

UC Irvine

UC Irvine Previously Published Works

Title

Wrong-Site Surgery in California, 2007-2014

Permalink

<https://escholarship.org/uc/item/2m88b1zr>

Journal

OTOLARYNGOLOGY-HEAD AND NECK SURGERY, 157(1)

ISSN

0194-5998

Authors

Moshtaghi, O
Haidar, YM
Sahyouni, R
et al.

Publication Date

2017-07-01

DOI

10.1177/0194599817693226

License

CC BY 4.0

Peer reviewed

Wrong-Site Surgery in California, 2007-2014

Omid Moshtaghi¹, Yarah M. Haidar, MD¹, Ronald Sahyouni¹,
 Afsheen Moshtaghi¹, Yaser Ghavami, MD¹, Harrison W. Lin, MD¹,
 and Hamid R. Djalilian, MD^{1,2}

Otolaryngology—
 Head and Neck Surgery
 2017, Vol. 157(1) 48–52
 © American Academy of
 Otolaryngology—Head and Neck
 Surgery Foundation 2017
 Reprints and permission:
sagepub.com/journalsPermissions.nav
 DOI: 10.1177/0194599817693226
<http://otojournal.org>


Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. The implementation of a universal surgical safety protocol in 2004 was intended to minimize the prevalence of wrong-site surgery (WSS). However, complete elimination of WSS in the operating room continues to be a challenge. The purpose of this study is to evaluate the prevalence and etiology of WSS in the state of California.

Study Design. A retrospective study of all WSS reports investigated by the California Department of Public Health between 2007 and 2014.

Methods. Prevalence of overall and specialty-specific WSS, causative factors, and recommendations on further improvement are discussed.

Results. A total of 95 cases resulted in incident reports to the California Department of Public Health and were included in our study. The most common errors were operating on the wrong side of the patient's body ($n = 60$, 62%), performing the wrong procedure ($n = 21$, 21%), operating on the wrong body part ($n = 12$, 12%), and operating on the wrong patient ($n = 2$, 2%). WSS was most prevalent in orthopedic surgery ($n = 33$, 35%), followed by general surgery ($n = 26$, 27%) and neurosurgery ($n = 16$, 17%). All 3 otolaryngology WSS cases in California are associated with the ear.

Conclusion. WSS continues to surface despite national efforts to decrease its prevalence. Future research could establish best practices to avoid these “never events” in otolaryngology and other surgical specialties.

Keywords

wrong site, wrong side, surgical mistakes, timeout, complications, errors, surgery

Received June 29, 2016; revised December 21, 2016; accepted January 20, 2017.

The Joint Commission (JC) defines wrong-site surgery (WSS) as a general term that includes the wrong surgical procedure being performed or a surgical procedure

performed on the wrong side of a patient's body.¹ These errors constituted 12.7% of all unanticipated events in the health care setting that cause death or severe psychological or physiologic injury to a patient, or sentinel events, between 2004 and 2015.² Sentinel events are classified by the JC as “never events,” meaning that they should never occur under any circumstance.^{3,4}

One of the preliminary measures undertaken to mitigate the prevalence of sentinel incidents was introduced by leaders in the field of orthopedic surgery who spearheaded the “Sign Your Site” and “Sign, Mark, and X-ray” campaigns in 1998 and 2001, respectively.^{5,6} In 2000, a publication entitled *To Err Is Human* brought WSS to the national spotlight and sparked public awareness of this health care problem.⁷ Four years later, the JC mandated the use of a “timeout” prior to each surgical procedure as a requirement for hospital accreditation.⁸

These timeout checklists have demonstrated varying degrees of efficacy. Globally, the implementation of a surgical safety checklist reduced mortality rates from 1.5% to 0.8% and inpatient complications from 11.0% to 7.0%.⁹ However, despite the widespread implementation of the timeout checklist, the checklist alone would not have prevented a reported two-thirds of WSSs in the United States.¹⁰ To further reduce these events, efforts on a national scale focused on eliminating the WSS have commenced.

The JC has been tracking WSS since 1995, long before the implementation of the timeout protocols. However, hospitals are not required to report these incidents. Therefore, JC data may underrepresent the true prevalence of WSS. In addition to the JC database, Pennsylvania, Minnesota, and California have initiated statewide programs for mandatory reporting of WSS events for tracking and quality improvement purposes in all

¹Division of Neurotology and Skull Base Surgery, Department of Otolaryngology—Head and Neck Surgery, University of California—Irvine, Irvine, California, USA

²Department of Biomedical Engineering, University of California—Irvine, Irvine, California, USA

Corresponding Author:

Hamid R. Djalilian, MD, University of California—Irvine, Otolaryngology
 5386, 19182 Jamboree Road, Irvine, CA 92697, USA.
 Email: hjalili@uci.edu

Table 1. Definitions of the Most Common Causes of Wrong-Site Surgery per the Joint Commission.²

Cause	Definition
Leadership	Organizational planning/culture, community relations, service availability, priority setting, resource allocation, complaint resolution, leadership collaboration, standardization (eg, clinical practice guidelines), directing department/services, integration of services, inadequate policies and procedures, noncompliance with policies and procedures, performance improvement, medical staff organization, nursing leadership.
Human factors	Staffing levels, staffing skill mix, staff orientation, in-service education, competency assessment, staff supervision, resident supervision, medical staff credentialing/privileging, medical staff peer review, other (eg, rushing, fatigue, distraction, complacency, bias)
Communication Assessment	Oral, written, electronic, among staff, with/among physicians, with administration, with patient or family Adequacy, timing, or scope of assessment; pediatric, psychiatric, alcohol/drug, and/or abuse/neglect assessments; patient observation; clinical laboratory testing; care decisions
Information management	Information management needs assessment, confidentiality, security of information, data definitions, availability of information, technical systems, patient identification, medical records, aggregation of data
Operative care	Operative care planning, blood use, and/or patient monitoring
Physical environment	General safety, fire safety, security systems, hazardous materials, emergency management, smoking management, equipment management, utilities management
Patient rights	Informed consent, participation in care, end-of-life care, pain management, privacy
Anesthesia care	Planning, monitoring, and/or discharge
Continuum of care	Access to care, setting of care, continuity of care, transfer of patient, and/or discharge of patient

hospitals regardless of JC accreditation.^{2,11,12} This study seeks to analyze the reported cases of WSS in California.

Methods

A retrospective analysis of original WSS investigational reports spanning 2007 to 2014 provided by the California Department of Public Health (CDPH) was performed. Data were obtained by submitting a request to the CDPH for all WSS reports in California. The CDPH licensing and certification program investigators who visited the site after each incident and conducted interviews with the surgeon, nurses, and auxiliary team generated the complete reports, which included a description of the event from each interviewee. All reports were carefully reviewed to classify the cause of the error based on definitions set forth by the JC (Table 1).² Furthermore, WSS was stratified by anatomic location, medical specialty, and error type. Although WSS is a generic umbrella term in the literature, we stratified the subtypes of WSS to include wrong side (defined as a procedure performed on the contralateral side), wrong site (defined as a procedure performed on an incorrect location on the ipsilateral side), and wrong procedure (defined to be an incorrect or additional procedure that was conducted; eg, a C3-4 instead of a C4-5 fusion).

The average number of WSS cases per year was calculated and analyzed with PASW Statistics 18.0 software (SPSS Inc, Chicago, IL). Linear regression analysis was performed on each data set. A *P* value <.05 was considered statistically significant.

Results

A total of 142 WSS reports were generated by the CDPH from 2007 to 2014. In 95 of the 142 cases, the CDPH

investigator was able to substantiate that a facility had committed a violation that risked the patient's health and safety over the course of 7 years (Figure 1). In 47 cases, the investigator determined that no violation had occurred and did not generate an incident report; these cases were omitted from our study.

The cause for each event was classified per the JC definitions of etiologic causes (Table 1) and plotted (Table 2). The most common etiologic causes identified were leadership (30.9%) and human factors (23.4%). Other causes identified in CDPH data included errors in communication, assessment, information management, and operative care. Overall, the most common error was wrong side (62.5%), followed by wrong procedure (22.9%), wrong site (12.5%), and wrong patient (2.1%). Last, there was no statistically significant variation in the number of WSS cases over the analyzed period in California (*P* = .127).

Reported events were stratified by surgical specialty (Figure 2A) and anatomic site (Figure 2B). Although orthopedic surgery exhibited the highest rates of WSS, there was no statistically significant difference among various surgical specialties in the CDPH data (Figure 3).

Discussion

Despite substantial efforts to mitigate WSS by implementing timeout protocols, it is evident that these "never events" continue to occur in California. Since JC reporting of WSS is voluntary, it is difficult to assess the true prevalence of WSS in the United States, with estimates suggesting that >50% of WSS cases go unreported.¹³ Furthermore, hospitals that are not JC accredited are not subject to JC reporting requirements, and this may reduce the true prevalence of WSS accordingly.

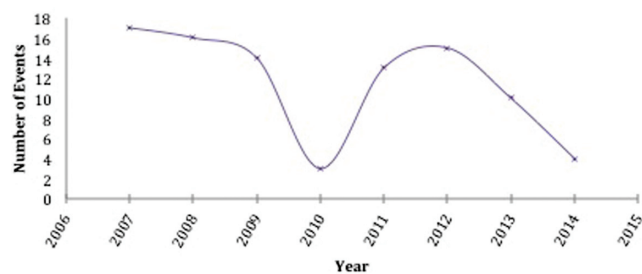


Figure 1. The annual prevalence of wrong-site surgery (WSS) in California.

Table 2. Cases per Cause of Error: California Department of Public Health (2007-2014).

Cause	n (%)
Leadership	29 (30.5)
Human factors	22 (23.1)
Assessment	15 (15.7)
Communication	9 (9.4)
Unknown	8 (8.4)
Operative care	7 (7.3)
Information management	5 (5.2)
Total	95

Causes of WSS

According to CDPH data, the most common cause of WSS was leadership, composing approximately one-third (31%) of cases. Failure of leadership was also identified by the JC to be the most common cause of WSS nationally.² Leadership etiologic causes are defined by the JC as a lack of organizational planning, resulting in noncompliance or ineffective implementation of timeout procedures (eg, not marking the correct site). The proper implementation of timeout protocols requires a concerted effort by administrators and clinicians to follow and complete the checklists, which lack uniformity. The variation in timeout procedures and site-marking policies is readily evident and has been reported in pediatric otolaryngology practices.¹⁴

Digitization of the timeout checklist has been proposed as a solution to improving compliance rates and checklist uniformity. Studies have reported enhanced compliance with surgical checklists via electronic white boards to digitally augment the timeout procedure, which can improve the transmission of critical information among surgical team members.^{15,16}

Human factors were the second-most common cause of WSS in California, which accounted for 25% of all WSS cases. Failure in marking the surgical site was the most common error, which includes marking the incorrect site, failure to mark any site, or markings being obscured by surgical drapes. In accordance with CDPH findings, JC data

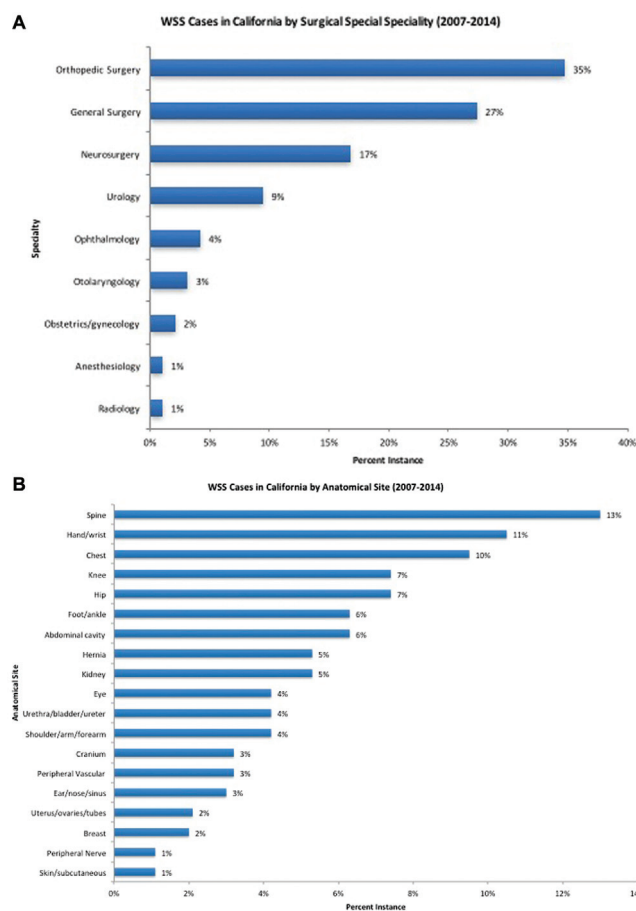


Figure 2. The percentage of wrong-site surgery (WSS) cases by (A) surgical specialty and (B) anatomic site.

also cite human factors as the second-most common cause.² In an attempt to mitigate human factor–related errors, some protocols require the patients to mark the surgical site themselves. However, patient-marked sites were correct only 60% of the time.¹⁷ Nevertheless, patients and family members have been determined to be the most effective source of preventing WSS before they occur.¹⁸ Clarke and colleagues report that while the circulating nurse detected and prevented 11% of potential WSS cases from occurring, patients detected 22% of near misses.¹⁸ The question of who should mark the site remains unclear, and unfortunately, noncompliance and inaccuracy are important issues regardless of whether a surgical team member or the patient is responsible.

The third-most common cause of WSS identified was miscommunication, which was responsible for 10% of cases in California. This parallels JC data, which reported miscommunication as the third-most common cause of WSS.² The importance of communication among surgical team members is well identified in the literature, with communication errors identified as the most common cause of WSS in a study that evaluated perioperative otolaryngology mistakes in a Veterans Administration hospital.¹⁹ To help address these issues, hospitals have implemented preoperative surgical staff briefings to

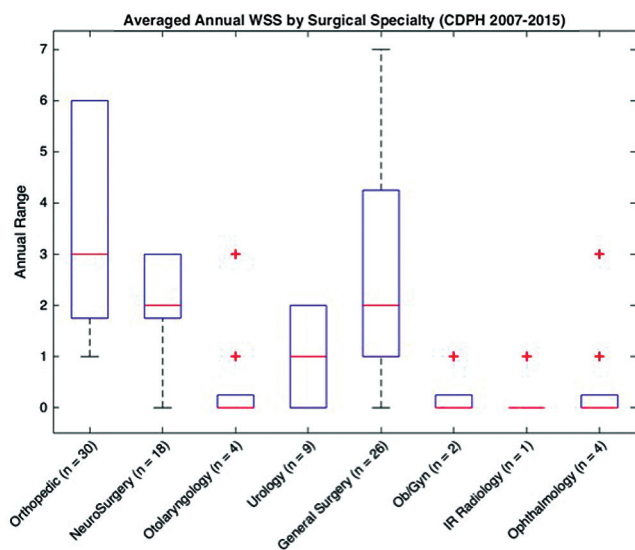


Figure 3. Box and whisker plot of the average number of annual wrong-site surgery cases demonstrates no significant difference across various surgical specialties (California Department of Public Health [CDPH] data, 2007-2015). The red line within each box designates the median number of cases per year, with the upper and lower borders of the box corresponding to the upper and lower quartiles. The vertical lines extending from the boxes depict the highest and lowest values per year. The crosshair symbols designate outlier data points outside the quartile range.

enhance interpersonal cohesion and communication, resulting in increased awareness of the surgical site by the entire surgical team.²⁰

WSS in Surgical Specialties

CDPH and JC data both determine WSS events to be most common in orthopedic surgery, general surgery, and neurosurgery, in order of prevalence.²¹ This may in part reflect the increased case volume of these specialties or the bilateral or multilevel (ie, spine) nature of the procedures conducted by these specialists. A recent survey-based study demonstrated that medical errors and adverse events continue to be a common occurrence in otolaryngology, finding that otolaryngology cases constitute 0.3% to 4.5% of all WSS.^{22,23} Although official reporting of these events is difficult to authenticate, voluntary surveys of 681 otolaryngologists identified 8 cases of WSS based on survey responses.²⁴ Additionally, an estimated 9% of otolaryngologists have reported experiences with wrong-site sinus surgery.²⁵ Furthermore, WSS accounts for up to 6% of all self-reported medical errors in otolaryngology.²⁶ As demonstrated by CDPH data, otology cases accounted for 2 of the 3 otolaryngology WSS cases. In contrast, Mathew et al found that otology cases composed only 4.4% (6 of 137) of all otolaryngology negligence claims filed nationwide.²⁷

Finding Solutions to WSS

The analyzed CDPH data failed to demonstrate any downward trend or reduction in WSS prevalence. Although steps

have been taken to enforce JC-mandated timeout protocols as previously discussed, they fail to completely prevent WSS. Furthermore, a comprehensive review of all WSS malpractice claims from 1985 to 2004 revealed that even if the universal JC protocols were correctly implemented, only 62% of the malpractice claims would have been prevented.¹¹ Despite the prevalence of WSS, it continues to be categorized as a “never event,” which should never happen under any circumstances, with even an isolated case considered unacceptable by the JC. Further modifications and optimization of existing protocols to enhance compliance and mitigate the most common causes of WSS are warranted.

Conclusion

Despite widespread implementation of mandatory JC timeout protocols, WSS continues to occur in various surgical specialties. Proper compliance with timeout protocols and interpersonal communication should be cultivated. Additionally, modifications to current protocols to address the most common causes of WSS cases may reduce the prevalence of WSS.

Author Contributions

Omid Moshtaghi, contributed to the acquisition and analysis of work, drafting of manuscript, final approval, and agrees to the work integrity; **Yarah M. Haidar**, contributed to the acquisition and analysis of work, drafting of manuscript, final approval, and agrees to the work integrity; **Ronald Sahyouni**, contributed to the acquisition and analysis of work, drafting of manuscript, final approval, and agrees to the work integrity; **Afsheen Moshtaghi**, contributed to the acquisition and analysis of work, drafting of manuscript, final approval, and agrees to the work integrity; **Yaser Ghavami**, contributed to the interpretation of data, revising the work, final approval, and agrees to the work integrity; **Harrison W. Lin**, contributed to the interpretation of data, revising the work, final approval, and agrees to the work integrity; **Hamid R. Djalilian**, contributed to the interpretation of data, revising the work, final approval, and agrees to the work integrity.

Disclosures

Competing interests: Hamid R. Djalilian, Mindset Technologies—owns stock; OticPharma—consultant.

Sponsorships: None.

Funding source: None.

References

- Gibbs VC. Patient safety practices in the operating room: correct-site surgery and nothing left behind. *Surg Clin North Am.* 2005;85:1307-1319.
- The Joint Commission. Sentinel event data root causes by event type 2004–3Q 2015. http://www.jointcommission.org/assets/1/18/Root_Causes_Event_Type_2004-3Q_2015.pdf. Accessed April 28, 2016.
- The Joint Commission. Sentinel events: comprehensive accreditation manual for hospitals. http://www.jointcommission.org/assets/1/6/camh_2012_update2_24_se.pdf. Published 2013. Accessed April 28, 2016.

4. Mehtsun WT, Ibrahim AM, Dienerwest M, Pronovost PJ, Makary MA. Surgical never events in the United States. *Surgery*. 2013;153:465-472.
5. American Academy of Orthopaedic Surgeons. Information statements: surgical site and procedure confirmation. <http://www.aaos.org/CustomTemplates/Content.aspx?id=22291&ssopc=1>. Published March 2015. Access April 28, 2016.
6. Wong D, Bartol S, Brooks A, et al. *Sign, Mark and X-ray Prevention of Wrong-Site Spinal Surgery*. Burr Ridge, IL: North American Spine Society; 2014.
7. Kohn LT, Corrigan JM, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academies Press; 2000.
8. The Joint Commission. *Comprehensive Accreditation Manual*. Oak Brook, IL: The Joint Commission; 2016.
9. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med*. 2009;360:491-499.
10. Kwaan MR, Studdert DM, Zinner MJ, Gawande AA. Incidence, patterns, and prevention of wrong-site surgery. *Arch Surg*. 2006;141:353-357.
11. Arnold T. Quarterly update on wrong-site surgery: eleven years of data collection and analysis. *Pa Patient Saf Advis*. 2015;12:119-120.
12. Rydrych D, Apold J, Harder K. Preventing wrong-site surgery in Minnesota: a 5-year journey. *Patient Safety & Quality Healthcare*. 2009;20:30.
13. Seiden SC, Barach P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: are they preventable? *Arch Surg*. 2006;141:931-939.
14. Shah RK, Arjmand E, Roberson DW, Deutsch E, Derkay C. Variation in surgical time-out and site marking within pediatric otolaryngology. *Arch Otolaryngol Head Neck Surg*. 2011;137:69-73.
15. Shear T, Deshur M, Avram MJ, et al. Procedural timeout compliance is improved with real-time clinical decision support [published online April 16, 2015]. *J Patient Saf*.
16. Mainthia R, Lockney T, Zotov A, et al. Novel use of electronic whiteboard in the operating room increases surgical team compliance with pre-incision safety practices. *Surgery*. 2012;151:660-666.
17. Digiovanni CW, Kang L, Manuel J. Patient compliance in avoiding wrong-site surgery. *J Bone Joint Surg Am*. 2003;85:815-819.
18. Clarke JR, Johnston J, Finley ED. Getting surgery right. *Ann Surg*. 2007;246:395-403.
19. Dedhia RC, Shwaish K, Snyderman CH, Monte R, Eibling DE. Perioperative process errors and delays in otolaryngology at a Veterans Hospital: prospective study. *Laryngoscope*. 2013;123:3010-3015.
20. Makary MA, Mukherjee A, Sexton JB, et al. Operating room briefings and wrong-site surgery. *J Am Coll Surg*. 2007;204:236-243.
21. Croteau J. Wrong site surgery: the evidence base. https://www.health.ny.gov/professionals/patients/patient_safety/conference/2007/docs/wrong_site_surgery-the_evidence_base.pdf. Published 2007. Accessed April 28, 2016.
22. Lavin JM, Boss EF, Brereton J, Roberson DW, Shah RK. Responses to errors and adverse events: the need for a systems approach in otolaryngology. *Laryngoscope*. 2016;126:1999-2002.
23. Liou TN, Nussenbaum B. Wrong site surgery in otolaryngology—head and neck surgery. *Laryngoscope*. 2014;124:104-109.
24. Shah RK, Boss EF, Brereton J, Roberson DW. Errors in otolaryngology revisited. *Otolaryngol Head Neck Surg*. 2014;150:779-784.
25. Shah RK, Nussenbaum B, Kienstra M, et al. Wrong-site sinus surgery in otolaryngology. *Otolaryngol Head Neck Surg*. 2010;143:37-41.
26. Shah RK, Kentala E, Healy GB, Roberson DW. Classification and consequences of errors in otolaryngology. *Laryngoscope*. 2004;114:1322-1335.
27. Mathew R, Asimacopoulos E, Valentine P. Toward safer practice in otology: a report on 15 years of clinical negligence claims. *Laryngoscope*. 2011;121:2214-2219.