We are IntechOpen, the world's leading publisher of Open Access books Built by scientists, for scientists



186,000

200M



Our authors are among the

TOP 1% most cited scientists





WEB OF SCIENCE

Selection of our books indexed in the Book Citation Index in Web of Science™ Core Collection (BKCI)

# Interested in publishing with us? Contact book.department@intechopen.com

Numbers displayed above are based on latest data collected. For more information visit www.intechopen.com



# Wrong-Site Procedures: Preventable Never Events that Continue to Happen

Andrew Lin, Brian Wernick, Julia C. Tolentino and Stanislaw P. Stawicki

Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.69242

#### Abstract

A comprehensive discussion of "never events" or preventable and grievously shocking medical errors that may result in serious morbidity and mortality is incomplete without a thorough analysis of wrong-site procedures (WSP). These occurrences are often due to multiple, simultaneous failures in team processes and communication. Despite being relatively rare, wrong-site surgery can be devastating to all parties involved, from patients and families to healthcare workers and hospitals. This chapter provides a general overview of the topic in the context of clinical vignettes discussing specific examples of WSP. The goal of this work is to educate the reader about risk factors and preventive strategies pertinent to WSP, with the hope of propagating the knowledge required to eliminate these "never events." To that end, the chapter discusses pitfalls in current surgical practice that may contribute to critical safety breakdowns and emphasizes the need for multiple overlapping measures designed to improve patient safety. Furthermore, updated definitions regarding WSP are included in order to better characterize the different types of WSP. Most importantly, this chapter presents evidence-based support for the current strategies to prevent wrong-site events. A summary of selected recent wrong-site occurrences is also provided as a reference for researchers in this important area of patient safety.

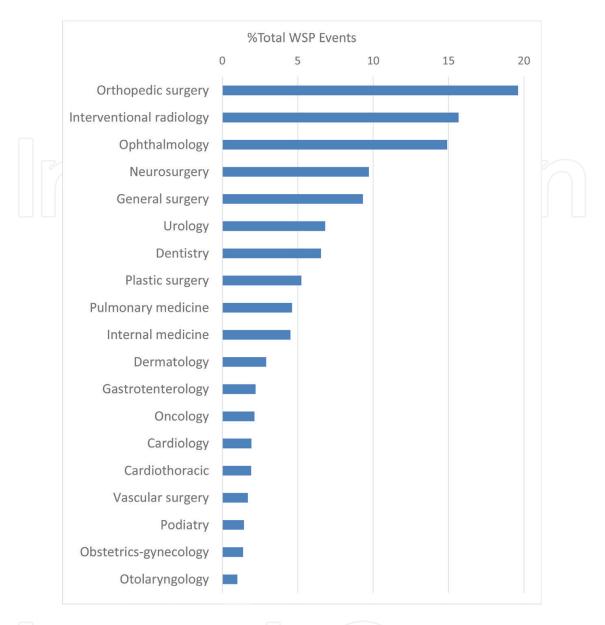
**Keywords:** never events, patient safety, patient safety errors, safety protocols, wrong-site surgery

## 1. Introduction

The rare but dramatic adverse occurrences as inexcusable and difficult to comprehend as wrong-site procedures (WSP) continue to shed negative light on our medical systems and



© 2018 The Author(s). Licensee InTech. This chapter is distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/3.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. [cc) BY



**Figure 1.** Relative frequency of wrong-site procedures (WSP) listed by specialty. Note that specialties with high percentage of laterality-specific cases (e.g., orthopedics, neurosurgery) report much higher percentage of WSP (data from 2007 to 2011). Data compiled from multiple sources.

bring into the light the fallibility of today's advanced healthcare environment [1, 2]. Dramatic news about the incorrect extremity amputation, spinal fixation above or below the intended level, or wrong rib being removed, intermittently appear on the landscape of headline news and "hard to believe" factoids. Personal, social, healthcare, and medico-legal burdens of WSP are significant, especially when one considers that these never events should never have happened in the first place [2, 3]. Indeed, well-functioning operating and procedural teams should be able to prevent these occurrences [4], especially when patients are actively participating in surgical site verification [5].

Malpractice database data suggest that approximately 1 in 113,000 surgical procedures are complicated by some sort of intervention at a "wrong site" [6]. For a typical hospital, it means

that WSP occur once every 5–10 years [7]. Wrong-site procedures constitute the second most frequent type of sentinel event reported, accounting for nearly 13% of all occurrences [8]. Literature regarding the frequency of WSP varies widely, depending on the reporting specialty and procedure type(s) involved. It is recognized that specialties performing frequent procedures involving various extremity [9], symmetric truncal/cranial/facial locations [2], or level-based surgeries [10] will inherently be more prone to WSP events (**Figure 1**) [6, 11–13]. For example, one study reported that 16% of hand surgeons reported prepping to operate on the wrong site but then noticing the error prior to incision, and >20% of respondents admitting to WSP at least once during their career [9]. Fortunately, major injury attributable to WSP is very rare [6].

Notable initiatives implemented to reduce WSP include the surgical safety checklist [14], the "sign, mark, and radiograph" initiative [15], various measures to empower the patient to participate in the perioperative safety process [5], as well as the Joint Commission's "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" [16]. It has been postulated that current site verification procedures aimed at reducing the incidence of WSP are questionably effective and not supported by scientific evidence [6]. To corroborate the effectiveness of the above measures, it has been shown that interventions such as operating room (OR) briefings have been shown to produce benefits in terms of the perceived risk of WSP [1], and that the surgical safety checklist is not only productive but also non-disruptive—an accusation frequently heard during initial implementation phases of various patient safety initiatives [17]. As previously mentioned, it is undisputable that insufficient communication is among the most commonly identified root causes of patient safety events [18–20], with various verification and safety procedures being only "as good as" the implementation team.

## 2. Definitions

It is important to utilize uniform language conventions and definitions when discussing WSP. DeVine et al. [8], defined the conceptual framework for WSP that will be utilized in this chapter (**Table 1**). Additional important definitions have been defined in the introductory chapter of this book, and the reader is referred to that resource for further information and guidance. Although this language was originally developed to reflect WSP that occur in spinal surgeries, it is certainly applicable to other types of invasive procedures and specialties. Additionally, the definition of the wrong implant is added to make these terms truly inclusive of all types of procedural settings. **Figure 2** shows the distribution of WSP events broken down according to the definitions provided in **Table 1**, with data derived from Neily et al. [11, 12].

#### 2.1. Clinical Vignette #1

According to a published report [21], a 15-year-old boy with seizure disorder was scheduled for surgery to remove epileptic foci on the right side of his brain. The patient was prepped and draped, but the surgical site was not marked, and no "surgical time-out" was documented.

Term	Definition	
Wrong-site procedure	Invasive procedures performed on the incorrect body part or incorrect patient. This is a "catch all" term for wrong level/part, wrong patient, and wrong side surgery	
Wrong level/part	Invasive procedure performed at the correct site but at the wrong level or part of the operative field	
Wrong procedure	Invasive procedure that unjustifiably differed from the originally planned procedure, performed at the correct site	
Wrong patient	Incorrect patient identification leading to a procedure performed on the wrong patient	
Wrong side	Invasive procedure that involves operating on the wrong side of the body	
Wrong level exposure	Surgical exposure performed on an unintended level, however, does not imply that surgery was performed at the incorrect level	
Wrong implant/prosthesis/ device	Placement of an implant, prosthesis, or device other than what was intentionally planned for the specific surgical procedure. This does not include intentionally placed implants, prostheses, or devices that are later found to perform optimally or fail	

Table 1. The conceptual and definitional framework for wrong-site procedural occurrences.

After removal of brain tissue, the surgical team realized that they were operating on the left side of patient's brain. They elected to continue with the intended procedure and went on to remove brain tissue from the right side of the patient's brain.

The neurosurgeon subsequently informed the patient's parents that he initially operated on the wrong side of the patient's brain, but switched to the correct side and completed the originally intended procedure. He reassured the parents that no brain tissue had been removed

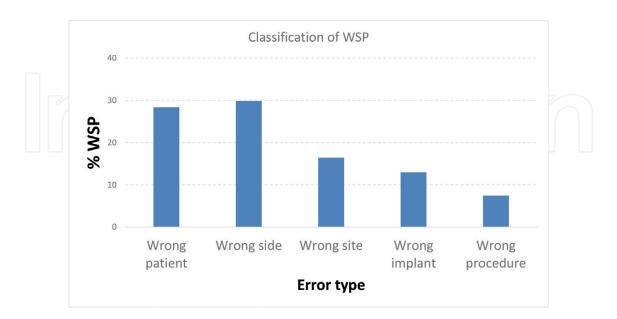


Figure 2. Bar graph showing WSP event frequency grouped by error type. The most common occurrences involve either wrong patient or wrong side.

from the wrong side and that overall "no harm was done." It was only after approximately 17 months that the parents discovered via magnetic resonance imaging that their child was missing portions of his left amygdala, hippocampus, and had a detectable injury to other regions of left cerebral hemisphere. The parents also claimed that their child had suffered cognitive problems, personality changes, and developed episodes of "blank and void look in his eyes."

Given the newly revealed information, the parents initiated a legal complaint against the surgeon, the hospital, and their insurance carrier citing medical malpractice. It was also alleged that the hospital administration failed to stop the surgery to the right side of the brain once the surgical team realized they have operated on the incorrect side. A \$20 million award to the parents of the patient was upheld by the state supreme court after a jury verdict in their favor [21].

#### 2.2. Clinical Vignette #2

A 53-year-old patient presented to the hospital with abdominal pain and hematuria. Diagnostic workup included a computed tomography (CT) scan which revealed a mass in the right kidney consistent with renal cell carcinoma (RCC). Despite this finding, all of the hospital medical records erroneously documented a left-sided tumor. The patient was subsequently transferred to another hospital for definitive surgical management. The CT scan from the initial hospital was not available, and the patient did not undergo repeat imaging at the receiving center prior to surgery.

Despite the lack of imaging, the surgeon decided to proceed with the surgery and removed the patient's left kidney based on the available medical record information. The left kidney was sent to the pathologist who detected no evidence of RCC. It was only after the pathologist called the surgeon the following day and after the surgeon reviewed the imaging that he realized that the incorrect kidney was removed.

The patient was then scheduled for a second surgery to remove the right kidney harboring the RCC. As a consequence, the patient was rendered dialysis-dependent having lost both kidneys, and due to his cancer, he is not eligible for renal transplant. No information regarding legal consequences was available for this case [22], but certainly, the risk of liability is extremely high.

### 3. Discussion

The two clinical vignettes presented above are both tragic cases of preventable wrong-site surgery occurrences. In addition to causing major harm to the patients involved, these events resulted in significant emotional distress to the patients' relatives as well as major medicolegal, professional, and reputational consequences to the healthcare providers and institutions involved. In the first case, where the tissue was removed from the wrong side of the patient's brain, a series of cumulative errors were made even before the surgery began. Available details from the subsequent legal proceedings indicated that during the day of the surgery, local

reporters were invited to take photographs and observe the surgery. This may have created an unacceptable level of distraction [23, 24]. Additionally, standard pre-procedural safety measures were not utilized, such as a pre-operative checklist and marking of the operative site. It has been shown that the presence of formalized OR briefing prior to making the incision increases the operative team's level of awareness (and thus confidence) regarding critical details of the procedure to be performed [1].

The occurrence of "never events" prompts clinicians, administrators, and patients to wonder why these errors continue to happen. **Figure 3** compiles data regarding contributing factors and causes of WSP from three studies reported between 2007 and 2010 [11, 13, 25]. Inadequate communication is the most frequent contributory cause of wrong-site surgery. In over 20% of cases reviewed during root cause analysis sessions, communication error was a major contributing factor in the wrong site, wrong procedure and wrong patient surgery [26]. Potential reasons for disorderly or deficient communication in Case Vignette #1 include the presence of reporters in the OR and the associated atmosphere of distraction. The presence of distractions and "unexpected" factors during the operation, in turn, has been shown to increase the risk of safety errors [27–29]. The latter may be due to lack of team or individual focus, and the subsequently diminished ability to "intercept and detect" errors [30–32].

The tragic cascade of errors in Clinical Vignette #1 was further compounded by the omission of the pre-operative checklist, surgical "time-out," and surgical site marking. This highlights the importance of the existing patient safety framework, mandated by the Joint Commission for continued institutional accreditation, and consisting of three specific measures to be conducted prior to all operations [16, 33]. Despite that, some have questioned the effectiveness of the measures required by the Joint Commission. For example, DeVine et al. noted the lack of data on the efficacy of pre-operative checklists and suggested the addition of intra-operative imaging, specifically for spine surgery, to verify the correct site [8]. However, a multicenter prospective study of the main components of the Joint Commission's recommendations did demonstrate the effectiveness of these simple and easy to implement measures [34].

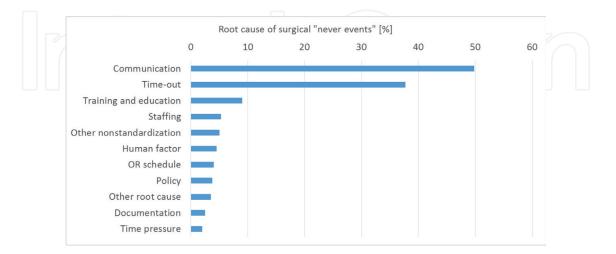


Figure 3. Most common causes of wrong-site procedure (WSP) events. By far, communication and "time-out" related issues predominate among all causes.

Surgical "time-outs" have been validated and studied thoroughly. One study showed that an extended pre-induction surgical "time-out" improved communication within the OR [35]. Marking of the surgical site is particularly important. Clarke et al. noted that the surgeon's actions in the OR are a major contributing factor to the occurrence WSP [36]. Others have emphasized that structured protocols combining various safety measures, and not their individual subcomponents, are the key to reducing wrong-site events [37] and improving patient safety in general [20, 31].

Appropriate measures, including redundant safety systems, to prevent catastrophic outcomes have been implemented in other high-risk areas including aviation, maritime, and nuclear industries [38]. Modern industrial safety systems emerged with the broader understanding that it is not any individual components or cross-check that by itself reduces the risk of failure, but rather a strategically designed combination thereof [19, 20]. This philosophy aligns itself with the idea that medical errors resulting in adverse outcomes usually stem from a series of individual and systemic failures, all "aligning" within the framework of the so-called Swiss Cheese model [19, 39]. Research on adverse events in the OR suggests that the "Swiss Cheese" theoretical framework can serve as a good foundation for improving not only safety and quality of care but also as an agent for lasting, sustainable institutional culture change [40].

Different "failure modes" exist in regard to WSP. For example, one report describes a scenario where a surgeon marked the correct operative site with a marker, but in the period between the original surgeon marking being made and the subsequent initiation of a surgical "time-out," the patient created an imprint of the mark on the other leg [41]. This occurrence highlighted the possibility of a new "failure mode" in a system designed to prevent WSP, and despite everyone's best intentions, the end result was two marked sites, one on each leg [41]. In addition, surgical "time-out" is an effective tool but may fail if it is not appropriately instituted, properly followed, or not taken seriously by the team [42]. Particularly in the office setting, where standardized protocols may not be universally implemented, WSP are a risk during invasive outpatient procedures, such as excision of a suspicious skin lesion. Under such circumstances, it has been proposed that WSP risk may be reduced by photographing and marking the surgical site, introducing "universal protocol," and examining any specimens of questionable quality before concluding the procedure [43].

Pre-operative verification is another critical component in the overall WSP equation. Again, failure may arise if the verification procedure is performed improperly if there is confusion, or when communication is deficient. Based on >400 reports of WSP, as many as 25% involved scheduling errors as a contributing factor. In addition, the authors stated that "…surgeons verifying procedure with the patient in pre-op holding had the greatest net contribution to the prevention of wrong-site errors" [36]. It has been suggested that the balance between the relative importance of various checklist items and the perception of risk associated with each respective element also plays a role in implementation and overall compliance with various patient safety verification procedures [44].

Various safety procedure compliance issues have been researched over time, both individually and at the health system level. In this domain, the implementation of simple but redundant checks to prevent occurrences of patient safety events has been proposed as an effective methodology [4]. However, non-compliance despite simplification of these safety checks continues to frustrate the attainment of "zero defect" safety goal [45]. Patient safety advocates continue to argue for more personal accountability at the level of key surgical team members [42]. In addition, it has been shown that non-compliance may be strongly related to the overarching themes in patient safety events—poor communication and ineffective team collaboration [44].

In the Clinical Vignette #1, non-compliance with established safety protocols was the root cause of the failure. However, the situation was made worse by the way the error disclosure was made and further compounded by the family finding out the true magnitude of the surgical mistake at a much later time. This brings us to the final issue in this particular patient scenario — professionalism and communication involving patients and their loved ones. It has long been established that honesty and apologetic stance both decrease, rather than increase, the likelihood of subsequent blame and anger [46–49]. Humble and honest acknowledgment, along with an authentic apology, can also improve the relationship and increase trust between the involved physician and patient or their family [46, 48, 50, 51]. By the time, it was discovered that significant damage occurred as a result of WSP, it was too late for any form of reconciliation outside of the legal system. Such confluence of factors is not unique to this particular case and has occurred in a number of high-profile occurrences including disclosure-related issues [52–54].

Clinical Vignette #1 demonstrates critical safety errors at multiple points in time and on multiple levels during the patient care. Beginning with distracting events prior to surgery and critical communication failures perioperatively, the subsequent series of mishaps involved the lack of adherence to mandatory safety protocols (e.g., the pre-operative checklist, a "time-out" before the surgery, and marking of the surgical site) followed by lax professionalism standards and incomplete disclosure of the magnitude of the error to the patient's family. In conclusion, this "never event" could have been prevented and any harm avoided or minimized had the OR team adhered to protocols and follow simple, standardized safety procedures.

The second case, outlined in Clinical Vignette #2, involves breakdowns at the systemic level as well as critical judgment errors that highlight the importance of the adherence to established Joint Commission safety measures [55]. Having said that it must be noted that the involved surgeon's actions and poor judgment may have been difficult to intercept without a more robust system of cross-checks at the institution where the procedure occurred. Although the error occurred at the referring hospital, the "Swiss Cheese" model discussed earlier in the chapter suggests that another omission at the receiving hospital likely "allowed" the error to continue undetected [19]. Communication errors, once again, played an important role here, with critical contributions to the mishap originating with the co-occurrence of incorrect medical documentation and the lack of source imaging data that could be used to "verify or rectify" the laterality of the involved kidney. In terms of human factors, the surgeon exercised extremely poor judgment by proceeding to the operating room without imaging [22].

A series of system errors were described in Clinical Vignette #2. As a consequence, the patient underwent unnecessary surgical procedures, experienced a complete loss of renal function, and was faced with the prospect of being dialysis dependent due to the underlying malignancy precluding him as a kidney transplant recipient. Much like in the first vignette, communication failures again arise as major contributors to WSP occurrence. Critical communication errors

have been reported both in the setting of intra- and inter-hospital transfers, especially in the context of the ever-evolving information systems infrastructure [56–59]. In Clinical Vignette #2, an unacceptable communication breakdown between two hospital facilities was further compounded by either the lack of appropriate verification policies or disregard for existing patient safety procedures. Failure to correctly document the kidney affected by malignancy, combined with the lack of confirmatory imaging greatly increased the risk of error. However, it was ultimately the judgment of the surgical team at the second hospital to forego preoperative and intra-operative imaging. In theory, any OR team member should have been empowered to stop an unsafe process (e.g., much like a flight attendant who is empowered to abort an airline flight departure) [19, 60–62]; however, this apparently did not occur in Clinical Vignette #2.

In a perfect scenario, the patient should not have been transferred without all necessary documentation, including the presence of all pertinent radiography data and results. Upon arrival at the receiving hospital, patient safety and verification procedures should have ensured that all required elements for the safe conduct of a surgical procedure with pre-specified laterality are satisfied. At the minimum, the lack of source imaging should be included as a "hard stop" during the conduct of pre-operative checklist and then during the surgical "time-out" [63, 64]. This applies to a variety of potential clinical scenarios, from the one outlined in Clinical Vignette #2 to extremity procedures performed on multiply injured orthopedic patient, to thoracostomy tube, or orthopedic traction pin placement [65, 66]. Invasive interventions classified as "wrong site," "wrong patient," or "wrong procedure" are all considered to be "never events" and require mandatory reporting and root cause analysis [19, 67].

As defined earlier in this book, the term "never event" includes a heterogeneous group of complications that involve unacceptable outcomes are considered preventable and have been deemed intolerable by both the public and the professional standards of the medical community [19, 68]. Just as airline customers should not be concerned about landing in a wrong city or airport, patients should never have to consider or be concerned about the potential risk of their procedure being potentially complicated by wrong site, incorrect patient identity, or wrong operation. As outlined throughout this text, any potential or actual harm to the patient carries the burden of legal liability and regulatory reporting [69]. Because of the cumulative costs associated with medical and surgical errors, government agencies and the medical community continue to devote significant resources to prevent "never events." Targeted interventions, such as the "surgical safety checklist," help reduce adverse occurrences applicable to specific circumstances [70], whereas more general interventions help optimize provider performance by reducing factors that lead to undue stress, inefficient team communication, distractions, or fatigue [20, 71, 72].

It is well established that medical errors are associated with more deaths per year than Alzheimer's disease and illicit drug use combined [73, 74]. In an effort to enhance patient safety in the United States, policies have been implemented to reduce and/or prevent a broad range of "never events," including wrong site, wrong patient, or wrong procedure occurrences. In 2004, uniform safety checks were put in place by the Joint Commission of Hospital Providers (JCAHO), now known and well recognized as the "universal protocol" (UP) [16, 33]. To help enforce this initiative at the institutional level, failure to adhere to UP jeopardizes the hospital's accreditation with the organization. The UP consists of three mandatory components:

- **1.** A preoperative verification of the patient, and the procedure to be conducted.
- 2. Any site to be operated on must be physically marked.
- 3. A "time-out" must be carried out immediately before any surgical procedure.

Despite the implementation of the universal protocol, cases of wrong-site surgery still surface at alarming rates (**Table 2**). Kwaan et al. [6] reported an incidence rate of 1 in 112,994 for WSP cases between 1985 and 2004, which includes all inpatient OR occurrences. However, an editorial that followed suggested that WSP rate may be as high as 1 in 5000 cases due to the under-reporting of these events [75]. Despite multiple calls to action and corresponding patient safety initiatives, medical errors are still considered among the leading causes of death in the United States on annual basis [76].

Location (year) [reference]	Details of occurrence(s)	Comment
Massachusetts, USA (1992) [77]	A 22-year-old man underwent surgery intended to treat his L4-5 disc herniation demonstrated on MRI. The patient underwent surgery, but his symptoms continued. Approximately 2 years later, he underwent another MRI, which showed that the original operation was carried out at the L3-4 level	The surgeon attempted to explain the error by suggesting that the original plan involved determining the level of intervention at the time of surgery. However, no mentions of such plan were ever made in the medical record or (according to the patient) communicated in such fashion. The case was settled for \$150,000
Florida, USA (1995) [78]	Incorrect leg was amputated following a series of communication and documentation errors	The physician involved was subject to disciplinary action and loss of license. Numerous potential systemic safety issues may have been involved
Rhode Island, USA (2009) [79]	Five separate wrong-site operations were carried out at a facility. Different anatomic locations were involved, including head/ neck, mouth, hand/finger, and the brain	Substantial fines were imposed by the Rhode Island State Department of Health. In addition, multiple additional safety checks were mandated, including the presence of OR video cameras for monitoring and oversight purposes. The involvement of multiple anatomic locations, and presumably different surgical teams, strongly suggests a systemic etiology of errors
Romford, UK (2011) [80]	A 5-month pregnant patient underwent surgery for acute appendicitis. During the procedure, her right ovary was removed in error. The patient was then readmitted with continued abdominal pain, suffered a miscarriage, required evacuation of appendiceal abscess, and subsequently died during repeat surgery to remove her appendix	Multiple errors, at multiple organizational levels, were made. The initial pathology result demonstrated that an ovary was removed instead of the appendix. Yet, this information was not read by relevant hospital staff. Based on available data, there were several opportunities to rectify the error, all of which were missed. Medical tribunal review followed
Basildon, UK (2012) [81]	Female patient required a superior segment of her lung removed. Instead, surgeons removed a basilar segment	Error was attributed to incorrect information in medical record. Similar to Clinical Vignette #2, the case involved inter-hospital transfer and a number of systemic factors

Location (year) [reference]	Details of occurrence(s)	Comment
Florida, USA (2013) [82]	Surgical incision was made into a patient's RLE instead of the LLE. The error was discovered intra-operatively and LLE surgery was completed	During disclosure, the error was allegedly presented as "justified mistake". Subsequent review of the facility found multiple patient safety and regulatory issues
Baku, Azerbaijan (2016) [83]	A 87-year-old woman was supposed to undergo LLE amputation for complications of diabetes. Instead, the RLE was amputated	Following the error, the surgeon avoided the family, later providing irrational explanations for the mistake Governmental committee was created to examine this event and improve patient safety in the country
Connecticut, USA (2016) [52]	Patient was undergoing surgery for 8th rib resection. Instead, part of the 7th rib was removed. Patient then required another operation shortly after	The patient alleged that the communication regarding the event was inadequate. Legal action followed as a result. It is likely that several different factors played a role in the event
New Delhi, India (2016) [84]	A 24-year-old man required surgery for RLE injuries. Surgeons erroneously inserted two rods into LLE	After filing unsuccessful complaints with the hospital, the family filed a lawsuit
Hanoi, Vietnam (2016) [85]	Surgical team mistakenly operated on a patient's RLE instead of the LLE	Errors at the team level were identified. The surgeon and the involved surgical team were suspended. The hospital agreed to cover all charges related to care
Massachusetts, USA (2016) [7]	It is alleged that a kidney was removed from the wrong patient	Communication and system errors at multiple points in the preoperative and operative process were involved, leading to patient misidentification and then propagation of the incorrect information

Reports are based on various publically available sources and only publically available information is included. Note the global nature of the problem, with events of similar type taking place around the world.

L3–4/L4–5, lumbar 3rd/4th/5th levels; LLL, left lower extremity; MRI, magnetic resonance imaging; OR, operating room; RLE, right lower extremity.

Table 2. Selected wrong site, wrong side, and wrong patient surgery occurrences.

# 4. Preventive strategies

Numerous preventive strategies to reduce rates of WSP have been proposed. It has been recommended that the UP be expanded to non-surgical specialties and that "zero-tolerance" philosophy be implemented in the setting of recurrent events [13]. In addition to vigilant adherence to the UP [86], calls have been made to foster open dialogue regarding WSP and other "never events," including frank discussions of each individual occurrence [87]. Others suggest the use of simulation training to achieve universal staff compliance with safety procedures [88, 89]. The addition of a formal pre-operative briefing as an additional "checkpoint" may also play a role [11]. Emphasis on professional behavior during periods of critical transitions (e.g., patient transfers, surgical "time out," and surgical site marking) is an important factor in preventing communication-related failures [90]. Team-based approaches that encourage both individual engagements and foster collective responsibility are critical to the safe operations of the modern OR [20, 26, 55].

# 5. Conclusions

WSP are a high-impact, low-frequency "never event" that occurs throughout all procedural specialties. Consequences of WSP are profound, beginning with the psychological and physical harm to the patient. In addition, the affected patient's loved ones are also highly likely to suffer emotional consequences of having been indirectly exposed to a wrong-site event. Finally, all individuals involved on the healthcare team are deeply affected by the event itself as well as by its aftermath [19]. Finally, WSP occurrences significantly damage the trust between the public and the healthcare system, creating a negative atmosphere that requires tremendous efforts and long periods of time to overcome. From the medico-legal perspective, there is little in the way of legal defense from an event as obvious as WSP. Consequently, physicians leave themselves and their institutions open to malpractice suits when such events occur.

Due to the damaging effects of WSP on all stakeholders involved, significant resources have been dedicated to the elimination of WSP, with the goal of "zero incidence." Measures implemented to achieve this goal include the UP, which involves a preoperative checklist and "time-out" prior to the start of any invasive procedure. Surgical site marking procedures are also of critical importance and should proactively involve the patient whenever feasible. In the end, every WSP event ultimately involves human teams. Among all the safeguards implemented and studied, the ultimate responsibility will always rest in the hands of the surgical team performing the procedure. No "checklist" or another safeguard can ever perfectly substitute for the astute and observant provider with the mindset of doing their best, ensuring safety, listening carefully, questioning and speaking up when needed, and conducting the operation according to the highest professional standards.

# Author details

Andrew Lin<sup>1</sup>, Brian Wernick<sup>2</sup>, Julia C. Tolentino<sup>2</sup> and Stanislaw P. Stawicki<sup>3\*</sup>

\*Address all correspondence to: stanislaw.stawicki@sluhn.org

1 Temple University School of Medicine—St. Luke's University Hospital Campus, Bethlehem, Pennsylvania, USA

2 Department of Surgery, St. Luke's University Health Network, Bethlehem, Pennsylvania, USA

3 Department of Research & Innovation, St. Luke's University Health Network, Bethlehem, Pennsylvania, USA

## References

- [1] Makary MA, et al. Operating room briefings and wrong-site surgery. Journal of the American College of Surgeons. 2007;**204**(2):236-243
- [2] Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery: Review of medical error. JAMA. 2009;**302**(6):669-677
- [3] Levy D. No defense for wrong-site surgery. AAOS Bulletin. 1998;46:18
- [4] Canale ST. Wrong-site surgery: A preventable complication. Clinical Orthopaedics and Related Research. 2005;433:26-29
- [5] DiGiovanni CW, Kang L, Manuel J. Patient compliance in avoiding wrong-site surgery. The Journal of Bone and Joint Surgery. 2003;85(5)815-819
- [6] Kwaan MR, et al. Incidence, patterns, and prevention of wrong-site surgery. Archives of Surgery. 2006;141(4):353-358
- [7] Cohen E. Surgeon accused of removing kidney from wrong patient. 18 March 2016, 2017]; Available from: http://www.cnn.com/2016/08/10/health/kidney-removed-fromwrong-patient/
- [8] DeVine J, et al. Avoiding wrong site surgery: A systematic review. Spine, 2010;35(9S): S28–S36
- [9] Meinberg EG, Stern PJ. Incidence of wrong-site surgery among hand surgeons. The Journal of Bone and Joint Surgery. 2003;85(2):193-197
- [10] Mody MG, et al. The prevalence of wrong level surgery among spine surgeons. Spine. 2008;33(2):194-198
- [11] Neily J, et al. Incorrect surgical procedures within and outside of the operating room. Archives of Surgery. 2009;**144**(11):1028-1034
- [12] Neily J, et al. Incorrect surgical procedures within and outside of the operating room: A follow-up report. Archives of Surgery. 2011;146(11):1235-1239
- [13] Stahel PF, et al. Wrong-site and wrong-patient procedures in the universal protocol era: Analysis of a prospective database of physician self-reported occurrences. Archives of Surgery. 2010;145(10):978-984
- [14] Van Klei W, et al. Effects of the introduction of the WHO "Surgical Safety Checklist" on in-hospital mortality: A cohort study. Annals of Surgery. 2012;255(1):44-49
- [15] Wong D, Mayer T, Watters W. Prevention of Wrong-site Surgery: Sign, Mark and X-ray (SMaX). La Grange, IL: North American Spine Society; 2001
- [16] AHRQ. Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. 5 March 2003, 2017]. Available from: https://psnet.ahrq.gov/resources/ resource/3643/universal-protocol-for-preventing-wrong-site-wrong-procedure-wrongperson-surgery

- [17] Smith E, et al. Surgical safety checklist: Productive, nondisruptive, and the "right thing to do". Journal of Postgraduate Medicine. 2015;**61**(3):214
- [18] Saufl NM. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery. Journal of PeriAnesthesia Nursing. 2004;19(5):348-351
- [19] Stawicki S, et al. Fundamentals of Patient Safety in Medicine and Surgery. New Delhi: Wolters Kluwer Health (India) Pvt Ltd; 2014
- [20] Stawicki SP, et al. Natural history of retained surgical items supports the need for team training, early recognition, and prompt retrieval. The American Journal of Surgery. 2014;208(1):65-72
- [21] Rubin JD, Janovic EV, Gulinello C. \$20 million award to parents for removal of the wrong side of child's brain. Healthcare Risk Management. 2013(AVR):3-4
- [22] Girard, NJ. Two Wrongs Don't Make a Right (Kidney). AORN Journal. 2016;104(2):186
- [23] Sevdalis N, et al. Annoyances, disruptions, and interruptions in surgery: The Disruptions in Surgery Index (DiSI). World Journal of Surgery. 2008;32(8):1643-1650
- [24] Wiegmann DA, et al. Disruptions in surgical flow and their relationship to surgical errors: An exploratory investigation. Surgery. 2007;**142**(5):658-665
- [25] Lee JS, et al. Prevention of wrong-site tooth extraction: Clinical guidelines. Journal of Oral and Maxillofacial Surgery. 2007;65(9):1793-1799
- [26] Hempel S, et al. Wrong-site surgery, retained surgical items, and surgical fires: A systematic review of surgical never events. JAMA Surgery. 2015;150(8):796-805
- [27] Goodell KH, Cao CG, Schwaitzberg SD. Effects of cognitive distraction on performance of laparoscopic surgical tasks. Journal of Laparoendoscopic & Advanced Surgical Techniques. 2006;16(2):94-98
- [28] Antoniadis S, et al. Identification and interference of intraoperative distractions and interruptions in operating rooms. Journal of Surgical Research. 2014;188(1):21-29
- [29] Sevdalis N, Healey AN, Vincent CA. Distracting communications in the operating theatre. Journal of Evaluation in Clinical Practice. 2007;13(3):390-394
- [30] Etchells E, O'Neill C, Bernstein M. Patient safety in surgery: Error detection and prevention. World Journal of Surgery. 2003;27(8):936-941
- [31] Stawicki SP, et al. Retained surgical items: A problem yet to be solved. Journal of the American College of Surgeons. 2013;**216**(1):15-22
- [32] Moffatt-Bruce SD, et al. Risk factors for retained surgical items: A meta-analysis and proposed risk stratification system. Journal of Surgical Research. 2014;**190**(2):429-436
- [33] The\_Joint\_Commission. Universal Protocol. 5 March 2017, 2017]; Available from: https:// www.jointcommission.org/standards\_information/up.aspx

- [34] Haynes AB, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. New England Journal of Medicine. 2009;**360**(5):491-499
- [35] Lee, SL. The Extended Surgical Time-Out: Does It Improve Quality and Prevent Wrong-Site Surgery? Perm J. 2010 Spring;14(1):19-23
- [36] Clarke JR, Johnston J, Finley ED. Getting surgery right. Annals of Surgery. 2007;246(3):395-403. discussion 403-5
- [37] Zahiri HR, et al. Prevention of 3 "never events" in the operating room: Fires, gossypiboma, and wrong-site surgery. Surgical Innovation. 2011;**18**(1):55-60
- [38] Portner M, et al. Learning from Others: Examples from Air Transportation and Industrial Realms. Fundamentals of Patient Safety in Medicine and Surgery, Edition: 1st, Chapter: 10, Publisher: Wolters-Kluwer. 2014;89-98.
- [39] Reason J. The contribution of latent human failures to the breakdown of complex systems. Philosophical Transactions of the Royal Society of London B: Biological Sciences. 1990;327(1241):475-484
- [40] Collins SJ, et al. Effectiveness of the surgical safety checklist in correcting errors: A literature review applying Reason's Swiss cheese model. AORN Journal. 2014;**100**(1):65-79. e5
- [41] Knight DM, Wedge JH. Marking the operative site: A lesson learned. Canadian Medical Association Journal. 2010;182(17):E799–E799
- [42] Wachter RM, Pronovost PJ. Balancing" no blame" with accountability in patient safety. The New England Journal of Medicine. 2009;361(14):1401
- [43] Ibrahim SF. Practice gaps. Wrong-site surgery in dermatology. JAMA Dermatology. 2014;**150**(5):558-559
- [44] Rydenfält C, et al. Compliance with the WHO surgical safety checklist: Deviations and possible improvements. International Journal for Quality in Health Care. 2013;25(2): 182-187
- [45] Nguyen MC, Moffatt-Bruce SD. What's new in academic medicine? retained surgical items: Is "zero incidence" achievable? International Journal of Academic Medicine. 2016;2(1):1
- [46] Dippolito A, et al. Republication: History of physicians fighting frivolous lawsuits: An overview. International Journal of Academic Medicine. 2016;2(3):34
- [47] Lamb R. Open disclosure: the only approach to medical error. Qual Saf Health Care Wellington, New Zealand. British Medical Journal Publishing Group: London, UK. 2004;13:3-5 DOI: 10.1136/qshc.2003.008631
- [48] Kraman SS, Hamm G. Risk management: Extreme honesty may be the best policy. Annals of Internal Medicine. 1999;**131**(12):963-967

- [49] Finkelstein D, et al. When a physician harms a patient by a medical error: Ethical, legal, and risk-management considerations. The Journal of Clinical Ethics. 1996;8(4):330-335
- [50] Robbennolt JK. Apologies and medical error. Clinical Orthopaedics and Related Research. 2009;467(2):376-382
- [51] Wojcieszak D, Banja J, Houk C. The sorry works! Coalition: Making the case for full disclosure. The Joint Commission Journal on Quality and Patient Safety. 2006;**32**(6):344-350
- [52] Gavin P, Post J. Patient sues YNHH after botched surgery. 2017. Available from: http:// yaledailynews.com/blog/2016/03/28/patient-sues-ynhh-after-botched-surgery/
- [53] Giove CM. 'Coverup' investigation after city hospital patient 'set on fire' during surgery. 16 March 2012, 2017]. Available from: http://nypost.com/2012/05/06/coverup-investigationafter-city-hospital-patient-set-on-fire-during-surgery/
- [54] Wu AW. Handling hospital errors: Is disclosure the best defense? Annals of Internal Medicine. 1999;131(12):970-972
- [55] Seiden SC, Barach P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: Are they preventable? Archives of Surgery. 2006;**141**(9):931-939
- [56] Knight PH, et al. Complications during intrahospital transport of critically ill patients: Focus on risk identification and prevention. International Journal of Critical Illness and Injury Science. 2015;5(4):256-264
- [57] Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: The nature of patient care information system-related errors. Journal of the American Medical Informatics Association. 2004;11(2):104-112
- [58] Boockvar K, et al. Adverse events due to discontinuations in drug use and dose changes in patients transferred between acute and long-term care facilities. Archives of Internal Medicine. 2004;164(5):545-550
- [59] Parry C, et al. The care transitions intervention: A patient-centered approach to ensuring effective transfers between sites of geriatric care. Home Health Care Services Quarterly. 2003;22(3):1-17
- [60] Richardson A, Storr J. Patient safety: A literative review on the impact of nursing empowerment, leadership and collaboration. International Nursing Review. 2010;**57**(1):12-21
- [61] Nadzam DM. Nurses' role in communication and patient safety. Journal of Nursing Care Quality. 2009;24(3):184-188
- [62] McNamara SA. Incivility in nursing: Unsafe nurse, unsafe patients. Association of Operating Room Nurses. AORN Journal. 2012;95(4):535
- [63] Steelman VM, Graling PR. Top 10 patient safety issues: What more can we do? AORN Journal. 2013;97(6):679-701
- [64] Wald H, Shojania KG. Prevention of misidentifications. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. 2001;3(43):487-495

- [65] Wong DA, et al. Medical errors in orthopaedics. The Journal of Bone and Joint Surgery. American Volume. 2009;**91**(3):547-557
- [66] Bernstein M. Wrong-side surgery: Systems for prevention. Canadian Journal of Surgery. 2003;46(2):144-146
- [67] AHRQ. Never Events. 5 March 2016, 2017]. Available from: https://psnet.ahrq.gov/ primers/primer/3/never-events
- [68] Rosenthal J., Hanlon C. (2009). Nonpayment for preventable events and conditions: Aligning state and federal policies to drive health system improvement. Washington, DC: National Academy for State Health Policy (December 2009); 2009
- [69] Mehtsun WT, et al. Surgical never events in the United States. Surgery. 2013;153(4):465-472
- [70] Smith EA, et al. Surgical safety checklist: Productive, nondisruptive, and the "right thing to do". Journal of Postgraduate Medicine. 2015;**61**(3):214-245
- [71] Bates, DW., et al. Global priorities for patient safety research. BMJ 2009;338:b1775
- [72] Jhawar, BS., Mitsis, D., Duggal, N. Wrong-sided and wrong-level neurosurgery: a national survey. Journal of Neurosurgery: Spine. 2007;7(5):467-472
- [73] Donaldson MS, Corrigan JM, Kohn LT. To err is human: Building a safer health system. Vol. 6. Institute of Medicine. National Academies Press. Washington DC; 2000
- [74] Mokdad AH, et al. Actual causes of death in the United States. 2000. JAMA. 2004;291(10): 1238-1245
- [75] Rothman G. Wrong-site surgery. Archives of Surgery. 2006;141(10):1049-1050
- [76] Makary MA, Daniel M. Medical error—the third leading cause of death in the US. BMJ. 2016;353:i2139
- [77] www.kolpan.com. Medical malpractice: Removal of wrong disc \$150,000 settlement.
  18 March 2017, 2017]. Available from: https://www.kolpan.com/medical-malpractice-removal-of-wrong-disc-150-000-settlement.html
- [78] The\_New\_York\_Times. Doctor Who Cut Off Wrong Leg Is Defended by Colleagues. 18 March 1995, 2017]. Available from: http://www.nytimes.com/1995/09/17/us/doctor-whocut-off-wrong-leg-is-defended-by-colleagues.html
- [79] Brownstein J. Rhode Island Hospital Fined for Fifth Surgery Error in Two Years. 18 March 2009, 2017]. Available from: http://abcnews.go.com/Health/rhode-island-hospitalfined-surgery-error-years/story?id=8988619
- [80] Griffith A. Pregnant patient dies after wrong organ is removed. 18 March 2013, 2017]. Available from: http://www.patient-safety-blog.com/2013/06/21/pregnant-patient-diesafter-wrong-organ-is-removed/
- [81] Bates C. Surgeons remove wrong part of patient's lung at scandal-hit hospital. 18 March 2013, 2017]. Available from: http://www.dailymail.co.uk/health/article-2273160/ Surgeons-remove-wrong-patients-lung-scandal-hit-hospital.html

- [82] Indest\_III GF. Daytona Beach Hospital Facing Recommendation for Medicare and Medicaid Termination After Wrong-Site Surgery. 18 March 2013, 2017]. Available from: http://www.thehealthlawfirm.com/blog/posts/daytona-beach-hospital-facing-recommendation-for-medicare-and-medicaid-termination-after-wrong-site-surgery.html
- [83] MEYDAN\_TV. Wrong leg amputated in Baku hospital operation. 18 March 2016, 2017]. Available from: https://www.meydan.tv/en/site/society/15515/
- [84] NDTV. Doctors Operate On Wrong Leg Of 24-Year-Old In Delhi Hospital. 2016 March 18, 2017]. Available from: http://www.ndtv.com/delhi-news/wrong-leg-of-youth-operatedupon-at-fortis-hospital-says-family-1422335
- [85] Thanh\_Nien\_News. Man has wrong leg cut open at leading Vietnam public hospital. 18 March 2016, 2017]. Available from: http://www.thanhniennews.com/health/man-haswrong-leg-cut-open-at-leading-vietnam-public-hospital-64414.html
- [86] Cohen FL, Mendelsohn D, Bernstein M. Wrong-site craniotomy: Analysis of 35 cases and systems for prevention: Clinical article. Journal of Neurosurgery. 2010;**113**(3):461-473
- [87] Cima RR. Wrong-site craniotomy: Editorial. Journal of Neurosurgery. 2010;113:458-460
- [88] Miller KE, et al. Wrong-side thoracentesis: Lessons learned from root cause analysis. JAMA Surgery. 2014;**149**(8):774-779
- [89] Mallett R, et al. Preventing wrong site, procedure, and patient events using a common cause analysis. American Journal of Medical Quality. 2012;**27**(1):21-29
- [90] Whittemore AD. The impact of professionalism on safe surgical care. Journal of Vascular Surgery. 2007;45(2):415-419

