Using Safety Checklists Outside of the Operating Room

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"Using Safety Checklists Outside of the Operating Room"

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Capstone Written Proposal

Using Safety Checklists outside of the Operating Room

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Abstract

The use of a Time Out checklist for patient safety in non-operating room procedural areas is equally important for positive patient outcomes as in the operating room (OR). In this busy southwestern United States hospital, the procedural teams in the non-operating room areas were reported to not be fully engaged during the performance of the Time Out pre-procedural pause prior to gastroenterological (GI) procedures. This study was conducted to improve compliance with the scripted Time Out checklist and promote full engagement of the GI procedural team during the Time Out thus reducing risks of wrong site surgery. Literature has shown that team engagement in the Time Out process decreases the risk of wrong site surgery by improving teamwork and communication. A purposive, non-participant structured observation comparing the proportions between two separate groups (pre-and post-education intervention) was conducted with the GI procedural team at the New Mexico Veterans Health Care System (NMVAHCS). The observations were completed prior to providing an education component and again after the completion of the education. The study demonstrated improvement of compliance using a scripted Time Out checklist and engagement of the GI procedure team after education.

Keywords: Timeout checklists, communication skills, communication strategies, effective communication, effective teams, interpersonal communication, patient safety, safety checklists, safety culture
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Introduction and Background

“I am very sorry but we operated on the wrong ----.” That would be a never event, one of the events that are NEVER supposed to happen as identified in the National Quality Forum (NQF) report 2002. Per the Joint Commission (TJC) wrong patient, wrong procedure, and wrong site surgery occurs as often as 40 times per week in the United States (TJC, 2014). The term of wrong site surgery represents a group of errors that include wrong patient, wrong side, wrong procedure, wrong site, and more recently wrong implant surgeries. These procedures can occur in an operating room or any setting that performs invasive procedures including such areas as dental clinic, podiatric clinic, radiology, the patient bedside, gastroenterology suite (GI).

As part of wrong site surgery prevention, hospitals use Universal Protocol (UP) which consists of three crucial components, pre-procedure verification, site marking and timeout. UP begins when the patient enters the hospital because errors can occur at the bedside or in procedure areas. The importance of team work and clear communication during all phases pre, intra, and post of the procedure is critical. The report from the Institute of Medicine (IOM), *To Err Is Human: building a Safer Health System*, estimate that approximately 44,000 to 98,000 Americans die annually secondary to preventable medical errors with costs ranging from $17 to 29 billion a year (Institute of Medicine, 1999).

The Department of Veterans Affairs (VA) National Center for Patient Safety (NCPS) was founded in 1999 to lead the VA’s patient safety efforts and to develop and support a culture of safety throughout the Veterans Health Administration (VHA). The NCPS principal goal is to reduce and prevent unintentional harm to patients because of care. Standardized pre-procedural checklists are required for use in all invasive procedural areas and can reduce harm to the patient
by increasing awareness and safety (U.S. Department of Veterans Affairs, 2014). This aligns with highly reliable industries such as the airline industry which utilizes methods to mitigate errors including the employment of safety checklists which have been shown to improve communication and teamwork (O’Daniel & Rosenstein, 2008). A standardized safety checklist is a method where actions are listed and performed by the procedural team. In contrast to a verbal checklist or communication where the nurse relies on past behaviors and knowledge. The NMVAHCS performs approximately 18,000 surgeries of all complexity levels each year which include open heart and Da Vinci robotic procedures however there are no complete records of the total number of non-Operating room procedures performed each year.

The procedural Time Out is based on standards for the operating OR from the Joint Commission in 2003 where a time out, or surgical pause became a requirement by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in the National Patient Safety Goals (Dailey, 2003). Also from the World Health Organization (WHO) Surgical Checklist which is designed in three phases, “Sign-in” (before anesthesia induction), “Timeout” (before incision), and “Sign-out” (following the procedure before team members leave the OR) as reviewed by Russ et al. (2013). The WHO intended the checklist as a guide to be modified based on facility needs and to be used for surgical procedures as well as for invasive procedures outside of the OR.

The purpose of promoting safety protocol, such as the “Time Out” in non-OR procedure areas, is consistent with the Joint Commission Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery (The Joint Commission, 2011). The Institute for Clinical Systems Improvement (2012) reports adverse events are thirty-six percent due to the wrong site, patient or procedure that occur in a non-OR setting. The Joint Commission National
Patients (2016) goals target both operating room and non-operating room settings for Universal Protocol for Preventing Wrong Site Surgery. One of the issues that the Veterans Health Administration (VHA) faces is how the hospital defines invasive, high-risk or non-surgical procedures. The Joint Commission offers an appendix listing invasive, high-risk or non-surgical procedures, but it is left up to the hospital to define and create a patient safety protocol. Procedures that expose patients to more than minimal risk, including procedures done in a setting other than the OR and procedure areas such as clinics and the bedside are defined as surgical and non-surgical invasive procedures (The Joint Commission, 2011). Within the VHA “Time Out”, in the OR, data is monitored within each of the hospitals and reported to the national databases; in contrast, there is no database available for “Time Out” in non-OR areas.

The U.S. healthcare organizations started looking at improving safety after the Institute of Medicine (IOM) made its critical report, *To Err is Human* in 1999. The WHO reports that human error is the leading cause of wrong-site surgery while the Joint Commission ranks wrong-site surgery as the second most frequently reported event (Devine, Chutkan, Norvell & Dettori, 2010). The Joint Commission Center for Transforming Healthcare (2011) reports that over three hundred wrong-site surgeries occur annually and forty to sixty wrong-site surgeries occur within the U.S. each week. Seventy-two percent of wrong-site surgeries analyzed had defects in the “Time Out” category (Mulloy & Hughes, 2008). This suggests that wrong-site surgery is a preventable adverse event. Wrong-site surgeries do not only occur in the OR, but also in non-OR procedure areas (Neily, 2011).

**Problem Statement**

Safety checklists are valuable for OR and non-OR teamwork and communication, which improve patient outcomes and need to be used throughout the facility for invasive procedures.
Omissions or lack of engagement by a procedural team can lead to catastrophic errors including wrong-patient surgery (Lingard et al., 2016). However, standardized safety checklists can result in staff complacency if they are not used correctly (Cullati et al., 2012). Walker, Reshamwalla, and Wilson (2012) state teams who “check the box” without thinking about the impact on the patient could lead to patient endangerment and harm. While information is not available on wrong-site (patient) surgeries in non-OR areas, the use of a Time Out checklist is a proven risk reduction tool that is applicable for use in the non-OR procedure areas. The hypothesis is that the non-OR GI procedural teams will demonstrate improved compliance after education on the importance of Time Out checklists.

**Objectives and Aims**

The delivery of highly reliable, quality patient care depends on the communication of the procedural team and is an important component of patient safety and advocacy. The object and aim is to reduce the risks of wrong site surgery in a non-OR procedure area measuring affective compliance with Time Out protocol in the GI procedure area at the NMVAHCS. The PICOT question is that for (P) GI procedural teams (I) does education on Time Out and Patient Safety improve observed compliance with Time Out protocol post education (C) comparison to pre-education intervention, (O) improved scores on post-education intervention and increased compliance with the scripted Time Out checklist and full engagement of the GI procedural team during Time Out measured by observation, (T) in three months?

**Review of Literature**

**Introduction**

Communication by the surgical team affects patient safety and outcomes. The operating room (OR) is intense, fast paced, and detailed oriented which requires the OR staff to
communicate quickly and efficiently. As perioperative nurses strive to safeguard the rights of the surgical patient through patient advocacy, effective communication by the OR team is essential. The delivery of highly reliable, quality patient care depends on the communication of the OR team and is an essential part of the operating room culture. Therefore, the team is accountable in their communications efforts to produce positive outcomes for the patient.

Fudickar, Horle, Wiltfang, and Bein (2012) stated that, common errors in patient safety in the OR are credited to poor communication and teamwork. This literature review will discuss the target population, the perioperative team, and the effect that a standardized safety checklist makes on perceived teamwork and communication compared with the use of a verbal safety checklist that incorporates the similar elements. A standardized safety checklist is a method where actions are listed and performed by the surgical team in the OR. A verbal checklist or communication is one where the nurse relies on past behaviors and knowledge. The hypothesis is that a standardized safety checklist will promote teamwork and open the lines of communication in the perioperative team.

**Literature Review**

Of the over 67 articles found from the library searches using the keywords noted above, many studies were found to be ten to twelve years old and thus were read for content but were not included in this review. Narrowing the searches using Boolean limiters, date limiters, and scholarly and peer review search result requirements provided appropriate articles and studies. The nine articles chosen that support the topic meet the requirements of being current (published within the past five years with one notable exception), peer reviewed, and from reliable sources.

In the systematic review by Russ, Rout, Sevdalis, Moorthy, Darzi, and Vincent, (2013) the systematic review was completed with the purpose of how to measure the power of surgical
safety checklists on the quality of team work and communication in the operating room. There were 315 articles reviewed by two researchers, and twenty articles formed the basis of the systematic review. In 20 of the articles, the following methods in the articles were comprised of surveys, observations, interviews and 360-degree assessments. All the 20 articles described a case-specific safety checklist for surgery with some improvement in teamwork and communication of the surgical team. This study supports the hypothesis with the extensive information on the effectiveness of formalized checklists and the benefits for OR communication. A limitation of the study was how the checklists assisted staff by improving teamwork and communication but the topic of verbal checklists was not explored and addressed as a topic for future research.

In the grounded theory study by Waehle, Haugen, Softeland, and Hjalmhult (2012), deductions were made after the researchers gathered and analyzed data from observations of the checklist used in the OR. This allowed for conceptualizing an understanding based on the information gathered from a focus group of perioperative team members. This study used 14 nurse-anesthetists and OR nurses from a single teaching hospital and consisted of “adjusting team involvement” which used three strategies; distancing, moderating, and engaging team involvement (Waehle et al., 2012). The nurses had a strong positive confidence based on the use of the WHO checklist in their everyday OR assignments as compared to verbal lists that were used in past practice. The nurses continued to adjust their perioperative participation during the Time Out (pause before the surgical incision is made and where the team confirms surgical site, patient, and procedure), utilizing the safety checklist and adapting to the conditions of their work environment (Waehle et al., 2012). Thus, the perioperative nurses used the checklist in some fashion in their practice settings, although not always as fully as required, based on self-reporting
in the surveys. As in the first study, the use of a standard checklist in surgery increased communication and teamwork of the surgical team. Limitations of the study included a small study group that may not fully reflect the perioperative team dynamics of OR teams.

Lingard, Espin, Whyte, Regehr, Baker, Reznick, Bohnen, Orser, Doran, and Grober, (2004) discussed the fact that ineffective team communication is one of the essential foundations of medical mistakes. The object of the study was to detect common characteristics of intraoperative communication failures. The study used observers who recorded 90 hours of observations during 48 different surgical procedures. The team members were divided into groups from surgical services including anesthesia, surgeons, and nurses and involved staff members, fellows, residents, and three clerks (Lingard et al., 2004). Per Lingard et al. (2004), of the 421 communication events observed, 129 were deemed to contain some form of communication failures. These failures were categorized as occasion, purpose, content, and audience failure. The definition of occasion failures included poor timing, content, and occasions of missing or incomplete information. Content failures were where essential information was omitted while the purpose failures included situations where specific issues were not identified. Audience failures included situations where key individuals were discounted or bypassed due a variety of reasons including system process issues such as inefficiency, frictions within the surgical team, workarounds, and procedural errors (Lingard et al., 2004). In summary, this study demonstrated that communication failures in the OR contain a common theme of interruption of routine, team stressors, and multitasking (Lingard et al., 2004). A full thirty percent of the negative perioperative communication resulted in patient safety issues (Lingard et al., 2004). This study was a part of a larger development a team surgical checklist.
Forse, Bramble, and McQuillian (2011) conducted a study at a Veterans Health Administration hospital to determine if team training using a federally sponsored team training programs would improve OR performance and perioperative culture. Medical Team Training (MTT) was used for the purpose and response of the patient safety crisis. The MMT was developed for effective teamwork and communication. The researchers conducted a meta-analysis and review showing that there was literature to support team training to build effective teams with improved team communication. Team training was performed and evaluated after nine months to assess whether there was perception of significant improvement in OR team work, communication and improved data linked to regulatory compliance as measured by the Surgical Quality Improvement Program measures (Forse, Bramble, & McQuillian, 2011). The conclusions drawn from this study verified that team training did improve OR staff team skills and communication, which in turn, positively affected patient care. Limitations of the study were that the team trainings were conducted in a narrow-focused environment, one hospital, and may not be applicable in the general population.

A study by Carney, Wes, Neily, Mills, and Bagain (2016) investigated whether Medical Team Training (MTT) improved the perceptions of organizational commitment to safety in a facility of the Veterans Health Administration. The study included a Safety Attitudes Questionnaire that was administered before and at the completion of the MTT program (Carney, Wes, Neily, Mills, & Bagain, 2016, p. 181). MTT training was introduced in the effort to address communications failures in healthcare and was based on a systems approach to problem solving. The Safety Attitudes Questionnaire (SAQ) was utilized and investigated as a tool to determine responses in a population study to assess perceptions toward patient safety. A five-point Likert scale was used (Carney et al., 2016) and rated seven safety climate items to assess
differences or similarities between ORs with varying levels of complex caseloads. A limitation of this study was the use the staff perceptions and not the actual behavior.

Walker, Reshamwalla, and Wilson (2012) recognized that safety checklists promoted safer patient care. The idea of the article was an implementation of evidence based practice for the WHO surgical safety checklist and literature review of related studies on use of the safety checklist. While the use of the safety checklist was noted to have significant effectiveness in urgent/emergent surgical procedures, this editorial revealed that the implementation of the safety checklist was not that simple. Effective use of communication tools and reminders must be endorsed and supported by leadership and mandated for use in a meaningful and interactive manner in the surgical arena. The authors noted that if the tool was created with flexibility and adaptability in mind as perioperative nursing practice changes then substantial improvements in safe patient care would happen. Implementing the use of checklists through teamwork was a major point. Walker, Reshamwalla, and Wilson (2012, p. 2) stated “Checklists should be evidence-based and address key safety items that are often overlooked, and which if omitted, would lead to serious adverse outcomes.” This article supports the concept that teamwork and active use of safety checklists improve patient outcomes. A limitation identified was a lack of guidance on how to encourage participation from all the team members which was cited as vital.

Cullati et al., (2013), discussed the importance of the implementation of the safety checklist by the surgical team citing that their use effectively reduced wrong site surgeries. An observation study was completed to determine if Time Out and the Sign Out checklists were used as check box items or as a memory enhancement based on the severity or criticality of the surgical intervention. The goal was to assess whether the items on the Time Out were confirmed and validated by at least one surgical team member based on the staff member’s signatures
Time Out was defined as including patient identification, type of procedure, surgical site confirmation, equipment available, and dosing of the antibiotic prophylaxis (Cullati et al., 2013). Sign Out was defined as performance and completion of the sponge and needle counts, if the full and proper procedure was documented, and if the specimens were labelled (Cullati et al., 2013). During the observations, it was noted if the number of checked items on the checklist was significantly different if the nursing staff was conducting the Time Out from strictly memory, such as from past experiences. A total of 34 observations were conducted and all the surgery types were elective. The observations were announced to the staff to eliminate the surprise factor. After the observation, the observers identified the discrepancies and immediately resolved them with the team during a debriefing (Cullati et al., 2013). The conclusion of the study was that appropriate implementation of the surgical checklist was more complicated than predicted (Cullati et al., 2013) and recommendations were made that when surgical checklists are introduced to a facility they should be done with training and in-services and reviewed regularly. The limitation of the study is that the staff members were under the Hawthorne effect and were, because of this observer bias may have influenced the utilization of the checklists (Cullati et al., 2013).

Capella et al., (2010) investigated whether formal team training improves team behaviors in a trauma situation. The intervention consisted of a pre-training/post-training design which included a simulation (Capella et al., 2010). The tool created and utilized was the Trauma Team Performance Observation Tool (TPOT). This method used trained evaluators to evaluate the trauma team’s performance in trauma resuscitations (Capella et al., 2010). Although this study is more than five years old, the results pertain to effectiveness of formal team training’s influence on team performance. The team was comprised of surgical residents, attending surgeons, and
trauma nurses. The results demonstrated that teamwork improved from pre-training to post-training. Improvements were noted in communication, leadership skills, situational awareness and monitoring, mutual respect and support, and overall response times and teamwork. Delays documented by the operating room teams were significantly reduced post training (Capella et al., 2010). In summation, this study stated that teams could not exclusively rely on individual or extensive technical skills; in addition, team simulation and practice drills improved communication and teamwork which enhanced efficiency in the trauma setting (Capella et al., 2010). A limitation to this study was the inability to compare experience in individual team members.

A study of inter-rater reliability (IRR) conducted by Huang et al. (2014) measured the use of two surgical safety checklists for performance and teamwork. The observation tools, used for the Safe Surgery 2015 program, were developed through literature reviews and expert consultations (Huang et al., 2014). The study described the development, pilot testing, and IRR of two tools for measuring surgical checklist performance and communication in surgery. Two observers worked side by side in a South Carolina hospital; they both observed fifty surgical cases and individually rated surgical teams using both surgical safety checklists. Observers discovered that there were no changes in the tools in reliability from the first ten cases observed to the last ten cases. One of the limitations in this study was that it was completed in one institution and the experience of other institutions may have been different (Huang et al., 2014). Out of the nine articles reviewed this was the only article that tested the reliability of the surgical safety checklist.
Summary of Findings

This literature review consisted of nine articles pertinent to the topic of this paper; three descriptive studies with observation methods, one was a study of inter-rater reliability, one qualitative evaluation, one intervention study, two systematic reviews, and one was a grounded theory study. A descriptive study is when information is collected using observations, and not changing the setting. Inter-rater reliability is the consistency of agreement produced by different raters. Qualitative evaluation is used to evaluate a person’s feelings about specified activities. Intervention studies randomly assign participants to one of two groups; the group receiving the intervention and the group not receiving the intervention. Systematic reviews gather existing knowledge and create a hypothesis for future studies. In all nine studies, the common theme was improving patient care using safety checklists, teamwork and communication, improved patient outcomes with the use of the safety checklists, teamwork training improving patient care, and proper education and leadership support for implementing safety checklists.

Conclusion of Literature Review

Conclusions drawn from this literature review supported communication as one of the most essential tools used by the surgical team and is significant to ensuring quality safe patient outcomes. Nonverbal checklists are heavily relied upon in OR teams but are based on individual nurses’ past experiences or specifics are from memory, which may cause the potential to omission of essential information and lead to surgical errors and omissions. Standardized safety checklists can lead to staff complacency if they are not used appropriately, which can also cause negative patient outcomes. Human errors occur when safety checklists are used inappropriately such as “checking the box” without thinking about the impact on the patient. Checklists, like any skill, require education and training for use and implementation and nursing leaders must use
evidence and existing research to ensure proper and consistent use of the safety checklist. The information in this literature review discussed the target population and the effects of the utilization of a standard safety checklist on perceived effective teamwork and improved communication compared to the use of a verbal safety checklist with comparable elements.

**Theoretical Model**

**Approaches to quality improvement outcomes model’s theoretical frameworks**

The quality improvement (QI) project chosen for this scholarly project is to improve compliance in the performance of Time Out in the non-OR GI procedure area. Looking at the Deming’s Plan-Do-Study-Act model from the Institute for Healthcare Improvement (IHI), the Baldrige Works from the Baldrige Performance Excellence Program, and the Outcome Measures tools from Agency for Healthcare Research and Quality (AHRQ) inspired the idea of using a change model for the QI/patient safety project planned. A change model guides the change process from start to sustainability and is particularly appropriate for a patient safety and compliance improvement project.

**Quality Improvement Change Model**

The methodology that will be used for promoting patient safety through evidence based practice (EBP) in the GI procedure area is the Advancing Research and Clinical Practice through Close Collaboration or ARCC model. The use of such change models provides an organized approach to EBP changes (Schaffer, Sandau, & Diedrick, 2013). Using evidence to support optimal patient care outcomes is the goal of evidence based practice and the ARCC model is used in high reliability organizations to implement and sustain changes (Melnyk, Fineout-Overholt, Gallagher-ford, & Stillwell, 2011). This change model is expressly helpful in the
implementation of a system wide change and can be easily applied to health care institutions as well as clinical settings (Melnyk & Fineout-Overholt, 2015). The primary steps of the ARCC model are:

1. Assessment of both organizational culture and readiness for EBP
2. Identification of barriers and strengths of the proposed EBP change
3. Develop (and use) of EBP Mentors
4. EBP Implementation
5. Outcome Evaluation

**Application of the theoretical framework or model**

Assessment of both organizational culture and readiness for EBP: The application of the ARCC model starts with the organizational culture assessment which includes an assessment of the readiness for EBP changes. For the New Mexico Veterans Health Care System (NMVAHCS), organizational change has provided motivation from both internal and external pressures to improve performance. The assessment of readiness to change the culture of the Gastrointestinal Procedure area (GI) using evidence based practice is verbally supported by key stakeholders throughout the facility.

Identification of barriers and strengths of the proposed EBP change: Evaluating barriers and strengths to the proposed EBP changes will be part of the involvement with key stakeholders during the initial planning stages. These stakeholders will be instrumental to supporting change in the GI procedural areas.

Develop (and use) of EBP Mentors: In nursing literature mentorship sets up a positive strategy for engaging new nurses into the culture of the workplace (Wallen et al., 2010). The use of EBP mentors will support this scholarly project by allowing selected personnel in the GI
procedural areas to be supportive change agents. Providing the GI procedural area personnel with education on patient safety and the Time Out process and introducing a written Time Out tool will promote awareness of the critical nature of the Time Out process. The Time Out is part of the Universal Protocol for patient safety and is an essential part of the improvement of compliance process. Creating an environment of education and awareness is essential and the EBP mentors will be thoroughly involved to promote a positive experience and deflect any blaming or shaming that could arise.

EBP Implementation: Implementation will occur in phases. Step one will be the pre-education intervention observations (n=94) in the GI procedural areas to assess the current compliance to the Time Out. Step two will be the education portion using a power point on the importance of Universal Protocol and the Time Out process per TJC and NMVAHCS policies. Step three will be the post-education intervention observations (n=94) with the same GI staff. Step four will be to review the data and compare pre-and-post education intervention.

Outcome Evaluation: Outcome evaluations will be in the form of the pre-and post-education intervention data, this be analyzed to create an overall picture of compliance to the Time Out process assessing for improvement.

Project and Study Design

For this study, a non-participant structured observation comparing the proportions between two separate groups (pre-and post-education intervention) will be used. A power calculation will be used to determine sample size. Pearson’s Chi-square and Fisher’s exact test used, with a four-fold table/frequency table will be used to display results. 188 GI procedures (estimated three months) will be observed for staff engagement and the use of a scripted Time Out checklist using an audit form for pre-and post-education intervention. Preliminary
information was collected from the GI procedural areas shows an average of fifteen procedures performed each day averaging 300 procedures per month. For a power analysis, a two-tailed independent sample \( t \)-test with a large effect size (Cohen’s \( d = 0.8 \)) will be used. The power analysis using G*Power is 95%, resulting in a total sample size of 188 observations total for pre- and post-education intervention. This power analysis is adequate for the current study which uses Pearson’s Chi-square tests, since large sample \((n=94)\) pre-education intervention and \((n=94)\) post-education intervention theory of the Chi-square test in a \( t \)-test yields. One observer will be chosen based upon their experience with the Time Out process. Education will be provided to the observer from the investigator on how to complete the five-question audit form. Per IRB protocol the pre-and post-educational intervention in the GI procedure area were not paired. The comparison between the pre-and post-responses will be completed using the Pearson’s Chi-square and Fisher’s exact test. If the sample size is too small the Fisher’s exact test will be completed. Chi-square is a large sample method, a rule for determining large sample size is if all cell frequency in the four-fold table is greater than or equal five. The four-fold table is the frequency table obtained by the classification of responses yes or no and time epic as pre-versus post-education intervention. The significance will be determined when Pearson’s Chi-square or Fisher’s exact \( p \) value is less 0.05 after 94 pre-observations. Education will be provided using a Power Point presentation to all GI staff members on the significance of Universal Protocol and the use of a scripted Time Out checklist prior to any type of GI procedure. The investigator will emphasize that literature demonstrates utilization of a scripted Time Out checklist have high impact on adherence and significant improvement of patient outcomes. Post-education intervention will be completed by the same observer. The data analysis will be conducted and assess the results of improvement in compliance and engagement during the GI pre-procedural
Time Out. EBP will be based on: team awareness of patient safety, team communication, value and participation in the Time Out process, and how reducing risks of patient harm by using UP.

The steps required to gather data for the study are as follows:

1. IRB approvals at University of New Mexico (UNM) and NMVAHCS will be obtained
2. Will provide the GI Nurse Manager with the general requirements of the study/education
3. Educated observer will complete observations utilizing an audit tool for pre-and post-education intervention:
   a. Question one, was there a silence/Pause prior to the Time Out?
   b. Question two, did each team member verbally acknowledge the Time Out?
   c. Question three, did each GI team use two patient identifiers?
   d. Question four, did each GI team confirm procedure?
   e. Question five, is the “non-OR Procedure/Time Out Note Completed?
4. Complete education via Power Point on UP and the Time Out process
5. Conduct post-education observations
6. Analyze data

**Setting and Resources**

The New Mexico Veterans Administration Health Care System (NMVAHCS) is a Level I tertiary referral center with a 24-hour Emergency Room. The NMVAHCS provides services for over 90,000 Veterans on an outpatient basis per year serving all eligible Veterans of all ages (U.S. Department of Veterans Affairs, 2014). The medical center is authorized to operate 310 beds, which include 184 acute hospital beds, 26 beds Spinal Cord Injury Center beds, and 90
Residential Rehabilitation Treatment Program beds. The facility has 12 operating rooms supported by 24 Post Anesthesia Care Unit bays (PACU), 10 Surgical Intensive Care Unit (SICU) beds, and 26 surgical ward beds. The NMVAHCS GI clinic has 10 GI procedural rooms and performs approximately 4,200 non-OR GI procedures each year.

**Study Population**

Participants in the study will be members of the GI procedural teams which will include an GI attending, GI resident, anesthesia provider, RN, GI Health Technologist, and all the staff members included in the surgical teams are employees of the acute care teaching hospital in the study and are deemed to have experience in the OR based on the hiring criteria, educational requirements, and current performance in the OR. No students will be included in the research.

**Sources of Data**

Observations of compliance to the Time Out policy will be the source of data collected for this study. The observations will be to assess engagement and compliance of the non-OR GI procedural teams to the Time Out process. Post education observations will assess the same as pre-educational assessments and an improvement is anticipated in both compliance to the Time Out and the engagement of the team.

**Data Analysis**

**Question one: Was there a silence/pause prior to the Time Out?**

There was a slight pre/post difference of 88% versus 92% in percentage of observed silence/pause prior to the Time Out, \( n=188 \). A Pearson’s Chi-squared test indicated this difference was not statistically significant, \( x^2(1, n=188) = .53, p=.47 \).
Question two: Did each team member verbally acknowledge the Time Out?

There was a major pre/post difference of 81% versus 95% in percentage of each team member verbally acknowledging the Time Out, \((n=188)\). A Pearson’s Chi-squared test indicated this difference was statistically significant, \(x^2(1, \ n=188) = 8.4, \ p=.004\).

Question three: Did each GI team use two patient identifiers?

There was a major pre/post difference of 90% versus 99% in percentage of each GI team using two patient identifiers, \((n=188)\). A Fisher’s exact test indicated this difference was statistically significant, \(x^2(1, \ n=188) = .02, \ p=.009\).

Question four: Did each GI team confirm procedure?

There was a slight pre/post difference of 98% versus 99% in percentage of each GI team member confirming procedure, \((n=188)\). A Fisher’s exact test indicated this difference was not statistically significant, \(x^2(1, \ n=188) = 1.0, \ p=.57\).

Question five: Is the non-OR Procedure/Time Out Note completed?

There was a slight pre/post difference of 94% versus 95% in percentage of observed in the non-OR Procedure/Time Out Note completed, \((n=188)\). A Pearson’s Chi-squared test indicated this difference was not statistically significant, \(x^2(1, \ n=188) = .09, \ p=.76\).

Discussion

The findings of the study reveal that there was less than optimal compliance with the use of the facility required standardized checklist during the Time Out in non-OR procedural areas. The five data points chosen for the study were representative of the critical elements in the overall Time Out process. To increase patient safety, regulatory compliance, and standardization of the facility procedure this study was conducted as a pilot to assess the success of an educational intervention.
The literature review supported the educational intervention plan as this pathway for improvement is an established concept. Creating effective teamwork and communication supports improved patient safety measures through education and the development of team awareness in areas such as impact to patient care and regulatory compliance. Improved team communication and compliance in the use of the standardized Time Out checklist was supported statistically. Overall the PICOT was found to be answered in the positive as the findings showed that engagement and compliance was improved after an educational intervention. Areas that showed the most statically significant change were that each team member engaged in verbal acknowledgement of the Time Out and the use of the two patient identifiers. The other three questions were demonstrated to have a less significant improvement but did improve. The silence or pause prior to the start of the Time Out improved slightly but needs to continue to improve as engagement and involvement of the team must include the awareness that failure to hear all of the Time Out could lead to content failures where essential information could be omitted. The very slight post educational improvement of each GI team member confirming procedure is partly due to the high compliance rate with this service prior to the study. This is an area for future assessment of why this is not 100% compliant in every procedure.

Lastly the documentation of the Time Out is an area recommended for future education as there could be more significant compliance. The Time Out note was created for the streamlined capturing of compliance data. There is a facility Time Out note for the providers however the note is used for multiple purposes or the Time Out, while documented, is in the wrong part of the patient record. Further improvement in this area would likely bring the statistical compliance with regulatory requirements into the significant range for the unit.
Limitations to the study was that the investigator did not personally complete the observations because of the possibility of the Hawthorne effect. A Hawthorne effect happens when the group is aware of the investigators presence and purpose and the observed behavior could be affected. Behavior changes due to this effect could have created a higher compliance baseline in the use of the structured written checklist and engagement of the Time Out process.

Another limitation of the study was the relatively short period of time that observations were performed post educational intervention. A short follow up observational period could have missed a tendency for the staff to revert to previous less compliant behaviors. In the future, the GI Nurse Manager will have the tools to observe her staff or appoint one of the GI staff members to monitor for continued engagement and compliance.

This researcher’s goal was to minimize bias and decrease presumptions that could alter the interpretation of the findings. A method to decrease bias is to use a neutral observer. The study was conducted using a non-biased third party as an observer to complete both pre-and post-education intervention observations.

The delivery of highly reliable, quality patient care depends on the clear and direct communication of the procedural team and is an essential part of the safety process. A standardized safety checklist is a proven safety tool that can be applied to procedural areas throughout the facility. As the documented in the literature review support communication as one of the most essential tools used by the surgical team and is significant to ensuring quality safe patient outcomes. Checklists, like any skill, require education and training for use and implementation and nursing leaders must use evidence and existing research to ensure proper and consistent use of the safety checklist. The information in this literature review discussed the target population and the effects of the utilization of a standard safety checklist on perceived effective
teamwork and improved communication compared to the use of a verbal safety checklist with comparable elements.

This project was supported enthusiastically by the facility leadership with the goal to duplicate the theorized positive findings throughout the non-OR procedural areas. When used in this manor this study will be a pilot in a series of PDSA cycles to implement system wide change in non-OR procedural areas of the facility.

**Ethics and Human Subjects Protection**

All the participants observed during the Time Out process are employees of the procedural teams in the GI unit of the NMVAHCS and deemed to have experience based on the hiring criteria, educational requirements, and current performance in the GI unit. No students were included in the research. No patient information was collected or identified for this study. No demographic data on the staff was collected for this study so no regard was made for experience level, age, gender, ethnicity, or education levels on the individuals who made up the non-OR GI procedural teams. The cases observed were identified by a number to record a tally of the quantity of procedures observed. No procedural team names were identified or recorded.

**Timeline**

Once the project was approved by the College of Nursing and the NMVAHCS IRB the study began with the observations. The target reporting period was one month for pre-intervention data collection, one month for educational intervention and one month for post-intervention data collection. The three-month period pre-and post-education intervention allowed for rich data assessment of improved engagement and compliance to the Time Out process.
**Budget**

There were no financial costs to study participants other than their time. The resources required for this project were minimal requiring educational materials for the Time Out safety as well as computer and researcher time. There were no other costs associated with this study.

**Conclusion**

The requirements to perform a Time Out prior to any invasive procedure in non-OR areas have been reportedly met with varied levels of resistance and non-compliance (Waehle et al., 2012). The value of the Time Out as a proven tool for the prevention of wrong site surgeries was not deemed relevant to the non-OR GI procedural team due to the scope of their procedures. The literature review disclosed that the limited variety of procedures does not exclude a wrong patient event. Literature revealed that events in the GI area included wrong patient, wrong laboratory specimens or pathology tissue sent for analysis, allergies not disclosed appropriately, or wrong procedure situations such as a colonoscopy patient entering an upper esophagostomy suite in error.

This study demonstrated that an educational intervention was effective in improving the compliance and full application of the Time Out process in a non-operating room environment. Improved participation was noted in two areas; each GI team member verbally acknowledged the Time Out and the GI team consistently used two-patient identifiers when identifying the patient prior to the procedure. Increasing the awareness of the team was the key to improved compliance and the verbalization of understanding of the critical nature of active involvement with the time out process (Carney, West, Neily, Mills, & Bagian, 2016). Full Time Out compliance and procedural team engagement is critical to safe patient care as well as regulatory
compliance and improvement has been demonstrated with proper education to improved staff awareness.
References


The National Quality Forum. (2012). The national quality forum (NQF) has released its updated list of serious events (SREs) to offer standards for healthcare providers in reporting on adverse events. *Healthcare Financial Management, 66*(2), 14


**Appendix A: Pre-and Post-Education Intervention table**

Table 1  
*Pre-and post-education intervention*

<table>
<thead>
<tr>
<th>Question</th>
<th>Pre-education intervention (N=94) Frequency/Percent</th>
<th>Post-education intervention (N=94) Frequency/Percent</th>
<th><em>p</em> value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question 1</strong> Was there a silence/Pause prior to Time Out?</td>
<td>83/88%</td>
<td>86/92%</td>
<td>0.47</td>
</tr>
<tr>
<td><strong>Question 2</strong> Did each team member verbally acknowledge the Time Out?</td>
<td>76/81%</td>
<td>89/95%</td>
<td>0.004</td>
</tr>
<tr>
<td><strong>Question 3</strong> Did each GI team use two patient identifiers?</td>
<td>85/90%</td>
<td>93/99%</td>
<td>0.02</td>
</tr>
<tr>
<td><strong>Question 4</strong> Did each GI team confirm procedure?</td>
<td>92/98%</td>
<td>93/99%</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Question 5</strong> Is the &quot;Non-OR Procedure/Time Out Note Completed?</td>
<td>88/94%</td>
<td>89/95%</td>
<td>0.26</td>
</tr>
</tbody>
</table>
Appendix B: Education Intervention

The Time Out Process in the GI Studies Lab

My Project Overview

- GI Studies chosen randomly
  - Multiple non-OR procedural areas in the facility
- Quality Improvement Project
  - VHA Directive 1039 Ensuring Correct Surgery and Invasive Procedures
  - AORN (Association of Operating Room Nurses) and SGNA (Society of Gastroenterology Nurses and Associates, Inc)
My Project Overview

Plan of Action
- Pre-education audit of 89 cases
- Education sessions on the ‘Time Out’
- Re-evaluation of 89 GI studies cases
- Observation tool used
  - Were two patient identifiers used?
  - Was the procedure confirmed with the GI team?
  - Was there a surgical pause/hard stop prior to the ‘Time Out’?
  - Did each team member verbally acknowledge the ‘Time Out’?
  - Was the ‘Time Out’ documented correctly?

Content

- Background
- Methodology
  - Process observation
  - Identification process
  - Time out
  - Checklist
  - Audit results
How Do Errors Happen?

How Do Errors Happen?

What happens if Time-Out process is not followed in GI?

- Two patients with similar Names - New Jersey Hospital, 2012
  - Patient A for gastroscopy, Patient B for bronchoscopy
  - Dr called for A, B responded, consented and had a gastroscopy. Bronchoscopy was rescheduled
- Wrong patient Label on Specimen - Rochester, Minnesota
  - Multiple patients labels in procedure room
  - Wrong patient label on specimen
  - Wrong diagnosis
  - Patient with cancer was returned to procedure room for biopsy
What does NMVAHCS say about Time Out?

- MCM 11-28 "Ensuring Correct Surgery and Invasive Procedures"
  - Pt must have procedure site marked OR have a special wristband
  - Time Out must be documented in the "Non-OR Procedure/Time Out Note"
  - Time Out must be incorporated in the provider procedure note
  - Time Out should occur after prepping and draping; directly prior to procedure start
  - Time Out must have the attendance and participation of the primary GI MD listed on the consent

Required Items in the Time Out

- Time out Checklist must contain:
  - Patient Identification
  - Procedure
  - Site
  - Consent confirmation
  - Position
  - Site mark/wrist band confirmation
  - Imaging confirmation, if applicable
  - All implant data, if applicable
  - Antibiotic prophylaxis, if applicable
  - DVT prophylaxis, if applicable
  - Blood Availability, if applicable
  - Special Equipment, if applicable
Areas for improvement

- The time out is for all team members
- Two identifiers for every patient (Full name, full Social Security number (patient’s date of birth may be used as an extra measure)
- Hard stops are required (Surgical Pause)
- Acknowledgment by all team members
What is Next?

- Completion of the Education presentations
- Post-Education audit
- GOAL—Improvement of engagement of the Time Out, providing a safe culture for change, increase patient safety for our Veterans

Thank You!!!

- Thank you to all team members from the GI Studies Lab for allowing me to become a part of your department and for your continued commitment to our veterans!