5-1-2023

Implementation of a Standardized Universal Protocol Process at a Large Academic Medical Center

Lisa Ann Heard
University of Massachusetts Boston, lisa.heard001@umb.edu

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Lisa Ann Heard, DNP, MSN, RN, CGRN, CPHQ, CPPS

College of Nursing and Health Science, University of Massachusetts Boston

May 1, 2023

Submitted in Partial Fulfillment of the Requirements for the Doctor of Nursing Practice Degree

Project Committee

Faculty Advisor: Eileen Stuart-Shor PhD, ANP-BC, FAHA, FAAN

Practice Site Mentor: Patrice Osgood, DNP, RN, CNOR, NE-BC

Committee Mentor: Linda Curtin PhD, RN, CCRN

Abstract

BACKGROUND: Decreasing the risk of wrong site, wrong procedure and wrong patient surgery is an essential healthcare safety initiative. The Joint Commission's Universal Protocol along with the World Health Organization (WHO) Safe Surgery Checklist were designed to aid in this patient safety effort and have been implemented in hospitals worldwide.

LOCAL PROBLEM: Perioperative and procedural areas at the project hospital areas have adopted the Universal Protocol and Safe Surgery Checklist. Despite agreement in their importance, there is a lack of uniform application of all components. This leads to variation in practice which may impact team compliance with the protocol and patient safety if critical components of the process are missed.

METHODS: A review of the literature revealed standardization of the universal protocol process as an evidence-based, promising intervention to decrease variability across perioperative and procedural areas. The overarching aim was to evaluate current practice of the universal protocol process in procedural and perioperative areas, identify gaps, and design a hospital-wide, standardized approach to universal protocol.

INTERVENTION: The intervention was executed in 3 phases. Phase 1 evaluated current universal protocol tools and practice in procedural and perioperative areas and identified gaps. Phase 2 convened a working group of nursing experts from each project area to design a standardized process consisting of critical elements for each phase of the universal protocol. Phase 3 obtained consensus agreement and approval for the hospital wide dissemination of the recommended standardized process and tool from all area stakeholders.

RESULTS: Analysis of universal protocol tools and direct observation of practice illustrated wide variation in the universal protocol process across 12 perioperative and procedural areas at the project hospital. These findings supported project approval by perioperative and procedural stakeholders for the development and implementation of the standardized universal protocol process and tool.

CONCLUSION: This project demonstrated that it is feasible to standardize universal protocol practice across 12 complex and diverse perioperative and procedural settings. The effective use of the Kotter change theory engaged essential stakeholders and provided the foundation for the acceptance and completion of the project aims.

Implementation of a Standardized Universal Protocol Process at a Large Academic Medical Center

Problem Description

Surgical safety has long been a focus of quality and safety efforts in healthcare. The Joint Commission has noted that surgeries involving wrong site, wrong intended procedure and/or wrong patient were the fourth most reviewed sentinel events in 2021 (The Joint Commission, 2022). Decreasing the risk of wrong site, wrong procedure and wrong patient surgery is essential to patient safety and to the reputation of those facilities performing the procedures.

In 2004, the Joint Commission introduced a process called the Universal Protocol, which was developed to confirm correct patient identity, correct procedure, and correct operative site (Stahel et al., 2009). The universal protocol consisted of three components, pre-procedure verification, surgical site marking and a "time out" immediately before the start of the procedure.

Concurrently with the Joint Commission initiative, the World Health Organization (WHO) brought together an international coalition of surgical experts to examine how to improve patient safety in surgery on a global scale. The "Safe Surgery Saves Lives" group convened surgeons, anesthesiologists, nurses, infectious disease experts, epidemiologists, biomedical engineers, quality and health system professionals, patients, and patient safety organizations from around the world to find strategies to improve perioperative care. Their work culminated with the publication of the WHO Guidelines for Safer Surgery 2009 (World Health Organization. Patient Safety, 2009).

Based on evidence-based standards of care, the WHO Safe Surgery Guidelines provided a structure and process to improve perioperative patient safety outcomes and reduce postoperative mortality (Haynes et al., 2009). This process encompasses safety checks of the

patient's care throughout the perioperative care continuum. The WHO Safe Surgery Checklist built upon the universal protocol through the addition of a safety checklist component embedded into three expanded process steps: sign in (briefing), time out and sign out (debriefing).

Implementation of checklists in healthcare settings arose from the aviation industry. The use of cockpit checklists to map critical process steps eliminated the reliance on memory during emergency situations. The aviation industry's use of checklists and their adoption of a culture of safety has led to important safety improvements in their industry. Aviation crew members participate in rigorous training and drills of emergency scenarios and recognize the necessity of the checklists (Hirche & Kneser, 2019). Drawing on this experience of the aviation industry, the WHO Safe Surgery Saves Lives group developed a tailored Safe Surgery Checklist to help teams remember critical steps for safe surgery and decrease the dependance on memory. The checklist exists as a component of the universal protocol and calls on the team to pause and review all elements of the checklist prior to initiating a procedure or progressing to the next step in the procedure. The use of the universal protocol and the Safe Surgery Checklist has been shown to improve patient safety. The seminal work in this area is a multicenter, international study that found that the use of the checklist significantly deceased mortality and complications among surgical patients 16 years of age and older (Haynes et al., 2009).

Local Problem

The universal protocol and WHO Safe Surgery Checklist have been widely implemented in hospitals all over the world. Policies and procedures guiding their use have been written and adapted for facilities and, in some cases, for each department within a hospital. At the project hospital all procedural and surgical areas have adopted the universal protocol into their practice. Although there is agreement about the importance of the universal protocol, there is a lack of

uniform application of all its components. Despite a hospital wide policy instructing clinicians in the appropriate use and steps of the protocol, each perioperative and procedural area has tailored the universal protocol to meet the needs of their environment. This has led to variation in practice across the perioperative and procedural settings. This variation causes challenges with team buy in, compliance with the protocol and, ultimately, may impact patient safety if the critical components of the process are not performed.

As noted earlier, evidence supports the use of a standardized approach to the steps in the universal protocol as a contributor to improved patient safety (Rafiei et al., 2016). Despite this supportive evidence in the literature, there is still variability in approaches to the universal protocol process. This is true in the project hospital as some areas do not consistently perform all components of the process. For example, some areas may not perform a briefing or huddle in advance of the procedure, others do not complete a full debriefing before the patient leaves the procedure room. These varied practices occur for many reasons including, specialty practice needs, lack of alignment between checklists and the electronic medical record documentation, production pressure, time constraints or simply the lack of space in the practice area.

Available knowledge

A PRISMA guided systematic review of the literature search using CINHAL and Medline was undertaken to examine the most effective strategies to improve compliance with all components of the universal protocol process across perioperative and procedural areas. The search was refined to include peer reviewed publications from 2009 – 2021. This yielded 38 relevant articles. The settings of these projects included operating rooms, interventional radiology, and endoscopy departments.

Within the overall search, it was discovered that the majority of evidence compiled in this focus area emanated from the quality improvement literature. The search did not uncover many

studies which empirically tested the effectiveness of an intervention. An overview of the relevant articles and their interventions used to improve compliance of teams using universal protocol in perioperative and procedural areas is contained in the Evidence Synthesis /Summary Table (Appendix A). The evidence to support improvement in compliance of the use of the universal protocol process categorized into the following thematic areas: universal protocol process standardization, customization by specialty area, improved shared mental model, novel monitoring approaches, team education and role designation/clarity.

Evidence to support the impact of standardization of the universal protocol process as an intervention to improve patient safety was reported in five papers. Haynes et al., described the results of multicenter, international study of the implementation of a standardized surgical checklist. This seminal study's results revealed a statistically significant decrease in mortality and complications from surgery after implementation of the process. This study launched the implementation of the universal protocol with the surgical safety checklist in hospitals world-wide. Several quality improvement projects tested the use of a standardized universal protocol process with resulting improvements in teamwork, safety culture and compliance.

The second theme, which focused on customization of the time out and specifically, the surgical safety checklist, was shown to be effective in four improvement projects. Allowing specialty areas such as interventional radiology and endoscopy to tailor questions pertinent to their particular practice area improved the team's buy in and engagement in the use of the tool (Boyum et al., 2020; Matharoo et al., 2014).

Creating a shared mental model using audio or visual prompts was a theme found in the literature that brought teams together to complete the universal protocol process in an organized and consistent manner. One study compared the use of an audio prompt to aid the team in compliance with the surgical time out and checklist completion verses the standard practice of a

team member reading the time out checklist to the team. Findings revealed that there was an increase in communication of all surgical checklist information with active participation of the team when prompts were used as compared to standard practice (Reed et al., 2016).

Other methods for that were found to be successful in creating a shared mental model in the universal protocol approach were described in the literature. Two quality improvement projects identified success with the use of visual and audio cues to signify the start of the process. One initiative used the intervention of a team member holding up a yellow card to signify the start of the time out while another used the auditory stimulus of a Tibetan gong to alert the team to pause and participate in the process (Raphael et al., 2019; Brenckle et al., 2020). Both projects described resulting improvements in team engagement and compliance with the process.

Novel monitoring to improve compliance and use of the universal protocol was described as an approach in two quality improvement initiatives. Remote audiovisual observation as an intervention revealed that teams completed all elements of the universal protocol processes more consistently when they believed they may be randomly observed and audited (Dobbie et al., 2019). Additionally, a quality improvement project testing the intervention of remote video auditing of the surgical time out process found significantly higher compliance and team engagement when remote observations were used (Raphael et al., 2019).

After consideration of these interventions, the most promising strategy that aligned with the current needs of our institution is standardization of the universal protocol process. This strategy will involve the design and development of a standardized process to assure there is consistent practice and aid in provider's comfort when they move between practice areas. This project therefore focused on the implementation of a standardized universal protocol process

across all perioperative and procedural areas in the project hospital. The SQUIRE 2.0 Guidelines were used for the development of this project proposal (Ogrinc et al., 2016).

Rationale

No specific guiding framework or theory to guide the systematic examination of an organization wide practice emerged from the evidence reviewed however the elements described in these studies fits well with the Donabedian model for quality improvement. Donabedian's model includes three areas, structure, process, and outcome. In relation to structure, the proposed project structure encompasses the setting where care is delivered; this includes several procedural and surgical intervention areas across the hospital. These areas include endoscopy, interventional radiology, cardiac catheterization lab, electrophysiology lab, interventional pulmonology, two ambulatory surgery centers and the project hospital's main operating room. Process comprises the delivery of the intervention by providers and outcomes incorporate the effects of the intervention or strategy on the status of patients or populations (Ayanian & Markel, 1990). The desired outcome for this work is safe procedural and surgical patient care.

Implementation of the change project was guided by the Kotter's change model. The model has eight steps including: creating a sense of urgency, forming a guiding coalition, creating a vision, communicating the vision, empowering others to act on the vision, creating quick wins, building on the change, and institutionalizing the change (Kotter, 1998, p.7). Although this model is more commonly used for the business industry, this framework aligns well with gaining consensus across a large healthcare institution with competing demands and needs. The Kotter model recognizes the necessity of gaining support and seeking input from key stakeholders and teams involved in the processes. The intent of using this model was to engage teams in the change and ensure a successful and sustainable implementation (Kotter, 1998).

Specific Aims

The purpose of this improvement project was to ensure patient safety during surgery and procedures across procedural and perioperative settings in a large academic medical center. The overarching aim was to develop, implement and evaluate a standardized approach to universal protocol. The objectives of this project included the following:

- To gain consensus for the project from stakeholders across the perioperative and procedural areas
- To identify gaps in the current universal protocol practice
- To design a standardized universal protocol process that includes agreed upon key elements across all perioperative and procedural areas at the project hospital
- To gain stakeholder consensus for the designed standardized process use throughout the project hospital
- To implement the standardized process into one pilot area and measure pre and postimplementation compliance with all components of the Universal Protocol

Methods

This project was conducted using W. Edward Deming's PDSA Model for Improvement. The PDSA Model has been widely applied to quality improvement programs to analyze change. The PDSA cycle consists of the elements: Plan, Do, Study and Act. The "Plan" component is the body of work where the problem that needs change is identified, and proposed change is developed. The "Do" component refers to the proposed implementation of the change. The "Study" part of the cycle encompasses analysis of the data collected. Finally, the "Act" portion provides the guidance on the implementation's sustainability. In the Act part of the cycle, changes to the intervention may be undertaken and re-tested for increased improvement. The

PDSA model aligns well with this project as the within a large complex hospital, the smaller phased changes are more likely to result in desired outcomes (Donnelly & Kirk, 2015).

Although the initial design of the project included a pilot of the newly designed universal protocol process, the 12-week implementation timeline for this project was not adequate to hold 3 focus groups, complete evaluations of all the area tools, and allow for 3 observations of each phase in the 12 project areas. This resulted in a midterm correction, and it was decided that this PDSA would stop with the standardized process development and approval. For next steps, a future project to implement the standardized process will be in undertaken.

Context

The project hospital is a large academic medical center located in Boston Massachusetts with 1019 licensed beds and over 29,000 employees. As a founding member of the largest health care system in the state, the project hospital performs over 45,000 surgical cases per year (FY21 at a Glance, 2021). Central to this large volume of surgery is the patient. The microsystem of care for the patient in the perioperative or procedural area is displayed in Appendix B.

Procedural and perioperative areas are complex environments that require interprofessional teams to work collaboratively to deliver safe outcomes. The project hospital has a strong safety culture evidenced by robust safety reporting for both errors and near misses. All safety reports are treated in the spirit of learning from the event in a just culture of no blame. Quality leaders at the department level work in teams that include nursing, administrative and medical partnerships. This infrastructure aligns well with the hospital's culture of continuous improvement. Process and quality improvement efforts are supported by hospital department local leaders as well as hospital wide by senior leadership.

Patients undergo surgical and invasive procedures in complex specialty areas. Team members in each of these areas follow the hospital-wide universal protocol policy to assure

safety for each patient who arrives for their surgical or procedural care. As mentioned previously, different specialty areas have unique needs for patient care readiness. This has led to customization of the policy's requirements to fit the individual practice areas. The variations in approach to universal protocol may be related to several contributing factors.

A Fishbone Cause and Effect Diagram (Appendix C) was developed to assess the factors that influence the varied approaches to the universal protocol process across the institution. There were myriad causes for the variation in universal protocol practices identified in the analysis including diverse practice settings, the procedure or surgery type, the physical location and space constraints, overall team culture and lack of department-based champions. Additional factors associated with inconsistent use of universal protocol is the need for education about the importance of each step in the protocol in the reduction of patient harm. Despite a widespread application of the universal protocol at the project hospital, each area has developed their own individual approach to the process. The multiple factors that lead to this variation will be discussed in the work to develop the standardized approach to the universal protocol as the key components that create the safest procedural and surgical environments for patients are defined.

Traditionally, there is a hierarchical culture in surgical and procedural areas with the surgeon or proceduralist poised as the "captain of the ship." Historically, this structure often created barriers to the team's comfort with addressing concerns. Improving the culture of safety within teams, regardless of rank, is necessary to creating a safe space where all members of the care team feel empowered to speak. Every team member, no matter their role, is involved in identification and verification of the procedure and patient, steps essential to a safe outcome. For the team to feel empowered to speak up, there must be a flattening of the hierarchical structure to a more democratic culture in these areas. This may be achieved by involving all members of the team in the change and engaging the more senior, higher ranking team members as champions

for the change. There is keen interest at the project hospital to implement a standardized process as a means to improve patient safety by empowering team members to speak up. There is a commitment on the part of senior leaders in nursing and medicine to support and foster an environment of psychological safety in teams. The project has been accepted and endorsed by the hospital leaders as it provides a process for all team members to follow which, ideally, will lead to greater team engagement.

An example of a component of the universal protocol process that improves team member empowerment is the introductions of the team at the time out, immediately before the procedure. Standardizing the process and including introductions into all area time out processes increases the team's familiarity with each other. When team members know one another, they may feel introductions are superfluous however, if one person does not know another team member's name, he or she may be less likely to speak up to that person if there is an issue. The use of introductions is purposeful as it helps ensure the team knows each other's name and role. This contributes to creating a safety culture by easing team member's reluctance to speak about issues during the surgery or procedure by helping them to feel included in the team and empowered. (Rydenfält et al., 2013).

Understanding the contextual factors within an organization that facilitate or block change is important to the success of any improvement project. A force field analysis was created (Appendix D) to better understand the driving and restraining forces that may impact the successful implementation of this change. Patient safety is the predominant driving force for change at the project hospital. Achieving zero patient harm, where patients do not experience injury through procedural or surgical complication, aligns with the project aims. The consistency of a standardized approach to the universal protocol will improve safety through putting a clearly defined process used and understood across all areas of the hospital into practice. Another force

for this change is compliance to regulators such as The Joint Commission. The Joint Commission's 2023 National Patient Safety Goals identify the prevention of mistakes in surgery as a focused area. The goal, comprised of three components addresses prevention of wrong site, wrong procedure or wrong patient events and emphasizes the use of the surgical team pause, or "time out" before the surgery to assure no mistakes are made (The Joint Commission, 2023). The universal protocol, when performed correctly, mitigates the risk of making these errors.

Another motivating factor for the success of this project is mitigating potential risk for litigation from errors in surgery or procedures. Errors and sentinel events carry the weight of patient harm as well as financial risk for hospitals. Sentinel events are deemed "never events" and must be a focus of patient safety efforts. All efforts to prevent these harms and avoid these risks must be made. To that end, there is leadership support to enact a more defined, hospital wide initiative that will assure all health teams are completing the universal protocol in the safest manner for all patients. Finally, improving the safety culture of teams in surgical and procedural areas is another driving force for this change. It is a hope that convening groups, utilizing open communication, and collaborating to work on this project will aid in the team's ownership of the process, assist in their willingness to speak up for safety, and allow full participation in this process.

A force that may be a barrier to this initiative is the general feeling by the operating room and procedural team members that there is nothing that needs to be fixed. As compliance with universal protocol is high across the institution, there is a sense of complacency within the departments and their leadership. Teams feel the universal protocol is being performed well as evidenced by the fact that errors are not occurring. Education about the importance of following a standard process for patient safety and remaining vigilant are key to increasing their buy-in for the initiative.

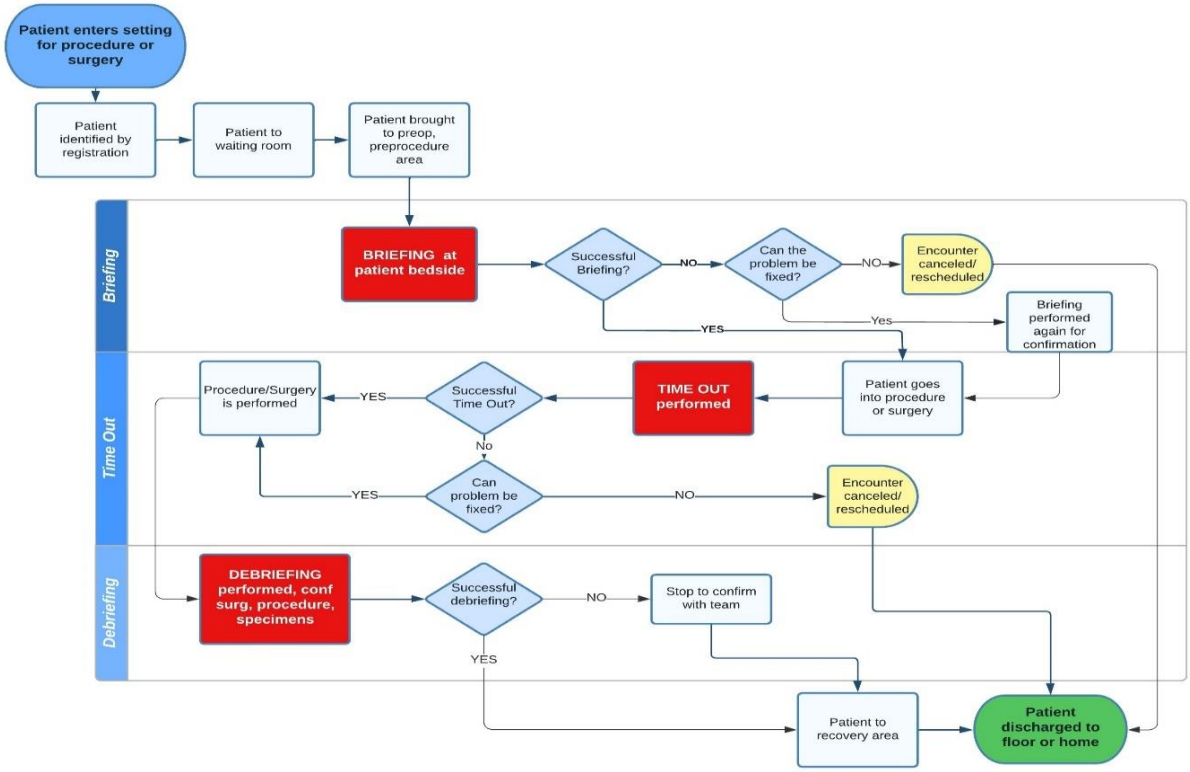
Intervention

Description of the Universal Protocol

To best understand the intended intervention for this project, it is important to first have a general understanding of what the universal protocol entails. The universal protocol process consists of three distinct phases: briefing, time out and debriefing depicted in figure 1.

Figure 1

Universal Protocol Process Flow



Each phase of the universal protocol has essential elements to ensure the safe delivery of care and reduce the risk of wrong site, wrong procedure, and wrong site procedures and/or surgery. These elements exist in the World Health Organization Surgical Safety Checklist (World Health Organization, 2009). This checklist consists of nineteen items all of which are considered vital to safety including verification of patient, procedure, and site (Appendix E).

When the patient arrives to the hospital, the first point of confirmation is with the registration staff. The patient is asked for two patient identifiers, usually full name and date of birth, and a band with the two identifiers along with their hospital identification number is placed on the patient. Should a breech in the patient identification process occur at this point, the risk of an error becomes a real possibility.

The patient is then seen in the preprocedural or holding room area and the universal protocol process begins. The components of the briefing are performed with the care team and the patient should be actively involved in this process whenever possible. If there are any discrepancies in the briefing, the process is stopped, and the problem is discussed and rectified. If there is no resolution, the procedure is postponed or canceled until there is clarity in the communication and a resolution. If the issue is resolved, the next component or the protocol is completed.

The "Time Out" consisting of confirmation and verification of all items on the safety checklist, is completed immediately before the skin incision or procedure start. As with the briefing, any discrepancy must be addressed and resolved before the intervention can commence.

Finally, after the completion of the procedure or surgery, and before the patient leaves the room, the team performs the debriefing. The debriefing is a final check to confirm the procedure or surgery performed, reconcile all pathology specimens obtained, confirm completion and correctness of instrument and sponge counts (when applicable), and identify any specific needs of the patient for the recovery phase. If there are any discrepancies in the information obtained, the team must stop and resolve the issue before moving to the next phase of care. Once resolved or if the debriefing has no discrepancies, the patient is brought to the hospital recovery area.

Should there be discrepancies in the any phase of the universal protocol, the process is stopped until resolution is found or, if unable to clarify or solve the issues, the patient's

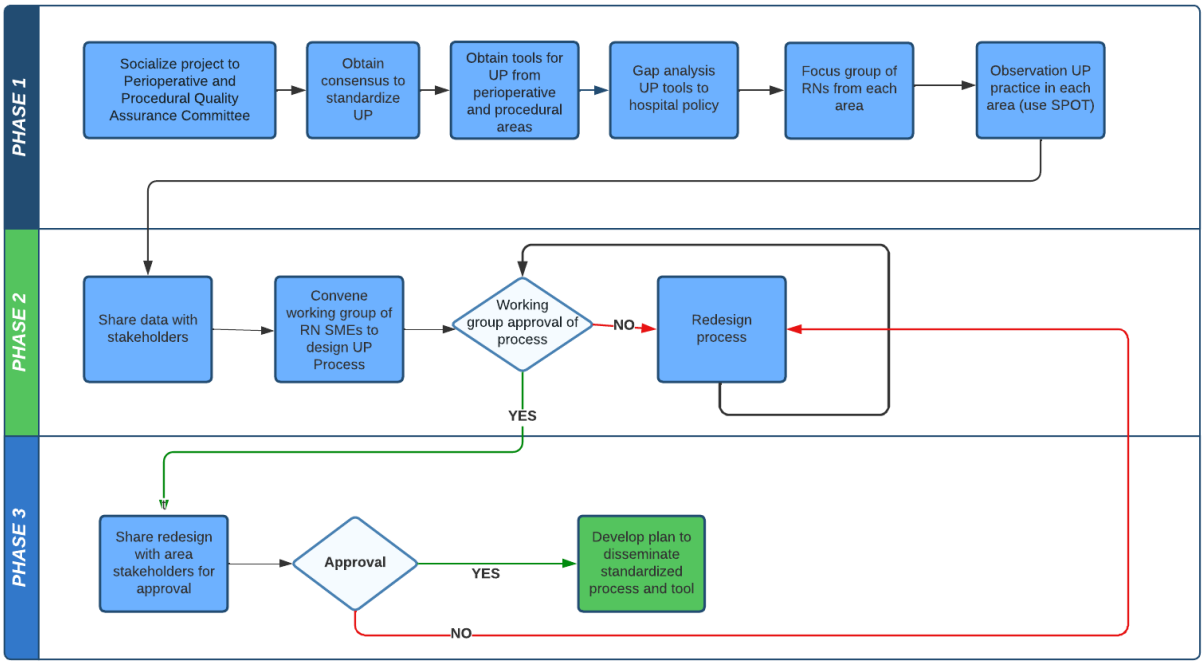
procedure or surgical is put on hold or canceled. This “stop the line” format is intended to ensure the safety of the patient and team by bringing to light any confounding issues that could lead to wrong procedure, wrong site, or wrong patient errors from occurring.

Description of Implementation of the Intervention

Due to the complexity of the project facility, the historical hierarchy of roles and the competing priorities across the diverse settings, predetermination of a standardized approach to the project was not possible. Instead, a phased approach was undertaken using evaluation of current practice, determination of common critical components of the universal protocol and, finally, the design of a standardized universal protocol approach that met the needs of all project areas. The project intervention process flow map is shown in Figure 2.

Figure 2

Intervention Process Flow Map



In Phase 1, an evaluation of the current practice of the universal protocol in the procedural and perioperative areas were performed and gaps were identified. This was achieved

through direct observations of the process and review of tools used to guide the practice for each setting. Focus groups with frontline nurses from each area were held to gain qualitative information about the use of the universal protocol in their setting. Phase 2 consisted of subject atter experts from all the perioperative and procedural areas at the project hospital collaborating on the development of a standardized universal protocol process that could work across the varied settings hospital wide. The new process outlined all the critical components required for each phase and created a standardized tool for use by teams in each of the project areas. In Phase 3, the draft of the standardized universal protocol and tool was socialized to stakeholders (surgeons, proceduralists, anesthesiology, and nursing) in all perioperative and procedural areas. Feedback was solicited and changes were made based on expert input. Finally, consensus approval of the standardized process and critical elements from was obtained from all stakeholders. The working group of subject matter experts played a pivotal role in the presentations with the project lead at perioperative and procedural quality and leadership committee meetings.

The initial plan for the project included a pilot of the newly designed process in one procedural or perioperative area with remeasurement of the universal protocol overall compliance in that area. Due to the timing for the project, a midterm correction was made, and it was decided that this PDSA would stop with the standardized process development and approval.

Using the PDSA framework, Phase 1 correlates with the planning phase of the PDSA framework. Phase 2 correlates with the “do” phase of the change cycle and Phase 3 correlates with the “study and act” phases of the change cycle.

To improve the way the universal protocol is implemented across the operative and procedural areas at the project hospital, this project evaluated current practice, convened subject matter experts, and designed a standardized universal protocol process and tool. This

standardization of the critical components of the universal protocol assures the same safe practice irrespective of the location and setting of care.

Phase I

The first step of phase 1 of this project was gain consensus for standardization of the process across the project hospital. Presentations at the Procedural and Perioperative Quality Committee meetings were used to socialize the project and field questions from the committee. Following the socialization, outreach to key stakeholders from each area was made with the intention of alleviating concerns and scheduling an on-site visit to observe their area's universal protocol practice. To implement successful change in the project environments, surgeons, proceduralists, anesthesiologists, nurses, technicians, and trainees must feel the need for, and value of, the change. Using the Kotter Change Theory to guide this improvement project, the first step was to create a sense of urgency to motive the team to change. This urgency was conveyed through these discussions with stakeholders and sharing of data from document reviews, observational audits, and focus groups. The urgency focused on the driving force for this change, to prevent wrong site, wrong procedure and wrong patient procedures and surgery. This step formed a coalition of appropriate stakeholders and thought leaders to promote and contribute to this change.

The next step was to assess for gaps in the way the universal protocol was implemented across the operative and procedural areas. This step consisted of a review of each area's universal protocol tools used to guide their individual practice and observational audits of the team's performance of the universal protocol process in each area. The universal protocol tools and checklists used by each procedural and operating room area throughout the hospital were collected by the project leader from each area's Nurse Director. The tools were assessed to determine: 1) if they aligned with the hospital wide universal protocol policy and, 2) if the

essential components of the World Health Organizations Safe Surgery Checklist and universal protocols were included.

The project lead then performed direct observations of teams performing the universal protocol in the procedural and surgical areas throughout the hospital. The observations were guided by the use of the Surgical Patient Observation Tool (SPOT) (Heideveld-Chevalking et al., 2018). This validated tool includes the patient pathway from admission to the hospital, through the surgical intervention, and finally, to the inpatient unit. For the purposes of this improvement project, the SPOT was modified for observation of procedural and surgery briefing, time out, and debriefing phases only. The use of the modified SPOT (Appendix F) allowed for auditing the universal protocol performance in clinical practice and provided a quantitative analysis of practice. The specific use of the tool was to a) determine which phases of the universal protocol teams were performed in each area, and b) to inform the stakeholder group of the critical components for each phase of the universal protocol that should be considered in the newly designed standardized process.

A focus group of procedural and perioperative staff was convened to learn about relevant barriers and the feasibility of using a standardized approach to universal protocol in their specific practice area. This step included both qualitative and quantitative information obtained from one nurse from each department prior to the design and development of the standardized universal protocol process.

Practice gaps determined from focus group interviews, area tool reviews, and direct observations, where shared with the stakeholders at the project hospital's Procedural Services Quality Committee and the Perioperative Quality Assurance Committee meetings. These committees share and review perioperative and procedural area data monthly and have established a culture of mutual respect and psychological safety. This transparency allows the

committees to disclose strengths and opportunities openly without defensiveness or fear of blame. The Procedural and Perioperative Quality committees were instrumental in this project providing support for the development of the protocol and for their feedback in the revisions of the standardized approach. The committee participation provided the assurance that the needs of each practice area was met. The standardized process with a tool containing the key components of each phase of the universal protocol, was approved by consensus from the committee as well as frontline team members. Ultimately the new process and tool will be disseminated to each practice area and will provide all patients with a safe procedural or surgical experience by assuring that all critical safety checks are completed for every patient across the institution.

Phase 2

A working group of nursing subject matter experts from each perioperative and procedural site was convened to review each phase of the universal protocol. The universal protocol working group met ten times over a period of twelve weeks and utilized their expertise as well as the Joint Commission standards, WHO Safe Surgery Checklist and the project hospital policy to develop the standardized process and tool. The qualitative and quantitative data obtained from the aforementioned project steps was shared with the group and was also utilized in the development of the standardized universal protocol.

The standardized universal protocol process included the following components for the briefing, time out, and debriefing phase (a) language to initiate the process; (b) who, where and when the phase occurred; (c) a standardized checklist (tool) containing the critical elements to be addressed in each phase. The working group meetings provided a space for their feedback, participation, and to achieve consensus on the appropriateness and feasibility for the standardized universal protocol process in all their respective settings. Each meeting included a vote for consensus approval on work completed. When initial consensus could not be reached,

the group had discussions and considered all members perspectives to achieve group agreement. This work culminated in a draft of the standardized universal protocol and tool to be utilized to guide the team in each phase of the newly designed process. This tool was socialized with leaders and stakeholders in the perioperative and procedural areas and will be used for dissemination for future stages of this work.

Phase 3

After completing the draft standardized process and tool, the work was shared with the stakeholder group for review and discussion. Presentations for stakeholders were made by the project lead with three nurses from the project working group. The project presentation at the Perioperative Quality Committee meeting was successful. The committee reviewed and approved the tool to move forward into an implementation pilot. The Procedural Quality Committee presentation also resulted in the approval of the standardized process tool. There was committee consensus to move forward with the implementation of the project.

Although the initial design of the project included a pilot of the newly designed universal protocol process, the 12-week implementation timeline for this project was not adequate to hold 3 focus groups, complete evaluations of all the area tools, and allow for 3 observations of each phase in the 12 project areas. This resulted in a midterm correction, and it was decided that this PDSA would stop with the standardized process development and approval. For next steps, a future project to implement the standardized process and tool will be in undertaken.

Measures and Analysis

The measurement and analysis for this intervention focused on the following project objectives:

- To gain consensus for the project from stakeholders across the perioperative and procedural areas

- To identify gaps in the current universal protocol practice
- To design a standardized universal protocol process that includes agreed upon key elements across all perioperative and procedural areas at the project hospital
- To gain stakeholder consensus for the designed standardized process

The evaluation of this project was measured in several ways as illustrated in Table 1.

Objective 1: *Gain consensus for the project from stakeholders across the perioperative/procedural specialty areas.* Consensus and buy in from key stakeholders were necessary for this project's success. Evidence of consensus from the stakeholders to move forward with this project was abstracted from meeting minutes, by results of a 100% approval vote. The minutes were examined to assure all stakeholders were present and all areas were represented. A survey of both quantitative results and qualitative themes which emerged from the focus groups was used to ascertain the group's feedback was captured (Appendix G).

Table 1
Process Measures

Aim/Objective	How Measured
Gain consensus for project	Convene stakeholders from each perioperative and procedural area.
Complete gap analysis of tools and practice	Use of validated Observation tool (SPOT)
	Review of departmental UP tools
	Focus group feedback from nurses from each perioperative and procedural area.
Design and develop standardized UP process approach	Development of a standardized process approach consisting of key elements of each UP phase that has stakeholder input, consensus, and approval
Gain stakeholder consensus for the designed standardized process	Hold meeting of the stakeholders for final review. Consensus will be measured by an approval vote from 100% of the group members

Objective 2: *Identify gaps in the current universal protocol practice.* A gap analysis of the universal protocol tools used in each area and practice observations was undertaken. Attainment of this objective was measured by direct observation and document review. The SPOT tool, adapted to the context of this project, was utilized for the in-person

observations of the universal protocol process in each area. SPOT is a validated tool developed and tested in a multicenter observational pilot study by a researcher in the Netherlands (Heideveld-Chevalking et al., 2018). The SPOT is divided into three sections (briefing, time out, debriefing) with five to fifteen observed behaviors for each section. Behaviors are rated as accomplished or not (met/unmet). Means for frequency and proportion of each behavior as well as a total score by section was calculated. The failure to complete a process step specifically, the briefing, time out or debriefing, was considered a gap. The threshold for success in this process is meeting all key elements defined in the SPOT 100% of the time. The expectation of 100% compliance was used as the both the Procedural and Perioperative Quality Committees are committed to creating a culture of zero harm. In the spirit of transparency, these data were shared with each individual area and by aggregate to the committees.

A quantitative and qualitative review of existing tools from each procedural and perioperative area was completed. As a quantitative means to measure documentation, the site-specific tool was examined to determine if each universal protocol element for the project site policy was included. All elements in the hospital wide universal protocol policy had to be present in the tool to be considered "included." Each element was scored "yes" for included and "no" for not included (Appendix H). Frequencies and proportions were calculated and aggregated to describe attainment of the goal. Qualitative data was gathered from focus group comments about the use of their area's tools. These data, quantitative and qualitative, were shared with the area stakeholders.

Objective 3: *Design a standardized universal protocol process that includes key elements across all perioperative and procedural areas at the project hospital*. This was accomplished by sharing qualitative and quantitative results with stakeholders and convening a working group to collaborate on the development of the standardized approach for each phase of

the universal protocol. The group was asked to identify the components from the WHO Safe Surgery Checklist and the Joint Commission universal protocol that are essential for their areas and represent the key patient safety steps (e.g., identification of the patient, verification of laterality, etc.). The newly designed standardized approach was mapped to the briefing, time out and debriefing steps to assure all integral parts of the process were included. The newly designed standardized approach emerged from this work and evidence of attainment of this objective will be drawn from the finished product, a drafted standardized universal protocol tool.

Objective 4: *To gain stakeholder consensus for the designed standardized process and tool.* The standardized universal protocol process and tool designed by the stakeholders was presented at a meeting of the stakeholders for a final review. All attendees had the opportunity to discuss concerns before finalizing the process. Area stakeholders were reassured that the newly designed approach contains minimal required elements for each universal protocol phase and that additional elements may be added based on their individual area needs but no elements could be removed from the standardized list. Consensus was measured by an approval vote of 100% from the group members.

Ethical considerations

This project was endorsed by the nursing and medical leaders of the Department of Perioperative and Procedural services at the project hospital. The Clinical Quality Improvement Measurement Checklist, developed by the healthcare system in which the project hospital is a member, was used to determine need for IRB review. Based on the results of this checklist, the initiative was deemed a Quality Improvement project and therefore did not require IRB review at the project hospital.

The focus of this intervention was solely process improvement and not human subjects review. The potential ethical concerns of implementing this project were considered. The project

did not pose ethical risk for patients or staff and no conflicts of interest were identified. The results of this project did not impact employee performance appraisals in any manner.

Individuals participating in the project had no performance expectations linked to this work nor were there consequences to them for their participation. The University of Massachusetts Boston Clinical Quality Checklist (Appendix I) was completed for this project and led to the determination that this work was deemed a quality improvement project. As such, the project hospital did not require an IRB Review. The University of Boston Massachusetts recognized that this project is an improvement initiative and did not meet the definition of human subjects research because it was not designed to generate generalizable findings but rather to provide immediate and continuous improvement feedback in the local setting in which the project was carried out. The University of Massachusetts Boston IRB has determined that quality improvement projects do not need to be reviewed by the IRB.

Results

Consensus for the Project

The first project aim was to gain consensus agreement from hospital perioperative and procedural stakeholders to commence with the project. The problem and aims, along with the proposed project intervention, was presented to the Procedural Quality Assurance Committee at their monthly meeting with representation from area stakeholders present. The committee gave their approval to move forward with the project and a project charter was created.

Gap Analysis of Tools and Practice

The second project aim was to complete a gap analysis of tools and practice utilization of the universal protocol across the project hospital. This was accomplished through evaluation of the tools used and observations of current practice of the universal protocol in the procedural and

perioperative areas. Focus groups consisting of one front line nurse from each project area were held and both qualitative and quantitative information were obtained.

Evaluation of Universal Protocol Tools Used Across Project Facility

Each area that utilized a universal protocol tool provided a copy of their tool to the project lead. The tools were evaluated based on their alignment with the hospital-wide universal protocol policy. Of the 12 areas included in this project, seven (58%) utilized physical tools to guide their universal protocol practice. These physical tools consisted of either a paper form, laminated card, or wall poster. The results of the gap analysis revealed variation in the contents of each tool as outlined in Table 2 and described in the paragraphs below.

Table 2

Results from gap analysis of policy elements contained in universal protocol tools (n=7 areas)

	Proportion of areas (n=7) that include this phase in their written tool n/%	**Number of required policy elements for each phase**	**Proportion of required policy elements contained in area UP tools n/% range**
Briefing Tool	3/43%	12	22 of 36 possible elements /61% (range 38-69%)
Time Out Tool	7/100%	8	41of 56 possible elements/ 73% (range 50-100%)
Debriefing Tool	5/71%	1	5 of 5 possible elements/ 100%

For the briefing phase, of the seven areas with physical tools, three (43%) used their tools to guide the briefing phase. The hospital policy required completion of 12 elements in the briefing phase. Review of the three tools revealed that of the 36 possible elements required by the hospital policy, only 22 (61%) appeared in the tools (n = 12 total required elements for each tool).

For the Time Out phase, all seven areas using tools (100%) included the time out phase as a component to guide their practice. The hospital policy required completion of 8 elements in the time out phase. Review of the seven tools revealed that of a possible 56 elements required by the hospital policy, 41 (73%) appeared in the physical tool (n = 8 total required elements for each tool). Two area tools contained 100% of the time out phase required policy elements while the remaining tools contained a range of 50 – 75% of the required elements.

For the debriefing phase, five (71%) of the seven areas using tools included debriefing to guide their practice. The hospital wide policy identified only one required element for the debriefing phase, confirmation of specimen reconciliation. Review of the five tools revealed that out of a possible five elements required by the hospital policy, all 5 (100%) appeared in the physical tool (n = 1 total required element for each tool). Of note, the two areas that did not include this phase on their tool do not routinely collect specimens for their procedures.

Universal Protocol Observations

In addition to the gap analysis of paper tools, direct observations of practice using the SPOT tool were completed in all procedural and perioperative areas identified in this project. Observations were done in areas that stated they performed the phase being observed. Aggregate results of observations of each phase of the universal protocol process were obtained (Table 3).

Table 3

Frequency and Percentage of Universal Protocol critical elements observed in each phase

	# of O**bservations* ***done for each phase	***# SPOT elements for each phase***	***Total possible elements that could be observed***	***Proportion of elements observed in each phase n/%***
Briefing observations (5 areas)	*13*	*21*	*273*	*139/51% (range 12-87%.)*
Time Out observations (12 areas)	*32*	*20*	*640*	*518/81% (range 50-100%)*
Debriefing observations (5 areas)	*9*	*11*	*99*	*54/56% (range 10-81%)*

Total possible elements: # of SPOT elements × # of Observations
Result is the actual # number of elements observed ÷ total possible elements

Of the 12 project areas, five areas (42%) performed formal (explicit) briefings. Of these five areas, a total of 13 observations of the briefing phase revealed that of the possible 273 aggregated elements in the SPOT, 139 were observed resulting in 51% completion of the critical elements (range 12-87%).

All 12 of the project areas (100%) performed a time out prior to the start of the procedure or surgery. Of these 12 areas, a total of 32 observations of the time out phase revealed that of the possible 640 aggregated elements in the SPOT, 518 were observed resulting in 81% completion of the critical elements (range 50-100%).

Five of the 12 project areas (42%) performed formal debriefings. A total of 9 observations in these 5 areas revealed that of the possible 99 aggregated elements in the SPOT, 54 elements were observed resulting in 55% completion of the critical elements (range 10 – 81%).

Focus Groups

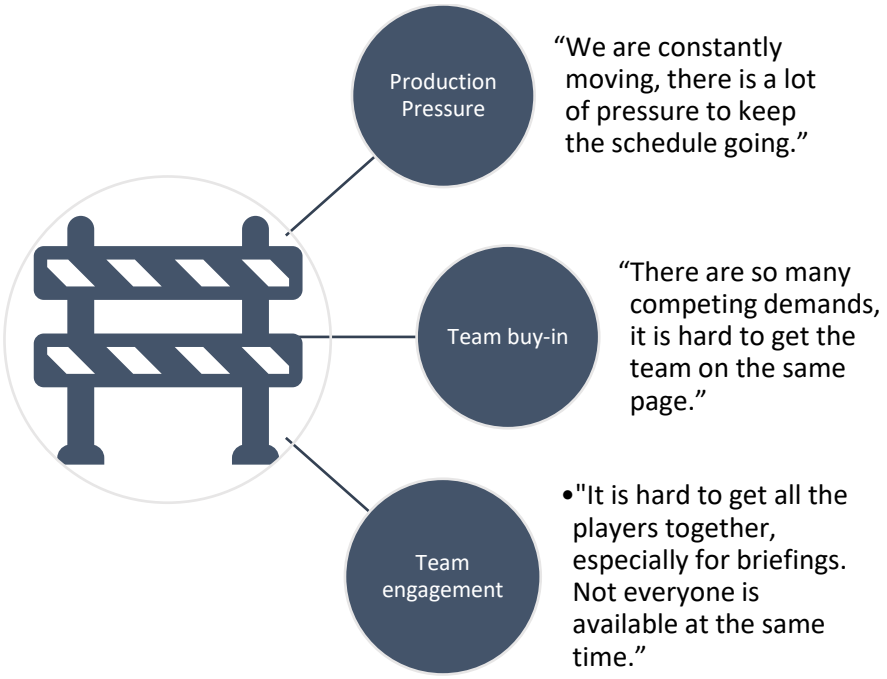
Three focus groups were held to complete the gap analysis of universal protocol practice. A total of 12 nurses participated in the focus groups. Each of the three focus group meetings had four nurses, one from each project area. This allowed each nurse the opportunity to describe their practice and voice their thoughts on the universal protocol process in their area. Quantitative assessment was achieved through completion of polling questions during the one-hour focus group meeting. Results revealed that all the focus group nurses felt the universal protocol process was essential for safety of the patent and the team. The nurses unanimously agreed that 76-100% of anesthesia providers highly value the universal protocol process, however, one quarter of the nurses felt that less than 75% of the surgeons and proceduralists highly value the universal protocol. In response to the question, "*how often are all the universal protocol components completed in your area"*, 67% felt they were always completed, 17 % said they were often completed, 8% felt they were sometimes completed and the remaining 8% felt they were rarely completed. This further illustrates the variation in practice as perceived by front line nurses.

Qualitative responses to focus group questions were also extracted from the meetings. Discussions were held about perceived barriers for completing each phase of the universal protocol. Figure 3 displays themes of the focus group participant responses. Themes that emerged as barriers were:

- production pressure;
- engagement of the team;
- accountability for initiating process;
- bringing the team together at the same time.

Figure 3

Themes expressed by focus group participants as barriers to completing the universal protocol



Design and Develop a Standardized Universal Protocol Process Approach

Aim 3 focused on designing and developing a standardized universal process approach. To assure that the standardized process for the universal protocol met the needs of all the project areas, a working group representing nurses from each project area was assembled. The Nursing Director from each of the 12 areas was approached to solicit a volunteer frontline nurse and a clinical nurse educator or clinical nurse specialist from their area to participate in the standardization working group. The Nursing Directors identified the volunteers and the project lead reached out to invite them to the meetings. Agendas were sent the working group in advance of each meeting as well as necessary reading materials for preparation. The project lead facilitated each meeting. Minutes from each meeting were scribed and emailed to all working group members and the project site mentors within 24 hours of the meeting.

At the initial kickoff meeting, the project problem and aims, the evidence to found to support the intervention, and the goals of the working group were presented and discussed. A series of ten, one-hour working group meetings were held over a 12-week period. The working group utilized their collective expertise as well as specialty guidelines (WHO Safe Surgery Checklist, Joint Commission universal protocol standards and SPOT observation tool) to assist with the development of each phase of the standardized process.

The working group's efforts culminated in a standardized universal protocol process draft that included: a) who should be involved in each phase, b) where the phase should take place, c) when the phase should take place, d) the recommended role group to initiate the phase, e) the language to be used to initiate the phase, f) the universal protocol tool for each phase (Appendix J).

Gain Stakeholder Consensus for the Designed Standardized Process

Aim 4 was to gain stakeholder consensus for the designed standardized process. Meetings to gain consensus were held with the following stakeholders:

- the Chief Quality Officer (CQO) of the hospital;
- the project site mentors (Associate Chief Nurse of Perioperative and Procedural Services, Medical Director of Procedural Services);
- the Perioperative Quality Assurance Committee;
- the Procedural Quality Committee.

A presentation of the work was provided for each stakeholder group. The project lead along with nurse representatives from the working group provided presentations of each universal protocol phase at the stakeholder meetings. The meeting with the hospital CQO was held as a one to one with the project lead. Approval was obtained from each stakeholder group. Feedback and guidance were incorporated into the processes when provided.

Discussion

Summary

Overall, the project was well received by the procedural and perioperative leaders and stakeholders. Use of the Kotter Change Model contributed to the success of the project. Forming a coalition of invested subject matter experts who understood the urgency for improved patient safety in the procedural and perioperative settings propelled the work forward. The early development of a working group consisting of frontline nursing staff and Clinical Nurse Specialists from each project area to help create the new universal protocol process gave increased credibility to the work and resulting tools. The working group members directly communicated the vision for the change through their presentations of the work at major stakeholder meetings.

Initially, there was an overall perception that universal protocol was being done appropriately in each area. This was endorsed by the low frequency of adverse events involving wrong site, wrong procedure, wrong patient. Presenting compelling data on the incidence of these adverse events from the Joint Commission as well as the Massachusetts Department of Public Health helped set the stage that this was a necessary improvement project. The potential for serious harm to patients as well as financial and reputational risk to the project hospital and emotional risk to providers was a key component of all presentations to frontline staff, project area leaders, and hospitals stakeholders. The reporting of the actual project findings of the wide variability in essential universal protocol practice elements aided in the acceptance of the project.

Stakeholders were receptive to the work and agreed that it would have a positive effect on patient safety. This empowered the project lead and working group to continue the standardized universal protocol development. This effective integration of the Kotter change model helped to create the wins needed to motivate collaboration on an effort that was impactful

across the entire project hospital. This project brought together subject matter experts from procedural and perioperative areas who had never had the opportunity to meet or work together in the past. This was a value add as it aided in the formation of a dedicated community of experts to impact a meaningful change and improvement.

This quality improvement project highlighted wide variation in all phases of the universal protocol throughout the large academic medical center and confirmed the need for a standardized approach to this important safety process. The examination of the project hospital tools illustrated a paucity of tools used to guide practice and, for those areas using tools, an overarching omission of items required in the hospital wide universal protocol policy. The deficit of comprehensive tools to guide practice forces teams to rely on memory to complete the required elements of the universal protocol.

The project revealed variations in the elements completed between the project areas and the need to align tools with the hospital wide policy. This alignment becomes more important as providers cross procedural and perioperative sites to care for patients as differences in practice can lead to gaps and may leave the team susceptible to missing vital aspects of the universal protocol. Observations of universal protocol practice in the project areas revealed additional variation. This variation spanned all three phases of the process.

Briefing phase

The briefing phase was the most arduous phase to standardize. This was primarily due to the wide variation in how teams perceived the need for the briefing and the differences in each area's routines for preparing patients. Barriers to completing the briefing phase were the lack of physical space to ask patient questions in privacy as well as the inability to have all team members together at the same time.

The focus group sessions revealed the common feeling that the briefing phase was the most difficult phase to complete. Participants voiced frustration noting the difficulty in bringing the necessary team members together to participate in the process. Unique to the three universal protocol phases, the briefing phase is the only phase where the team is not all assembled in the same place at the same time. This occurs as team members are involved in other tasks such as room turn over and set up, completion of consent forms, and tending to previous or upcoming patient needs.

To help resolve the issue with these competing demands, the working group proposed a phased approach to the briefing. This phased process allows for all the essential briefing components to be completed with the appropriate team members at various times prior to anesthesia, sedation and any preprocedural or preoperative intervention. Specifically, the group recommended that certain elements may be completed with the team while performing tasks for the next procedure or surgery, while other elements that must be done in the presence of the patient, may be completed add a separate time with essential team members. Allowing critical components to be completed in this manner assures that all the essential briefing elements are reconciled with the necessary team members before the patient has any surgical or procedural intervention, and ideally, before they enter the procedural or surgical room.

Time Out Phase

The time out is the most embedded phase in the project facilities culture. All 12 project area teams perform a timeout prior to the procedure or surgery. Every area documents the time out in the patient's electronic health record (EHR). The EHR was not considered a tool for this project because the team member completing the universal protocol form in the EHR is the only person who is able to view the checklist on the computer. As a result, the team is not able to view

the prompts interfering with their ability to read and assure all the critical components of the time out are being completed.

Of the 12 project areas, only seven used physical tools to prompt the teams to review the time out elements. The hospital policy describes eight required elements for confirmation during the time out phase. Despite all projects areas completing the time out phase, the areas varied considerably in elements included in their time out tools. This variation aligned with the range of procedures and surgeries being performed in each individual area.

Observations of time out process practice using the SPOT occurred in all 12 project areas. The observations revealed disparate approaches to the team's performance of the time out. In some areas the time out is led by the physician and, in others, by the nurse. Since providers may work in more than one procedural or surgical area this differing approach may lead to role confusion as they cross areas. Standardization in the role group who initiates the timeout is important to establish accountability and decrease potential confusion. For this reason, the working group recommended that each area determine which role group (based on their individual culture) would be responsible for initiation of the phase and to create a corresponding departmental policy to align with their practice.

Focus group comments supported the project hospital's culture that time out is an essential process in all procedural and surgical areas. Nurses in the focus group commented that although there is an overall acceptance of the importance of the time out, they felt engagement of all team members could be improved.

Debriefing Phase

The debriefing phase uniformly revealed a lack a formality in the tools utilized as well as the team's performance of the components. The hospital policy requires only one item for this phase, reconciliation of specimens however, the WHO Safe Surgery Checklist, the Joint

Commission and SPOT have included additional elements that are considered essential upon completion of procedures and surgery. The additional elements provide the team the opportunity to stop and verify not only the specimens, but also the procedure performed, sponge and instrument counts (if applicable) and any concerns from the team regarding the procedure, the patient, or any of the equipment used. These additional elements were not included in any of the hospital area tools. The work to include these debriefing elements in the standardized process are meant to promote formality to assure these critical elements are consistently performed in all perioperative and procedural areas.

Conclusions and Recommendations

Procedural and perioperative wrong site, wrong procedure, and wrong patient errors are sentinel events that are deemed "never events." Assuring all patients are safe from potential harm is vital to quality of care and patient safety. This quality improvement project was developed to learn current practice of the universal protocol across a large academic medical center. The findings were helpful to illustrate the vast variation in practices. Evidence supports the use of standardized checklists and processes in surgery and procedural areas to improve teamwork, safety culture and process compliance (Clay-Williams & Colligan, 2015). Improving this hospital wide process represents an opportunity to improve patient safety and reduce potential harm to patients, provider's wellbeing and hospital reputation that would occur from a wrong site, wrong procedure. or wrong patient surgical or procedural event.

Utilization of the Kotter Change Model assisted in the acceptance of the new standardized universal protocol process and tool. Overcoming the disparate needs and practice of the 12 project areas was achieved through strong collaboration and clear, consistent communication. The project engaged nursing experts, anesthesiologists, procedural and surgical

physicians. Throughout the process these groups were updated on the project status and were engaged in providing feedback on each phase of the standardized process.

This collaborative process throughout all phases of the project resulted in a change that will be disseminated throughout all the perioperative and procedural areas at the project hospital. The completion of this project illustrates the feasibility in bringing together subject matter experts from many different areas to come to agreement on the critical elements for patient safety in procedures and surgery.

This quality improvement project unveiled the challenge in bringing teams together during the briefing process. This difficulty was confirmed by the focus group participants as well as by members of the standardization working group. The competing demands of procedural and perioperative team members and the increased production pressure in these highly complex and fast-moving settings were identified as contributors to this barrier. Use of technological devices or virtual communication should be evaluated in future universal protocol research or improvement projects. Procedural and perioperative stakeholders and leaders should be actively engaged in this work as increasing the time needed for teams to complete these essential tasks may have the unintended impact of slowing production. This disadvantage of slowing of the process may prove to have the added value of increasing team satisfaction and, more importantly, reducing risk of inadvertent patient harm. Future work should be focused on the how to optimize teamwork in the briefing phase.

Inclusion of obstetrical teams is encouraged for future universal protocol process projects. Obstetrical patients face the same risks of harm during the course of surgical and vaginal deliveries. During the course of the project, the team recognized that the obstetrical areas would have benefited from participating in this work. Future implementation of this

universal protocol standardization process will engage the project hospital's obstetrical leaders and stakeholders.

Additional recommendations include the integration of the standardized universal protocol tool into one common EHR form to further reduce variation in different procedural and perioperative area processes. Finally, alignment of the hospital wide universal policy with actual clinical practice and the newly designed process and tool is another opportunity for improvement.

Despite several years of focused work by the Joint Commission and the WHO, patient harm from wrong site, wrong procedure and wrong patient procedures or surgery continues to be a significant quality and safety concern. This quality improvement project demonstrates the need for more research and quality improvement initiatives to address gaps in universal protocol policies and actual practice.

References

Ayanian, J. Z., & Markel, H. (1990). HISTORY OF MEDICINE: Donabedian's Lasting Framework for Health Care Quality. *Archives of Pathology Laboratory Medicine*, *114*, 1115–1123. https://doi.org/10.1056/NEJMp1605101

Boyum, J. H., Rosier, A. S., Tibor, L. C., Turner, M. A., Hess, A. R., & Kurup, A. N. (2020). Improving universal protocol performance in radiology through implementation of a standardized time-out. *Radiographics*, *40*(4), 1182–1187. https://doi.org/10.1148/rg.2020190127

Brenckle, E. A., Gealer, D., & Milligan, M. (2020). Using a Tibetan Gong to Increase Staff Member Engagement During Time Outs. *AORN Journal*, *111*(1), 81–86. https://doi.org/10.1002/aorn.12898

Clay-Williams, R., & Colligan, L. (2015). Back to basics: Checklists in aviation and healthcare. In *BMJ Quality and Safety* (Vol. 24, Issue 7). https://doi.org/10.1136/bmjqs-2015-003957

Dobbie, M., Fitzpatrick, M., Kent, M., & Wojtal O'Neill, M. (2019). Improving Preprocedure Time Out Compliance Using Remote Audiovisual Observation. *AORN Journal*, *109*(6), 748–755. https://doi.org/10.1002/aorn.12695

Donnelly, P., & Kirk, P. (2015). How to… Use the PDSA model for effective change management. In *Education for Primary Care* (Vol. 26). http://qualitysafety.bmj.

Haynes, A. B., Weiser, T. G., Berry, W. R., Lipsitz, S. R., Breizat, A.-H. S., Dellinger, E. P., Herbosa, T., Joseph, S., Kibatala, P. L., Lapitan, M. C. M., Merry, A. F., Moorthy, K., Reznick, R. K., Taylor, B., & Gawande, A. A. (2009). A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. *New England Journal of Medicine*, *360*(5), 491–499. https://doi.org/10.1056/nejmsa0810119

Heideveld-Chevalking, A. J., Calsbeek, H., Emond, Y. J., Damen, J., Meijerink, W. J. H. J., Hofland, J., & Wolff, A. P. (2018). Development of the Surgical Patient safety Observation Tool (SPOT). *BJS Open*, *2*(3), 119–127. https://doi.org/10.1002/bjs5.44

Hirche, C., & Kneser, U. (2019). What We Really can Learn From Aviation: Checklist-based Team Time-Out in Conjunction With Interpersonal Competence Training for the Daily Management of a Surgical Department. *Business of Surgery Surgical Innovation*, *28*(5), 642–646. https://doi.org/10.1177/15533506211018439

Kotter, J. P. (1998). Leading Change: Why Transformation Efforts Fail. In *Harvard Business Review on Change*. Harvard Business School Press. https://www.ebsco.com/terms-of-use

Matharoo, M., Thomas-Gibson, S., Haycock, A., & Sevdalis, N. (2014). Implementation of an endoscopy safety checklist. *Frontline Gastroenterology*, *5*(4), 260–265. https://doi.org/10.1136/flgastro-2013-100393

Ogrinc, G., Davies, L., Goodman, D., Batalden, P.B., Davidoff, F., Stevens, D. (2016) SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised publication guidelines from a detailed consensus process. *BMJ Quality and Safety*, 25, 986-992.

Rafiei, P., Walser, E. M., Duncan, J. R., Rana, H., Ross, J. R., Kerlan, R. K., Gross, K. A., Balter, S., Bartal, G., Abi-Jaoudeh, N., Stecker, M. S., Cohen, A. M., Dixon, R. G., Thornton, R. H., & Nikolic, B. (2016). Society of Interventional Radiology IR Pre-Procedure Patient Safety Checklist by the Safety and Health Committee. *Journal of Vascular and Interventional Radiology*, *27*(5), 695–699. https://doi.org/10.1016/j.jvir.2016.03.002

Raphael, K., Cerrone, S., Sceppa, E., Schneider, P., Laumenede, T., Lynch, A., & Sejpal, D. v. (2019). Improving patient safety in the endoscopy unit: utilization of remote video auditing

to improve time-out compliance. *Gastrointestinal Endoscopy*, *90*(3), 424–429. https://doi.org/10.1016/j.gie.2019.04.237

Reed, S., Ganyani, R., King, R., & Pandit, M. (2016). Does a novel method of delivering the safe surgical checklist improve compliance? A closed loop audit. *International Journal of Surgery*, *32*, 99–108. https://doi.org/10.1016/j.ijsu.2016.06.035

Stahel, P. F., Mehler, P. S., Clarke, T. J., & Varnell, J. (2009). The 5th anniversary of the "Universal Protocol": pitfalls and pearls revisited. *Patient Safety in Surgery*, *3*(1), 14. https://doi.org/10.1186/1754-9493-3-14

The Joint Commission. (2023). Hospital National Patient Safety Goals *2023-hap-npsg-goals-102122_simple.pdf (jointcommission.org)*

The Joint Commission. (2022, March 9). *Sentinel Event data released for 2021*. The Joint Commission. https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/joint-commission-online/march-9-2022/sentinel-event-data-released-for-2021/#.Y3Essi2B1bV

World Health Organization. Patient Safety. (2009). *WHO guidelines for safe surgery 2009: safe surgery saves lives*.

Appendix A

Evidence Synthesis Table

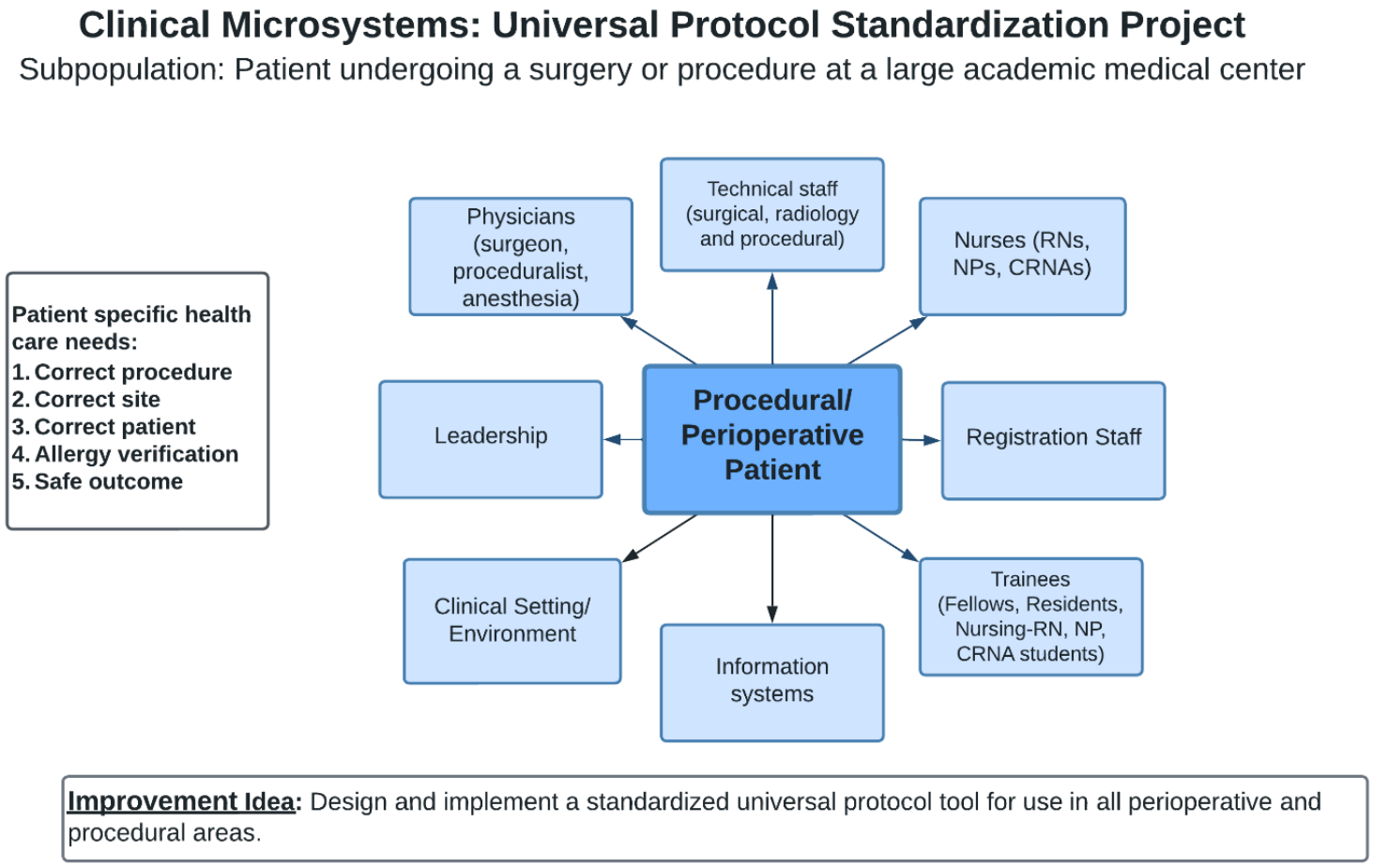
What strategies promote optimal teamwork and compliance during use of universal protocol in procedural and perioperative areas?

Intervention	Evidence	Overall Quality/ Population	Significant Findings
UP Process Standardization	E. Haynes et al., (2009) B. Boyum, et al. (2020) C. Cabral et al., (2016) D. Dobbie, et al. (2019) F. Rafiei et al., (2016)	E. II/A; N= 3733 patients baseline N=3955 after intervention B. V/B; N=87 procedures C. V/A D. V F. V	E. Landmark paper illustrating the implementation of standardized Safe Surgery Checklist reduced mortality and complications from surgery. B. Implementing tailored, standardized time-out resulted in improved compliance C. Implementation of standardized universal protocol (briefing, time out, debriefing) resulted in improved teamwork behaviors and enhanced safety culture in OR. D. Standardized time out that included the creation of a standardized time-out script improved compliance. F. Standardization of process with the allowance of customization of details within process steps (e.g., individualized checklist) is necessary for successful implementation
Customization by Specialty area	B. Boyum, et al. (2020) F. Rafiei et al., (2016) G. Raphael et al., (2019) I. Rohsig (2020)	B. V/B; N=87 procedures F. V G. V/A; N=692 procedures I. V	B. Radiology tailored time-out resulted in improved compliance. F. Standardization of process with the allowance of customization of details within process steps (e.g., individualized checklist) is necessary for successful implementation. G. Development of an endoscopy-specific checklist improved team buy in. I. Engaged local team to modify Safe Surgery Checklist for area as part of intervention which improved buy in.
Improved shared mental model	H. Reed et al., (2016) K. Raphael et al., (2019) A. Brenckle et al., (2020)	H. IIB N=92 procedures K. V/A; N=692 procedures A. V	H. Use of audio prompt to start time out and use of full audio delivery of time out improved compliance with completion of the Safe Surgery Checklist. K. Use of a visual cue (yellow card) to designate start of time out engaged the team to begin process A Use of auditory cue, Tibetan gong, to indicate start of time out improved engagement of team and was spread to other hospital procedure areas.
Novel monitoring (remote audiovisual auditing)	C. Dobbie, et al. (2019) K. Raphael et al., (2019)	C. V/A K. V/A; N=692 procedures	C. Used audiovisual observation to verify that team members address every element of the preprocedure time out. K. Remote video auditing is a highly effective tool. Improved compliance with endoscopy Time Out Process significantly.

Education	K. Raphael et al., (2019) C. Cabral et al., (2016) I. Rohsig (2020)	K. V/A; N=692 procedures C. V	G. Enhancement of the patient safety culture was obtained through team education and information socialization. C. Education of OR team was provided in phase II of their implementation and aided in the buy in and use of tools. I. Education of OR using data and scientific evidence of its success assisted the surgeons to participate in use of Safe Surgery Checklist.
Role designation/ Role clarity	K. Raphael et al., (2019)	K. V/A; N=692 procedures	K. Designation of Time Out Process leader aided in compliance.

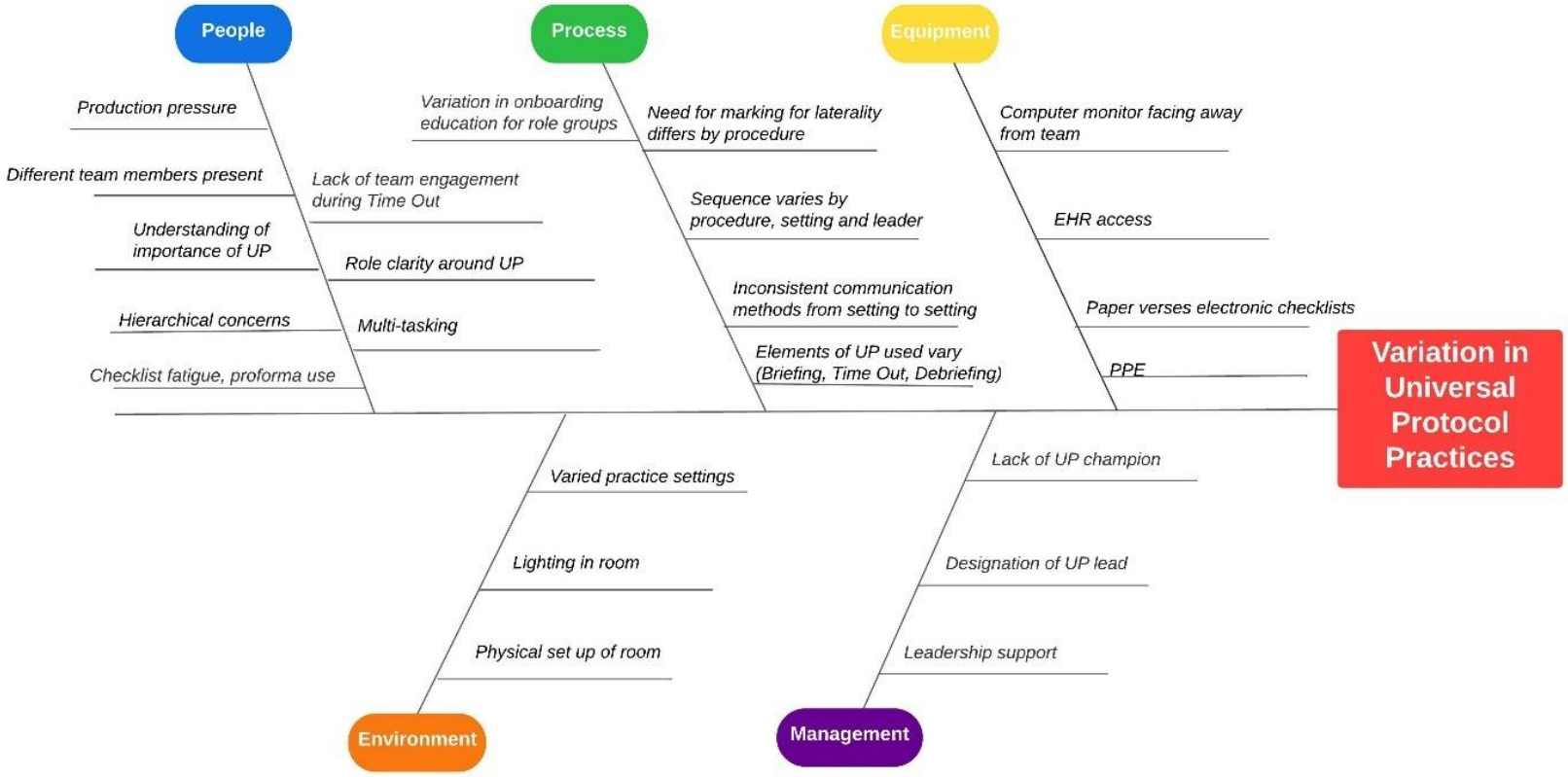
Appendix B

Microsystem of Care for Patients undergoing Surgery or Procedures



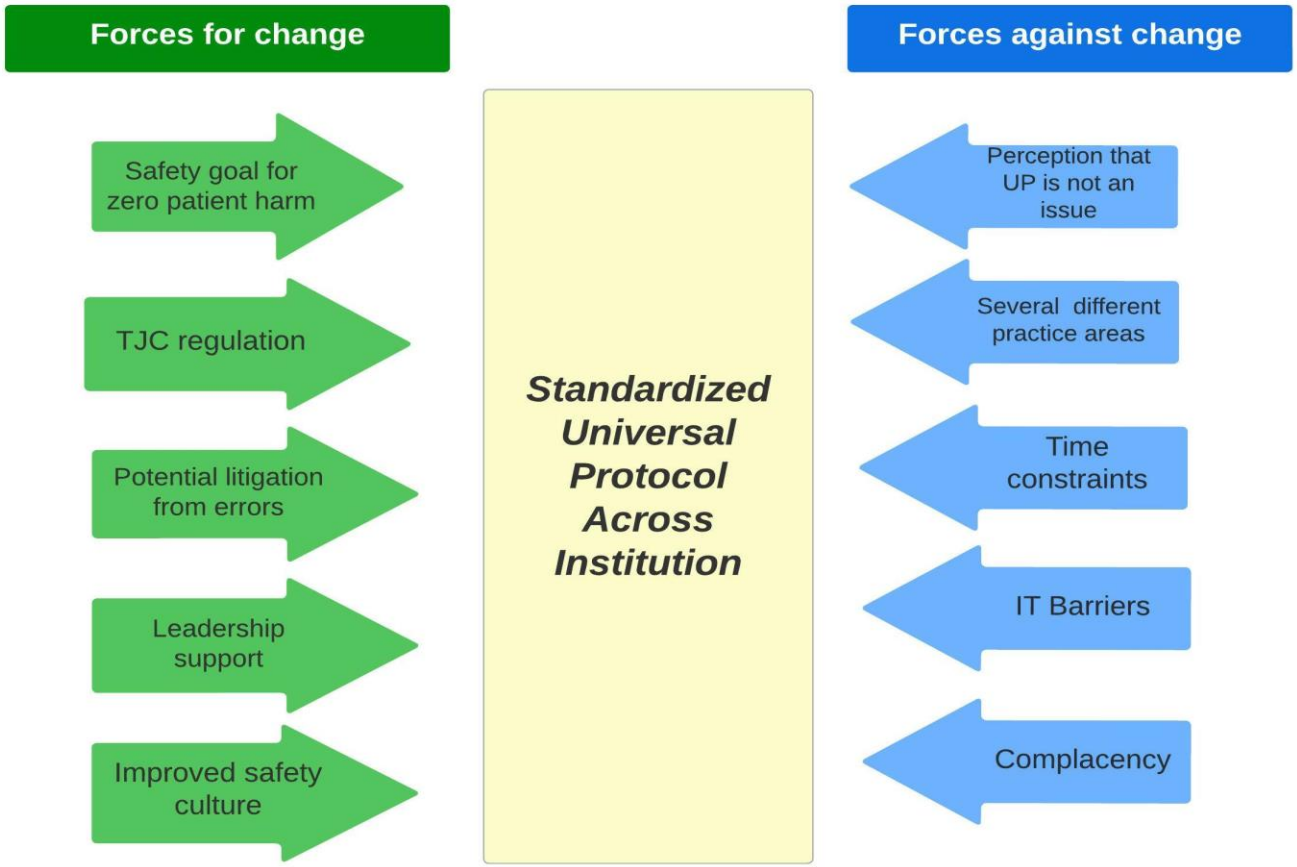
Appendix C

Fishbone diagram



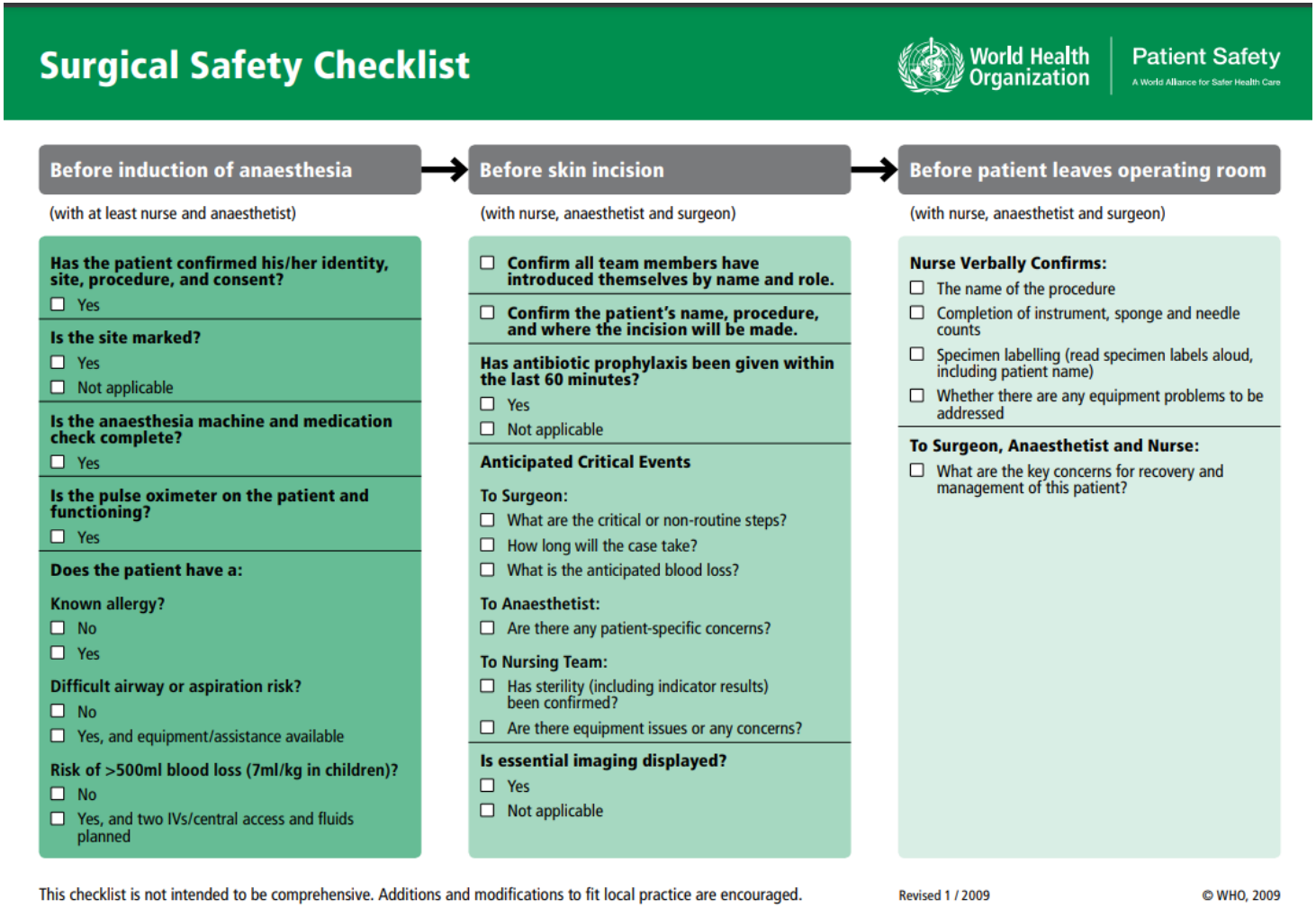
Appendix D

Force Field Analysis



Appendix E

World Health Organization (WHO) Surgical Safety Checklist (Safe Surgery Checklist)



Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia
(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision
(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room
(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

World Health Organization. Patient Safety. (2009). *WHO guidelines for safe surgery 2009: safe surgery saves lives*.

Appendix F

Modified Surgical Patient Observation Tool (SPOT) used for direct observations

A3	**Briefing - Pre-time-out before the operation**	MET	NOT MET	N/A	CLARIFICATION
3.1	A huddle/briefing is performed in case any invasive preparations (e.g., regional anesthetic block) are done				
3.2	The huddle/briefing is performed by the attending MD or anesthesiologist and a second team member				
3.3	Check on patient's identity: oral confirmation by the patient (if possible) or use of two identifiers (full name, DOB, MRN)				
3.4	Check on correctness of patients' identity with respect to the patient medical record and consent				
3.5	Check and verify operation or procedure that will be performed				
3.6	Check and verify site, level, laterality				
3.7	Check on possible allergies				
3.8	Check on patient related items with respect to anticoagulation and VTE Prophylaxis				
3.9	Check on availability of all necessary imaging, implants & equipment				
3.10	The result of the pre-time-out is documented in the patient's medical record by, or on behalf of, the attending anesthesiologist				
3.11	Check and verify position for surgery/procedure				
3.12	Check HCG results for menarchal patients				
3.13	Ask does anyone have concerns?				

	IN THE PROCEDURAL ROOM/OPERATING ROOM				
A4	**Time-out**	MET	NOT MET	N/A	CLARIFICATION
The time-out is performed:					
4.1	- Prior to the induction of anesthesia/procedural sedation **HARD STOP TIME-OUT** initiated in procedural or surgical area				
4.2	- In presence of the (wakened) patient Local anesthesia				
4.3	- In presence of the essential team members for area				
4.4	- Check patient's identity: oral confirmation by the patient (if possible) or identification bracelet				

4.5	- Check correctness of patients' identity with respect to the patient medical record and match to patient consent				
4.6	- Check type of operation procedure that will be performed				
4.7	- Check and verify site, level, laterality				
4.8	- Check patient related items with respect to anticoagulation				
4.9	- Check necessity for prophylactic antibiotics				
4.10	- Check allergies				
4.11	- Check possible co-morbidities patient history concerns				
4.12	- Check items needed for patient positioning on table/bed				
4.13	- Check on presence of all necessary qualified personnel and Introductions				
4.14	- Check availability of all necessary equipment/materials				
4.16	The result of the time-out is documented in the patient's medical record by, or on behalf of, the attending surgeon/proceduralist				
A15	**Debriefing/Sign-out - in the operating room**	**MET**	**NOT MET**	**N/A**	**CLARIFICATION**
Debriefing/Sign-out is done before the patient will leave the operating room:					
15.1	-The attending surgeon, anesthesiologist and/or anesthesia nurse, the circulating and scrub nurse/procedural nurse and technician participate				
15.2	Confirm performed surgical procedure				
15.4	Confirm completion of sponge, needle, instrument, and other used equipment counts (if applicable)				
15.5	Conform/reconcile correct labelling of patient specimens if obtained (e.g., for pathological examination)				
15.9	The result of the sign-out is documented in the patient's medical dossier by, or on behalf of, the attending surgeon/proceduralist				

Heideveld-Chevalking, A. J., Calsbeek, H., Emond, Y. J., Damen, J., Meijerink, W. J. H. J., Hofland, J., & Wolff, A. P. (2018). Development of the Surgical Patient safety Observation Tool (SPOT). *BJS Open*, *2*(3), 119–127. https://doi.org/10.1002/bjs5.44

Appendix G

<u>Phase 1</u> Focus Group – Virtual
Facilitator/Scribe: Lisa Heard
Attendees: One nurse from each procedural and each perioperative area (3 groups, 4 per group)

Timing	Discussion/Questions	Responsible Person(s)
5-7 minutes	Welcome Review of focus group purpose Recording of minutes Introductions	Leader
3 minutes	What do you think the value of the universal protocol is? How important is it to do? 1. Unimportant 2. Somewhat important 3. Important 4. Very important 5. Essential	Anonymous electronic poll of all attendees
3 minutes	What percentage of the anesthesia providers value the universal protocol process? 1. 76-100% 2. 51-75% 3. 26-50% 4. 0-25%	Anonymous electronic poll of all attendees
3 minutes	What percentage of the surgical and procedural providers value the universal protocol process? 1. 76-100% 2. 51-75% 3. 26-50% 4. 0-25%	Anonymous electronic poll of all attendees
3 minutes	Of those components you complete in your area, how often would you say all the components are completed? Likert response options: 1. Never 2. Rarely 3. Sometimes 4. Often 5. Always	Anonymous electronic poll of all attendees
7 minutes	Tell me about your experiences with universal protocol in your area. Comment on the tools used for universal protocol in your area.	Discussion
12 minutes total ▪ 1-minute instructions	What are the one or two most impactful barriers to completing the universal protocol components? Response – qualitative: • Stickies/Write in Chat	Make a slide as they talk when they return. Wordle?

Timing	Discussion/Questions	Responsible Person(s)
▪ 5 minutes in breakout ▪ 6 minutes to discuss responses	• Break out 2-3 each room – come back with two barriers each.	
7 minutes	How do feel about standardizing the process of universal protocol?	Discussion
3 minutes	Is there anything we may not have discussed you want to bring up?	

Total time: 50 minutes

Appendix H

Universal protocol department specific tools - Gap analysis

POLICY ELEMENTS (Yes/No Answers)	CCL	ECT	EP	IP	ENDO	OR - M	OR - W	OR - D	IR
Pre-procedure Huddle - at bedside preop or in procedure room prior to case start - Did tool include the following elements:									
Verify Patient w patient/family									
Verify Procedure - intended procedure must match on all documents									
Verify site and laterality									
Signed surgical/procedural consent									
Signed anesthesia consent									
Lab results									
Radiology results									
Blood products - Type and Screen									
Patient labels (verified)									
EHR matches correct MRN									
Required equipment, devices, implants, blood are available									
Mark Site									
Hard Stop Time Out - after patient is positioned prepped and draped and IMMEDIATELY before start of case in space where procedure will be done. Did tool include the following elements:									
All team participation, introductions									
Confirm Identity									
Confirm and agree on procedure being completed									
Confirm correctly marked site for confirmed procedure									
Confirm need for pre-procedure antibiotics									
Confirm any safety precautions d/t patient condition									
Multiple procedures require multiple time outs									
Document in EHR									
Debrief: Did tool include the following elements:									
Specimen reconciliation									
Tool used:									
Paper/laminated tool									
Computer									
No tool - verbal only									

Legend	
EP = Electrophysiology Lab	IP = Interventional Pulmonology
ENDO = Endoscopy	ECT = Electroconvulsive Therapy
EP = Electrophysiology	OR-M = Operating Room Boston
CCL = Cardiac Catheterization Lab	OR-D = Operating Room Danvers
IR = Interventional Radiology	OR-W = Operating Room Waltham

Appendix I

University of Massachusetts Boston Clinical Quality Improvement Checklist

CLINICAL QUALITY IMPROVEMENT CHECKLIST		
Date: 3/31/2022	**Project Leader: Lisa Heard**	
Project Title: Implementation of a Standardized universal protocol Process		
Institution where the project will be conducted: Massachusetts General Hospital		
Instructions: Answer YES or NO to each of the following statements about QI projects.	**YES**	**NO**
The specific aim is to improve the process or deliver of care with established/ accepted practice standards, or to implement change according to mandates of the health facilities' Quality Improvement programs. There is no intention of using the data for research purposes.	**X**	
The project is **NOT** designed to answer a research question or test a hypothesis and is **NOT** intended to develop or contribute to generalizable knowledge.	**X**	
The project does **NOT** 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 over-rides clinical decision-making.	**X**	
The project involves implementation of established and tested practice standards (evidence-based practice) 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 or 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 has been discussed with the QA/QI department where the project will be conducted and involves staff who are working at, or patients/clients/individuals who are seen at the facility where the project will be carried out.	**X**	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research**.**	**X**	
The clinical practice unit (hospital, clinic, division, or care group) agrees that this is a QI project that will be implemented to improve the process or delivery of care.	**X**	
The project leader/DNP student has discussed and reviewed the checklist with the project Course Faculty. The project leader/DNP student will **NOT** refer to the project as research in any written or oral presentations or publications.	**X**	
ANSWER KEY: If the answer to **ALL** of these questions is **YES**, the activity can be considered a Clinical Quality Improvement activity that does not meet the definition of human research. **UMB IRB review is not required**. **Keep a dated copy of the checklist in your files.** If the answer to ANY of these questions is NO, the project must be submitted to the IRB for review.		

Appendix J

Standardized universal protocol process tools - Briefing Standardized Tool

When - *Before the sedation, anesthesia, procedure or surgery (ideally in separate area).* *May be done in a phased manner however all components must be addressed.* **Who - *Should include Room RN, Surgeon/Proceduralist (or designee) and Anesthesia team member (if applicable).***
☐ Verified patient ID with two pt. identifiers. Oral confirmation by the patient (if possible)
☐ Confirmed ID with medical record and consent form
☐ Confirmed anesthesia consent signed and dated (if applicable)
☐ Confirmed surgical/procedural consent signed and dated, timed
☐ Confirmed H&P is up to date
☐ Verified planned surgery/procedure
☐ Verified site, level, laterality. Confirmed marking of site (if applicable)
☐ Allergies reviewed
☐ Confirm need for pre-procedure/preoperative antibiotics (if applicable)
☐ Verified anticoagulation use and VTE Prophylaxis (if needed)
☐ Checked HCG results (for eligible patients)
☐ Verified availability of required equipment and materials
☐ Verified position for surgery/procedure
☐ Verified imaging available
☐ Ask does anyone have concerns? If patient is awake – Does anyone have any additional comments?

Standardized universal protocol process tools - Time Out Standardized Tool

When - *Immediately before the start of the procedure or surgery in procedural or surgical room* **Who – *All team members in procedural or surgical room***
☐ All team members actively participate and introduce themselves by name and role
☐ Verify patient ID with two pt. identifiers
☐ Visualize and verify consent during pt. identification
☐ Verify planned surgery or procedure
☐ Verify site, level, laterality (if applicable)
☐ Confirm marking of site (if applicable)
☐ Confirm allergies
☐ Discuss medication(s) on procedural or surgical field (if applicable)
☐ Complete Fire Risk Assessment (if applicable)
☐ Confirm administration of antibiotics; time and medication given (if applicable)
☐ Discuss anticipated blood loss (if applicable)
☐ Confirm availability of required imaging, equipment, implants
☐ Ask “Does anyone have concerns?”

Standardized universal protocol process tools - Debriefing Standardized Tool

When - *Prior to patient leaving procedural or surgical room.* *May be done in a phased manner but all components must be addressed* **Who – *Should include RN, Scrub, X-ray or Procedural Technologist, Surgeon/Proceduralist (or designee) and Anesthesia team member (if applicable).***
☐ Confirmation of the surgery/procedure performed
☐ Confirmation and reconciliation of patient specimens (if obtained)
☐ Completion of sponge (RFID*wanding), needle, instrument, and other items counts (if applicable)
☐ Confirmation of correct counts with team (if applicable)
☐ Are there any concerns? If patient is awake/sedated – "Does anyone have any additional comments?"

**RFID = Radiofrequency Identification*