Health System Risk Management

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Wrong-Site Surgery

Executive Summary

Wrong-site surgery is a broad, generic term that encompasses all surgical procedures performed on the wrong patient, the wrong body part, or the wrong side of the body; it can also describe performing the wrong procedure on, or performing on the wrong part of, a correctly identified anatomic site. Events resulting from wrong-site surgery can result in devastating consequences for all involved. For example:

- Patients may die or suffer lifelong physical consequences. In addition, medical problems may go untreated, healthy structures may sustain trauma, additional surgeries may be required, and patients and families may lose trust in providers and organizations.
- Clinicians involved in wrong-site surgery may face disciplinary sanctions and malpractice litigation, as well as reputational damage, removal of professional licensure and/or privileges, and emotional fallout.
- Healthcare organizations risk liability, loss of accreditation, and regulatory sanctions if wrong-site surgery is performed. In addition, the potential financial impact is significant, not only because of the possibility of litigation and settlements, but also because the Centers for Medicare and Medicaid Services (CMS) does not cover any costs associated with wrong-site surgery. Wrong-site surgery also brings major reputational risk to the organization, as media coverage of such events is common.

Wrong-site surgery events are often perceived as rare; however, despite the Joint Commission introducing its Universal Protocol to address the problem in 2004, instances of wrong-site surgery continue to occur. For example, wrong-site surgery was the third most common sentinel event for the years 2016, 2017, and 2018 (Joint Commission "Sentinel"; Joint Commission "Summary"). Wrong-site surgery is also thought to be underreported—for example, a surgeon may not report a near-miss that is caught before surgery begins—and its true incidence is likely to be much higher than official reports indicate. Risk managers committed to decreasing risk of wrong-site surgery in their organizations will need to convene stakeholders from various disciplines and collaborate to implement strategies across the organization.

This guidance article reviews the various types of wrong-site surgery; discusses the incidence, risk factors, and causes of wrong-site surgery; examines barriers to effective risk reduction; highlights Joint Commission's elements of performance for the Universal Protocol and other accreditation and regulatory issues; and offers guidance for implementing strategies to prevent the occurrence of wrong-site surgery.

Action Recommendations

- Ensure that organizational policy and procedure facilitate prevention of wrong-site surgery and monitor compliance.
- Identify and adopt best practices for prevention of wrong-site surgery.
- Understand and disseminate information on the causes of wrong-site surgery.
- Encourage vigilance by raising awareness of risk for wrong-site surgery, and acknowledge that compliance with the Universal Protocol is only partially protective.
- Educate providers and staff about the organization's commitment to preventing all cases of wrong-site surgery.
- Consider use of a role-based time-out procedure.
- Investigate other approaches to minimizing the risk of wrong-site surgery.
- Ensure that site marks remain visible when prepped and draped.
- Use a proactive approach to preventing wrong-site surgery early in the process, including at scheduling.
- Ensure that providers understand that wrong-site surgery events are considered never events, and encourage a safety culture where staff are empowered to speak up if they perceive a problem.
- Take appropriate action in the event of a wrong-site surgery.

The Issue in Focus

Wrong-site surgery is a broad, generic term that encompasses all surgical procedures performed on the wrong patient, the wrong body part, or the wrong side of the body; it can also describe performing the wrong procedure on, or performing on the wrong part of, a correctly identified anatomic site.

Events resulting from wrong-site surgery can result in devastating consequences for all involved. For example:

- Patients may die or suffer lifelong physical consequences, including increased pain and psychological distress. In addition, medical problems may go untreated, healthy tissue may sustain trauma, additional surgical procedures may be necessary, and patients and families may lose trust in providers and organizations. (NASS)
- Clinicians involved in wrong-site surgery may face disciplinary sanctions and malpractice litigation, as well as reputational damage, removal of professional licensure and/or privileges, and emotional fallout.
- Healthcare organizations risk liability, loss of accreditation, and regulatory sanctions if wrong-site surgery is performed. In addition, the potential financial impact is significant, not only because of the possibility of litigation and settlements, but also because the Centers for Medicare and Medicaid Services (CMS) does not cover any costs associated with wrong-site surgery. Wrong-site surgery also brings major reputational risk to the organization, as media coverage of such events is common.

The public naturally regards wrong-site surgery as a shocking, egregious, and preventable medical error. Media coverage often follows these events, such as the following:

- A teenage boy whose seizure-treatment surgery was performed on the wrong side of his brain (Insurance Journal)
- A woman whose surgeon asked for retroactive consent after performing a vascular graft on the wrong leg (Jameson)
- A series of four wrong-site surgeries that occurred in a period of 40 days at one health system (Zimmerman)
- The erroneous removal of a healthy kidney due to a patient identification error (Kowalczyk)

Wrong-site surgery events are often perceived as rare; however, despite the Joint Commission introducing its Universal Protocol to address the problem in 2004, instances of wrong-site surgery errors still occur. For example, wrong-site surgery was the third most common sentinel event for the years 2016, 2017, and 2018 (Joint Commission "Sentinel"; Joint Commission "Summary"). Wrong-site surgery is also thought to be underreported, and its true incidence is likely to be much higher than official reports indicate. In addition, clinicians may perceive that, because such events are rare, such errors cannot happen to them—a mistaken perception that has been identified as a barrier to eliminating these events (Seiden and Barach).

Although some incidents of wrong-site surgery may be attributed solely to the clinician performing the procedure, the majority of wrong-site events occur because of multiple system or process failures that involve the entire multidisciplinary operating team, as well as organizational processes that set the stage for the occurrence of a catastrophe in the operating room (OR).

Risk managers committed to decreasing risk of wrong-site surgery in their organizations will need to convene stakeholders from various disciplines and collaborate to implement strategies across the organization.

Event Types

Several categories of wrong-site surgery exist, defined as follows.

- **Wrong-side surgery.** This category is useful in describing surgical procedures that involve extremities or distinct sides of the body. The operative field in which the procedure is carried out is generally some distance away from the originally intended operative field, such as on the opposite arm or leg. In many of these cases, the operative field and the OR should have been set up in a certain way for the surgery, but may have been set up differently for the other side of the body.
- **Wrong-level or wrong-part surgery.** This category includes surgical procedures that are performed at essentially the correct site but at the wrong level or part of the operative field. The correct part of the body is prepared for surgery, but the surgical procedure is performed on the wrong part of the field. An example of this type of procedure would be a lumbar laminectomy performed on the space between the fourth and fifth lumbar vertebrae (L4-5) instead of the space between the fifth lumbar and the first sacral vertebrae (L5-S1).
- **Wrong-patient surgery.** This category includes procedures that are performed on patients who were not scheduled for a procedure at all, were not scheduled for the procedure that was performed, or were scheduled for a different procedure than the one that was performed. Wrong procedures carried out at intended sites may also be included in this category. This classification depends primarily on the misidentification of the patient. For more information, see the guidance article Patient Identification. For information on how health information technology can facilitate patient identification, see resources available through the Partnership for Health IT Patient Safety.

- **Wrong-implant procedures.** Wrong-implant procedures are also considered a type of wrong-site surgery. Wrong-implant procedures, such as when the wrong intraocular lens implant is placed during cataract surgery, are known to have occurred in gynecology and ophthalmology and are likely to occur in other specialties (Paull et al.; Seiden and Barach).

Nearly all surgical specialties are susceptible to wrong-site surgery errors; however, some specialties appear particularly vulnerable. For example, according to one survey of 173 spinal surgeons, 68% admitted to wrong-level localization at some point in their careers—some of which were rectified intraoperatively (Mayer et al.). Additionally, certain procedures are particularly vulnerable to wrong-surgery events; in one study of a large integrated health system, spinal procedures, cataract implants, excision of skin malignancies, and prostatectomies constituted more than half of all identified events. (Paull et al.)

Claims and Litigation

The potential financial impact of wrong-site surgery on healthcare organizations, malpractice carriers, and insured parties is significant. One 2013 analysis of 9,744 paid malpractice claims of surgical never events occurring over a 30-year period found the following (Mehtsun et al.):

- 2,447 cases of wrong-procedure surgery, with a mean liability payment of $232,035
- 2,413 wrong-site surgery cases, with a mean liability payment of $127,159
- 27 cases of wrong-patient surgery, with a mean liability payment of $109,648

A well-executed and well-documented informed consent discussion can be instrumental in a successful defense. For example, a woman who underwent breast reconstruction surgery sued, alleging that she had requested a silicone gel implant, and that the plastic surgeon had inserted a saline gel implant instead. The surgeon was able to demonstrate that the patient had signed an informed consent that clearly specified the plan for a saline gel implant. (*Adams v. Doucet*) For more information, see the guidance article Informed Consent.

Regulations and Standards

Joint Commission

In 2002, Joint Commission made prevention of wrong-site surgery one of its first National Patient Safety Goals. In 2004, the organization introduced the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery, which broadly consists of preprocedure verification, site marking, and preprocedure time-out. The protocol applies to all accredited hospitals, ambulatory care, and office-based surgery facilities.

Wrong-site surgery is reportable by Joint Commission-accredited organizations as a sentinel event (an unexpected occurrence involving patient death or serious physical or psychological injury). Facilities that experience sentinel events are required to conduct a comprehensive systematic analysis (e.g., a root-cause analysis [RCA]) to identify what occurred and how and why the event happened. Joint Commission expects facilities to conduct a timely, thorough, and credible RCA; develop an action plan designed to implement improvements to reduce risk; implement the improvements; and monitor the effectiveness of those improvements. See the guidance article Getting the Most out of Root-Cause Analyses for more information. All events involving surgery on the wrong site, wrong procedure, and wrong patient are reportable under Joint Commission's sentinel event policy, regardless of the magnitude of the procedure or the outcome.

National Quality Forum's Serious Reportable Events

The National Quality Forum's (NQF) Serious Reportable Events is a list of 28 adverse events that are largely preventable and of concern to the public as well as healthcare providers. NQF includes wrong-site surgery as one of its reportable never events. NQF endorses adoption of Joint Commission's Universal Protocol as a safe practice for better healthcare and expects that facilities will report a wrong-site surgery event, investigate its cause or contributing factors, and act on the findings to prevent future occurrences. Many states have adopted full or modified versions of the NQF list, suggesting a growing interest in standardization. (NQF)

Det Norske Veritas Healthcare, Inc.

Det Norske Veritas Germanischer Lloyd (DNV-GL) quality management standards require accredited hospitals to undertake measurement, monitoring, and analysis for numerous aspects of care, including "operative and invasive procedures, to include wrong site/wrong patient/wrong procedure surgery" (DNV-GL).

Centers for Medicare and Medicaid Services

The Centers for Medicare and Medicaid Services (CMS) does not cover any costs associated with surgical or other invasive procedures in which the provider performs the wrong procedure, or the intended procedure on the wrong body part or wrong patient. CMS also does not pay for hospitalizations or other services associated with such surgical errors. (CMS)

State Regulations

Some states have enacted or adopted protocols for the prevention of wrong-site surgery. For example, the New York State Surgical and Invasive Procedure Protocol is the standard of care for hospitals, diagnostic and treatment centers, and individual practitioners in the state; its scope includes all operative and invasive procedures including endoscopy, general surgery, and interventional radiology (New York State Department of Health). Ohio and Tennessee each endorse the use of Joint Commission's Universal Protocol (OPSI/OHA; Tennessee Department of Health).

State regulators take wrong-site surgery seriously and have the capability to influence an organization's response. For example, after five wrong-site surgeries occurred in under three years at one East Coast hospital, state officials in 2009 ordered installation of video cameras in the organization's ORs (Boodman). A hospital medical director credited the director of the state department of health—who had experience in performance improvement—with giving the organization the opportunity to identify and remediate problems from a quality and performance improvement perspective (HRET and Joint Commission).

Professional Societies and Guidelines

Professional societies representing a variety of surgical specialties have published position statements, checklists, and other resources for the prevention of wrong-site surgery, including the following:

- American Academy of Ophthalmology
- American College of Surgeons
- World Health Organization (WHO)
- Joint Commission
- Association for periOperative Registered Nurses (AORN)

Action Plan

Assess Current Policies and Procedures and Monitor Compliance

Action Recommendation: Ensure that organizational policy and procedure facilitate prevention of wrong-site surgery and monitor compliance.

Action Recommendation: Identify and adopt best practices for prevention of wrong-site surgery.

Appropriate policies and procedures are instrumental in the prevention of wrong-site surgery; conversely, problematic policies and procedures and/or issues with executing policies have caused wrong-site surgery. For example, a 2013 systematic review identified several aspects of policies as a cause of wrong-site surgery, including lack of policies, staff failure to follow existing policies, and policies that were technically correct but difficult to implement. Problems with procedures were similar, including lack of procedures or standardization thereof; failure to follow procedures; and procedures that, although adhered to, were impractical. (Hempel et al.) In another study, researchers identified policy and procedure as the most common root causes of wrong-surgery events. Examples include lack of a standardized process, failure to follow a standardized process, failure to follow procedure according to organizational standards, unclear policies, and inadequate quality control or monitoring. (Paull et al.)

Broad organizational policies on wrong-site surgery—requiring adherence to Joint Commission's Universal Protocol and performance of a standardized time-out process, for example, are a required minimum to mitigate the risk of wrong-site surgery. However, policies and procedures may also require customization and healthcare organizations should update institutional policies and procedures in response to identified risks. In addition, risk may be difficult to discern in organizations that have not experienced a wrong-site surgery event.

Evaluating current practices through audits, monitoring, and real-time observation can help healthcare facilities identify and correct vulnerabilities. In addition, any at-risk or reckless behavior should be addressed, regardless of clinical outcome.

Clinical leaders should collaborate with frontline staff to solicit feedback and ensure that existing and new policies and procedures work as intended, then educate and train providers and staff accordingly. Furthermore, simply having a policy in place is just the beginning: regardless of what policies and procedures an organization elects to use, development of appropriate strategies to implement them is paramount (Wallace et al.).

Adopt Best Practices

Organizations should also ensure that policies and procedures designed to mitigate the risk of wrong-site surgery align with best practices from organizations such as WHO, the Joint Commission, and AORN. In addition, language and layouts for laterality information should be standardized on all presurgical documentation (paper and/or electronic), including the informed consent form. The Pennsylvania Patient Safety Authority has a number of resources to help organizations ensure that this documentation is standardized, including an OR scheduling form, a preoperative checklist, and day-of-surgery verification checklist 1 and checklist 2.

Using a checklist to guide the performance of patient safety measures can ensure that no requisite steps are overlooked. The WHO Surgical Safety Checklist, designed to help operative teams limit the risk of patient harm, is an excellent resource that can be integrated into an organization's wrong-site surgery prevention strategy. The checklist is divided into three phases of an operation (WHO):

- The "sign-in" phase, before induction of anesthesia
- The "time-out" phase, before the surgical incision
- The "sign-out" phase, before the patient leaves the OR

For each part of the process, the checklist includes basic steps such as confirming the patient's identity, discussing the patient's allergies, introducing all team members by name and role, and confirming that sponge, sharp, and instrument counts are correct. Users can customize the checklist and its accompanying implementation manual to suit their circumstances.

Additionally, many other best practices have been identified for prevention of wrong-site surgery, including the following (ECRI and the ISMP PSO):

- Implement an "operative/invasive procedure verification checklist" to capture laterality of site verification information.
- Incorporate into the preoperative verification process a reconciliation of the schedule, consent, and history and physical examination during each of the following times:
  - When the surgical procedure is scheduled
  - At the preadmission testing and assessment
  - Before the patient arrives at the preoperative area
  - Before the OR is set up for the procedure
  - Before the patient leaves the preoperative area or enters the OR
- On the day of surgery, have at least two members of the surgical team (e.g., preoperative nurse, surgeon, anesthesiologist) perform a documented, independent verification and reconciliation of patient information, patient's (or surrogate) understanding of the procedure, schedule, consent, surgeon's history and physical examination (before and day of surgery). If there is a discrepancy, require the presence of the attending surgeon and the patient to determine the resolution.
- Implement a method for monitoring progress of the wrong-site surgery prevention strategies and providing feedback to staff. This involves, among other things, tracking the successes of time-outs and determining areas for improvement. Organizations should also collaborate with frontline staff to ensure that existing and new policies and procedures work as intended.

Understand Causes

Action Recommendation: Understand and disseminate information on the causes of wrong-site surgery.

Potential causes for wrong-site surgery are many and varied. An error leading to wrong-site surgery may occur at any point in the process, from a presurgical office visit, to surgical scheduling, to the preoperative area, to the OR on the day of the procedure. One or more individuals may be involved in such an error, including surgeons, office staff, registration clerks, and nurses. Often, many of these errors are the result of ineffective communication among clinical staff.

Because each patient care encounter is unique, no accounting of potential causes could ever be entirely complete. Organizations should therefore become familiar with common causes of wrong-site surgery while ascertaining what may be similar or different in their facilities, then educate staff and intervene accordingly.

Common Causes

A 2016 review of wrong-site event data submitted to ECRI and the Institute for Safe Medication Practices (ISMP) PSO, known as ECRI PSO prior to August 2020, indicated that some of the most common wrong-site errors involve documenting the wrong surgical site during the presurgical process. Of the near misses reviewed, the wrong site was incorrectly documented most frequently on the informed consent, the physician's order, the OR schedule, and the preoperative checklist. Those who reported near misses indicated that conducting a thorough preprocedure verification—the first phase of the Universal Protocol—allowed staff to catch and correct wrong-site errors on various preoperative documents (ECRI PSO).

A 2015 systematic review examining root causes of wrong-site surgery identified the following frequently reported causes and contributing factors across a variety of studies (Hempel et al.):

- Missing information that should be available to the OR staff
- Omission of critical information
- Staff members who fail to speak up despite noticing a wrong-site procedure in process
- Surgeons who ignore staff questions regarding laterality
- Misperception (i.e., right-left confusion)
- Patient identification problems
- Incorrect information from patients and families
- Involvement of symmetrical structures (e.g., eyes, knees)
- Impact of policies and procedures

Joint Commission has also identified numerous common examples; see Follow Potential for Error through the Surgical Process for more information.

Organizational culture has also been identified as a causative factor in wrong-site surgery, such as when organizational focus on patient safety is inconsistent, when staff are not empowered to speak up, and when staff education regarding policy changes is inadequate or inconsistent (Joint Commission "Most Commonly"). See Shape Culture and Leadership to Facilitate Prevention, as well as the guidance article Culture of Safety: An Overview.

Event Reports

Information submitted to an organization's event reporting system—whether a near miss or actual event—may also provide valuable insight regarding systems failures that could lead to wrong-site surgery. Risk managers who analyze wrong-site surgery events and near misses submitted to their event reporting system can look for patterns, then dig deeper to determine causative factors and appropriate interventions. See the guidance article Event Reporting and Response for more information.

Raise Awareness of Wrong-Site Surgery Among Staff

Action Recommendation: Encourage vigilance by raising awareness of risk for wrong-site surgery, and acknowledge that compliance with the Universal Protocol is only partially protective.

Action Recommendation: Educate providers and staff about the organization's commitment to preventing all cases of wrong-site surgery.

From the perspective of individual surgeons and hospitals, wrong-site surgery is a rare occurrence, which can reinforce beliefs that safeguards are infallible. However, organizations that fail to appreciate the risks of wrong-site surgery do so at their peril, because the members of the healthcare team are human and, therefore, capable of making mistakes, regardless of training or intelligence. Complacency can dull provider perception of subtle risk indicators, increasing the likelihood of an event. Organizations that recognize complacency as a threat to safety and strive to prevent it from taking root can decrease the risk of wrong-site surgery. (Chassin and Loeb)

In addition to raising awareness of the risks, causes, and consequences of wrong-site surgery, organizations should provide formal education and training for every staff member who plays a part in surgery—from planning, to scheduling, to performing procedures. Providers and staff should also be educated on strategies for prevention (e.g., time-out processes) and trained on how to implement them (Knudson). Patients should also be made aware of their roles in the surgical process and how they can help prevent wrong-site surgeries.

Limitations of the Universal Protocol

A systematic review of interventions to prevent wrong-site surgery found the existing evidence base weak, with the exception of Joint Commission's Universal Protocol, for which the strength of evidence was moderate. (Hempel et al.)

However, the Universal Protocol is not without its limitations. It has been criticized as "overly simple," and has not eliminated wrong-site surgery, "in large part because it fails to account for the complexities of the surgical process and all the different ways in which risks of a wrong-site procedure may be introduced into it." (Chassin and Loeb) Therefore, compliance with the Universal Protocol cannot be an organization's sole prevention strategy for wrong-site surgery (Paull et al.).

Examining reports from the Veterans Affairs National Center for Patient Safety RCA database, researchers found that between 2004 and 2013, 16% (48) of 308 root cause analyses for reported wrong-surgery events "would have occurred despite adherence to the Universal Protocol and a well-performed time-out." "Upstream errors" (e.g., during a preoperative consultation) were defined as occurring prior to the Universal Protocol; "downstream errors" were defined as occurring after completion of the time-out (e.g., intraoperatively). Among identified events, 67% (32) were associated with upstream errors such as mislabeling of specimens and transposition of reports; 33% (16) were associated with downstream errors including intraoperative localization and intraprocedure diagnostic determinations (Paull et al.).

Based on identification of "upstream" and "downstream" events, researchers recommended supplementing the Universal Protocol with the following strategies (Paull et al.):

- Intraoperative radiographic verification of correct surgical level (e.g., spine, rib)
- Protocols for site marking of skin lesions for excision that include preoperative photographs and preprocedure verification of site, mark, and photographs
- Standard process for the preoperative calibration of equipment, performance of axial length and keratometry measurements, and preparation and transmittal of implant lens calculations
- Removing previous patient labels and paperwork from clinical work areas to prevent mistakes that could lead to identification errors

Training Strategies

Training should reflect the needs of the individual organization. Staff should be educated on how errors can lead to a wrong-site event and to the critical role that staff at all levels—from schedulers to the OR team to staff working at physicians' offices throughout the organization—can play in preventing wrong-site surgery. See Risk Factors for Wrong-Site Surgery for high-level information that can be shared with staff.

Training should include use of a checklist or other tool to evaluate all preprocedure documentation for consistency as well as to identify inconsistencies that require reconciliation before the surgical procedure starts. Once trained, staff should be held accountable in their performance of these tasks (HRET and Joint Commission). Staff should also be encouraged to speak up if they detect something is wrong. For more information, see Shape Culture and Leadership to Facilitate Prevention.

Just-in-time coaching. "Just-in-time" coaching is an educational approach that leverages leadership commitment and support to provide healthcare personnel with real-time reinforcement and feedback on a variety of clinical processes and can be critical to creating cultural change. Clinical leaders are trained as just-in-time coaches; they conduct direct observation and intervene in the moment to correct a process that is not being performed according to standard or policy. This approach is credited as "critical to creating a change in culture and behavior," and can be used to improve patient identification and time-out processes. (HRET)

Highlight success. Feedback is critical to cement learning and commitment to new policies and procedures. Providers and staff should be updated on improvements attributed to well-executed time-outs and other preventive strategies; the organization should celebrate the success of improved patient safety. (HRET and Joint Commission; Knudson)

Risk Factors for Wrong-Site Surgery

Risk factors for wrong-site surgery include the following (NASS):

- Emergencies
- Participation of more than one surgeon
- Multiple procedures performed during one trip to the OR
- Extraordinary time pressures
- Patient characteristics such as morbid obesity, anatomic variations, low bone density, and physical deformity
- Unusual equipment or positioning in the OR
- Repeat procedures
- Novel procedures

Patient Education

It is also important to educate patients and their families, which will not only prompt those involved to fully participate in preprocedure verification processes, it may also allay any irritation or anxiety as a result of repeated verification questions. The Pennsylvania Patient Safety Authority has published a variety of education materials including a poster, Patients and Surgical Teams Work Together to Avoid Wrong-Site Surgery.

In addition, the patient must fully understand the procedure that is being undertaken and which site is being operated on. If the patient has limited English proficiency, the healthcare facility must ensure that this information is communicated properly. For more information, see the guidance articles Informed Consent, Health Literacy, and Culturally and Linguistically Competent Care.

Implement Behavioral Strategies and System Support

Action Recommendation: Consider use of a role-based time-out procedure.

Action Recommendation: Investigate other approaches to minimizing the risk of wrong-site surgery.

Communication

Ineffective communication can contribute to wrong-site surgery events, including during time-outs, where interactive communication is a required element under the Universal Protocol. Such communication breakdowns include the following (Dunn; Edwards):

- Failure to involve the patient/family member in site identification
- Failure to share or communicate correct information
- Failure to communicate changes in information/correction of errors to the entire team
- Failure to correctly understand or interpret information concerning the correct site, as a result of language, accent, or other linguistic impediments to understanding
- Failure to ensure communication among the entire team when team members fill unfamiliar roles

To facilitate compliance, barriers to effective communication should be identified and addressed; strategies such as a role-based time-out should be considered.

Role-Based Time-Out

Role-based time out procedures, where individuals are assigned task-based roles and specific responsibilities, empower all members of the team to speak up—resulting in personal accountability and active participation in the process (Knudson). The time-out script should be required during each time out to ensure consistency. Additional time outs should be required if there is a surgeon or staff change or if the patient is repositioned.

For example, when physicians at a Virginia hospital analyzed performance of the organization's physician-led preprocedural pause (e.g., time-out), as it was traditionally performed, they found that only 54% of all items were completed. In order to improve empowerment and participation of all team members, they introduced an "attestation format" in which each team member was responsible for a specific scripted section of the

checklist. This version of a role-based time-out involves the following steps (Porter et al.):

- The circulating nurse attests to the completeness of the consent.
- The surgical technician attests to the presence of a surgical site mark and the availability of appropriate instruments.
- The anesthesiologist attests that the patient's allergies were reviewed, and that preoperative antibiotics were administered.
- The surgeon confirms the planned procedure, anticipated blood loss, and potential operative concerns.
- The surgeon solicits input or concerns from the rest of the team.

The above steps are always completed in the same order, with each participant introducing themselves by both first and last names, addressing their portion of the time-out, and then inviting the next participant to speak. The researchers reported significant improvement after implementation of the attestation checklist, with all items completed in 97% of cases. Compliance remained very high at an 18-month audit. The organization subsequently expanded use of the attestation format to interventional radiology, gastroenterology, and electrophysiology suites. (Porter et al.)

Other Approaches

Leveraging the electronic health record (EHR). The EHR can be a powerful tool in the prevention of wrong-site surgery. Proper utilization of the EHR through the use of checklists, clinical decision support, and hard stops can improve communication among OR personnel and between physically distant units, autopopulate data points (e.g., patient allergies, consent form, history and physical examination), and facilitate performance of best practices in the customary workflow of surgeons, anesthesiologists, and nurses. (Gitelis et al.)

Organizations should work with health IT vendors to develop business logic that validates consistency regarding the procedure, site, and side across the entire system—the physician's order, the history and physical examination, diagnostic images and test results, the consent form, the OR schedule, and the presurgical checklist—and highlight any discrepancies.

In addition, organizations should implement "hard stop" alerts in EHR technology to prevent users from taking an action or to require the user to obtain third-party override to proceed. Such hard stops are particularly important in the preoperative stage—if something doesn't match in the documentation, for example, then there should be a hard stop so that the user must confirm the correct site, procedure, and patient before proceeding.

Relocate instruments. Organizations should consider keeping surgical instruments in the back of the OR, away from the patient, until the end of the surgical time out. Doing so can help minimize distractions and mitigate hierarchical dynamics in which a surgeon might make other team members feel rushed (Ragusa et al.).

In addition, organizations should consider using a "knife check" as part of the verification process. During a knife check, the scalpel or scope is not handed to the surgeon until after final verification is complete.

Identify Optimal Tools and Supplies

Action Recommendation: Ensure that site marks remain visible.

Among all of the policies, procedures, education, and training involved in preventing wrong-site surgery, tools for site marking are especially important, and identifying optimal tools requires more than following Joint Commission's requirement that adhesive materials (i.e., stickers) cannot be the sole means of site marking. An appropriately placed site mark is of no use if it disappears or fades during normal preoperative processes involving preparing the skin for incision. Marks may disappear from contact with the skin preparation solution, the surgical marker, or both.

When one organization in the Center for Transforming Healthcare project discovered that a skin preparation solution was washing off site markings, they tested multiple pens with commonly used skin preparation solutions and ultimately changed to a more effective, indelible, single-use marker. The organization now ensures that a large supply of the markers is always available in the preoperative, holding, and OR areas. (HRET and Joint Commission)

Risk managers should work with clinical leaders to ensure that markings are required at the surgical site and to verify that the selected combination of marker and skin preparation solution is not vulnerable to removal. Markers and solutions should be tested and validated on individuals of various races and ethnicities to ensure reliability on all skin tones. Risk managers should also work with purchasing staff to ensure that surgical staff have ample supplies of selected marker(s).

Take a Proactive Approach

Action Recommendation: Use a proactive approach to preventing wrong-site surgery early in the process, including at scheduling.

Office staff are a critical first line of defense against wrong-site surgery. Receiving accurate primary documentation (e.g., history and physical examination, surgical orders, informed consent) from physician offices is instrumental in the prevention of wrong-site surgery, as is resolving any incomplete items or inconsistency

in that documentation. However, this step is an ongoing challenge for some organizations.

Standardize Scheduling Procedures

Scheduling is one area early in the process where errors may be introduced. Improving the scheduling process can help mitigate the risk of wrong-site surgery. For example, an East Coast hospital that has experienced wrong-site surgeries made several improvements to its scheduling process, including having dedicated staff responsible for completing chart assembly early in the process; only accepting bookings made through the computer scheduling system; and notifying physicians' offices of inconsistent or incomplete paperwork 48 hours before the scheduled procedure, and canceling procedures if the situation is not corrected within 24 hours. Project leaders report that these strategies help to prevent rushing and distractions in the OR caused by inconsistent or incomplete paperwork. (HRET and Joint Commission)

Organizations should implement strategies to standardize the surgical scheduling process, such as the following:

- Use a standardized electronic form or template that requires inputting the exact description of the surgical site or side, or else the procedure cannot be scheduled.
- Require the scheduler to verbally read back the information regarding site and side to the physician's office.
- Require a process in the preadmission phase to ensure that consent has been obtained and that the form matches the scheduled procedure.
- Request that the physician office submits the scheduling request and consent forms together.

Shape Culture and Leadership to Facilitate Prevention

Action Recommendation: Ensure that providers understand that wrong-site surgery events are never events, and encourage a safety culture where staff are empowered to speak up if they perceive a problem.

While risk managers will not single-handedly solve the problem of wrong-site surgery, they can urge their organizations to educate providers that wrong-site surgery events should never happen, to identify and implement preventive strategies, and to facilitate process improvements and compliance by the facility's clinical personnel.

Organizational Climate

As with all patient safety initiatives, strategies to prevent wrong-site surgery will be fully effective only if they are actively and visibly supported by executive and clinical leaders. See the guidance article Culture of Safety: An Overview for more information.

Communication in the OR has historically been hierarchical, moving downward from the surgeon. An environment where staff are afraid to raise a safety concern—and where they may even be retaliated against for doing so—is an environment at risk of wrong-site surgery. "Speaking up" in a critical moment to protect patients is a key duty of nurses in their roles as patient advocates; however, it can be difficult to do so, potentially leaving important information unsaid. For example, in a study cosponsored by the American Association of Critical Care Nurses, although half of nurses reported being involved in situations that should have resulted in speaking up, they reported doing so only 10% of the time. (Rainer) It is critical for everyone in the OR to be able to speak up, and to be supported in doing so. (For more information about creating a culture in which all staff members feel empowered to speak up, see Disruptive Practitioner Behavior and Communication.)

In addition, some orthopedic surgeons have provided the following suggestions (applicable to all specialties) for empowering the members of a surgical team to voice their patient safety concerns (Saleh et al.):

- Transform the operating culture from surgeon-centric to team-focused
- Abandon entrenched vertical hierarchy in favor of a more horizontal hierarchy in which all team members feel comfortable expressing their ideas and concerns throughout the patient care process
- Encourage communication and collaboration among members of the healthcare team
- Increase all team members' sense of "ownership" in the patient's safety

Executive Leadership

Senior leaders can also demonstrate their commitment to prevention of wrong-site surgery through active engagement and by holding every staff member accountable for their role in reducing risk (Knudson). Additionally, CEOs and other executive-level leaders may need to take a firm stance in response to surgeons accustomed to setting the agenda inside the OR. Other strategies may include designating physician and operational champions, staying informed regarding event reports and audit data, and reinforcing the importance of adhering to the organization's policies and procedures for reducing the risk of wrong-site surgery.

Implementing robust prevention strategies is labor-intensive and leaders must be willing to make resources available to support these strategies. For example, a large orthopedic hospital identified rushingin the OR (attributed to high volume) as an issue that created risk for wrong-site surgery. The team was able to support staff by providing one additional nurse

for every two ORs and was able to accomplish this in a budget-neutral manner by modifying shift, break, and lunch times. (HRET and Joint Commission)

Clinical Leadership

Support from clinical leaders is equally important. When one organization revamped its time-out process and introduced a customized surgical safety checklist that was viewed as a "major change for most staff, particularly surgeons," the leadership of a well-respected physician champion proved instrumental in ensuring cooperation in the surgical peer group. "Pushback" from some providers occurred after another hospital implemented a role-based time-out process; individual providers received coaching from team leaders as necessary. The support of a surgeon and the chief nursing officer was critical to the initiative's success. (HRET and Joint Commission)

Investigate and Disclose Instances of Wrong-Site Surgery

Action Recommendation: Take appropriate action in the event of a wrong-site surgery.

Wrong-site surgery may be identified as it occurs or shortly thereafter, or it may be identified at some later time; the individual who performed the procedure may or may not be the person who discovers the error. Therefore, effective communication among disciplines is essential in the discovery and investigation of wrong-surgery events. (Paull et al.)

Wrong-site surgery events require critical analysis to determine what happened, why it happened, and how to prevent such events from happening in the future. However, those who are involved in a particular wrong-site surgery event is pertinent to future risk only in the unusual event of reckless behavior—which would require disciplinary action. For most providers involved in patient safety events, coaching—not discipline—is the appropriate response. (Ring et al.) For more information, see the guidance article Event Reporting and Response.

Wrong-site surgery should be thoroughly investigated and disclosed appropriately, which may mitigate liability exposure from a wrong-site event. For example, when an orthopedic surgeon realized that he had performed wrong-site hand surgery, he immediately informed the staff and the patient, apologized, and offered to perform the correct procedure if she wished. The patient consented and underwent a trigger finger release without complication. The surgeon filed an event report and notified the hospital's risk manager; he also spoke with the patient's son on multiple occasions to apologize, waive fees, and arrange for the patient's follow-up care. The patient's son ultimately informed the surgeon that his mother had lost confidence in the surgeon and did not wish to return; a community clinic managed her postoperative care. The hospital negotiated a modest financial settlement. (Ring et al.)

In contrast, the Arkansas Supreme Court upheld an $11 million jury verdict against a hospital's professional liability carrier in the case of a neurosurgeon who operated on the wrong side of his patient's brain; the hospital's failure to disclose the harm, as well as to report the incident as a sentinel event, both influenced the verdict. The patient's parents alleged that those failures deprived their son of critical rehabilitation time; they also alleged that the liability carrier had advised the hospital not to report the wrong-site surgery as a sentinel event. (*ProAssurance Indem. Co. v. Metheny*)

Because the surgery took place at a state hospital, the Arkansas State Claims Commission, a state commission that hears and adjudicates claims against the state, also heard the case. The commission found that the hospital medical director was made aware of the event within one day, but never investigated the situation (e.g., examined documentation, interviewed those involved) or disclosed any information to the patient's parents. The claims commission found the hospital negligent and awarded an additional $2 million in damages (Arkansas State Claims Commission).

See the guidance article Disclosure of Unanticipated Outcomes for more information.

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Supplementary Materials

Risk Manager's Toolbox

- Ready, Set, Go: Wrong-Site Surgery
- Make a Plan: Wrong-Site Surgery
- Safety First for Staff: Wrong-Site Surgery

Guidance, Assessments, and Training

- Culture of Safety: An Overview
- Communication
- Disclosure of Unanticipated Outcomes
- Disruptive Practitioner Behavior
- Event Reporting and Response
- Getting the Most out of Root-Cause Analyses
- Informed Consent
- Patient Identification
- Health IT Safe Practices: Toolkit for the Safe Use of Health IT for Patient Identification

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