identifier, procedure, site, and surgeon to the surgery team. Many times members of the surgical team are actively engaged in other duties and are not listening to the TO information. Common contributing factors to the disengaged team is the belief that the TO is of little value to the team, team members may be distracted or talking during the TO, misinformation regarding who should initiate the TO, and confusion as to when the TO should be initiated. The standards of practice established by The Joint Commission (2015) are that 1) the TO should be initiated after patient prep and drape but immediately before skin incision, 2) all members of the team should be involved in the TO process and stop all other activities and conversations during the TO process, and 3) verbal confirmation of the TO information is then confirmed by all team members. The staff agreed that in order to improve the role-based TO process: 1) the TO will be scripted and consistent

across all surgical procedures and 2) adopted the *Comprehensive Surgical Checklist* established by the Association of periOperative Registered Nurses (AORN-Appendix C).

In order to avoid WSS and to promote patient safety, it is critical that the process for surgical site marking be standardized. Unfortunately, there are a myriad of site marking systems that are used, that is each surgeons may use a different mark, patients sometimes mark themselves, and the same mark may mean something different to each individual. A standardized system of site marking is a safety strategy for the patient, the surgical team and the facility. Finally, a standardized mark, such as the surgeon's initials versus the use of an 'X', which could be interpreted by some as 'no' and 'yes' by others, or use of dots or lines with arrows, creates less confusion over which site mark is correct. In order to clarify the various types of site markings, the surgery team decided to use the surgeon's initials as the standardized surgical site marking system. Standardization means that all personnel at the facility will know which site marking to look for and use. The staff agreed that in order to standardize surgical site markings, the surgeon's initials will be placed on the patient's skin closest to the site of proposed incision.

CHAPTER IV

SUMMARY

The purpose of this capstone project was to utilize the ‘Institute for HealthCare Improvement’s (IHI) Model of Improvement (Langley et al., 2009) as a consultation framework to facilitate organizational improvement in core processes for the prevention of wrong site surgery, i.e., wrong patient, organ, site, procedure, using The Joint Commission Targeted Solutions Tool for Safe Surgery© Quality Improvement Program among a surgical team (schedulers, preoperative personnel, perioperative personnel, and surgeons) at one ambulatory surgery center in South Mississippi. The chapter is organized as follows: 1) Summary of Findings, 2) Discussion, 3) Recommendations, and 4) Conclusions.

Summary of Findings

The major findings of this project were that by implementing the Targeted Solutions Tool for Safe Surgery© QIP program, the nurse consultant was able to assist the surgical center in reducing the risk of wrong site surgery from 16% to 9% in the surgery booking area, from 86% to 53% in the pre-op holding area, and from 73% to 25% in the operating room area. These results mirror the findings from the original 8 hospitals and ambulatory centers participating in the pilot test of the TST Program (Joint Commission, 2013). Further, the consultant empowered the surgical team to make nine (9) critical decisions in practice that would have the greatest impact on reducing the risk of WSS and creating a culture of safety:

- 1) Identified at least one just-in-time (JIT) coach, such as a manager, nurse, technician and/or surgeon to serve as an informal change agent and reinforce new

actions or behaviors in the surgical booking area, pre-op holding area, and the operating room;

- 2) Improved the communication system between scheduling and pre-admissions departments;
- 3) Established an OR schedule fax back;
- 4) Assured that primary documents would be available 48 hours before surgery;
- 5) Established a standardized patient verification process;
- 6) Implemented a regional block Time Out (TO);
- 7) Role-based TO;
- 8) Standardized a surgical site marking; and
- 9) Adopted the *Comprehensive Surgical Checklist* established by the Association of periOperative Registered Nurses (AORN-Appendix C).

Discussion

The findings from this QIP capstone project reflect the conceptual and evidence-based literature regarding the importance of reducing medical errors and, in particular, efforts to reduce the risks of WSS (Agrawal, 2014; IOM, 1999; Kelly, 2012; Mulloy & Hughes, 2008) through the use of 1) a universal protocol for preventing WSS (Agency for Healthcare Research and Quality, 2015; AORN, 2015; CTH, 2011; WHO, 2015); 2) a standardized system of site verification (IOM, 1999; Joint Commission, 2015b); and 3) resolving human and system failures contributing to WSS (DeVine et al., 2010; Dunn, 2006; Hempel et al., 2013; Mulloy, 2008; Stahel et al., 2010).

Nurse consultants play a critical role in empowering health care providers and organizations with the knowledge and skills necessary to provide quality-based, safe and

cost-effective patient care (Manley, 2001; Hicks et al., 2012). In this QIP project, the nurse consultant utilized both the IHI (Langley et al., 2009) and TST (Joint Commission, 2015d) programs to enable staff to reduce the risk of WSS. The consultant found that each step of the TST program was easy to use, readily understood by the organization, and amenable to replication. There were no difficulties in entering data or generating charts in the TST software program. In terms of data analysis, the software program is limited to generating rate of defective cases chart, the defect ranking chart, and the comparison chart. But after completing each step of the TST, the level of detail provided was adequate.

Recommendations

A limitation to this quality improvement program was the length of observation time in the baseline and improvement phases. When this QIP project is replicated, the Joint Commission recommendations should be adhered to, that is 100 observations from each of the three areas with no more than 4-5 observations per day.

Conclusions

The findings of this quality improvement program reflect great improvement in not only the way the surgery center reduced the risk of WSS but in the way the organization communicated their common goals of patient safety, job performance, and risk reduction. Most of the information presented was not new to the surgery team. When individuals were asked if they understood the elements of a Time Out, nearly everyone knew what they were 'supposed to do' yet the findings show that knowing and doing are sometimes far apart. Like all organizations, the challenge this organization faces lies in the last phase of the TST, Sustaining the Gains. As personnel leave the

organization and new employees are hired, the standing policies and lessons learned from the program risk fade from practice. Left in place to educate the surgery team on the importance of patient verification and risks of WSS are the JIT coaches, the administrators, and trained observers from this program. Without support of all three, changes adopted with each chosen Targeted Solution will be lost.

WSS is an avoidable event that compromises patient safety. Nurse consultants play a powerful role in enabling surgical staff to utilize the TST Program to re-examine their existing practice, change behaviors as needed, and create a culture of safety in reducing the risks of WSS and promoting patient safety.

APPENDIX A

THE UNIVERSAL PROTOCOL BY THE JOINT COMMISSION

SpeakUP™



The Universal Protocol

for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™

Guidance for health care professionals



Conduct a pre-procedure verification process

Address missing information or discrepancies before starting the procedure.

- Verify the correct procedure, for the correct patient, at the correct site.
- When possible, involve the patient in the verification process.
- Identify the items that must be available for the procedure.
- Use a standardized list to verify the availability of items for the procedure. (It is not necessary to document that the list was used for each patient.) At a minimum, these items include:
 - relevant documentation
Examples: history and physical, signed consent form, preanesthesia assessment
 - labeled diagnostic and radiology test results that are properly displayed
Examples: radiology images and scans, pathology reports, biopsy reports
 - any required blood products, implants, devices, special equipment
- Match the items that are to be available in the procedure area to the patient.

Mark the procedure site

At a minimum, mark the site when there is more than one possible location for the procedure and when performing the procedure in a different location could harm the patient.

- For spinal procedures: Mark the general spinal region on the skin. Special intraoperative imaging techniques may be used to locate and mark the exact vertebral level.
- Mark the site before the procedure is performed.
- If possible, involve the patient in the site marking process.
- The site is marked by a licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed.
- In limited circumstances, site marking may be delegated to some medical residents, physician assistants (P.A.), or advanced practice registered nurses (A.P.R.N.).
- Ultimately, the licensed independent practitioner is accountable for the procedure – even when delegating site marking.
- The mark is unambiguous and is used consistently throughout the organization.
- The mark is made at or near the procedure site.
- The mark is sufficiently permanent to be visible after skin preparation and draping.
- Adhesive markers are not the sole means of marking the site.
- For patients who refuse site marking or when it is technically or anatomically impossible or impractical to mark the site (see examples below): Use your organization's written, alternative process to ensure that the correct site is operated on. Examples of situations that involve alternative processes:
 - mucosal surfaces or perineum
 - minimal access procedures treating a lateralized internal organ, whether percutaneous or through a natural orifice
 - teeth
 - premature infants, for whom the mark may cause a permanent tattoo

Perform a time-out

The procedure is not started until all questions or concerns are resolved.

- Conduct a time-out immediately before starting the invasive procedure or making the incision.
- A designated member of the team starts the time-out.
- The time-out is standardized.
- The time-out involves the immediate members of the procedure team: the individual performing the procedure, anesthesia providers, circulating nurse, operating room technician, and other active participants who will be participating in the procedure from the beginning.
- All relevant members of the procedure team actively communicate during the time-out.
- During the time-out, the team members agree, at a minimum, on the following:
 - correct patient identity
 - correct site
 - procedure to be done
- When the same patient has two or more procedures: If the person performing the procedure changes, another time-out needs to be performed before starting each procedure.
- Document the completion of the time-out. The organization determines the amount and type of documentation.

This document has been adapted from the full Universal Protocol. For specific requirements of the Universal Protocol, see The Joint Commission standards.

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

e induction of anaesthesia

Before skin incision

Before patient leaves operating room


N IN	TIME OUT	SIGN OUT
<p>PATIENT HAS CONFIRMED</p> <ul style="list-style-type: none"> • IDENTITY • SITE • PROCEDURE • CONSENT 	<p><input type="checkbox"/> CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE</p> <p><input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM</p> <ul style="list-style-type: none"> • PATIENT • SITE • PROCEDURE 	<p><input type="checkbox"/> NURSE VERBALLY CONFIRMS WITH THE TEAM:</p> <ul style="list-style-type: none"> • THE NAME OF THE PROCEDURE RECORDED • THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE) • HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)
<p>SITE MARKED/NOT APPLICABLE</p>	<p>ANTICIPATED CRITICAL EVENTS</p>	<p><input type="checkbox"/> WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED</p>
<p>ANAESTHESIA SAFETY CHECK COMPLETED</p>	<p><input type="checkbox"/> SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?</p> <p><input type="checkbox"/> ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?</p> <p><input type="checkbox"/> NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?</p>	<p><input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT</p>
<p>PULSE OXIMETER ON PATIENT AND FUNCTIONING</p>	<p>HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?</p> <p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NOT APPLICABLE</p>	
<p>DOES PATIENT HAVE A:</p> <p>KNOWN ALLERGY?</p> <p>NO</p> <p>YES</p>	<p><input type="checkbox"/> IS ESSENTIAL IMAGING DISPLAYED?</p> <p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NOT APPLICABLE</p>	
<p>DIFFICULT AIRWAY/ASPIRATION RISK?</p> <p>NO</p> <p>YES, AND EQUIPMENT/ASSISTANCE AVAILABLE</p>		
<p>RISK OF >500ML BLOOD LOSS 7ML/KG IN CHILDREN?</p> <p>NO</p> <p>YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED</p>		

LIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

WORLD H

APPENDIX C

AORN COMPREHENSIVE SURGICAL CHECKLIST

COMPREHENSIVE SURGICAL CHECKLIST			
PREPROCEDURE CHECK-IN	SIGN-IN	TIME-OUT	SIGN-OUT
In Holding Area	Before Induction of Anesthesia	Before Skin Incision	Before the Patient Leaves the Operating Room
Patient/patient representative actively confirms with Registered Nurse (RN):	RN and anesthesia care provider confirm:	Initiated by designated team member All other activities to be suspended (unless a life-threatening emergency)	RN confirms:
Identity <input type="checkbox"/> Yes Procedure and procedure site <input type="checkbox"/> Yes Consent(s) <input type="checkbox"/> Yes Site marked <input type="checkbox"/> Yes <input type="checkbox"/> N/A by person performing the procedure RN confirms presence of: History and physical <input type="checkbox"/> Yes Preanesthesia assessment <input type="checkbox"/> Yes Diagnostic and radiologic test results <input type="checkbox"/> Yes <input type="checkbox"/> N/A Blood products <input type="checkbox"/> Yes <input type="checkbox"/> N/A Any special equipment, devices, implants <input type="checkbox"/> Yes <input type="checkbox"/> N/A Include in Preprocedure check-in as per institutional custom: Beta blocker medication given (SCIP) <input checked="" type="checkbox"/> Yes <input type="checkbox"/> N/A Venous thromboembolism prophylaxis ordered (SCIP) <input checked="" type="checkbox"/> Yes <input type="checkbox"/> N/A Normothermia measures (SCIP) <input checked="" type="checkbox"/> Yes <input type="checkbox"/> N/A	Confirmation of: identity, procedure, procedure site and consent(s) <input type="checkbox"/> Yes Site marked <input type="checkbox"/> Yes <input type="checkbox"/> N/A by person performing the procedure Patient allergies <input type="checkbox"/> Yes <input type="checkbox"/> N/A Difficult airway or aspiration risk? <input type="checkbox"/> No <input type="checkbox"/> Yes (preparation confirmed) Risk of blood loss (> 500 ml) <input type="checkbox"/> Yes <input type="checkbox"/> N/A # of units available _____ Anesthesia safety check completed <input type="checkbox"/> Yes Briefing: All members of the team have discussed care plan and addressed concerns <input type="checkbox"/> Yes	Introduction of team members <input type="checkbox"/> Yes All: Confirmation of the following: identity, procedure, incision site, consent(s) <input type="checkbox"/> Yes Site is marked and visible <input type="checkbox"/> Yes <input type="checkbox"/> N/A Relevant images properly labeled and displayed <input type="checkbox"/> Yes <input type="checkbox"/> N/A Any equipment concerns? Anticipated Critical Events Surgeon: States the following: <input type="checkbox"/> critical or nonroutine steps <input type="checkbox"/> case duration <input type="checkbox"/> anticipated blood loss Anesthesia Provider: <input type="checkbox"/> Antibiotic prophylaxis within one hour before incision <input type="checkbox"/> Yes <input type="checkbox"/> N/A <input type="checkbox"/> Additional concerns? Scrub and circulating nurse: <input type="checkbox"/> Sterilization indicators have been confirmed <input type="checkbox"/> Additional concerns?	Name of operative procedure Completion of sponge, sharp, and instrument counts <input type="checkbox"/> Yes <input type="checkbox"/> N/A Specimens identified and labeled <input type="checkbox"/> Yes <input type="checkbox"/> N/A Any equipment problems to be addressed? <input type="checkbox"/> Yes <input type="checkbox"/> N/A To all team members: What are the key concerns for recovery and management of this patient? _____ _____ _____ _____ _____ _____ June 2013 

The JC does not stipulate which team member initiates any section of the checklist except for site marking.
 The Joint Commission also does not stipulate where these activities occur. See the Universal Protocol for details on the Joint Commission requirements.

APPENDIX D

SURGICAL BOOKING PROCESS AUDIT TOOL



Surgical Booking Process Audit

Patient sticker can be placed here

Date*:	Case ID*: (or last 4 digits of med record)	Patient type*: (circle one below)	Physician*:	Number of Procedures*: (circle one below)
		Adult Pediatrics		1 2 3 4 5 6+
Specialty Type* (select one) <input type="checkbox"/> CTS <input type="checkbox"/> ENDO <input type="checkbox"/> ENT <input type="checkbox"/> GEN <input type="checkbox"/> HAND <input type="checkbox"/> NEURO <input type="checkbox"/> OB/GYN <input type="checkbox"/> OPHTHAL <input type="checkbox"/> ORTHO <input type="checkbox"/> PAIN <input type="checkbox"/> PLAS <input type="checkbox"/> POD <input type="checkbox"/> URO <input type="checkbox"/> VASC <input type="checkbox"/> OTHER (specify)				
How was booking received*? (circle one) <input type="checkbox"/> Fax <input type="checkbox"/> Verbal <input type="checkbox"/> Electronic <input type="checkbox"/> Other? (specify)				
Receipt of Forms Defects (Check if not correct the first time)				
1 <input type="checkbox"/> Booking not on the approved form				
2 <input type="checkbox"/> More than one surgical booking form received for the same patient for the same case				
3 <input type="checkbox"/> Surgical booking form not received within 48 hours of surgery				
4 <input type="checkbox"/> Booking forms not received, not realized until schedule verified				
5 <input type="checkbox"/> If changes were made during schedule verification, no new form (or change form) was faxed				
Booking Form Defect				
6 <input type="checkbox"/> There were errors on the original surgical booking form (check all that apply)				
<input type="checkbox"/> Wrong procedure <input type="checkbox"/> Unapproved abbreviation <input type="checkbox"/> Missing procedures <input type="checkbox"/> Date & time <input type="checkbox"/> Illegible <input type="checkbox"/> Cross-throughs <input type="checkbox"/> Incorrect diagnosis <input type="checkbox"/> Incorrect laterality <input type="checkbox"/> Laterality required but not addressed <input type="checkbox"/> Incorrect codes <input type="checkbox"/> Wrong physician <input type="checkbox"/> Other (specify)				
Comments: (continue on back if necessary)				Data collector*:

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APPENDIX E

PRE-OP HOLDING PROCESS AUDIT TOOL



Pre-Op Holding Process Audit Tool (With Blocks) - Page 1 of 2

Patient sticker can be placed here

Date*:	Case ID*: (or last 4 digits of med record)	Patient type*: (circle one below)	Physician*:	Number of Procedures*: (circle one below)
		Adult Pediatrics		1 2 3 4 5 6+
Specialty Type* (select one) <input type="checkbox"/> CTS <input type="checkbox"/> ENDO <input type="checkbox"/> ENT <input type="checkbox"/> GEN <input type="checkbox"/> HAND <input type="checkbox"/> NEURO <input type="checkbox"/> OB/GYN <input type="checkbox"/> OPHTHAL <input type="checkbox"/> ORTHO <input type="checkbox"/> PAIN <input type="checkbox"/> PLAS <input type="checkbox"/> POD <input type="checkbox"/> URO <input type="checkbox"/> VASC <input type="checkbox"/> OTHER (specify)				
Primary document verification check below if incorrect the first time (check all that apply)				
1 <input type="checkbox"/> Patient demographic was different than OR schedule at time of patient arrival. (if yes, check all that apply) <input type="checkbox"/> DOB <input type="checkbox"/> Patient name <input type="checkbox"/> Medical record number (MR#) <input type="checkbox"/> Other (specify)				
2 <input type="checkbox"/> What documents were missing? (if yes, check all that apply) <input type="checkbox"/> Consent <input type="checkbox"/> H & P <input type="checkbox"/> Other (specify)				
3 <input type="checkbox"/> What documents were incomplete or incorrect? (if yes, check all that apply) <input type="checkbox"/> Consent <input type="checkbox"/> H & P <input type="checkbox"/> OR Schedule				
Consent: What item(s) were incomplete or incorrect? (check all that apply)				
<input type="checkbox"/> Consent does not match OR schedule <input type="checkbox"/> Laterality incorrect <input type="checkbox"/> Incorrect patient demographics <input type="checkbox"/> Consent does not match H & P <input type="checkbox"/> Procedure incorrect <input type="checkbox"/> Signatures expected but missing <input type="checkbox"/> Laterality required but not addressed <input type="checkbox"/> Procedure incomplete <input type="checkbox"/> Other (specify)				
H & P: What item(s) were incomplete or incorrect? (check all that apply)				
<input type="checkbox"/> H & P does not match OR schedule <input type="checkbox"/> Laterality incorrect <input type="checkbox"/> H & P missing MD signature <input type="checkbox"/> H & P does not match consent <input type="checkbox"/> Procedure incorrect <input type="checkbox"/> Outdated <input type="checkbox"/> Laterality required but not addressed <input type="checkbox"/> Procedure incomplete <input type="checkbox"/> Other (specify)				
OR Schedule: What item(s) were incomplete or incorrect? (check all that apply)				
<input type="checkbox"/> OR Schedule does not match H & P <input type="checkbox"/> Laterality incorrect <input type="checkbox"/> Incorrect patient demographics <input type="checkbox"/> OR Schedule does not match consent <input type="checkbox"/> Procedure incorrect <input type="checkbox"/> Other (specify) <input type="checkbox"/> Laterality required but not addressed <input type="checkbox"/> Procedure incomplete				
4 <input type="checkbox"/> Changes were made to the consent in the Pre operative area? (if yes, check all that apply) <input type="checkbox"/> Incorrect laterality <input type="checkbox"/> Wrong procedure <input type="checkbox"/> Laterality required but not addressed <input type="checkbox"/> Added procedure <input type="checkbox"/> Missing portion of procedure <input type="checkbox"/> Other (specify)				

APPENDIX E

PRE-OP HOLDING PROCESS AUDIT TOOL



Pre-Op Holding Process Audit Tool (With Blocks) - Page 2 of 2

Pre-Op process critical to quality elements / Patient verification	
5 Surgeon verbally confirmed patient ID the first time: Name and second patient Identifier from patient arm band, procedure including site and side with the patient or legal representative's involvement	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unable to determine
6 Anesthesia verbally confirmed patient ID the first time: Name and second patient Identifier from patient arm band, procedure including site and side with the patient or legal representative's involvement	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unable to determine
7 Circulating RN verbally confirmed patient ID the first time: Name and second patient Identifier from patient arm band, procedure including site and side with the patient or legal representative's involvement	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unable to determine
Rushing Elements	
8 <input type="checkbox"/> I felt rushed to get patient prepared for surgery (if yes, check all that apply):	
<input type="checkbox"/> Add-on	<input type="checkbox"/> Last case ran over
<input type="checkbox"/> Labs/EKG	<input type="checkbox"/> Case reassigned
<input type="checkbox"/> Anesthesia delay	<input type="checkbox"/> Other (specify)
<input type="checkbox"/> Staff delay	<input type="checkbox"/> Surgeon delay
<input type="checkbox"/> Emergent/urgent procedure	<input type="checkbox"/> Paperwork Issues
Pre-Op Process Audit tool (With blocks)	
Elements of Time Out - Blocks Only (check all that apply)	
Was a Block performed? <input type="checkbox"/> Yes <input type="checkbox"/> No	
The Time Out was: (check only one below)	
<input type="checkbox"/> Initiated independently without a prompt	
<input type="checkbox"/> Initiated after prompt from a team member	
<input type="checkbox"/> Not done	
Who Initiated the Time Out? <input type="checkbox"/> Anesthesia <input type="checkbox"/> RN <input type="checkbox"/> Other (specify)	
Who conducted the Time Out? <input type="checkbox"/> Anesthesia <input type="checkbox"/> RN <input type="checkbox"/> Other (specify)	
<input type="checkbox"/> The patient's name, second patient Identifier and the Intended procedure, including site and side <u>was not read</u> .	
<input type="checkbox"/> Team members <u>did not</u> cease conversation / activities <u>without a prompt</u> from a team member (check only one below)	
<input type="checkbox"/> Cease after prompt from a team member	
<input type="checkbox"/> Cease after more than one prompt from a team member	
<input type="checkbox"/> Not cease conversations and activities	
<input type="checkbox"/> A team member did not reference the mark	
Comments:	Data collector*:

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APPENDIX F

OPERATING ROOM AUDIT TOOL



Operating Room Audit Tool - Baseline - Page 1 of 2



Patient sticker can be placed here

Date*:	Case ID*: <small>(or last 4 digits of med record)</small>	Patient type*: <small>(circle one below)</small>	Physician*:	Number of Procedures*: <small>(circle one below)</small>
		Adult Pediatrics		1 2 3 4 5 6+
Specialty Type* <small>(select one)</small>				
<input type="checkbox"/> CTS <input type="checkbox"/> ENDO <input type="checkbox"/> ENT <input type="checkbox"/> GEN <input type="checkbox"/> HAND <input type="checkbox"/> NEURO <input type="checkbox"/> OB/GYN <input type="checkbox"/> OPHTHAL <input type="checkbox"/> ORTHO <input type="checkbox"/> PAIN <input type="checkbox"/> PLAS <input type="checkbox"/> POD <input type="checkbox"/> URO <input type="checkbox"/> VASC <input type="checkbox"/> OTHER <small>(specify)</small>				
Consent Elements				
1	<input type="checkbox"/> Elements were missing or incorrect on the consent? <small>(if yes, check all that apply)</small>			
<input type="checkbox"/> Consent does not match OR schedule <input type="checkbox"/> Procedure incorrect <input type="checkbox"/> Consent not signed by surgeon <input type="checkbox"/> Consent does not match H & P <input type="checkbox"/> Procedure incomplete <input type="checkbox"/> Consent not signed by patient <input type="checkbox"/> Laterality incorrect <input type="checkbox"/> Consent not signed by witness <input type="checkbox"/> Other <small>(specify)</small> <input style="width: 50px;" type="text"/> <input type="checkbox"/> Laterality required but not addressed				
Rushing Elements				
2	<input type="checkbox"/> I felt rushed to get the patient prepared for surgery? <small>(if yes, check all that apply)</small>			
<input type="checkbox"/> Equipment set up <input type="checkbox"/> Case re-assigned <input type="checkbox"/> Add on <input type="checkbox"/> Staff late <input type="checkbox"/> Surgeon late <input type="checkbox"/> Other <small>(specify)</small> <input style="width: 50px;" type="text"/> <input type="checkbox"/> Last case ran over <input type="checkbox"/> Anesthesia late				
Site Marking Elements <small>(check all that are applicable)</small>				
Was site mark required? <input type="checkbox"/> Yes <input type="checkbox"/> No <small>(if yes, check all that apply)</small>				
How was the site marked?				
<input type="checkbox"/> An "X" <input type="checkbox"/> Dot <input type="checkbox"/> MD Initials <input type="checkbox"/> Not Applicable <input type="checkbox"/> Circle <input type="checkbox"/> Line/Arrow <input type="checkbox"/> Yes <input type="checkbox"/> Other <small>(specify)</small> <input style="width: 50px;" type="text"/>				
3	<input type="checkbox"/> Alternate site marking process required but not performed			
4	<input type="checkbox"/> Site mark required but not marked			
5	<input type="checkbox"/> Not every procedure incision site is marked <small>(if multiple procedures)</small>			
6	<input type="checkbox"/> Site mark not visible after draping			
7	<input type="checkbox"/> Mark not as close as anatomically possible			
8	<input type="checkbox"/> No team member referenced the mark			
9	<input type="checkbox"/> Site not marked with indelible marker			

APPENDIX F
OPERATING ROOM AUDIT TOOL



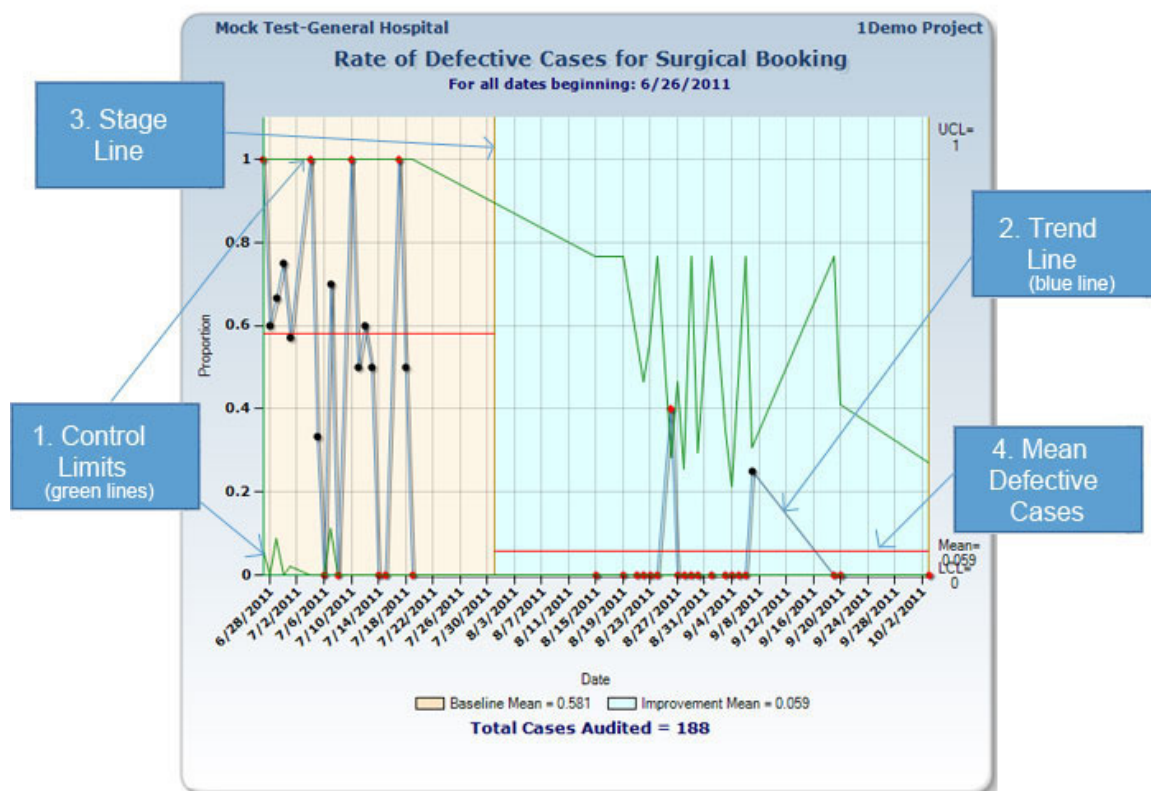
Operating Room Audit Tool - Baseline - Page 2 of 2

Time Out Elements	
<p><u>The Time Out was:</u> (check only one below)</p> <p><input type="checkbox"/> Initiated independently without a prompt</p> <p><input type="checkbox"/> Initiated after prompt from a team member</p> <p><input type="checkbox"/> Not done</p>	
<p>When did the Time Out occur? <input type="checkbox"/> Before prep and drape <input type="checkbox"/> After prep and drape</p>	
<p>Who Initiated the Time Out? <input type="checkbox"/> Circulating RN <input type="checkbox"/> Surgeon <input type="checkbox"/> Other _____</p>	
<p>Who conducted the Time Out? <input type="checkbox"/> Circulating RN <input type="checkbox"/> Surgeon <input type="checkbox"/> Other _____</p>	
<p><input type="checkbox"/> The patient's name, second patient identifier and the intended procedure, including site and side <u>was not read.</u></p>	
<p><input type="checkbox"/> Team members ceased conversation / activities without prompt If not, did they: (Check only one below)</p> <p><input type="checkbox"/> Cease after prompt from a team member</p> <p><input type="checkbox"/> Cease after more than one prompt from a team member</p> <p><input type="checkbox"/> Not cease conversations and activities</p>	
<p><input type="checkbox"/> A team member was relieved during the case. (check all that apply)</p> <p><input type="checkbox"/> OR tech <input type="checkbox"/> Circulating RN <input type="checkbox"/> Anesthesia <input type="checkbox"/> Other (specify)</p>	
Comments:	Data collector*:

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APPENDIX G

RATE OF DEFECTIVE CASES CHART (PROPORTION OR P CHART)

**What is a rate of defective cases chart?**

A rate of defective cases chart, also called a proportion or P chart, analyzes the percent (or proportion) of defective surgical cases. It also shows the rate of defective cases. This chart is especially helpful when dealing with inconsistent sample sizes, for example, when the number of observations varies widely on a daily basis.

Why do you need a rate of defective cases chart?

A rate of defective cases chart shows your percentage of defective cases on a daily basis and how it decreases over time. A key benefit of the rate of defective cases chart is that it shows when you have significantly improved.

What types of data are displayed in a rate of defective cases chart?

1. **Control limits:** Lines above and below the average line. The control limits reflect variations in the defective case rates over time. Typically, 95 percent of the data will fall within the control limits. Data that fall outside the control limits are represented by a red dot, signifying that the process has changed. These dots show when a process is “out of control” – either negatively (upper control limit) or positively (lower control limit). The control limits usually start wide as the rate of defective cases varies greatly day-to-day and become narrower as rates decrease and remain in a consistent, high range. Because the number of daily observations can

impact the width of the control limits, it is important to have a consistent number of observations every day. Five to 10 observations per day is recommended.

2. **Trend line:** Each point on the line represents the number of cases with one or more defects (i.e., defective cases) for each day. Most of these points will fall within the control limits (see #3). In the sample chart, you will see that the points on the line that fall outside of the control limit lines are represented by a red dot. Red dots signify special circumstances that should be investigated to determine what was different on this day compared to other days. For example, the special circumstances may be related to the successful implementation of an intervention. It is important to understand the cause of special circumstances because they can become “quick wins” to reduce the risk of wrong site surgery. For instance, if you can identify that the defects involve one particular type of surgery rather than all surgeries. **The goal is to move these points lower**, until they reach or exceed your goal defective case rate (i.e., 50 percent improvement from baseline rates) and sustain it. This means that you have achieved significant improvement in your process. Note: If you are collecting a very small sample size, such as one or two observations in a day, this can cause the trend line to vary significantly and make it difficult to determine the direction of improvement.
3. **Stage line:** The stage line shows the end of the baseline data collection period and the start of interventions to reduce the risk of wrong site surgery. The stage line provides a before and after comparison of rates of defective cases.
4. **Average line:** The red line represents the overall average (or mean) rate of defective surgical cases that have been found to have at least one defect. The average may be recalculated every time data is entered into the database. The goal is to move the average line **down** from the baseline phase, which means the rate of defective cases is decreasing.

APPENDIX H

THE UNIVERSITY OF SOUTHERN MISSISSIPPI IRB APPROVAL LETTER



THE UNIVERSITY OF
SOUTHERN MISSISSIPPI

INSTITUTIONAL REVIEW BOARD

118 College Drive #5147 | Hattiesburg, MS 39406-0001

Phone: 601.266.5997 | Fax: 601.266.4377 | www.usm.edu/research/institutional.review.board

NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months.
Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 14121001

PROJECT TITLE: Reducing the Risks of Wrong Site Surgery Using the Joint Commission's Targeted Solutions Tool for Wrong Site Surgery

PROJECT TYPE: New Project

RESEARCHER(S): Stephanie Parks

COLLEGE/DIVISION: College of Nursing

DEPARTMENT: Department of Advanced Practice

FUNDING AGENCY/SPONSOR: N/A

IRB COMMITTEE ACTION: Expedited Review Approval

PERIOD OF APPROVAL: 01/20/2015 to 01/19/2016

Lawrence A. Hosman, Ph.D.

Institutional Review Board

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