MEDICAL ERRORS IN THE OPERATING ROOM ATTRIBUTABLE TO COMMUNICATION BREAKDOWN AND ITS EFFECTS ON PATIENT SAFETY

Ву

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Surgical Errors in the Operating Room Attributable To Communication Breakdown and Its Effects on Patient Safety

Rinku Saju Skaria

ABSTRACT

Preventable medical errors in the United States have been a leading cause of death in the United States. Within the operating room, surgical errors occur at alarming rates. Accordingly, a review of studies was performed to identify how communication breakdown caused surgical errors, specifically with wrong-site surgery and retained surgical instruments. Based on the root cause analysis in both types of errors, communication failure played a large role in the cause of error. Current preventative methods involve open communication between team members, using checklists, and integrating time-outs in the operating room. Further standardization and repetitive assessments prior to, during, and after surgery can ensure a safer environment that leads to fewer adverse events.

INTRODUCTION

Medical errors in the United States are too high, making preventable medical errors the sixth leading cause of death in America. The Institute of Medicine (IOM) performed a seminal study on preventable medical errors in 1999 and revealed that over 98,000 people die every year at a cost of \$29 billion. According to the Congressional Budget Office, 181,000 severe injuries were attributed to medical negligence in 2003. Moreover, Harvard School of Medicine conducted a study that revealed approximately 18% of patients in hospitals were injured during their care, many of which were considered life threatening.

Shockingly, "never event" defined by government and private health insurers as events that should never occur in a hospital, take place at startling rates. The Joint Commission Center on Transforming Healthcare informed about 40 wrong site surgery and procedures occur every week in the United States.¹⁷

L	eading Cause of Death in Unite	d States
1	Heart Disease	652,091
2	Cancer	559,312
3	Stroke	143,579
4	Chronic Lower Respiratory Disease	130,933
5	Accidents (unintentional injuries)	117,809
	Preventable Medical Errors	98,000
6	Diabetes	75,119
7	Alzheimer's Disease	71,599
8	Influenza/Pneumonia	63,001
9	Nephritis/Nephrosis	43,901
10	Septicemia	34,136

Figure 1: Leading Cause of Death in the U.S.¹⁷

The root cause of these can stem from multiple areas including errors in judgment, lack of technical knowledge, communication breakdown, patient related factors, and lack of supervision. ²⁴ These underlying patterns demonstrate that systems failure rather than single individual error is the principal cause of medical errors. Within surgery, the same is true. Communication breakdown contributed to error in 25% of the cases in Rogers' surgical error analysis study, majority of which had occurred intraoperative. ²⁴

This paper will demonstrate how communication breakdown leads to surgical errors and its effect. But before, a background about medical errors will be provided.

DEFINITION OF MEDICAL ERROR

A medical error can be defined "as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)." ¹⁰ A more clinical definition of a medical error is "a commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were negative consequences." ¹³

According to the previous definitions, a medical error can either cause harm or no harm, and harmful events can cause temporary or permanent injury or even death. In contrast, a near miss is when the patient can recover from a potential harm before the error affects the patient. ¹³ More specific definitions and examples are provided in Figure 2.

Definition **Near Miss** Unsafe conditions. The event did not reach the individual because of chance alone. The event did not reach the individual because of active recovery by caregivers. Nonharmful Event The event reached the individual but did not cause harm, or an error of omission, such as a missed medication dose, reached the patient. The event reached the individual, and additional monitoring was required to prevent harm. **Harmful Event** The individual experienced temporary harm and required treatment or intervention. The individual experienced temporary harm and required initial or prolonged hospitalization. The individual experienced permanent harm. The individual experienced harm and required intervention necessary to sustain life. Death The individual died

Figure 2: Defining Medical Error¹³

INSTITUTE OF MEDICINE REPORT

Aside from defining medical errors, the Institute of Medicine (IOM) in 1999 identified different types of medical errors. These included errors due to drug outcomes, improper transfusions, injuries from surgery, falls, burns, and wrong patient identities. High error rates were known to cause serious consequences in operating rooms, intensive care units, and emergency departments. In addition to the lives lost, preventable medical errors estimate to result in total costs of \$17-\$29 billion per year including expenses for additional care, lost income, disability, etc. Errors can also lead to decreased trust in the healthcare system and decreased satisfaction for both patients and medical personnel.

Many Americans evidently have experienced medical errors. One in three Americans reports they or a family member suffered from a medical error. ¹² Furthermore, one in five Americans reports the error caused serious health problems or even led to death. ¹² However despite these numbers, Americans greatly underrate the number of medical error deaths and believe it to be 5000 or less, which is about 20 times lower than IOM's estimate. ¹²

The IOM report concludes that majority of medical errors result from system errors, not individual errors. System errors include imperfect processes and conditions that cause mistakes or fail to prevent them. Thus, designing a healthcare system that prevents medical errors at all levels promotes and ensures patient safety.

ROOT CAUSES OF MEDICAL ERRORS

Several root causes of medical errors exist such as error of commission, omission, communication, context, and diagnosis that lead to increased healthcare costs.⁷

Error of Commission: Error of commission is the easiest error to identify and takes place when a mistake injures a patient because of procedural error, poor judgment, or despite good judgment, the procedure was performed improperly.⁷

Error of Omission: Omission errors occur when an obviously needed action was not performed. For example, not prescribing a proven medication for an eligible patient would be considered an error of omission.^{7, 16}

Errors of Context: Contextual errors occur if a provider fails to take into account patient's unique circumstances that would allow them a successful, post-discharge treatment. For example, a patient who

might not be able to comply with medical treatment due to dementia or a patient who may not have proper access to follow up care should be provided resources for supportive care.⁷

Diagnostic Errors: Errors in diagnosis could be dangerous due to errors of commission. If a patient receives overtreatment or mistreatment due to a diagnosis error, patient can become critical if the mistake is not discovered. The U.S. healthcare industry's apparent need to over diagnose patients often causes harmful outcomes for patients.

Error of Communication: Communication errors can occur between medical staff or between the provider and the patient either through verbal or written communication.⁷

Communication Breakdown

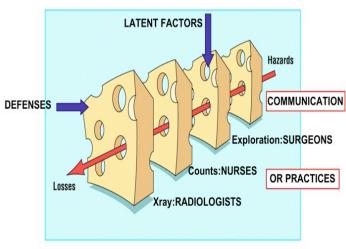


Figure 3: Swiss Cheese Model 1

Sir James Reason's Swiss cheese model llustrates how failed defenses at multiple evels can contribute to communication error. Several independent studies have correlated communication failure and medical error.

According to the root cause analysis from the VA National Center for Patient Safety, communication failure remains one of the contributing factors in medical errors for 82% of cases.² Sutcliffe and colleagues also support the result after conducting interviews with 26 residents. Communication failure accounted 91% or 64 cases of reported errors.² Data collected through confidential interviews by Gawande and colleagues reveal that 43% of adverse events were a direct result of communication breakdown between two physicians.²

In another study, Lingard and colleagues revealed that 30% (129 of the 421) of procedurally related communication exchanges in the operating room led to communication failures. Of these, one third resulted in effects that decreased patient safety due to increased "cognitive load, interrupting routine, and increasing tension in the OR." More specifically, communication can be categorized as:

- 1. Timing failure (45.7%) timing when communication requested, transferred, or resulted
- 2. Content failure (35.7%) inaccurate or missing information
- 3. Purpose failure (24.0%) unclear purpose or lack of understanding to accomplish the purpose
- 4. Audience failure (20.9%) absence of needed team members⁹

Such failure types can lead to visible effects including "inefficiency, team tension, resource waste, workaround, delay, patient inconvenience, and procedural error." According to Lingard and colleagues, current communication weaknesses are due to lack of standardization and team integration.

Table II. Circumstances of injuries attributable to surgical errors

	Frequency $(n = 258)$	%
Phase of care in which an error		
occurred		
Preoperative	65	25
Intraoperative	193	75
Postoperative	89	35
Errors spanning >1 phase of	79	31
care		
No. of clinicians contributing		
to error		
1	99	38
2	91	35
≥3	68	26
Type of personnel contributing		
to error		
Attending physicians	237	92
Intern, resident, or fellow	118	46
Nurse	45	17
Other	19	7

Figure 4: Surgical Error Circumstances²⁴

Within surgery, majority of these communication errors occur intraoperative. Rogers and colleagues article reviewed surgical errors from 444 close malpractice claims at four liability insurers. After analyzing the files, 258 of the 444 cases (58%) were identified to have a surgical error that resulted in patient injury. Sixty four percent involved significant injury and 23% led to death. All the cases, 75% of errors occurred intraoperative, 23% occurred preoperative, and 35% occurred postoperative. In 61% of the cases, more than one clinican played a role in the error. System factors identified in the study include technical competence (41%), communication breakdown (24%), and technical errors (54%).

Communication breakdown within most of these cases involved inadequate information provided during hand-offs (11%), failure to clearly establish specific responsibility to each team member (9%), and miscellaneous including insufficient communication between providers and nurses and inablity to reach attending physicians.²⁴

SURGICAL ERROR: WRONG SITE SURGERY

It was not until the IOM report was released that physicians were aware of the number of injuries, deaths, and near misses that occurred due to surgery. This was primarily due to the lack of a process that ensured quality and patient safety as well as the lack of recognizing and reporting such cases. One of the most troubling errors in surgery is wrong-site surgery. Wrong-site surgery (WSS) is defined as "surgery performed on the wrong side or site of the body, wrong surgical procedure performed, and surgery performed on the wrong patient." WSS also comprises of any procedures that involves more than minimal risk that occur outside the OR such as within the special procedures unit, endoscopy unit, and interventional radiology suite. The Joint Commission (TJC) defined WSS also involving any sentinel events causing death or serious physical or psychological injuries.

Causes of Wrong-Site Surgery

The root causes of wrong-site surgery involve more than one factor with majority involving communication breakdown between the surgical team and the patient and family members. Other causes include:

- 1. Inadequate policy such as marking the surgical site
- 2. Lack of a comprehensive checklist
- 3. Incomplete patient assessment prior to operation
- 4. Staffing issues
- 5. Distraction factors
- 6. Lack of pertinent information in the operating room
- 7. Organizational cultural issues.8

The prevalence of WSS is possibly due to lack of an adequate system to verify the site of surgery. The Joint Commission found that WSS is due to communication failure (70%), procedural noncompliance (64%), and leadership (46%). Risk factors associated with WSS include "emergency cases, multiple surgeons, multiple procedures, deformities, time pressures, and unusual equipment or change in setup, and room changes."

Consequences of Wrong-Site Surgery

WSSs are considered rare events, but studies illustrate their high prevalence. Since reporting sentinel events is voluntary, it is likely only 10% of actual WSSs are reported.⁸ Despite the exact numbers, WSSs

are considered preventable medical errors, and with standardized procedures in perioperative setting, incidences can be reduced.

WSS can negatively affect the patient and the morale of the surgical team. Penalties are placed on surgeons by state licensure boards for WSS cases. Some insurers have also decided to no longer pay providers who have been involved in WSS, who perform surgery on the wrong person, or who leave foreign objects in a patient's body after surgery.⁸

Preventing Wrong-Site Surgery

The American Academy of Orthopedic Surgeons created an awareness campaign in 1998 called the "Sign your Site." ⁴ The campaign was created after reviewing 10 years of malpractice claims. By adding an additional step by putting "No" on the incorrect site and requiring the surgical team to work together to verify the correct site, the campaign was able to increase awareness and reduce errors. The North American Spine Society further developed the program by adding the specific location and site of the spine in its "Sign, Mark, and X-ray" program in 2001. ⁴ The program compelled surgeons to also add a checklist for patient and procedure verification.

In 2003, the Joint Commission convened a summit to create *The Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery* to standardize care and further improve patient safety. This protocol was devised to be used to reduce or eliminate WSS in any situation that required invasive procedures. The protocol includes:

- 1. Verifying the correct patient and the exact site before the procedure
- 2. Marking the site with the physician's initials before the patient is sedated
- 3. Taking a time out⁸

Since July of 2004, the Joint Commission started to incorporate these three components in its accreditation process for healthcare organizations.

The Association of periOperative Registered Nurses worked collaboratively with the Joint Commission to develop a Correct Site Surgery Tool Kit to help implement the Universal Protocol. The Veterans Affairs National Center for Patient Safety added the Ensuring Correct Surgery and Invasive Procedures directive. The two steps supplemented the Universal Protocol by verifying the consent form is completed and followed properly as well as ensuring two members of the surgical team review the patient's information and radiological images prior to surgery.

Research Evidence Related to Wrong-Site Surgery

According to Meinberg and Stern's study, after the Sign your Site campaign, about half of surgeons modified their preoperative practices. ⁸ In another study, providers who were responsible for 62% of preventable WSS cases decided to follow the Universal Protocol. The authors in this study concluded that the remaining third of the cases would not be preventable through the Universal Protocol. This was because the errors were initiated in weeks prior to surgery such as wrong documentation and inaccurate labeling of radiological reports.⁸

A checklist itemizing preoperative verification, marking the site, and time out need to be adhered. Studies have assessed effectiveness of marking the site and determining success rate when patients mark the correct site. In DiGiovanni and colleagues' study, patients marked the correct site after receiving instructions. About 60% of patient marked the site correctly by marking "no" on the wrong foot or ankle. However, patients who mark the site should have complete physical, cognitive, and emotional ability.

Studies also conclude time outs can prevent majority of WSS. In Makary and colleagues' study, a two minute OR briefing prior to surgery with surgeons, anesthesiologists, and nurses on the surgical site and side improved communication and decreased WSS. ¹¹ The briefing (APPENDIX) included

- 1. Each member stating their name and their role in the OR
- 2. The surgeon leading the time-out according to the Joint Commission guidelines to review important aspects of the surgery including the surgical site
- 3. Care teams discussing and mitigating potential safety hazards

The briefings in the study occurred after anesthesia was performed and before incision. 67.9% agreed pre-briefing and 91.5% agreed post-briefing that "surgery and anesthesia worked together as a well-coordinated team." ¹¹ 52.4% agreed pre-briefing and 64.4% agreed post-briefing that "preoperative discussion increased their awareness of the surgical site and side being operated on." ¹¹ Below are summarized graphs from the study.



Figure 5: Makary Study Results¹¹

Such results from these studies illustrate the effects of communication breakdown in WSS cases and directives taken to prevent more cases.

SURGICAL ERROR: RETAINED SURGICAL INSTRUMENTS

Another surgical type of error that arises due to communication failure is Retained Surgical Instruments (RSI). RSI occurs when medical or surgical items intentionally placed by providers are unintentionally left in various body spaces after an operation. About 1500-2000 RSI cases occur each year in the United States. RSIs can be uncovered hours to years after surgery, and a follow-up surgery may be required to remove the object. Similar to WSS, RSIs are rarely a result of individual error.

Most frequent RSI is the cotton gauze surgical sponge which is found in a number of different sizes. Over 80% of retained sponges had surgical counts that were considered correct. Other frequent items found include surgical towels, "broken pieces of instruments, small micro-needles, trocars, guide-wires and sheaths." The most common sites where RSI are found are in the chest, abdomen, pelvis, and the vagina.

According to The Joint Commission, RSI is a serious patient safety issue that can cause harm or even death to patients. From 2006-2013, TJC has received 700 voluntary reports of unintended retention of foreign objects. Of these cases, 16 resulted in deaths and about 95% of these incidents resulted in additional or extended hospital stay. Apart from patient harm, RSI cases can cost as much as \$200,000 per case in medical and liability payments.

Causes of Retained Surgical Instruments

Initially, studies in the early 2000s indicated that patient related factors such as obesity and case-specific characteristics such as emergencies increased the risk of RSI. However according to Gibbs' study from 2011, RSI cases are related to operating room culture and environment rather than patient characteristics or emergency of an operation. Specifically, more retained sponge cases occur in planned surgery cases than emergency cases. In addition, errors have occurred even when only ten sponges were used. So, RSIs occur primarily due to multi-stakeholder operating room practices and problems in communication. Wrong surgical count can lead to failure in written communication. Some specific root causes include:

- 1. Failure in communication with physicians
- 2. Failure of staff to communicate relevant patient information
- 3. Lack of policies and procedures
- 4. Failure to comply with existing policies and procedures
- 5. Problems with hierarchy and intimidation
- 6. Inadequate or incomplete education of staff²¹

Consequences of Retained Surgical Instruments

Retained surgical instruments such as scissors or clamps are very rare in open surgical cases. The most frequently reported RSI, about ten publicly reported cases, is a malleable or ribbon retractor. Instruments are usually and preferred to be removed laparoscopically within two weeks of operation so they do not induce an inflammatory reaction. Retained sponges can lead to infection or cause an inflammatory response leading to an abscess formation. Most of these cases cause the patient to be symptomatic days to weeks after the surgery. In cases where X-ray in early postoperative period is not performed or patients do not come in with symptoms of infection, the RSI presents as a mass that is found months to years after the initial operation, requiring a second surgery to be performed.

Prevention Methods for Retained Surgical Instruments

NoThing Left Behind is a voluntary surgical patient safety initiative that was started in 2004 to prevent RSIs and to ensure they become a "never happen event." ⁵ The program provides a three step approach to account for surgical items. Since 80% of retained sponges had originally had the correct count, the initiative takes into account human error.

The three step approach includes:

- 1. Only X-ray detectable sponges and towel be used in the operating room. Nurses and technician should confirm number of sponges being used in procedures.
- 2. Nurses should use hanging sponge holders and a white board to keep count of the type and number of surgical sponges being removed as the surgery is complete.
- Surgeons should perform a methodical wound exam to verify that all sponges and instruments are out. If the sponge count is incorrect, X-ray wands should be used to determine whether the missing sponge is retained in the patient.¹⁴

Two known standardized retained sponge prevention practices include the manual Sponge ACCOUNTing system and the electronic Computer Assisted Sponge Counting System.⁵ Both utilize X-rays to find a missing sponge. The sponges need to be removed from the patient and individually be passed under the scanner.⁵

By creating and implementing an effective, evidence-based standard policy for the organization, RSI cases can be reduced.²³ Effective communication through documentation, team briefings, and debriefings and open culture that allows members to express concern can improve patient safety.²³

Research Evidence Related to Retained Surgical Instruments

Gibbs' article identified that over 80% of RSI cases originally reported a correct surgical count, suggesting that discrepancies occur within the operating room.⁵ Therefore, studies performed postoperatively cannot detect such errors. One study documented prospective field observation in 148 elective general surgery

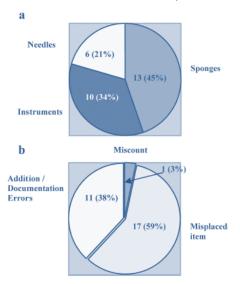


Figure 6: Description of RSI and Medical Discrepancies²⁵

operations.²⁵ Data collection centered on the frequency and counting discrepancies as well as the performance of counting protocols.²⁵ According to Greenberg and colleagues' study, one in eight surgeries or one every 14 hours of operation time involves at least one counting discrepancy.²⁵ Fifty nine percent of these discrepancies found a misplaced item, which signifies a potential RSI case. The study also identifies that 41% of discrepancies are due to human error including addition, miscounting, and documentation.²⁵ This suggests technological solutions that eliminate human error should be considered. Further results from the study are provided in the graphs to the left.

The study also identifies that potential errors originate during intraoperative hand-offs and staff changes. According to the study, staff change of either the circulating nurse or the surgical technician led to three times the likelihood that a discrepancy would occur. Therefore by reducing the number of hand-offs and staff changes intraoperative, the chance of RSIs can be reduced. Because 59% of miscounts are due to misplaced items, a thorough search and reconciliation process needs to also be administered.

PATIENT SAFETY

With the large number of surgical errors occurring each year, the importance of safe surgical care has been ever more pressing. With increased complexity of diagnostic and therapeutic tools and need for collaboration between surgical team members, a methodical procedure must be followed to ensure patient safety.

The Center for Medicare and Medicaid Services (CMS) has recognized financial savings by incentivizing hospitals to avoid "reasonably preventable" hospital acquired conditions. ¹⁸ In 2008, laws were enacted to save taxpayers \$21 million annually. ¹⁸ Medicare and private insurers have implemented policies where providers will not be reimbursed for problems or complications that occur due to error. ¹⁸

Communication failures due to power relationships, gatekeeping practices, and hierarchy issues can impact patient safety. ¹⁸ By understanding the nontechnical skills in the OR, surgical team members can improve patient safety. Part of this requires defining the roles and expectations of each member in the surgical team in order to provide continuous quality teamwork. Team members should feel comfortable to communicate and speak up to prevent patient harm.

Similar techniques such as refining surgical count techniques and abiding to checklists can reduce the number of medical errors that occur every year. One such initiative carried out by the World Health Organization is the Safe Surgery Checklist.

Safe Surgery Checklist

The checklist identifies three components of an operation including sign in, time out, and sign out.²² Within each phase, a checklist coordinator has to confirm that surgery team has completed the listed tasks before proceeding with the surgery.²²

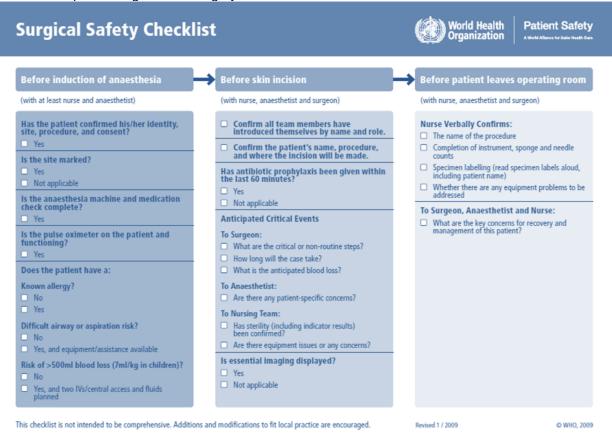


Figure 7: Surgical Safety Checklist²²

Kwok and colleagues introduced the WHO Surgical Safety Checklist in every operating room in a general and trauma hospital in Chisinau, Moldova to determine its impact on surgical hazards and complications. The study also introduced pulse oximetry at the hospital where they originally only owned three oximeters for the 22 operating stations. Compared to the pre-intervention cases, safety increased from 0.00% to 66.9%. Infectious complications decreased from 17.7% to 6.7% and noninfectious complications decreased from 2.6% to 1.5%. With these results, the authors concluded that implementation of the Checklist can significantly reduce complications and errors even in a resource limited setting. Adopting such innovations and safety practices can not only eliminate patient harm but also decrease financial costs.

CONCLUSION

Medical errors have been a leading cause of death in the United States. With increased research and publications, awareness and preventative methods have been underway. According to root cause analysis, poor communication cause a large number of preventable medical errors and account up to 82% of cases according to the VA National Center for Patient Safety. Errors such as wrong-site surgery and retained surgical instruments that occur in the OR have been revealed to be largely caused by communication failure. Through checklists and time outs, such errors can be decreased and improve patient safety. Further standardization and repetitive assessments prior to and during surgery can improve patient safety.

APPENDIX

☐ Introduction of first names and roles which are written on the whiteboard
□ Review critical information □ Do we have the correct patient? □ Is the correct side or site marked? □ Has the procedure been agreed upon? □ Have antibiotics been given?
☐ Identify and Mitigate Hazards
□ SURGERY: Discuss plans for the surgical procedure: □ Describe critical steps □ Provide team with pertinent information, including problems that may be encountered □ Ask team: If something were to go wrong with this procedure, what would it be, and how could we prevent the problem? □ Risks during procedure, such as bleeding, fluid loss □ Surgeon suggests, "If anyone has a concern during the case, please let me know."
□ ANESTHESIOLOGY: Discuss all relevant issues: □ Patient co-morbid disease that will increase risk □ Aspects of surgery that increase risk, such as need for IV access □ Availability of blood products □ Interventions to prevent complication, such as myocardial infarction, surgical site infection
□ NURSING: Discuss all relevant issues: □ Are all necessary instruments available? □ Will any special equipment be considered? □ Plan for breaks (relieving nurse to introduce himself or herself when switching)

Figure 8: Operation Room Briefing Checklist¹¹

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