Reducing the Risks of Wrong-Site Surgery:
Safety Practices from The Joint Commission Center for Transforming Healthcare Project

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Executive Summary

Although rare and difficult to study, wrong-site surgery is a serious risk recognized by health care organizations. Health care organizations in a variety of settings, from small to large and from rural to urban, both teaching and nonteaching, must manage the risks of wrong-site surgery to ensure the safety of patients. Preventing wrong-site surgery—which includes wrong-patient, wrong-procedure and wrong-side surgeries—is accomplished by creating a culture of safety and improving perioperative processes.

As part of The Joint Commission Center for Transforming Healthcare wrong-site surgery project, eight U.S. hospitals and ambulatory surgery centers measured the risk of wrong-site surgery in their perioperative processes, pinpointed the specific factors that caused those risks and developed specific solutions to reduce them. These health care organizations used The Joint Commission's Robust Process Improvement, which incorporates tools from Lean Six Sigma and change management methodologies. The organizations identified and validated factors that increased risks of wrong-site surgery in four main areas: 1) scheduling, 2) pre-op/holding, 3) operating room and 4) organizational culture. Targeted solutions were developed and thoroughly tested in real-life situations.

As a result, the organizations reduced the number of surgical cases with risks for wrong-site surgery by 46 percent in the scheduling area, 63 percent in the pre-op/holding area and 51 percent in the operating room. Additional organizations tested the work of the original participating organizations and demonstrated similar results.

This report describes the types of risks introduced during each stage of the perioperative process, the root causes for those risks, and the solutions designed to reduce them, and includes examples and lessons learned from the participating health care organizations. The last section highlights individual case studies.

Background

There were 463 incidents of wrong-patient, wrong-site, wrong-side and wrong-procedure surgeries voluntarily reported to The Joint Commission's sentinel event database from January 1, 2010, through December 31, 2013. The national incidence rate —not only in operating rooms but in many other settings in hospitals and ambulatory surgery centers, such as radiology and cardiology departments and patients' bedsides—is estimated to be much higher, perhaps as often as 50 incidents per week in the United States.[1]

A group of eight hospitals and freestanding ambulatory surgery centers joined a project of The Joint Commission Center for Transforming Healthcare to prevent wrong-patient, wrong-site, wrong-side and wrong-procedure surgical procedures (hereafter referred to as "wrong-site" surgeries). These organizations identified 29 main causes of wrong-site surgeries, ranging from scheduling processes to operating-room procedures to organizational culture.

In the late 1990s, The Joint Commission identified wrong-site surgery as a *sentinel event*—that is, any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. The Joint Commission has issued two *Sentinel Event Alerts* on wrong-site surgery, the first published in 1998 and the follow-up in 2001.[2, 3] Organizations such as the Institute of Medicine, National Quality Forum, and Agency for Healthcare Research and Quality have identified and published safe practices to prevent wrong-site surgeries. In 2003, The Joint Commission held its first Wrong-Site Surgery Summit and in 2004 introduced the Universal Protocol. In 2009, the Center for Transforming Healthcare launched its wrong-site surgery initiative.

Participating Hospitals and Surgical Centers

Eight hospitals and surgical centers participated in the Joint Commission Center for Transforming Healthcare's wrong-site surgery project:

- AnMed Health, Anderson, South Carolina

- Center for Health Ambulatory Surgery Center, Peoria, Illinois

- Holy Spirit Hospital, Harrisburg, Pennsylvania

- La Veta Surgical Center, Orange, California

- Mount Sinai Medical Center, New York, New York

- Rhode Island Hospital, Providence, Rhode Island

- Seven Hills Surgery Center, Henderson, Nevada

- Thomas Jefferson University Hospital, Philadelphia, Pennsylvania

These health care organizations range from small to large and from rural to urban, both teaching and nonteaching. Their differences underscore the importance of managing the risks of wrong-site surgery regardless of an organization's size or setting.

The last section of this guide includes individual case studies on seven of the participating organizations.

Robust Process Improvement

This project applied a systematic and data-driven problem-solving methodology called Robust Process Improvement™ (RPI). The methodology incorporates tools and methods from Lean Six Sigma and change management. Using RPI, teams measure the magnitude of a problem, pinpoint the contributing causes, develop specific solutions targeted to each cause and thoroughly test the solutions in real-life situations.

Invasive surgical procedures occur in many settings; the scope of this project included all procedures performed in the operating room and all regional blocks performed by anesthesia either in the preoperative area or the operating room. Within the project scope, the time frame begins when a procedure is scheduled for surgery and ends with incision.

Main Causes of Wrong-Site Surgeries

Using Robust Process Improvement, the eight participating hospitals and surgical centers identified and validated root causes for risk of wrong-site surgery. These root causes fall into four main areas: 1) scheduling, 2) pre-op/holding, 3) operating room and 4) organizational culture. Although all of these causes of failure were not evident in every organization, each appeared in one or more of the participating organizations.

1: Scheduling

During the scheduling of surgeries—whether the process is done verbally by phone, manually by paper or fax, or electronically by websites or emails—several factors were found to contribute to the risk of wrong-site surgery.

Causes	Solutions	Case Examples
Office schedulers do not verify presence and accuracy of booking documents.	Confirm the presence and accuracy of all primary documents—such as original surgical or procedure orders, patient chart, etc.—before the day of surgery.	**La Veta Surgical Center** now requires offices that are scheduling surgery to verify that all information is appropriate and correct. All information must be validated and signed on the day before surgery; previously, this was done when a patient arrived. At **Rhode Island Hospital**, if documents are not in agreement or are incomplete, the physician's office is notified 48 hours in advance. All paperwork must be completed 24 hours in advance, or the case is canceled.
Schedulers accept verbal requests for surgical bookings instead of written documents.	Discontinue verbal bookings, and accept only written bookings. If schedulers attempt to schedule verbally, redirect them to submit written requests.	At **Holy Spirit Hospital**, scheduling for most surgeries was previously done verbally by phone, in many cases without using written documentation as follow-up. Now, verbal bookings are accepted only when verified by written documents.
Unapproved abbreviations, cross-outs and illegible handwriting are used on booking forms.	Educate physician offices regarding nonacceptance of unapproved abbreviations and requirement for consent to be clear and correct, legible and without cross-outs. Return all consents not meeting criteria to physician offices for correction.	The scheduling process at **Holy Spirit Hospital** now includes extra checks and verification, such as requiring correction of illegible handwriting and cross-outs.

2: Pre-op and Holding

Pre-op defects include inconsistent use of site-marking protocol, marks made with unapproved surgical-site markers, and inadequate patient verification.

Causes	Solutions	Case Examples
Primary documents—such as consent, history and physical, surgeon's booking orders, operating room schedule—are missing, inconsistent or incorrect.	Require accurate primary documents 48 hours before surgery. When inconsistencies are found, flag operating room schedule to alert staff and treat case as high risk.	A new policy at **Rhode Island Hospital** now stipulates that if paperwork is not complete and accurate, the case is canceled.
Inconsistent use of site-marking. Examples include someone other than surgeon marks site; site mark is made with unapproved surgical-site marker; stickers are used instead of marking the skin; and inconsistent site marks are used by surgeons.	Create new protocol requiring surgeons to use a single-use surgical-site marker with a consistent mark type (e.g., surgeon's initials) placed as close as anatomically possible to the incision site.	The **Center for Health Ambulatory Surgery Center** has approximately 100 different providers on its active medical staff, with 50 participating in 80 percent of its cases. Staff found inconsistencies in surgical-site marking, including how it was done, where it was done and when it was done. The center standardized site-marking procedures and eliminated variations based on provider preference to reduce the chance of wrong-site surgery.
Time-out process for regional blocks is inconsistent or absent.	Verify patient, side and site for all regional blocks using a standardized time-out process. Educate staff about the value of standardized processes. Hold all caregivers and staff accountable for their role in risk reduction; the organization should define roles.	**La Veta Surgical Center** added a time-out to the process for all cases requiring an anesthesia block. **Holy Spirit Hospital** has implemented a role-based time-out.
Inadequate patient verification by the team because of rushing or other distractions.	Educate staff about the value of standardized processes, and ensure that standardized verification protocols are followed in all cases. Create an environment where staff members are expected to speak up when they have a patient safety concern.	**Thomas Jefferson University Hospital** now uses "just-in-time" education, with coaches available to provide feedback in order to improve patient verification. The **Center for Health Ambulatory Surgery Center** eliminated unnecessary tasks that prevented the health care team from listening.

3: Operating Room

Operating-room defects include distractions and rushing during time-outs. Defects occur when the time-out is performed without full participation or if there is an ineffective hand-off communication or briefing process.

Causes	Solutions	Case Examples
When the same provider performs multiple procedures, there is no intraoperative site verification.	Stop between each procedure within a single case to ensure that the procedure, site and laterality of each procedure are performed accurately and according to the signed surgical consent.	At **La Veta Surgical Center**, when multiple procedures are done on one patient, a time-out now occurs between procedures.
Hand-off communication or briefing process is ineffective.	Perform a pre-operative briefing upon arrival in the operating room with patient involvement, if possible, to verify patient identity, procedure, site and side, along with any other critical information.	**AnMed Health** used "secret shoppers" to observe the process in the operating room before surgery and found that the circulating nurse was not communicating important information from patients' charts. The process was revamped, including using a checklist based on the World Health Organization surgical safety checklist.
Primary documentation is not used to verify patient, procedure, site and side immediately prior to incision.	Ensure use of primary documentation during time-out to verify patient, procedure, site and side.	At **Rhode Island Hospital**, once the patient is in the operating room, the team initiates the verification process using primary documents to confirm correct patient, site, side and procedure. The surgeon calls for time-out, and all members of the team stop what they are doing and follow a role-based script.
Site marks are removed during prep.	Switch to one-time-use indelible markers; keep a large supply of these markers in pre-op, holding, and operating room; and test selected pens for satisfactory results with prep solutions used at the organization.	**Thomas Jefferson University Hospital** discovered that a particular skin preparation product was washing off site markings. In response, the hospital changed to markers that make a permanent mark.

Causes	Solutions	Case Examples
Distractions and rushing occur during time-out, or the time-out occurs before all staff members are ready or before prep and drape.	Develop a role-based time-out process that works for all team members and that is performed after the prep and drape.	The **Center for Health Ambulatory Surgery Center** eliminated some elements of its time-out, narrowing its intent and making it consistent and streamlined. Time-out is now strictly about verifying the correct patient, procedure, side and site. **Thomas Jefferson University Hospital**, the participating organization with the most annual surgeries and most operating rooms identified revamping time-out among its most important improvement opportunities during the project. To reduce distractions, the hospital changed its policies to prevent anyone entering the room during time-out and at other critical points during surgery (induction, emergence from anesthesia. etc.). By making staffing adjustments, the hospital provided an additional nurse for every two operating rooms (without adding any full-time employees) to prevent nursing staff from being rushed.
Time-out is performed without full participation.	Perform a standardized time-out process and give every team member an active role. Create an environment where staff members are expected to speak up when all team members do not participate.	**Seven Hills Surgery Center** involved all team members in the room to increase everyone's attention. The surgery center developed a robust process for time-out with a script that includes every team member. At **La Veta Surgical Center**, the process was improved so time-out always occurs just before incision, a critical moment when everyone is paying attention. The surgical center focused on overcoming communication challenges and empowering team members to speak up.

4: Organizational Culture

Organizational culture defects include senior leadership that is not actively engaged, staff that is passive or not empowered to speak up, and policy changes made without adequate or consistent staff education.

Causes	Solutions	Case Examples
Organizational focus on patient safety is inconsistent.	Develop a measurement system for identifying inconsistencies in real time. Hold all caregivers and staff members accountable for their role in risk reduction.	**AnMed Health** emphasizes the importance of focusing on patient safety and continual service readiness, using national patient safety tools. The medical center emphasizes the role of physicians and shows them the benefits of examining and improving processes, including developing a minimum checklist and then expanding it. At **Seven Hills Surgery Center**, staff is now actively engaged in improving patient safety. Physicians have called out areas for improvement. The director of nursing has observed "passionate discussion on important issues like time-out and marking."
Staff is passive or not empowered to speak up.	Share the data and allow the team to ask questions. Create an environment where staff members are expected to speak up when they have a patient safety concern; support all team members' participation.	Daily huddles with the operating room staff at **Holy Spirit Hospital** meet the challenge of involving several disciplines. The team uses a huddle educational video, shared with all groups and new employees. Speciality coordinators move in and out of the orthopedic rooms, leading the coaching and speaking to physicians individually.
Policy changes are not followed by adequate and consistent staff education.	Use a team approach when teaching all staff how new processes should be executed. Celebrate success; everyone should be aware of improvement. Provide ongoing education and just-in-time coaching.	**Rhode Island Hospital** closed its operating rooms for one day for education, assembling 1,200 staff and physicians in two hospitals. During that day, all staff, including leadership, went through safety-culture training.

Results

Using Robust Process Improvement tools during the project, the participating organizations reduced the number of surgical cases with identifiable risks for wrong-site surgery by 46 percent in the scheduling area, 63 percent in the pre-op/holding area and 51 percent in the operating room. Additional hospitals and ambulatory surgery centers that tested the work of the original organizations experienced the same improved results.

Targeted Solutions Tool

The Joint Commission's Center for Transforming Healthcare coordinated the work of the original wrong-site surgery project organizations as they measured and analyzed the causes of wrong-site surgery at their organizations and then worked toward solving the problems. Recognizing that every organization has its own unique combination of problems, the center then created a tool that maps individual causes of increased risk to solutions specifically designed to address those causes. The instrument, called the [Targeted Solutions Tool]® (TST), is formulated in such a way that Lean Six Sigma expertise is not required to use it. The first TST was created in 2010 for the center's hand hygiene project, and TSTs for hand-off communications and wrong-site surgery followed in 2012. Since 2010, hundreds of health care organizations have used the tool to improve safety and quality.

Since wrong-site surgery is a rare occurrence, monitoring the incidence of wrong-site surgery for a project may take many years. It is possible to monitor surgical cases for weaknesses that could result in wrong-site surgery, which is the purpose of the TST. Organizations that do not have Lean Six Sigma expertise can work to decrease the risk of wrong-site surgery by using the TST to guide them through a data-driven project. The TST includes data collection forms, training modules for data collection, and built-in data analysis to determine the specific factors that contribute to a particular organization's risk of wrong-site surgery. The TST also gives instructions about which solutions to use and how to implement them.

To date, health care organizations using the wrong-site surgery TST have had results similar to those of the participating organizations. These organizations have reduced risks for wrong-site surgery by 45 percent in their scheduling areas, 30 percent in pre-op/holding and 55 percent in the operating room.

Conclusion

Health care organizations in a variety of settings must manage the risks of wrong-site surgery and create a culture that ensures the safety of patients. Preventing wrong-site surgery is accomplished through improving the perioperative process from scheduling to incision.

Using The Joint Commission's Robust Process Improvement methodology, eight U.S. hospitals and ambulatory surgery centers measured their risk of wrong-site surgery, pinpointed the contributing causes and developed specific solutions targeted to each cause. These targeted solutions were then tested in real-life situations. As a result, the participating organizations reduced the number of surgical cases with risks for wrong-site surgery in scheduling, pre-op/holding and the operating room. By reducing risks in these areas and working to improve the culture of safety, health care organizations can significantly reduce the chances of a wrong-site-surgery at their facilities.

AnMed Health
Anderson, South Carolina

Organizational Profile

AnMed Health is a 588-bed, nonprofit health system. AnMed Health has 21 operating rooms and performs about 10,000 surgeries annually.

Project Team Leaders

- Paul Frassinelli, MD, General Surgeon
- Dale Duncan, RN, Director of Medical Affairs
- Martha Rush, RN, Nurse Manager

Background

Like all major medical institutions, AnMed Health has struggled with the issue of preventing wrong-site procedures. "Near misses have happened at every major institution," Paul Frassinelli, MD, said. After five weeks of collecting baseline data, AnMed Health focused on two major areas: scheduling and time-outs in the operating room.

Causes and Solutions

Scheduling: AnMed Health averaged about 15 scheduling defects a day—that is, incorrect or missing information on scheduling forms. Cross-outs and unapproved abbreviations were also tracked and recorded as a defect. Staff working in scheduling offices were trained using an electronic scheduling module. When measurement was repeated after the solutions were implemented, the rate for defects was less than one percent for electronically scheduled cases.

Dale Duncan noted that changes in the scheduling process were "one of the most exciting changes for the entire project." Communication improved between the hospital and scheduling office, which gave the offices more ownership and helped them prevent errors.

Time-out: AnMed Health used "secret shoppers"—staff members who normally would be in the operating room but were assigned to do direct observation, unknown to others. Staff identified two potential problems: 1) Not everyone in the room was ceasing other activities during time-outs; and 2) the circulating nurse was not communicating important information from patients' charts. In response, the time-out process was revamped. The hospital instituted a checklist based on the WHO surgical safety checklist, but customized for AnMed Health. Realizing the new process would be a major change for most staff, particularly surgeons, Frassinelli led the cause with all of the hospital's surgeons. Duncan emphasized the importance of having someone like Frassinelli as a champion for the initiative: "All of us [staff] can go to the meetings and have opportunities to change, but it's really peer to peer. Frassinelli was our physician champion, which was critical. It needs to be a physician leader who is well respected."

Part of the new surgery checklist is having physicians point out the site mark.

Results

AnMed Health trained all offices in electronic scheduling. Subsequent measurement demonstrated a defect rate of less than 1 percent for electronically scheduled cases.

One week after implementing the surgery checklist, AnMed Health improved its compliance from 68 percent of cases having one or more defects in scheduling to 37 percent. The rate continued to decrease from 16 percent in October 2011 to less than 2 percent in 2013.

According to the team at AnMed Health, it had been doing time-out since 2004 when The Joint Commission made it part of the Universal Protocol. However, the process was never standardized but left to the team. Team members said the new structure has helped them improve–not by being perfect but by being better and making surgery a safer process for patients.

Barriers

Physicians do not think in terms of systems and process, although their hearts are in the right place, Frassinelli said. Pushback is more likely to come from a doctor than an administrator or nurse, he added. The key is demonstrating to physicians that there is benefit in doing this. "Even if you have some negativity [about changing the process], at some point you have to draw a line in the sand. You may not get 100 percent, but we got pretty close. Even though a couple of people didn't buy in at the beginning, they are doing it and doing fine now," Frassinelli observed.

Lessons Learned

Although it is hard to demonstrate that a small checklist will turn into something meaningful, one must demonstrate exactly that to doctors and staff, according to Frassinelli. "Every surgeon's nightmare is operating on the wrong site." It is important to get input along the way—to decide and include what is meaningful and useful—so people are making the new process their own. Having a physician champion that is "visible and engaged" is important, so physicians knew change was coming from someone who was doing it themselves and it was not "another mandate coming from above," Frassinelli said.

Keeping the work in perspective is also important. "We are not perfect and will never be. We're better now though, and that will make a safer process for our patients," Frasinelli explained.

The AnMed Health team emphasized the value of collecting the data—you don't know where to go until you know where you are, observed one AnMed Health nurse. Continued measurement is the only way to see if gains are sustained. AnMed Health continues to perform ongoing audits of the time-out process to ensure that all elements are addressed and the entire team participates.

Contact Info

Paul Frassinelli, MD, General Surgeon: pfrass@charter.net

Martha Stratton, RN, Director, Surgical Services: martha.stratton@anmedhealth.org

Center for Health Ambulatory Surgery Center
Peoria, Illinois

Organizational Profile
Center for Health Ambulatory Surgery Center is a freestanding center and a joint venture owned by OSF Saint Francis Medical Center and four different physician groups. It has six operating rooms and performs 7,400 surgeries annually.

Project Team Leaders

- Tom Feldman, CEO

- Debra Lee, Compliance and Clinical Education

Background
The facility has 100 different providers on its active medical staff, and 50 of them perform 80 percent of cases. The center used trained auditors to observe preoperative verification, site marking and time-outs. According to CEO Tom Feldman, "We tracked down our process from start to finish and looked for opportunities for closing some gaps. And we looked at consistency."

Causes and Solutions
Site marking: The Center for Health Ambulatory Surgery Center handles many cataract cases, and site marking was inconsistent with the ophthalmologists. For instance, when the mark was made, some patients were marked while in the pre-op area, and others were marked in the operating room before incision. Standard practice is marking the correct site in the pre-op area. Another issue was the inconsistency of the mark itself. Some physicians used their initials; others used a dot by the eye; and others used a "yes" written above the eye. The center's protocol limits site marking to the surgeon's initials, using a skin marker and placed near the site so it will be visible after prep and drape.

Other variations influence site marking. "Not everyone's skin is the same, and eyebrows get in the way," observed Feldman. "For us, [the project] was more about eliminating variations based on provider preference that will lend itself to lessen the chance of wrong-site surgery." Debra Lee, compliance and clinical educator, observed, "We thought we were doing a good job but were not naive and knew we could be doing better." Initial data showed that the teams were employing elements of the Universal Protocol. A time-out was performed prior to every procedure, but there were lots of variations." For example, Lee said auditors witnessed a time-out done differently with the same surgeon but a different surgical team. "We saw the holes in the Swiss cheese," Lee noted.

Time-out: The center streamlined the time-out by eliminating many tasks. Lee explained, "We had started to confuse time-out with the WHO surgical safety checklist. Too many things were being added to time-out, and that was turning the health care team away from listening." Although the team uses a surgical safety checklist prior to each case, the time-out has been narrowed to its intent—verifying the correct patient (name and birthdate), correct procedure and correct site—and is performed prior to incision or injection.

Training: The center created a video demonstrating how each element of the Universal Protocol is used during scheduling, preadmission, registration and admission processes, and concluding in the operating room with the time-out. This video was used for employee education. The team used coaching, briefing and debriefing with the surgeons.

Results

The Center for Health Ambulatory Surgery Center has made notable improvements in site marking of cataract patients. Surgeons now confirm the correct eye with the patient in the operating room and then write their initials above the operative eye before draping. There still is variation with the "timing" of the time-out and who is initiating it, and coaching of the surgical teams continues.

Barriers

If specific staff or physician issues developed and became potential barriers, Feldman got involved. He notes that, in general, surgeons are leaders in the operating room and less accustomed to being followers; staff and employees are more willing to follow. Therefore, changes and tweaks to the process might take longer for surgeons to become comfortable with. If needed, Feldman spoke individually with any physicians who were deemed "stragglers," explaining the priority and importance of the changes. "We weren't asking for volunteers," Feldman emphasized to them. "It was an all-or-nothing proposition."

Lessons Learned

During the pilot study, a young child had the wrong eye operated on in a hospital in another region of the country. Feldman noted, "We live in such a real-time age….Our center has a fairly significant pediatric population, and that kind of tragic story really resonates. Our business is to provide high-quality care, and patient safety is number one."

The center has very little staff turnover. "No one leaves," Feldman said. "The good news is the team knows its responsibilities, but we might get too comfortable." Process improvement is important "to help us look critically at ourselves and stay sharp," he added.

Lee recommends educating staff before implementing changes. "Education is critical. I thought we could do it simultaneously, but we needed to take our time and engage our staff." The staff not only needed education on the Universal Protocol but also "scripting" on how to help the surgeons and anesthesia providers on their roles and responsibilities using the protocol. "Set a timeline for training, implementation and evaluation," Lee added.

Contact Info

Debra Lee, Compliance and Clinical Education: dlee@cfhasc.com

Holy Spirit Hospital
Harrisburg, Pennsylvania

Organizational Profile
Holy Spirit Hospital is a 319-bed facility with 15 operating rooms, performing more than 10,000 surgeries annually.

Project Team Leaders

- Bret Delone, MD, General Surgeon and Surgical Champion

- Natalie Hattingh, Orthopedic Specialty Leader

- Susan McQuade, RN, Director, Quality and Organizational Performance

- Joseph Torcia, MD, Internist and Chief Medical Officer

Background
Holy Spirit Hospital had previously used the Hand Hygiene Targeted Solutions Tool from The Joint Commission Center for Transforming Healthcare. "We are certainly aware that we're always at risk for wrong-site surgery, and we want to be proactive and do everything we can possibly do to avoid it," said Susan McQuade, RN, director, quality and organizational performance. "There was a feeling that anesthesia and time-outs were not what they could have been," said Bret Delone, MD, general surgeon and surgical champion. "The pilot study was an opportunity to get everyone to participate in a more active process."

Causes and Solutions
Scheduling: Holy Spirit had done a lot of scheduling over the phone, and not all of those calls were followed up with written documentation. So verbal scheduling often meant there was no written record. "If there's no documentation, it can have a downstream effect in the operating room," McQuade pointed out. "When physician offices send in the scheduling form, we now compare it with our schedule, which gives us an extra check," she explained. The team identified many opportunities for improvement in the outpatient scheduling department. One example: "It seems minor, but a handwriting issue or cross-through [words that are crossed out] is considered a defect because it creates confusion. We cleaned that up and implemented higher standards for documents and quality of documents," McQuade noted.

Time-out: Previously, the hospital had a nurse running the time-out process, being the speaker and getting everyone's attention. Now the hospital has a role-based time-out with every member on the team participating. For example, the circulating nurse starts by calling attention, and all team members must cease conversation and turn down music and stop anything that interrupts the team from concentrating. The anesthesiologist verifies the patient's name and date of birth from the armband. The surgeon points to his or her mark and confirms that everyone can see it. The surgical technician verifies. The circulating nurse ends time-out by asking if everyone on the team agrees and has any concerns. "We've expanded time-out so everybody can actively participate," McQuade said. Every surgical team does time-outs at the exact same time—immediately before incision—when everyone on the team is focused and paying attention. Surgical stops also have been added to the process. For example, before doing pre-op injections, there is a surgical stop. Before moving from operating on one finger to another, there is a stop.

Daily huddles with the operating room staff help to meet the challenge of crossing so many disciplines. Specialty coordinators move in and out of the orthopedic rooms every day, leading the coaching and speaking to physicians individually.

Results

The team is catching defects and potential problems very quickly. Potential problems are being caught at the first checkpoint. "Before, it wasn't practice for people to be so careful and interview the patient [if there was a discrepancy]. We have a different culture of safety in the operating room because of it," McQuade reported.

Barriers

The hospital had pushback from some providers. The pilot process was "completely data driven," and for every case, all providers are listed, McQuade said. If a specific provider proved to be a source of contention, a team leader would talk with him or her and emphasize the hospital's commitment to the project. "There may be a handful of providers who do it because they have to," McQuade said.

Hattingh and other team members audit the entire process, continuing to focus on how time-outs proceed. There's been an "increase of awareness and standardization," according to Joseph Torcia, MD, internist and chief medical officer. "That's what I think changes the culture of safety and awareness. Once culture is changed, when new things are introduced, it becomes more easily accepted. Barriers become hills, and hills become smaller and smaller," he explained.

Lessons Learned

Evidence-based research on many topics was provided by The Joint Commission. The team shared these articles with physicians, and they provided "a good resource to drive change," McQuade said.

The Targeted Solutions Tool helped to keep the team on track with data collection. Staff has learned the value of data collection and is following through. "Once you make the change, it is important to keep collecting, making changes and staying on track," McQuade emphasized. Torcia noted the team successfully learned about "making change and rapid cycling change to get to the desired outcome as quickly as possible." He added, "This project has re-informed me on the importance of doing checks early in the process."

Having the support of the hospital's chief nursing officer and a surgeon was key; they attended meetings, supported the team in presentations to The Joint Commission and did presentations for the hospital's quality board. According to Delone, "They have spoken to our board about the project, which has received a lot of attention. We haven't had to use them to fight any battles. We handled naysayers ourselves, but they would have been there if we needed them."

Contact Info

Susan McQuade, RN, Director, Quality and Organizational Performance: susan.mcquade@hsh.org

La Veta Surgical Center
Orange, California

Organizational Profile
La Veta Surgical Center is an ambulatory surgical center that has five operating rooms and performs 6,600 surgeries annually.

Project Team Leaders

- Maurice Berry, RN, current Administrator, former Director of Nursing

- Kelli J. Ruiz, former Administrator

Background
At the time of the pilot study, La Veta was planning an expansion and relocation. Although La Veta had not had a wrong-site surgery in 23-plus years at its facility, others in the community have had wrong-site surgeries. According to Kelli Ruiz, administrator, "We wanted to be able to stay on top of the processes and look at what we're doing to do everything possible to mitigate. Our participation in the pilot was more defensive—to maintain what we've been able to accomplish in the midst of expansion."

Causes and Solutions
Scheduling: Using The Joint Commission's data analysis tools to collect data, the surgical center identified scheduling as an area for improvement. Information was being taken verbally over the phone, and errors were found in that process. Now offices that are scheduling surgery fax back forms to the ambulatory center, verifying that all information is appropriate and correct. The day before surgery, all information must be validated and signed. Previously, this confirmation was done when a patient arrived.

Site marking—particularly alternate-site marking—was another area identified for improvement. For some operations, such as removing tonsils and adenoids, the surgical site cannot be marked. In these cases, a colored wristband is used to validate the site.

Time-out: The center wasn't doing time-outs for anesthesia blocks. Those time-outs were added to the process. "In the past, we didn't do a lot of cases that required [an anesthesia block], [so] we hadn't done it. Now we do more cases and are 100 percent accurate every time," Ruiz said. In addition, when multiple procedures are done on one patient, a time-out occurs between procedures, which also had not been done before at La Veta.

Results
La Veta expanded from three to five operating rooms. Process changes have been incorporated, and validations and time-outs have been maintained. According to Ruiz, "We absolutely have to keep checking in and be very deliberate. It definitely has become part of our culture."

Barriers

The surgical center encountered some pushback regarding alternate-site marking from some participants who did not agree with the process. According to Ruiz, "We felt strongly we needed some sort of system for cases that we couldn't mark. Many hospitals use different colored wristbands." La Veta now uses wristbands so every case has some sort of validation. "Preoperatively, that was our biggest change," Ruiz added.

"Old habits die hard," Ruiz noted. Some surgeons wanted patients to be actively involved during time-out. But if a patient is draped for surgery, he or she cannot participate. "We compromised," Ruiz explained. "If surgeons want patients to be involved, they must use best-demonstrated practices."

Although data collection was "impactful," it was also "tedious and not easy," Ruiz said, noting it was another area of pushback. Pre- and post-data collection is important to identify weaknesses and solutions, she emphasized.

Lessons Learned

Communication and "empowering the team to speak up" are important, said Maurice Berry, RN, current administrator and former director of nursing. To improve communication and increase empowerment, time-out was moved to just before incision. "It heightens everyone's awareness. Everyone knows the critical part of the procedure and is paying attention," Berry noted.

For scheduling, La Veta seized on a "great opportunity" to involve its business team. "They played a crucial role," Ruiz explained. If errors are not stopped by the business team, it could result in a wrong-site surgery. "We're all a team," Ruiz noted. "That was a huge learning opportunity."

Senior leaders played an important role, too. La Veta has many physician partners, and two of the anesthesiologists—one who served as chief of staff and the other on the medical staff—presented at partnership meetings. "Their approach was positive, not negative. Our chair of the board, a surgeon, was involved and helped as one of our champions," Ruiz said.

Contact Info

Maurice Berry, RN, Administrator: Maurice.Berry@scasurgery.com

Rhode Island Hospital
Providence, Rhode Island

Organizational Profile

Rhode Island Hospital is a 719-bed academic medical center that has 33 operating rooms and performs about 24,400 surgeries annually. It is the major teaching hospital of Brown University's medical school. The hospital is a member of Lifespan health system in Rhode Island.

Project Team Leaders

- Mary Reich Cooper, former Senior Vice President and Chief Quality Officer

- Edward J. Marcaccio Jr., MD, Medical Director, RIH Operating Rooms

- Barbara Riley, RN, Senior Vice President and Chief Nursing Officer

Background

In 2007, Rhode Island Hospital experienced a highly publicized wrong-site neurological case. Shortly afterward, it began working with the state health department's director to rectify the situation and make process improvements. The hospital revised its procedures, policy and site-marking protocol, but two wrong-site surgeries occurred in 2009. According to Edward Marcaccio, MD, "At the time it was fortunate to have a state department of health director who had lots of background in quality and performance improvement. He understood that this was not something solved by coming down harshly, which gave us the ability to come together as an organization for the performance improvement effort."

Rhode Island Hospital began its performance improvement work in early 2008 and later began using Robust Process Improvement tools. It invested $4 million in video cameras for learning purposes. On November 20, 2009, the hospital closed its operating rooms for a day of education, assembling 1,200 staff and physicians in two hospitals.

Causes and Solutions

Site marking: According to Marcaccio, "Instead of going back and revising our policy to correct the gaps to not allow another one [wrong-site surgery] to slip through, we went back and drilled down to determine our root causes." Surgical-site marking was identified as an area for improvement. The issues included distractions, missing paperwork or lack of adequate paperwork and reliance on memory. The hospital designed a process that incorporates initialing, which was not part of the protocols previously. The process also includes the physician pointing and touching where the incision will be made.

Scheduling: The scheduling process also was improved. Paperwork is typed, and handwritten bookings are no longer allowed. Chart assembly is completed early in the process with dedicated individuals assigned to collate and assemble. If paperwork is not in agreement or is incomplete, the office is notified 48 hours in advance. All paperwork must be completed 24 hours in advance or the case is canceled. This improvement helps prevent rushing and distractions in the operating room, which in some cases had been caused by incomplete or nonmatching paperwork.

Time-out: To further alleviate distractions, when the surgeon calls for a time-out, everyone in the operating room must stop what they are doing. A script is used, starting with the surgeon asking,

"Can everyone see my mark?" Every person with a role in the room has a script to follow. For example, the anesthesiologist states the patient's name, and the nurse states the procedure. All documents have been verified before the patient is in the operating room and then the correct patient, correct site and correct procedure are verified again.

Organizational culture: Improving communication and increasing the willingness and comfort of all staff members to speak out were important. "The team is the greatest ally when it comes to preventing wrong-site surgery," Marcaccio observed.

Results
Since, shutting down its operating rooms for one day in November 2009, Rhode Island Hospital has not had a wrong-site surgery.

Barriers
Any pushback from staff is addressed with real-time live coaching. Pushback from surgeons was handled by the medical director, who explained why the process was important. According to Marcaccio, "It's important to get an active group of clinical surgeons to help lead the improvements. Though it took persuasion, the surgeons know that I'm doing it myself. We got the busiest surgeons to [follow the protocol]."

Since lack of education was a barrier, the hospital scheduled a day of education, closing its operating rooms for one day. The team prepared videos to demonstrate the new process. After a one-hour didactic session by the chief of surgery, small groups convened in the operating rooms with leaders trained to model the process.

Lessons Learned
Buy-in is a critical aspect, Marcaccio noted. During the education day, everyone was able to observe all regular staff going through the training, as well as hospital leadership. The organization was ready to accept a change in culture—so people understand that standardization can provide a safety net in the operating room—and be ready to drive it. According to Barbara Riley, RN, senior vice president and chief nursing officer, "All the training we've done with leaders and the safety-culture training with staff have been well received. People are much more likely now to speak up, which is a change."

When designing its new process, the hospital held forums for all staff to contribute points of possible disruption to the process. "We made enormous lists and ranked them—things most likely to occur and things most catastrophic when they occurred," Marcaccio said. "Then we prioritized."

Every single procedure was audited to complete the task correctly and the reason for the procedure change was discussed. For example, if the surgeon did not initially do time-out, was he or she prompted? Prompted more than once? What was his or her attitude? Now, if surgeons or other staff members do not follow the rules in place, there is an intervention. The hospital continues to audit every case, every day.

Contact Info
Barbara P. Riley, RN, Senior Vice President and Chief Nursing Officer: BRiley1@Lifespan.org

Seven Hills Surgery Center
Henderson, Nevada

Organizational Profile
Seven Hills Surgery Center is an ambulatory surgery center that has seven operating rooms and performs about 5,000 surgeries annually.

Project Team Leaders

- Tracy Helmer, RN, Director of Nursing

- Rudy Manthei, MD, DO, President and CEO

Background
The same issues that occur in hospitals preparing for surgery also occur in freestanding surgery centers. One difference is that Seven Hills Surgery Center did more scheduling and paperwork by hand, and not being fully electronic leaves some margin for error, according to Tracy Helmer, director of nursing. "Some of the human elements still exist in small freestanding surgery centers," he said.

Seven Hills looked at its scheduling department, pre-op department and operating room and drilled down to find defects in process in the three areas. No sentinel event had been singled out as important, but the surgical center wanted to be proactive. "It doesn't require an event from our facility to recognize there is susceptibility," Helmer noted.

Causes and Solutions
Scheduling: Seven Hills implemented a confirmation process with the scheduling department that requires the scheduler to fax back exact wording for a procedure from the physician's office. Schedulers in physician offices are asked to review the data and ensure wording is correct. Once checked and confirmed, they sign and fax back. "Prior to using this process, we could get transcription errors because we hadn't closed that loop of communication," Helmer pointed out.

Site marking was improved by implementing more structure and process. Seven Hills used The Joint Commission guidelines, and physicians marked their initials in close proximity to the incision site "Implementing a procedure like that, for site marking, helped us in our OR area as well. Because of quality checks and our time-out procedure, more information is available," Helmer said.

Time-out: Seven Hills developed a robust time-out protocol, adapted from The Joint Commission. Because surgery centers do not handle the broad scope of surgeries that hospitals do, staff had to "fine-tune" their procedures, Helmer said. To involve all team members in the operating room, staff tailored a time-out script so that everyone in the room has a role.

Results
The defect rate at Seven Hills dropped from 20 percent to 8 percent, which the team attributes to attention to detail in pre-op areas, marking and scheduling, especially ensuring all documents are accurate. "All types of improvements gained in the operating room are shared in different departments," Helmer said. For instance, in the pre-op department, the percentage of cases encountered that had one defect or more dropped from 15 percent to 8 percent.

Helmer noted that while the center did not necessarily show "numerical improvement" in the scheduling process, they did find that some of the process improvements made in scheduling greatly reduced the number of defects in other departments.

Helmer and others also observed a culture change at Seven Hills. Staff, including physicians, have shown "intimate interest in the project" and will often call out areas for improvement. "I have walked into rooms where people were having a passionate discussion on important issues like time-out and marking," Helmer said.

Barriers

Though the team did not encounter much pushback, they acknowledged that physicians "have a certain way of doing things and don't like to be told what to do," noted Rudy Manthei, MD, DO, president and CEO. "Our approach was to engage not demand. If you engage physicians to do the right thing, they come on board. If you demand it, they resist," Manthei said.

One physician at the hospital was "stubborn," according to Helmer. The physician said we were "creating more stuff that gets in the way" of getting the procedure done and complained it distracted him. Helmer replied that it's "not always about the physician" but "making sure patients get what they ask for." After reading some material on his own, the physician changed his mind and realized "a person can be as focused as possible but the team members are the ones that increase that focus." Helmer added, "We realized we are stronger as a team than operating alone. That was an important message for [the physician] to acknowledge."

With technology improvements for transitioning cases, freestanding surgery centers are doing more cases, and turnover times become important, as does quality and cost effectiveness, Manthei emphasized. "We must do more cases in the same amount of time. But people slow down to prevent medical errors from occurring. With so many cases, we have to have these policies in place." Manthei noted the difference when medical errors occur at a facility with a high volume of cases versus one that doesn't have the same number of surgeries: "If one patient [at our surgery center] has an issue, potentially you may have many different patients involved, particularly if it's an infection-control issue."

Lessons Learned

Seven Hills staff found that one mistake or defect in process, even if it happened early on, increased risk for the event to become bigger or to progress toward a wrong-site surgery event.

Manthei said he believes improvement initiatives like the wrong-site surgery project reinforce that health care providers are addressing issues like accountability and quality parameters, which the Centers for Medicare & Medicaid Services are looking for health care organizations to measure. "It is everything to decrease medical errors and get the best patient outcomes, which will tie into cost of health care and decrease overall health care spending," Manthei noted. "In the United States, we spend $8,000 per patient per year, while the rest of the word spends half of that. We don't provide the highest quality of care, yet we spend the most. Projects like this provide quality parameters and address problems we're having."

Contact Info
Tracy Helmer, RN, Director of Nursing: thelmer@promednv.com

Thomas Jefferson University Hospital
Philadelphia, Pennsylvania

Organizational Profile
Thomas Jefferson University Hospital is a 957-bed hospital that has 57 operating rooms and performs about 38,200 operations annually.

Project Team Leaders

- Carol Kelly, Senior Director of Performance Improvement and Patient Safety

- Richard Webster, RN, Chief Operating Officer

- Monica Young, RN, Vice President, Perioperative Services

Background
Thomas Jefferson University Hospital is a large orthopedic hospital. Though it has not had a wrong-site or wrong-procedure surgery, orthopedic surgery presents an increased risk for problems to occur. The hospital used baseline data and a standardized tool, providing an opportunity to collect information at sample sites. Having "lots of data" created opportunities to compare and measure the number of defects, said Carol Kelly, senior director of performance improvement and patient safety.

Those defects were identified, and solutions were determined and standardized. "It's all about defects," said Monica Young, RN, vice president, perioperative services. "If we have these defects, the hospital is at risk." Richard Webster, RN, chief operating officer, noted that though the Universal Protocol "has been around for a few years," the project was an experience to "revisit our current process, remind everyone of its importance and get the staff's recommitment for the process."

Causes and Solutions
Scheduling: The hospital's scheduling form was revised simply by deleting areas that patients had not completed or that were not needed. Other process improvement changes took longer. Also, the hospital reached out to physician offices, particularly the highest volume providers, and helped educate staff on the importance of accurate and complete information using The Joint Commission requirements.

OR staffing: Rushing in the operating room was identified as an issue, due to high volume and the impetus to keep things moving along. Using one of The Joint Commission's recommendations, the hospital changed its staffing model. According to Webster, "We looked at staffing and—without adding any more FTEs—provided an additional nurse for every two ORs, by modifying the times that later shift nurses arrived for providing breaks and lunches." Designated roles for these nurses include providing support for cases getting started and cases closing, as well as giving breaks for staff during long surgeries. "[The change] gave our staff the support they felt they needed. And it didn't cost anything extra," Webster said. The hospital also changed its policies to prevent anyone entering the operating room during time-out and at other critical points during surgery (induction, emergence from anesthesia, or any unexpected event).

Time-out: Changes to time-out included collaborating with anesthesiologists. "We cannot do surgery without them, and we gave them a role in the time-out process," Webster said. "We have to monitor this and make sure all appropriate people are not only engaged but also participating." In general, people's participation in time-out became more role-based. In addition, based on Joint Commission recommendations, the hospital used "just-in-time" education, providing coaches during the time-out to provide feedback.

Site marking was improved. For example, staff discovered a particular skin preparation product was washing off markings, so the hospital obtained different marking pens that made a permanent mark. "We drilled down to the essence of what we're doing every day," Kelly said.

Results
Defects were significantly reduced in all areas measured.

Barriers
The size of the organization—with large numbers of students, residents, fellows and doctors working around the clock—created some barriers. "Getting that number of people to do the right thing every day requires a tremendous effort," Young said. "It's getting the message across to all people." Kelly added that the hospital used "all avenues" to get buy-in, including videos from other hospitals, service-line meetings, visual checklists and more.

Lessons Learned
Asking front-line staff—people who do the work every day—to share what works and what does not is important. For example, staff provided feedback to streamline and customize a general checklist. Although surgeons initially resisted using the checklist, after they provided input for suggested changes, the checklist has become standard practice.

Contact Info
Carol Kelly, Senior Director of Performance Improvement and Patient Safety:
Carol.a.Kelly@jefferson.edu

Endnotes

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