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Implementation of a Surgical Safety Checklist

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Abstract

Lack of standardization in the perioperative area leads to variations in practice that can cause preventable errors. In a 200-bed hospital in Northern California with eleven operating rooms preforming approximately 11,000 procedures a year, there was an increase incidence in sentinel events such as wrong site surgery (n=1), wrong patient surgery (n=1), and retained foreign body (n=5). Safety checks observed in the operating room (OR) were preformed differently among each surgical team and sometimes did not occur at all. Through the use of a Surgical Safety Checklist (SSC), efforts were aimed to standardize safety practices in the OR. The goal was to ensure 90% adherence to the requirements on the SSC based on observational assessment of the process within four months of implementation. Weekly observational audits were conducted over a four-month period to examine the adherence to each checklist component. The mean overall compliance increased in all three phases: Sign In (63% to 70%), Time Out (60% to 73%,) and Sign Out (85% to 100%). Seventeen good catches were identified in Patient Safety Reports that were identified in the following phases: Sign In (n=2), Time Out (n=9), and Sign Out (n=6) phase. The use of the Surgical Safety Checklist encouraged a standardized approach to enhance multidisciplinary teamwork and communication by ensuring the completion of critical tasks which lead to early recognition of "near misses".

Implementation of a Surgical Safety Checklist

Effective team communication among perioperative staff is essential in creating a safety culture in operating rooms (ORs). The Joint Commission (2007) conducted a root cause analysis that identified common causes of adverse events in the surgical area. Failures in communication and procedural non-compliance were the two most common causes of adverse events related to surgery. The Universal Protocol was created by the Joint Commission to prevent wrong person, wrong procedure and wrong site surgery in any setting where invasive procedures occur. The Universal Protocol consists of three steps involving a preoperative verification process, a briefing, and a debriefing period. A checklist adapted from the Universal Protocol was introduced by The World Health Organization (WHO) (2009) to reduce the number of these avoidable events. As a part of this initiative, the Surgical Safety Checklist (SSC) that was developed to serve as a tool to reinforce safety practices and help facilitate communication among perioperative staff. The SSC represents the safety practices designated in the Universal Protocol. The SSC has can promote patient safety and foster communication and teamwork among perioperative staff.

Problem Statement

In a hospital located in Northern California, there was an increasing trend of wrong-site, wrong-person, wrong-procedure incidents in 2016. While the Universal Protocol served as a guide for patient safety, there was significant variation in how the Universal Protocol was being performed. A baseline observation was conducted from June 2017 to July 2017 to assess the safety practices in the surgical enter. An observational form (Appendix A) was adapted from the facility's Universal Protocol to serve as a tool for the assessment. The results (Appendix B) of this assessment highlight the variations in the standards of practice when preforming a

surgical pause. In order to verify the patient, procedure, side, and site the consent form is read aloud during the time out process. There were four cases (Time Out; n=10) in which the preoperative checklist was read for verification in place of the consent. There were two instances in which a surgical pause did not occur before the procedural start. In one instance, the surgeon stated the patient's age and planned procedure solely from memory before making an incision. When a pause did occur, teams were often distracted and not everyone was attentive and engaged in the process. In the cases where patient safety was compromised by variations in practice, team members did not attempt to address these safety issues but proceeded with the surgery. While gathering baseline data on this surgical center, it was evident that procedural non-compliance and failures in communication were prevalent. In order to eliminate preventable surgical errors, a systems approach is necessary to address the breakdown in perioperative processes.

Literature Review

In examining the PICO search statement, the research question that was considered is the following: In surgical populations, does the use of checklists for quality improvement in the operating room compared past management systems without checklist enhance patient safety? For specific literature reviews and support for the project, alternative keywords such as "patient safety", "surgical briefing", "compliance", "teamwork", "communication", and "wrong site surgery" were used.

Cabral, Eggenberger, Keller, Gallison, and Newman (2016) aimed to evaluate the impact if an adapted World Health Organization Surgical Safety Checklist could strengthen the department's culture of safety by improving the perception of communication, teamwork climate and safety climate among the surgical team. A single-group, pretest/two-moth intervention and

posttest design was used to evaluate the effectiveness of this program. When compared to the pretest data, responses to the Safety Attitudes Questioner indicate an improvement in the staff's perception of communication (6% improvement). The results of this study indicate that the locally adapted checklist increased surgical team member's perception on communication which can help in fostering a culture of safety in the operating room.

Mayer et al. (2016) conducted a longitudinal research study to evaluate the impact of the World Health Organization (WHO) checklist compliance on clinical outcomes and the impact of individual checklist sections (Sign-in, Time-out, Sign-out) on outcomes. Data was collected from surgical patients (n=6714) across five healthcare organizations from March 2010 to June 2011. The results of this study indicate that there is significant variability in how the checklist was used (fully/partly). The checklist was only fully completed in 62.1% of the cases while it was partly completed in 96.7% of the cases. Completing the checklist fully did not reduce mortality however, completion of the checklist reduced the risk of postoperative complications (16.9% vs. 11.2%). A calculated population-attributable fractions revealed that fully completing the checklist could prevent 14% of complications.

Papaconstantinou, Jo, Reznik, Smthe, and Wehbe-Janek (2013) conducted a study to evaluate the provider perspectives on team communication, efficiency, patient safety, and patient care before and after a surgical checklist was implemented. Providers (n=437) perceptions improved in the perceived value of the time out process as many felt as it provided better understanding on patient needs. Communication perception improved significantly following checklist us.

A study conducted by Valerio, Amaya, Cole, and Hendrix (2017) aimed to evaluate the impact of a surgical checklist on communication and teamwork among the surgical teams at

LAC+USC. Utilizing a design of a pre- and postinnovation survey among two independent groups (n=219), the researchers analyzed staff's perception of communication and teamwork among the perioperative team on November 2015 and February 2016. An independent *t* test, *p* value <0.05 analysis was used to determine the clinical impact of the checklist on these two measures. The results of this study indicate a mean improvement on communication *(p*< 0.001) and teamwork (*p*=0.003) for the postinnovation group when compared to the preinnovation group. The results from this study indicate that when the safe surgical checklist is implemented adequately at a facility it can foster improvements in interdisciplinary communication and teamwork. The authors suggest that with improved communication and teamwork in the operating room adverse events may be identified more readily leading to the safer delivery of care.

Singer et al. (2016) conducted a study to evaluate and explore the connection between teamwork and adherence to the surgical checklist. From April 2011 to January 2013, surgical teams were observed across 207 procedures. Two tools were used to observe and coach interdisplinary teams in the operating room to evaluate clinical leadership, communication, coordination, and respect. Surgical teamwork characterized by shared clinical leadership, open communication, active coordination, and mutual respect were essential in prompting conversations, but not in completing procedural checks. These findings highlight high-quality, consistent teamwork for promoting checklist use and ensuring a safe surgical environment.

Zingiryan, Paruch, Osler, and Hyman (2017) conducted a study to evaluate the perceptions of the surgical team and to evaluate complication rates before and after checklist implementation. The staff members perceived that it improved patient safety (mean 3.96; 72.6%), communication (mean 3.97; 76.4%), and helped to prevent errors (mean 3.82; 67.2%).

Although there was no significant decrease in perioperative morbidly or mortality, the checklist improved the perception of safety culture by operating room staff.

Rationale: Theoretical Model

In the book *Leading Change* (1996), John Kotter describes an eight-step process for creating and leading change within an organization (Appendix C). Kotter's eight-step change model offers a framework to generate and implement and sustain a change initiative. Kotter's eight stage change model is one change management strategy in literature that has demonstrated efficacy in the successful implementation of the SSC (Hayes, 2012). Therefore, Kotter's eight step change model was used as a guide in the development of an implementation plan for the SSC initiative.

Project Aim

This quality improvement project explored whether the Safe Surgical Checklist can be used as a tool to change practices in the operating room to integrate a standardized surgical pause. The goal of the safety surgical checklist is to improve the safety of surgical care by ensuring 90% adherence to the requirements on the Safe Surgical Checklist based on observational assessment of the process within four months of implementation.

The objectives of this initiative include the following:

1. Enhance the culture of safety in the surgical department.
2. Staff will speak up and 'stop the line' when a safety concern is present.

Methods

Context

This evidence-based program was conducted in the surgical center at a hospital in Northern California. This hospital is an acute care facility located in an urban setting. The

surgical department consists of eleven operating rooms, including two designated for cardiac cauterization. The surgical center includes a variety of surgical specialties and completes approximately 11,000 procedures annually (Office of Statewide Health Planning and Development (OSHPD) Report Center, 2016) (Appendix D).

Stakeholders. Stakeholder support and involvement is necessary from the perioperative unit. It is well documented that when stakeholders are supportive of a surgical safety checklist, the checklist will be completed with accuracy and performed correctly (Sendlhofer et al., 2015). Every staff member has a unique task to perform designated by the checklist and all staff are required to partake in the surgical pause. For this project, the principal stakeholders include the Clinical Nurse Leader (CNL), surgeon, anesthesiologist, circulating nurse, preoperative nurse, post-anesthesia nurse, the scrub technician, and the patient. Other key stakeholders include the quality improvement office, manager of perioperative services, perioperative nurse director, perioperative charge nurses, perioperative nurse educator, surgeon- in-chief, and director of patient care.

Cost. An analysis was conducted to determine if the checklist would be a cost savings **(**Appendix E). The implementation cost of the intervention was compared to the facilities standard of practice. Based on the expected cost of resources, the cost for the implementation of the posters and training is $2,448.80. The costs and benefits are converted to a benefit/cost ratio (B/C) by dividing the total savings costs by the implementation programs costs. The medical cost B/C ratio is estimated at $2,777 ($6,785,320 / $2,448.80).

Financial Analysis. The potential for cost savings can be estimated by the types of near misses that were identified. Litigations regarding the failure to receive adequate consent have approximately a 52% of compensation (Harrison, Narayan, Newton, & Banks, 2015) (Appendix

E). Failure to receive adequate consent was identified in 6 of the 17 cases. Even by adverting one adverse event, there is a great potential for cost savings. The mean cost per claim (failure to obtain adequate consent) is $59,201.85, mean cost per compensation is $33,418.75, and total cost per claim $7,461,335.80 (Harrison, et al., 2015).

SWOT analysis. An analysis of the organization's strengths, weaknesses, opportunities, and threats (SWOT) was conducted for this project (Appendix F). The values of the organization highlight the standard to provide quality care to patients. This is a strength as these values led the movement for this quality improvement project. With an opportunity to improve care quality, there was strong support from key stakeholders such as the quality and risk management departments. By standardizing workflow practices to ensure critical safety checks, this project had the potential to enhance perioperative teamwork and communication, prevent errors, and improve patient safety. By improving patient safety and reducing errors, there is an opportunity for cost savings. One weakness is that there was limited time before the proposed implementation date that could affect the adequacy of staff training. The proposed implementation was a threat as it was implemented system wide rather than unit based.

Safety Checklist Tool

The locally modified checklist consists of three parts (Appendix G). The first section is the Sign In. The Sign In occurs the induction of anesthesia and includes the anesthesiologist, nurse, patient, and surgical technologist. The second section is the Time Out which occurs after the induction of anesthesia and immediately prior to incision. This component involves a briefing process that requires participation from the entire surgical team. This briefing portion helps facilitate key patient information while verifying this information with consent. Furthermore, it provides the opportunity for staff to speak up if a safety concern is present. The

last section is the Sign Out and is completed before anyone, including staff and patient, leaves the operating room. This section incorporates a debriefing component where the team addresses specimen labeling, instrument counts, and other concerns, such as equipment issues.

Timeline. Utilizing the framework from Kotter's (1996) eight stages of change, this project was preformed over an eight-month period during a three phases process (Appendix H).

Intervention

Phase 1. The baseline observational period occurred from June 14th, 2017 to July 21th, 2017. While a total of 30 procedures were observed in total, a total of 10 procedures were observed in the operating room. The audit tool (Appendix B) was created from the non-revised Universal Protocol policy to evaluate key components of the Sign-In, Time-Out, Sign-Out. The audits were completed partly and fully from different procedures. The results of these observations were presented to the task force committee which was comprised of key stakeholders including: surgeons, anesthesiology personnel, scrub technicians, unit managers, quality and safety officers, and unit directors. The task force met weekly one month leading up to the implementation date to better address unit needs.

Phase 2. The change in practice had been discussed at unit meetings to prepare staff for change. To educate perioperative staff members, many different approaches were utilized. The staff were educated on the changes in policy during unit meetings (Appendix I) and were provided with a handout. Flyers (Appendix J) were placed around the entire facility and a newsletter was sent out to inform staff regarding the change in practice. In August 2017, all perioperative staff members were required to complete a HealthStream (a staff online educational module) that included interactive videos on how to utilize the checklist. 100% of perioperative staff completed this module by August 31st, 2017. The escalation process

(Appendix K) was discussed at staff meetings and posted in the perioperative area. Finally, large, laminated posters were placed in each operating room to serve as a visual tool for perioperative staff. Champions and team leaders were trained in an empty room and coaching was provided. Chosen champions had strong leadership skills and an assertive presence in the operating room who served and the team's role models, advocate, and resource on site. The checklist was then implemented in all procedural areas of the hospital on October 1st, 2017. Perioperative staff members were trained on how to utilize the audit form as observers by safety officers with experience in the implementation of the checklist.

Phase 3. Weekly audits were conducted over a four-month period from November 1st, 2017 to January 31st, 2018.

Study of the Intervention

From November 1st, 2017 to January 31st, 2018, an audit was conducted to evaluate the compliance of the checklist use. Staff members were responsible for evaluating the adherence to the Universal protocol at the three stages: Sign in, Time out, Sign out. The auditing process began on November 1st, 2017 and 30 observational audits were required a month with a 90% compliance rate. Audits were tallied weekly by unit managers, scanned, and sent to the Risk Management Department. The audit forms and tallies were documented and tracked on an excel spread sheet.

Clinical incidents and near misses were reported by staff through the completion of a Patient Safety Report (PSR) on Midas software. This software allowed for tracking to identify incidents that were identified with a surgical pause.

Measures

The outcome measures used in evaluation of the project are summarized in Table 1.

TABLE 1. Metrics Used in Evaluation

Outcome Measure	Definition	Data Source
Errors that were prevented	Number of near misses	Patient safety reports
Adherence to using the SSC	Percentage of surgical cases where SSC was implemented by surgical team	Audit data
Safety climate	Number of times staff stopped the line when a safety concern was present, compare to preimplantation data	Audit data Written responses

Results

Patient Safety Reports were retrieved from October 1st, 2017 to January 31st, 2018 utilizing the criteria "wrong site, wrong procedure, and wrong patient invasive procedures". A total of 17 reports were documented and examples of these reports are represented in Table 2.

TABLE 2. Patient Safety Reports

Phase	Category	Criteria	Occurrence
Sign In	Wrong site	Wrong site written on consent form	2
Time Out	Wrong site	Wrong site written on consent form	2
		Site was not marked	1
		Site was not visible after draping	1
	Wrong procedure	Procedure stated in Time Out differed from procedure on consent (i.e. laparoscopic rather than open)	1
	Other	Consent was not received for a scheduled surgery	1
Sign Out	Specimen	Labeled incorrectly	3
		Wrong instructions for specimen handling	1
	Count	Incorrect count	3

Failure to receive adequate consent was an event that was recognized the most (29%) when staff completed their safety checks. Discrepancies in site verification occurred most frequently. Factors causing these discrepancies were in site verification include the following: laterality on consent (n=4), site not marked (n=1), and a site that was not visible after prepping the patient (n=1). Improvements in the quality and safety of surgical care can be attributed to the surgical

checklist. In addition to this, the checklist tool generates the potential for cost savings and enhanced multidisciplinary communication.

Culture of Safety

The escalation process was utilized in one of the good catch cases when the surgical site was not marked. The patient safety report provided a detailed account of the process. The circulating nurse stopped the line and presented this concern to the surgical team. All team members with the exception of the surgeon, agreed that the marking was necessary before beginning the procedure. There was still disagreement from the surgeon concerning the need to mark the site for the procedure. The nurse retrieved the policy and gave it to the physician who then agreed to mark the site.

Adherence to Checklist Items

The results from the audits conducted from November 2017 to January 2018 were compared to the baseline observational data (Appendix L). This comparison indicates an improvement in adherence to the Universal Protocol with the implementation of the checklist. Table 3 and Table 4 highlight the mean compliance to each of the three sections on the checklist for the observational and post intervention period.

TABLE 3. Pre-intervention audit data (June 2017 to July 2017)

	Sign In (n=8)	**Time Out (n=10)**	**Sign Out (n=5)**
Mean Compliance	63%	60%	85%
Items with lowest level of adherence	Anesthesiologist verified scheduled procedure (63%) Anesthesiologist visualized and verified the surgeon's initials (63%)	Surgeon visualized and verbalized initials on the body (43%) All activities were suspended (40%)	Procedure performed and wound class confirmed (40%) Counts reconciled (40%)

TABLE 4. Post-intervention audit data (November 2017 to February 2018)

	Sign In (n=73)	**Time Out (n=73)**	**Sign Out (n=34)**
Mean Compliance	70%	73%	100%

Items with lowest level of adherence	Anesthesia lead Sign-In (81%) Anesthesiologist visualized and verified the surgeon's initials (91%)	Surgeon lead Time Out (82%) Two patient identifiers confirmed (88%) All activities were suspended (88%)	

The overall compliance rate in the Sign In phase increased from 63% to 70%, Time Out phase increased from 60% to 73%, and Sign Out phase increased from 85% to 100%. In the post intervention phase, areas with the lowest compliance include: Surgeon lead Time Out (82%), two patient identifiers were confirmed during the Time Out (88%), and all activities suspended in the Time Out phase (88%). During the first month following the implementation of the checklist, adherence of physician involvement in leading the Time Out was low. The task force committee concluded that adherence to the checklist item would be met if a nurse leads the Time Out. The audit data for the following two months reflected higher rates of continued team activity during the surgical pause. In the Sign In phase, there were 22 cases in which necessary checklist items were not addressed. Perioperative staff stopped the line for 19 of these cases. In the Time Out phase, there were 19 cases in which checklist items were not addressed and the line was stopped for 8 of these cases. When comparing adherence to the checklist with other units (Appendix M), the perioperative staff scored lower in adherence for checklist items for the first three months.

Discussion

Adherence to safety standards as mandated by the Universal Protocol increased with the implementation of the safe surgical checklist from in all three components (Sign In, Time Out, Sign Out). Implementation of the checklist also resulted in early identification of events that had the potential to cause harm to patients. Identification of these events has the potential cost savings for the organization. When these events are identified and patient harm is avoided there

the risk of litigation is reduce Since breakdown in communication is one of the leading causes of medical errors (Lingard et al., 2004), the result of this project demonstrated that the use of the checklist can potentially improve patient safety in the OR through the early identification of near misses. By creating a standardize approach to surgical safety practices, this initiative has a potential to enhance the safety culture in the surgical center.

Literature indicates that successful implementation of the checklist relies heavily on participation from physicians and implementing the checklist on a team basis. Physician involvement and the organization of the implementation were two barriers to this quality improvement project. Designating a physician champion was a lengthy process and physician representation at the task force meetings was absent. When the initiative began, physicians were not leading the process and the task was reassigned to the registered nurse instead. The most commonly cited barrier to implementation of a safety checklist is active or passive non-compliance from staff, especially from the physicians (Bergs et al., 2015). Having physicians led the checks themselves is known to improve compliance and completion (Bergs et al., 2015). Addressing physician involvement is essential in order to sustain this initiative long term.

This initiative was implemented organization wide, meaning that all departments were required to perform these safety checks. Instead of implementing this project one department at a time, the project was implemented for all departments on the same day. The training and teaching involved for this implementation did not meet the unit needs. While the goal of achieving a rate of 90% compliance was not achieved there was an increase in adherence to the standardized practices. Compared to other departments, adherence rates to the checklist in the operating room were significantly lower than other units. This finding was unexpected as the

perioperative staff were more familiar to practices associated to the Universal Protocol compared to other departments.

Conclusion

This study evaluated the degree of adherence to safety criteria on the checklist. The implementation of the checklist resulted in numerous good catches and has the potential for cost savings. The sustainability for this project relies on additional education efforts that focus on empowering staff members to speak up when the checklist is not being performed correctly. In addition to this, obtaining physician involvement for this initiative will be a key for long-term success. For long term sustainability, continuous education efforts, reassessment of checklist elements, periodic audits, and feedback are necessary. Even though adherence to the checklist did not meet the organization's standard rate of 90% compliance, perioperative team members completed a more standardized approach to completing surgical safety checks.

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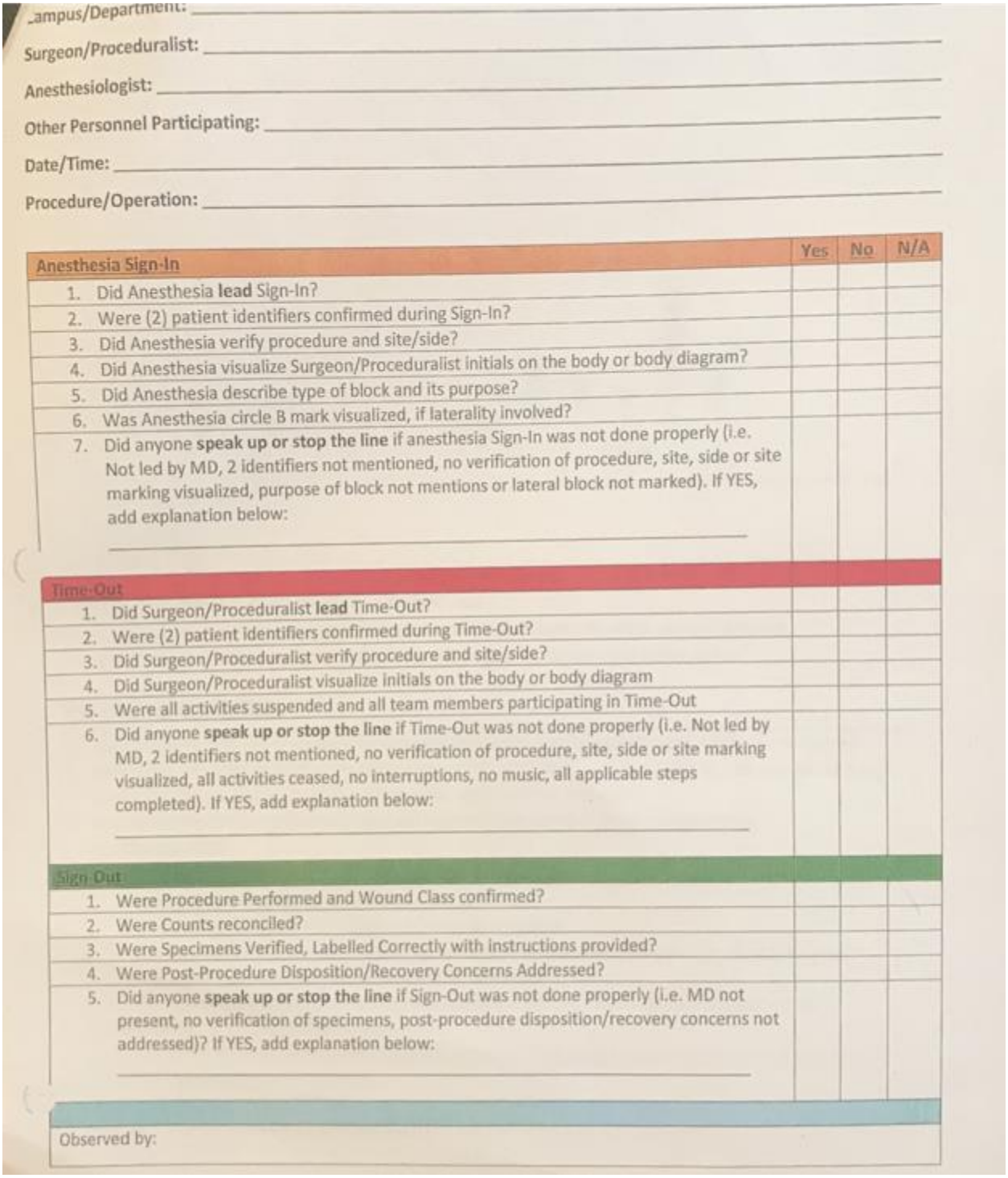
Appendix A
Audit Tool



_ampus/Department: _____

Surgeon/Proceduralist: _____

Anesthesiologist: _____

Other Personnel Participating: _____

Date/Time: _____

Procedure/Operation: _____

Anesthesia Sign-In	Yes	No	N/A
1. Did Anesthesia **lead** Sign-In?			
2. Were (2) patient identifiers confirmed during Sign-In?			
3. Did Anesthesia verify procedure and site/side?			
4. Did Anesthesia visualize Surgeon/Proceduralist initials on the body or body diagram?			
5. Did Anesthesia describe type of block and its purpose?			
6. Was Anesthesia circle B mark visualized, if laterality involved?			
7. Did anyone **speak up or stop the line** if anesthesia Sign-In was not done properly (i.e. Not led by MD, 2 identifiers not mentioned, no verification of procedure, site, side or site marking visualized, purpose of block not mentions or lateral block not marked). If YES, add explanation below: _____			
Time-Out			
1. Did Surgeon/Proceduralist **lead** Time-Out?			
2. Were (2) patient identifiers confirmed during Time-Out?			
3. Did Surgeon/Proceduralist verify procedure and site/side?			
4. Did Surgeon/Proceduralist visualize initials on the body or body diagram			
5. Were all activities suspended and all team members participating in Time-Out			
6. Did anyone **speak up or stop the line** if Time-Out was not done properly (i.e. Not led by MD, 2 identifiers not mentioned, no verification of procedure, site, side or site marking visualized, all activities ceased, no interruptions, no music, all applicable steps completed). If YES, add explanation below: _____			
Sign-Out			
1. Were Procedure Performed and Wound Class confirmed?			
2. Were Counts reconciled?			
3. Were Specimens Verified, Labelled Correctly with instructions provided?			
4. Were Post-Procedure Disposition/Recovery Concerns Addressed?			
5. Did anyone **speak up or stop the line** if Sign-Out was not done properly (i.e. MD not present, no verification of specimens, post-procedure disposition/recovery concerns not addressed)? If YES, add explanation below: _____			

Observed by:

Appendix B
Audit Results

Sign-In	**Baseline**			**Post Intervention**		
Criteria Statement	**Yes**	**No**	**Compliance (%)**	**Yes**	**No**	**Compliance (%)**
Anesthesia lead Sign-In	6	2	75	58	14	81
Two patient identifiers were confirmed	6	2	75	69	4	95
Procedure was verified	5	3	63	63	5	93
Anesthesia visualized the Surgeon's initials	5	3	63	47	5	91
Anesthesia described the type of block and purpose	3	3	100	10	0	100
Was the marked site a circled B	n/a	n/a	n/a	10	0	100
Time-Out	**Baseline**			**Post Intervention**		
Criteria Statement	**Yes**	**No**	**Compliance (%)**	**Yes**	**No**	**Compliance (%)**
Surgeon lead Sign-In	5	5	50	60	13	82
Two patient identifiers were confirmed	6	4	60	58	9	80
Surgeon verified procedure and side/site	6	4	60	71	2	96
Surgeon visualized initials on the body	3	4	43	57	0	100
All activities were suspended	4	6	40	63	9	88
Did anyone speak up or stop the line if the Time-Out was not done properly	1	4	10	8	19	42
Sign-Out	**Baseline**			**Post Intervention**		
Criteria Statement	**Yes**	**No**	**Compliance (%)**	**Yes**	**No**	**Compliance (%)**
Procedure performed and wound class confirmed	4	1	80	34	0	100
Counts were reconciled	4	1	80	40	0	100
Specimens were verified, labelled corrected	2	0	100	26	0	100
Post-procedure disposition and recovery concerns were addressed	4	1	80	36	0	100
Did anyone speak up or stop the line if the Sign-Out was not done properly	0	1	0	0	N/A	

Appendix C
Kotter's Eight Steps of Change

Phase	Kotter's Eight Steps of Change	Task	Start Date	Completed
I	1. Increase urgency	Review protocol	14-Jun-17	21-Jul-17
		Baseline observation	14-Jun-17	7/11/17
		Create observation tool	15-Jun-17	19-Jun-17
	2.Build a team	Join and partake in task force committee	21-Jun-17	1-Dec-17
		Recruit physician champion	5-Jul-17	1-Aug-17
	3.Create a vision	Analyze baseline data	12-Jul-17	19-Jul-17
II	4. Communicate the vision	Present baseline data to task force	19-Jul-17	26-Jul-17
	5. Empower action	HealthStream module available to staff	1-Aug-17	31-Aug-17
		Modify checklist for unit needs	8-Aug-17	23-Aug-17
		Recruit team leads	9-Aug-17	16-Aug-17
		Create demonstration video with team leads	16-Aug-17	30-Aug-17
		Protocol is published	4-Sep-17	5-Sep-17
		Protocol shared at meetings	4-Sep-17	15-Sep-17
		Newsletter of protocol sent	18-Sep-17	22-Sep-17
		Checklist available in Epic Optime	19-Sep-17	20-Sep-17
	6.Create short term wins	Practice checklist with one team	25-Sep-17	27-Sep-17
		Modify checklist for unit needs	27-Sep-17	29-Sep-17
		Posters visible in all procedural areas	1-Oct-17	2-Oct-17
		Go live	1-Oct-17	25-Oct-17
		Teach know do share at staff meeting	4-Oct-17	11-Oct-17
		Flowsheets available in Epic	21-Oct-17	22-Oct-17
III	7. Build on Change	Conduct audits	1-Nov-17	1-Feb-18
		Create standardized audit tracking tool	8-Nov-17	15-Nov-17
		Create outcome tracking tool	8-Nov-17	15-Nov-17
	8. Make it stick	Synthesize data	5-Feb-18	19-Feb-18

Appendix D
Microsystem Assessment of Surgical Department

Unit Profile		
19 ***Purpose:*** Why does your unit exist?		
	Site Contact:	Date:
Administrative Director:	Nurse Director:	Medical Director:
B. Know Your Patients: Take a close look into your unit, create a "high-level" picture of the PATIENT POPULATION that you serve. Who are they? What resources do they use? How do the patients view the care they receive?		

Est. Age Distribution of Pts:	**%**
birth-19 years	3.82
20-39 years	10.27
40-59 years	28.7
60-79 years	43.88
80 + years	13.28
% Females	56.55

List Your Top 10 Diagnoses/Conditions	
1. Nervous system (eye disorder)	6. injuries/ poisoning
2. digestive system	7. respiratory system
3. musculoskeletal	8. nervous system
4. circulatory system	9. all pregnancies
5. genitourinary	10. endocrine disorder

Patient Satisfaction Scores	% Always
Nurses	81
Doctors	82
Environment	NA
Pain	74
Discharge % Yes	86
Overall % Excellent	

Principal Procedure Groups	**%**
Surgery- Digestive system	22.47
Surgery- eye and ocular	20.63
Surgery- musculoskeletal	11.69
Surgery- integumentary	8.41
Surgery- cardiovascular	8.21
Surgery- urinary system	4.21
Surgery- nervous system	4.18

Point of Entry	**%**
Admissions	78.69
Clinic	N/A
ED	49.69
Transfer	N/A
Discharge Disposition	**%**
Home	69.45
Home with Visiting Nurse	13.48
Skilled Nursing Facility	**9.10**

Health Outcomes	**Y/N**
Pt Census by Hour	N/A
Pt Census by Day	N/A
Pt Census by Week	N/A
Pt Census by Year	N/A
30 Day Readmit Rate	N/A
Our patients in Other Units	N/A
Off Service Patients on Our Unit	N/A
Frequency of Inability to Admit Pt	N/A

Patient Type	**LOS avg.**	**Range**

Medical	N/A	N/A	Other Hospital	N/A	***Complete "Through the Eyes of Your Patient", pg 8***	
Surgical	N/A	N/A	Rehab Facility	N/A		
Mortality Rate			Transfer to ICU	N/A		

C. Know Your Professionals: Use the following template to create a comprehensive picture of your unit. Who does what and when? Is the right person doing the right activity? Are roles being optimized? Are all roles who contribute to the patient experience listed?

Current Staff	**Total FTEs**	**Total Productive Hours**		**# Surgeons by specialty**		**Admitting Medical Service**	**%**
Surgery and recovery total	91.20	216,595		9 Vascular Surgeons		Internal Medicine	NA
Anesthesiology	9.41	12, 195		3 Neurologic Surgeons		Hematology/Oncology	NA
Surgery and recovery-Nursing	66.61	105,979		17 General Surgeons		Pulmonary	NA
Surgery and recovery Clerical and admin		20,737		32 Orthopedic Surgeons		Family Practice	NA
Surgery and recovery- aids		21,891		15 Plastic/Reconstructive Surgeons		ICU	NA
Surgery and recovery-management and supervision		8,159				Other	NA
Service	Classification	Total units of service	Total Inpatient units of service	Total Outpatient units of service		**Supporting Diagnostic Departments**	
Surgery and Recovery	operating minutes	1,149,914	490,890	659,025		(e.g. Respiratory, Lab, Cardiology, Pulmonary, Radiology)	
Surgery and Recovery	# Surgeries	11,081	3,475	7,606			
Anesthesiology	Anesthesia minutes	1,192,275	533,250	659,025			

(The Dartmouth Institute Microsystem Academy, 2015)

Appendix E
Cost Analysis

Materials/Labor	First Year Costs
Nurse Training	1 Hour Meeting with nurses (20 FTE) 20 FTEs x 50$ (hour) = $1,000
CNL Educator	1 Hour Meeting with nurses 1 CNL (50$/hour) x 1 hour =50$
Checklist posters	2 posters 23"x28" 2($69.99) x 11 operating rooms=$1,539.78
Total Cost	$2,589.78

Likelihood of successful claims and subsequent cost analysis					
Type of Claim	Percentage compensated	Mean compensation ($)	Mean defense cost ($)	Mean cost per claim ($)	Sum cost ($)
Wrong-site surgery	89	43,706.50	17,339.49	61,046.00	6,785,319.60
Failure to obtain adequate consent	52	33,418.75	25,783.10	59,201.85	7,461,335.80
Retained foreign body	46	21,677.92	12,052.09	33,731.01	1,821,391.20

(Harrison, Narayan, Newton, & Banks, 2015)

Base Case	
Benefits-annual avoided hospital costs	$6,785,320
Benefits- annual avoided ACC payments	$150,00

Appendix F

SWOT Analysis: Strengths, Weaknesses, Opportunities, Threats

SWOT Analysis: Strengths, Weaknesses, Opportunities, and Threats	
Strengths: • Dedication to improving healthcare quality • Education support and accommodation for change • Stakeholder involvement	**Weaknesses:** • Workflow changes • Limited personnel (lack of perioperative educator) • Limited time and education for staff
Opportunities: • Reduction in preventable errors • Improvement in patient safety and satisfaction • Enhanced care coordination and collaboration • Improvement in quality	**Threats:** • Limited physician champions (leaders) • System wide initiative

Appendix G
Checklist Tool

UNIVERSAL PROTOCOL SAFETY CHECKLIST FOR SURGICAL AND NON-SURGICAL INVASIVE PROCEDURES

Page 1 of 2

1. ANESTHESIA SIGN IN / REGIONAL BLOCK TIME OUT:

(If Anesthesia not involved, proceed to Step 2)

Perform PRIOR to induction of anesthesia
Anesthesia Led with R.N.
Patient to be involved when possible
- Patient I.D. (2 identifiers)
- Procedure, site & side, surgeon/proceduralist initials verified
- Allergies / Sensitivities ☐ NKDA

For Regional Block:
- States block being performed and purpose
- Circled B for anesthetic block visible/verified

Signature RN/MD/Licensed, certified personnel | Date | Time

2. TIME OUT

Immediately PRIOR to procedure start
Surgeon/Proceduralist LED with R.N./Procedural Team
Patient to be involved when possible

	TIME OUT #1 Primary Procedure (✓ or N/A)	TIME OUT #2 As Necessary (✓ or N/A)
Correct Patient I.D. (2 identifiers)		
Correct Procedure with Consent		
Correct Site and Side		
Surgeon/Proceduralist initials verified on patient or body diagram		
Correct Patient Position		
Allergies/Sensitivities		
Antibiotics administered, as ordered		
Relevant labs, Blood Products available		
Images displayed and ID verified		
Required Implant(s), Special Equipment, Unique Patient Needs		
Appropriate VTE Prophylaxis, as indicated		
Specimen(s) Instructions given		
Potential Fire Hazard(s)		
Confirm agreement with Time Out		
	Signature MD/RN or Licensed Personnel Date/Time	Signature MD/RN or Licensed Personnel Date/Time

3. SIGN OUT

Prior to surgeon/proceduralist and patient leave procedural room
R.N. LED with Procedural Team

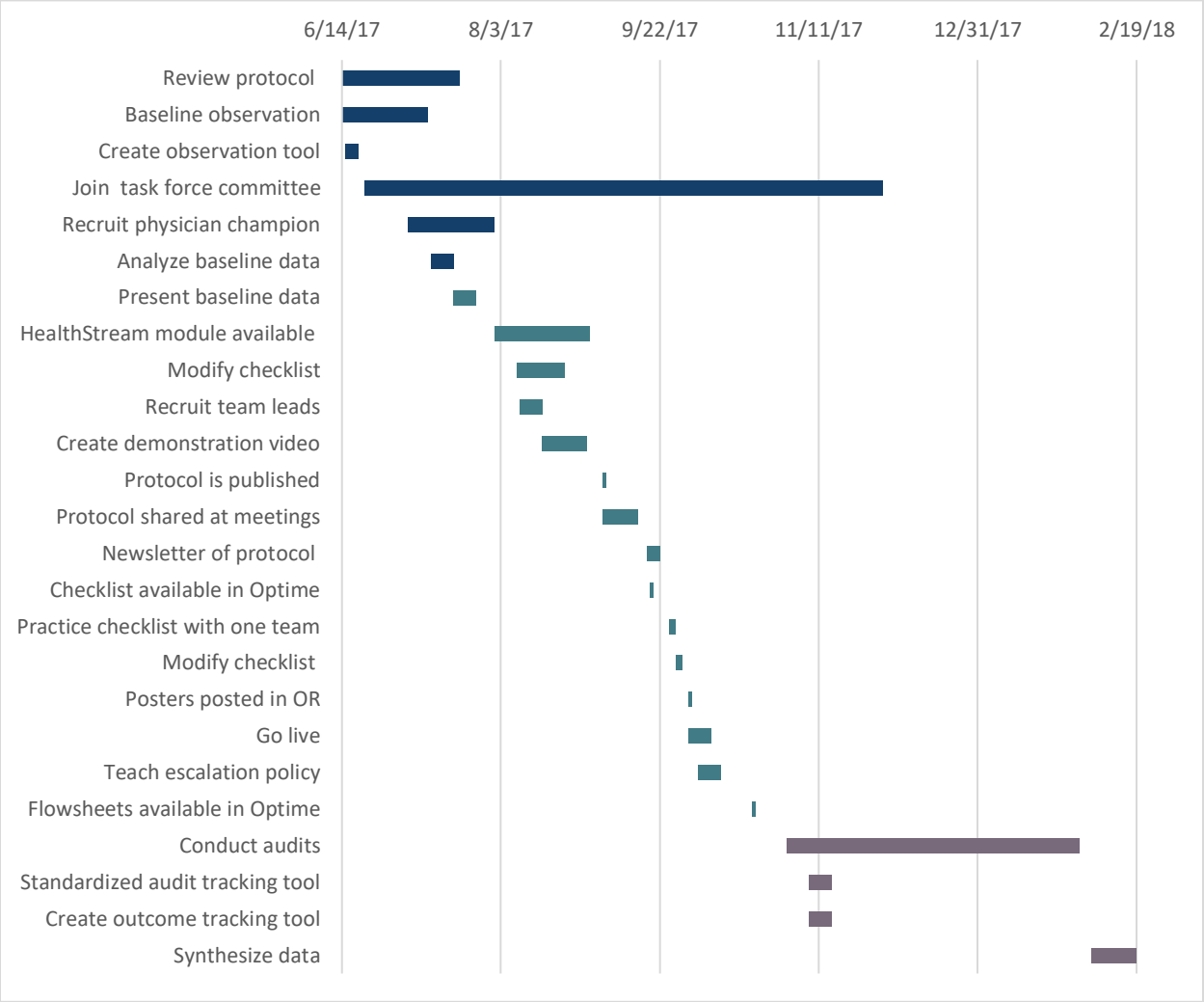
- ☐ Instrument/sponge/sharp count reconciled ☐ N/A
- ☐ Specimen(s) verified and labeled correctly ☐ N/A
- ☐ Procedure performed and Wound Class confirmed ☐ N/A
- ☐ Post-Procedure Disposition/Recovery Concerns

Signature RN/MD/Licensed, certified personnel | Date | Time

200233 OR PRE OP

SH-0061 (05.25.2017) Distribution: SCAN

Appendix H
Timeline



Appendix I
Education Tool

	Old policy	New policy
Site marking	Required	Surgeon's initials
Site marking -Time out	Professional staff who will be involved must be present in the procedure	Surgeon who is listed on the consent will be present for the timeout and the procedure.
Site marking- Obvious pathology	Obvious pathology does not need to be marked	Obvious pathology still has to be marked or a body diagram needs to be used
Impractical site marking	Dots or orange band used	Body diagram
Anesthetic nerve block	N/A	Site marked as (B)
Time out	Occurred at different times led by different people- after the patient was positioned	Occurs immediately prior to procedure after prepping, draping- immediately prior to incision

Appendix J
Educational Flyer

Universal Protocol Safety Checklist for Surgical and Non-Surgical Invasive Procedures

All activities are suspended and all team members participate.

Sign In	Time Out	Sign Out
ANESTHESIA SIGN IN/ REGIONAL BLOCK TIME OUT Prior to the start of anesthesia Anesthesia-led with RN *If anesthesia is not involved, no sign in required*	**PROCEDURAL TIME OUT** Immediately prior to procedure start Surgeon led with RN/procedural team Patient to be involved when possible	**POST-PROCEDURE SIGN OUT** Prior to surgeon and patient leaving the procedural room RN-led with surgeon, anesthesia and scrub technician

• **Patient I.D. (2 identifiers)**
• **Procedure verified:**
  ○ Side and site with patient consent
  ○ Surgeon's initials on patient or body diagram
• **Allergies/sensitivities**
• **Anesthesia verbalizes anesthesia plan**
• **For blocks, anesthesia:**
  ○ States block being performed and purpose
  ○ Visualizes the (B) when anesthesia block will be placed, if laterality involved
• For multiple blocks: Verbalizes all blocks to be performed at the same time
	• **Verification of consent aloud to verify**
	  ○ Patient I.D. (2 identifiers)
	  ○ Confirm procedure
	  ○ Confirm side and site
	• **Visualize site initials on patient or body diagram**
	• **Verbally confirm the following:**
	  ○ Correct position
	  ○ Allergies/ sensitivities
	  ○ Antibiotics administered, as ordered
	• **Verbally confirmed following as applicable to the case:**
	  ○ Relevant labs/ blood products available
	  ○ Images displayed and I.D. verified
	  ○ Required implant(s), special equipment, unique patient needs
	  ○ VTE prophylaxis as indicated
	  ○ Specimen instructions
	  ○ Potential fire hazard(s)
	• **ALL TEAM MEMBERS:**
	  ○ Confirm agreement with time out
		• **Instrument/sponge/sharp counts reconciled**
		• **Specimen(s)verified, labelled correctly and specimen instructions provided**
		• **Procedure performed and wound class confirmed**
		• **Post-procedure disposition/recovery concerns**

Appendix K
Education Tool: Escalation Process

Universal Protocol (UP)- STOP THE LINE Zero Wrongs, are RIGHT

Know

All employees, medical staff, students, and volunteers have the responsibility and authority to immediately intervene to protect the safety of a patient and avoid subsequent harm. It is the expectation that any person providing patient care will immediately stop and respond to a safety concern voiced by a team member. This expectation to SPEAK UP is advocating for patient safety is applicable for all patients receiving services.

Do

Review the Chain of Command Escalation policy for guidance.
In the clinical areas, role play with staff likely scenarios relative to the implementation of the UP so everyone feels comfortable with the process.
Encourage and support your team as you implement the new Universal Protocol safety standard.

Share

Review the following information with all employees and medical staff members:

1. Any person who observes or becomes aware of an imminently harmful situation in patient care, including to follow the Universal Protocol, has the authority and responsibility to speak up and requires the process be stopped in order to clarify the patient safety situation. This person needs to say in a firm, clear, and respectful manner: "STOP, I have a patient safety concern."
2. The "Stop the Line" request needs to be clear and timely to maintain patient safety while minimizing intrusion into the process of care.
    a. Staff are to assertively voice their concern at least two times to ensure the request has been heard.
3. If there is noncompliance in responding to a "Stop the Line" request, the Chain of Command or Escalation process should be invoked.
4. Situations in which "Stop the Line" request was invoked or was indicated but not invoked, should be reviewed and followed up by the appropriate staff leadership.
5. If any threat of or actual retaliation to a person requesting to "Stop the Line" occurs, follow-up will be conducted, as described in the Disruptive Behavior Policy.

Appendix L
Results

	July-August 2017 N(%)	**November 2017-Janurary 2018 N(%)**
SIGN IN	**N=8**	**N=73**
Anesthesia lead Sign-In	6(75%)	58(81%)
Two patient identifiers were confirmed	6(75%)	69(95%)
Procedure was verified	5(63%)	63(93%)
Anesthesia visualized site marking if applicable	5(63%)	47(91%)
Anesthesia described the type of block and purpose	6(100%)	10(100%) (n=10)
Was the marked site a circled B	N/A	10(100%) (n=10)
TIME OUT	**N=10**	**N=73**
Surgeon lead Time Out	5(50%)	60(82%)
Two patient identifiers were confirmed	6(60%)	58(88%)
Surgeon verified procedure and side/site	6(60%)	71(96%)
Surgeon visualized initials on the body	3(43%)	57(100%)
All activities were suspended	4(40%)	63(88%)
The line was stopped if the Time-Out was not done properly	1(10%) (n=4)	8(42%) (n=19)
SIGN OUT	**N=5**	**N=34**
Procedure performed and wound class confirmed	4(80%)	34(100%)
Counts were reconciled	4(80%)	34(100%)
Specimens were verified, labelled corrected	2/2(100%)	26/26 (100%)
Post-procedure disposition and recovery concerns were addressed	4(80%)	34(100%)
The line was stopped if the Sign-Out was not done properly	1(0%)	N/A

Appendix M
Audit Results for Each Department

Departments	October 2017 N(%)	November 2017 N(%)	December 2017 N(%)	January 2018 N(%)
Cath Lab	27(100%)	41(100%)	30(100%)	24(100%)
ED	25(95%)	24(100%)	23(100%)	23(100%)
FBC	30(96%)	23(100%)	5(100%)	12(75%)
ICU	8(100%)	11(100%)	2(100%)	1(100%)
SDICU	5(80%)	1(0%)	2(100%)	1(50%)
MS	10(100%)	6(100%)	1(100%)	5(100%)
OR (Ambulatory)	18(100%)	41(100%)	25(100%)	40(67%)
OR*	27(70%)	28(82%)	22(50%)	47(93%)
Rad-IR	36(100%)	32(100%)	30(100%)	47(100%)
WC	110(100%)	132(100%)	107(100%)	96(100%)

Cardiac Cath Laboratory
Emergency Department (ED)
Family Birth Center (FBC)
Intensive Care Unit (ICU)
Step Down Intensive Care Unit (SDICU)
Medical Surgical (MS)
Operating Room-Ambulatory
Operating Room-Microsystem
Radiology I (Rad IR)
Women's Center (WC)

Appendix N
Statement of Determination

UNIVERSITY OF SAN FRANCISCO | School of Nursing and Health Professions

Student Name: Nicole Stathatos

Title of Project: Implementation of a Surgical Safety Checklist

Brief Description of Project
To ensure a standardized approach towards safety practices in the surgical theater, a Surgical Safety Checklist (SSC) was implemented in a hospital in Northern California.

Data that Shows the Need for the Project
There was an increase incidence in sentinel events such as wrong site surgery (n=1), wrong patient surgery (n=1), and retained foreign body (n=5).

Aim Statement
The aim of this initiative is to improve the safety of surgical care by ensuring 90% adherence to the requirements on the Safe Surgical Checklist based on observational assessment of the process within four months of implementation.

Description of Intervention(s)
Completion of the criteria on the Surgical Safety Checklist (SSC) was required for all invasive procedures by perioperative staff members.

Desired Change in Practice
This initiative focused on creating standardized safety practices by ensuring the completion of critical tasks.

Outcome measurement(s)
Adherence to the criteria on the checklist and the number of near misses were outcome measures utilized in this initiative.

Appendix O
Non-Research Determination Form

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

Instructions: Answer YES or NO to each of the following statements:

Project Title: The Integrative Health Approach (IHA) Re-educational Program	**YES**	**NO**
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	**X**	
The specific aim is to improve performance on a specific service or program and **is a part of usual care**. ALL participants will receive standard of care.	**X**	
The project is **NOT** designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does **NOT** follow a protocol that overrides clinical decision-making.	**X**	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	**X**	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	**X**	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	**X**	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	**X**	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., **not** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	**X**	
If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: *"This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board."*	**X**	

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.