TARGETING: Wrong Site Surgery Risks

{ New Tool Hits the Bull’s-Eye }

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{ Pre-OP Holding Area Scenario }

The geriatric patient is a woman with mild dementia, but she is alert and oriented to person, place, and time. No immediate family is present. The nurse’s job is to first have the patient sign the consent, and then to sign the consent as the witness. The patient says she is having her right knee replaced but points to her left leg. This organization prides itself on its 99 percent on-time case start rate and this surgeon in particular hates to run late. The nurse has tried to page the surgeon, but she is in the OR finishing another case and will not have time to come to pre-op before her next case, which is this one. The pre-op charge nurse says that the OR team is coming to take the patient to the OR.

The nurse has two options:

1. Hold the patient until the paperwork issues are resolved by the surgeon
2. Flag the chart and hope that it’s taken care of by the next team.

What should the nurse do?
This is a scenario that no one wants to be in – not the nurse, not the surgeon and certainly not the patient. It’s evident that things started to go wrong long before the patient showed up in the pre-op area. Ideally, we would want to find out exactly when and where the problems first occurred and have solutions that are targeted to address or eliminate them. That’s exactly what the Joint Commission’s Center for Transforming Healthcare’s Targeted Solutions Tool™ (TST) does – and it’s working today to reduce risks for wrong site surgery in Joint Commission accredited hospitals and ambulatory surgical centers.

Wrong site, side, procedure or person surgery is a rare event, but it is still too common. It is estimated that wrong site surgery occurs approximately 40 times per week in the United States and it is the most common sentinel event reported to The Joint Commission. These errors can result in devastating injury to patients and families, damage the reputation of the organization, and have a significant emotional impact on the staff who participated in the case. In addition, cases that have gone to trial have resulted in multi-million dollar judgments against the facility and the staff who participated.

The causes for wrong site surgery vary but, as in our scenario, most occur due to multiple errors that reach the patient. It is common for these errors to cross through the departments of surgical booking, pre-op/holding and the OR. The Joint Commission Center for Transforming Healthcare worked with a group of leading hospitals and ambulatory surgery centers to identify the risks of wrong site surgery and to develop solutions targeted to impact these risks. Wrong site surgery is a devastating event, but with the right tools, effective change management, and a multidisciplinary team approach, it can be prevented.

Project Background

In 1999, the Institute of Medicine published To Err is Human: Building a Better Health System (http://www.nap.edu/catalog/9728.html) which states: “In health care, building a safer system means designing processes of care to ensure that patients are safe from accidental injury. When agreement has been reached to pursue a course of medical treatment, patients should have the assurance that it will proceed correctly and safely so they have the best chance possible of achieving the desired outcome.” Before that, The Joint Commission and its Sentinel Event program first identified wrong site surgery as a common type of sentinel event in 1996. The Joint Commission has also issued two Sentinel Event Alert newsletters on wrong site surgery—the first published in 1998 and the follow-up in 2001. In 2003, The Joint Commission held its first Wrong Site Surgery Summit, and in 2004, it launched the
Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™ as a National Patient Safety Goal. In 2009, the Joint Commission Center for Transforming Healthcare began work with a group of eight hospitals and ambulatory surgery centers using the tools of Robust Process Improvement™ (RPI) to focus on measuring baseline performance and generating strategies to reduce the risk of wrong site surgery.

The Center for Transforming Healthcare was launched in 2009 by The Joint Commission with the sole purpose of using the systematic approach of RPI to analyze specific breakdowns in care, discover their underlying causes, and develop solutions that are targeted to the causes of these complex problems. RPI incorporates tools and concepts from Lean Six Sigma and change management methodologies. In keeping with its objective to transform health care into a high reliability industry, the Joint Commission shares these proven solutions with the more than 19,000 organizations it accredits and certifies. The focus of this work is on improving the systems and processes used to drive care.

The original eight hospitals and ambulatory surgical centers helped to develop a measurement system designed to capture the risks in the surgical processes that could lead to a wrong site surgery in the areas of surgical booking, pre-op/holding and the OR. It is impractical to measure wrong site surgery events since they occur so rarely; instead, the project focused on identifying the risks that could lead to a wrong site, wrong procedure or wrong person surgery. The measurement system involves direct observation and monitoring by trained staff. The following charts show examples of risks for wrong site surgery from each area and a breakdown of how these risks were distributed among the eight participating organizations:
These examples represent how the RPI approach differs from other tools, bundles and checklists currently available to healthcare organizations to help tackle this issue. It’s interesting to note that the risks identified by organization A varied from those identified by organization H. So, for example, if organization A developed a checklist around their risks and processes, it would have worked well. But if organization H implemented the same checklist, it wouldn’t prove to be as successful for them. The key to successfully implementing effective solutions is that they must address the risks that are specific to the organization. For instance, a checklist for organization A may not evaluate the use of the appropriate site marking pen or the use of stickers to mark the site, while organization H struggles with these elements. Through the use of RPI methods, an organization measures its baseline performance to determine which risk factors are most prevalent. The data generated is then analyzed to determine the most common causes of failure or inconsistencies. Many of the organizations involved in the original Wrong Site Surgery project and the piloting uncovered risks they didn’t know they had. For instance, one organization found they were using seven different types of site marks, ranging from an “x,” surgeon’s initials, and a dot. Once risks like this are identified, the organization can develop solutions targeted to impact their specific risks, test the solutions to determine their effectiveness, and then continue to monitor them to ensure that success is sustained.

Results

How successful has this approach been?

The results of these pilots were impressive, with a reduction of risks identified in all three areas in the surgical processes leading up to the incision.

- **Surgical booking experienced a 46 percent reduction** in cases containing risks and a 57 percent decrease in cases containing more than one risk
- **Pre-op/holding experienced a 63 percent reduction** in cases containing risks and a 72 percent reduction of cases containing more than one risk
- **OR experienced a 51 percent reduction** in cases containing risks and a 76 percent reduction of cases containing more than one risk
The following sections illustrate some specific examples of how the solutions have been implemented in the areas of surgical booking, pre-op/holding and OR.

**Surgical Booking**

The preparation of the OR schedule can occur weeks in advance of the surgery and it can be difficult to fathom that an error occurring this far from the time the patient actually shows up in the operating room isn’t caught before harming the patient. In 2009, the Pennsylvania Patient Safety Authority (http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Sep6(3)/documents/104.pdf) identified incorrect OR schedules as a contributing factor to wrong site surgery. Most OR staff use the OR schedule as the roadmap for room set up; this set up creates a powerful visual cue to the entire team as to the laterality of the case and the procedure being performed. The audit tools developed to measure this part of the surgical process specifically evaluate the receipt of forms to the organization performing the surgery and the booking form itself. For the receipt of forms, the top three areas of weakness identified by the project teams were: verbal ordering of procedures without written documentation; multiple booking forms received for the same surgical case; and cases scheduled within 48 hours of the surgery date. While the findings weren’t surprising to the individuals who usually prepared the surgical schedule, it was surprising to the OR leadership, particularly the frequency of verbal scheduling without the support of written communication.

While errors on the booking form varied as well, the most common errors related to the use of unapproved abbreviations, particularly when used to identify laterality of the surgical site. For ambulatory surgical centers, conflicts between the procedural coding and written description of the procedure were frequently identified as risks and required follow up with the ordering physician’s office. The solutions for these also varied, but all involved engaging the physician’s office staff. Some solutions included sharing information needed to make the surgical booking process as easy as possible for the office staff. Other identified solutions included the development of a resource manual containing: a list of unapproved abbreviations; hard copies of the ordering form and the order change form; frequently used telephone and fax numbers; and frequently asked questions.

Most facilities began a series of lunch meetings with the offices that frequently book surgical cases. The purpose of these meetings was to engage these practices in collaborative conversations about improving the process for both parties and, most importantly, ensuring that cases are booked accurately. Other solutions, while seemingly simple, required a significant commitment by the organization performing the surgery. These solutions included implementing a single booking fax line where all documents pertaining to surgical cases could be faxed; or implementing electronic scheduling, even for practices that are not directly affiliated with their facility. The result of these solutions and others resulted in a 46 percent reduction in defective cases in surgical booking.
Pre-op/Holding

In the pre-op/holding areas, paperwork issues continue to be a problem, with documents critical to the patient verification process (e.g., signed surgical consent, history and physical, and operating room schedule) being incorrect, incomplete or missing. Exacerbating this issue is the metric on which many hospitals and ambulatory surgical centers pride themselves -- on-time OR case start rates. Many staff said that they felt rushed to get the patient ready for surgery because they were searching for or coordinating last minute revisions to primary documents. It was also common for staff to be uncomfortable stopping the patient flow to the OR due to paperwork concerns. Staff stated they would flag the documents in question, relying on the next caregiver to make corrections. Other risks identified included the identification of inadequacies in the patient verification process.

For instance, it was common to find the surgeon not using a second patient identifier or referencing the procedure site and side using one of the primary documents (e.g., history and physical or signed surgical consent). When asked why, many stated that they felt the patient might be offended if asked for a second patient identifier, or they assumed that another team member was verifying the procedure site and side using the primary documents.

The solutions to these problems were not simple; they involved strong leadership support to making change and holding staff accountable. The solutions required that the primary documents, specifically the history and physical and the signed surgical consent, be available the day before surgery. If the case was scheduled as a first case, it would be bumped to a later time so that the paperwork could be pulled and the patient information properly verified on the day of surgery. This solution required that the organization performing the surgery have a well established surgical booking process, and a mechanism for verifying the presence of the primary documents and for reporting any missing documentation back to the ordering practice within the 48 hours preceding the surgery date. Another key in changing behaviors of the surgical team was the use of “just in time” coaching – coaches who actively intervene when they observe noncompliance in order to understand an organization’s contributing factors, and to coach healthcare workers on proper compliance. These coaches helped address concerns about patient verification and patient perceptions. As a result, a new practice is to inform patients upon arrival on the day of surgery that they will be asked by all team members to recite their name, second patient identifier, procedure, site and side.

In addition to paperwork concerns, many of the pilot organizations also audited regional blocks performed by anesthesia in the pre-op areas. The group found many regional blocks were being performed without a formal timeout process or without a site mark specific to the block. These omissions were identified as risks for wrong side or site surgeries in 2009 by the Pennsylvania Patient Safety Authority. The solutions involve engaging anesthesia providers to design a time out process which includes a nurse in the pre-op area. The time out process ensures appropriate patient verification involving the alert patient to ensure the correct procedure, patient and laterality. In addition, the patient is engaged in a formal site marking process. The site mark consists of an unambiguous mark that is specific to anesthesia, such as the physician’s initials with an A with a circle around it (A) to differentiate the mark from the surgeon’s mark.

The impact of the solutions implemented in the pre-op/holding areas resulted in a 63 percent reduction in the rate of cases containing risks and a 72 percent reduction of cases containing more than one risk.

Operating Room

In the operating room, all of the participating organizations found that team attention during the time out process was lacking. It was not uncommon to find staff continuing to work and set up the OR suite while the time out was being performed. There were many causes for this inattention, including the timing of the time out itself. It was discovered that if the time out is performed before the patient is prepped, staff will continue to set up the room and find it difficult to stop what they are doing and to participate in the time out. In 2009, the Pennsylvania Patient Safety Authority identified time out processes that were performed before the patient was prepped and draped as a risk for wrong side or site surgery. In addition, staff inattention was found to be more of a problem if the entire team did not participate fully in the time out process. It was common to find a single circulating nurse...
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responsible for reciting the key elements from the signed surgical consent while all the other team members participated passively. The solution is to create a role-based time out process where every team member not only has the opportunity to participate, but is expected to participate. The data collected during the baseline period will help the organization identify which role is best suited to initiate the time out.

The TST provides scripts that outline a time out process that can be tailored to the organization. For instance, one organization’s time out process includes the Universal Protocol and may combine multiple elements, such as blood products, implants or radiographic images. Another organization may choose to pull out these elements and perform them during a briefing process that occurs before the prep and drape. This briefing process would include the Universal Protocol and be completely separate from -- but in addition to -- the time out, and it would occur after the prep and drape. Either approach is acceptable. The key to success is staff buy-in to the process and the sense that the multidisciplinary team is responsible for keeping patients safe, rather than the surgeon alone. The results of these solutions and others resulted in a 51 percent reduction in the rate of cases in the operating room containing risks and a 76 percent reduction of cases containing more than one risk.

Change Management

A key factor to the success of any process improvement project -- particularly one that requires such a diverse group of individuals as those found in most surgical services -- is active engagement of key stakeholders and the use of change management strategies. One of the first exercises that the Center’s project teams are asked to engage in is an evaluation of the stakeholders in the process. For the Wrong Site Surgery project, anyone directly affected by any changes made to the processes that lead up to the surgical incision should be engaged in the project.

Stakeholders can be groups or individuals; the goal is to determine early on if the project has the support needed for success. If not, strategies need to be developed early in the process to help bridge the gap where the group or individual is in supporting the effort and where they need to be. For example, the project may lack the support of anesthesiologists because they are wary of any project that might impact the way that they perform the time out for regional blocks. The project team may decide that the best way to engage this group is to ask the section head to attend team meetings and work with the team to refine processes, particularly those that directly impact anesthesiologists.

Organizations are encouraged to weave change management strategies throughout the improvement process to optimize success -- even after the project has been completed and solutions have been successfully implemented. It is important to continue to give staff feedback on their performance, validating that the hard work they have done to make change was worth the effort and to ensure that improvements are sustained. A great way to provide this feedback is to continue with the auditing process, sharing data during staff meetings, posting results in an area frequented by staff, and celebrating improvement and sustainment. The pilot organizations have found that this data can be easily captured with just one audit being performed per day in each area.

How the Solutions are Spread

The Center for Transforming Healthcare has taken the information learned through the original participating organizations and the pilot organizations and made them available via the Targeted Solutions Tool™ (TST) for Wrong Site Surgery. The TST for Wrong Site Surgery is explicitly designed for hospitals and ambulatory surgical centers with the goal of spreading these results throughout the country. The TST is now available free of charge to Joint Commission accredited and certified programs. The TST is a self paced, web-based application that provides a six-step process that guides an organization through the following steps:

- stakeholder analysis
- identification and training of data collectors
- data collection and entry
- automated data analysis, provided in a presentation ready format
- solutions targeted to the organization’s data results
- plans and tools for sustaining improvements

For more information about the Wrong Site Surgery project or the Targeted Solutions Tool for Wrong Site Surgery, visit the Center for Transforming Healthcare website at http://www.centerfortransforminghealthcare.org/multimedia/tst_wss/ or email cth@jointcommission.org.