

# Wrong-Site and Wrong-Patient Procedures in the Universal Protocol Era

## *Analysis of a Prospective Database of Physician Self-reported Occurrences*

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**Objective:** To determine the frequency, root cause, and outcome of wrong-site and wrong-patient procedures in the era of the Universal Protocol.

**Design:** Analysis of a prospective physician insurance database performed from January 1, 2002, to June 1, 2008. Deidentified cases were screened using predefined taxonomy filters, and data were analyzed by evaluation criteria defined a priori.

**Setting:** Colorado.

**Patients:** Database contained 27 370 physician self-reported adverse occurrences.

**Main Outcome Measures:** Descriptive statistics were generated to examine the characteristics of the reporting physicians, the number of adverse events reported per year, and the root causes and occurrence-related patient outcomes.

**Results:** A total of 25 wrong-patient and 107 wrong-site procedures were identified during the study period. Significant harm was inflicted in 5 wrong-patient procedures (20.0%) and 38 wrong-site procedures (35.5%). One patient died secondary to a wrong-site procedure (0.9%). The main root causes leading to wrong-patient procedures were errors in diagnosis (56.0%) and errors in communication (100%), whereas wrong-site occurrences were related to errors in judgment (85.0%) and the lack of performing a "time-out" (72.0%). Nonsurgical specialties were involved in the cause of wrong-patient procedures and contributed equally with surgical disciplines to adverse outcome related to wrong-site occurrences.

**Conclusions:** These data reveal a persisting high frequency of surgical "never events." Strict adherence to the Universal Protocol must be expanded to nonsurgical specialties to promote a zero-tolerance philosophy for these preventable incidents.

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**A**NY INTERVENTION INVOLVING a wrong site, wrong patient, or wrong procedure represents an unacceptable surgical complication, classified as a "never event" by the National Quality Forum.<sup>1,2</sup> In 1998, a task force from the American Academy of Orthopaedic Surgeons revealed that orthopedic surgeons have a 25% chance of performing a wrong-site surgery during a 35-year career, with a particular high risk for wrong-knee arthroscopies and wrong-level spine fusions.<sup>3</sup> This notion led to the academy's launch of the Sign Your Site campaign, advocating for orthopaedic surgeons to initial the surgical site before proceeding with a planned intervention.<sup>4</sup> In 2002, the American College of Surgeons published recommendations for hospitals and health care organizations to develop guidelines that ensure correct patient, correct site, and correct procedure

surgery.<sup>5</sup> Two years later, the Joint Commission introduced a Universal Protocol, which became effective on July 1, 2004, for all accredited hospitals, ambulatory care



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facilities, and office-based surgical facilities.<sup>6</sup> The Universal Protocol consists of 3 distinct parts: a preprocedure verification, a surgical site marking, and a "time-out" performed immediately before the surgical procedure.<sup>7-10</sup> Despite the widespread implementation of the Universal Protocol in recent years, wrong-site surgery continues to pose a signifi-

cant challenge to patient safety in the United States.<sup>11-18</sup> Until now, there has been an ongoing lack of reliable data about the true incidence of wrong-patient and wrong-site operations because these confidential data—derived from closed claims, sentinel event databases, or other types of surveys based on voluntary reporting—may represent just the tip of the iceberg of selected, most severe occurrences.<sup>11-13,19</sup> Previous reports<sup>19-21</sup> have revealed that only approximately one-third of all wrong-site surgery cases result in legal action and estimated that the Joint Commission sentinel event database comprises just 2% of all wrong-site procedures occurring in the United States.<sup>11,22</sup>

The present study was designed to analyze the frequency, root causes, and outcomes of wrong-site and wrong-patient procedures based on a comprehensive, prospective insurance database of 27 370 physician self-reported adverse occurrences in Colorado from 2002 through 2008.

## METHODS

### COPIC DATABASE

The Colorado Physician Insurance Company (COPIC) provides professional liability coverage to approximately 6000 practicing physicians in Colorado ([www.copic.com](http://www.copic.com)). At the time of data analysis for the present study, 5937 physicians were insured through COPIC. Of these, 1881 (31.7%) were surgical (procedural) and 4056 (68.3%) were nonsurgical specialists. The detailed physician specialties are listed in **Table 1**. The company's policy provides incentives for early reporting of adverse events and complications by its insured physicians. This system is based on "reporting forms" coverage, which attaches coverage to a particular occurrence, when reported, in the active policy year, even if a claim or lawsuit results many years later. Furthermore, COPIC offers real-time assistance for disclosure and resolution of adverse events with patients and their families. This proactive concept facilitates constructive and transparent communication about harm sustained by patients and expedites compensation in selected circumstances through the company's 3 R's (recognize, respond, and resolve) program.<sup>23</sup> All reported occurrences, independent of a filed claim, are prospectively captured in a database, termed the *Occurrence Tracking System*, the current version of which was initiated on January 1, 2002, and is populated in real time. A proprietary taxonomy is used to characterize occurrences (including those that progress to claims or lawsuits). The number of overall occurrences leading to a claim or lawsuit are given in **Table 2**.

### STUDY DESIGN

The present study was designed as a retrospective analysis of a prospective database, aiming to evaluate all cases of wrong-site and wrong-patient procedures reported to COPIC from January 1, 2002, to June 1, 2008. The study was approved by the institutional review board (Colorado Multiple Institutional Review Board). Identifying information about patients and involved physicians was redacted before analysis by non-COPIC researchers, and individual case numbers were used to identify occurrences. The total number of occurrences reported during the study period was 27 370. The flowchart of selection process and inclusion criteria for final analysis is depicted in **Figure 1**.

Deidentified data were obtained from all retrieved files, including the specialty, sex, and practice type of the reporting physician; diagnosis; performed procedure; and detailed case narra-

**Table 1. Characteristics of Physicians Involved in Wrong-Patient or Wrong-Site Procedures**

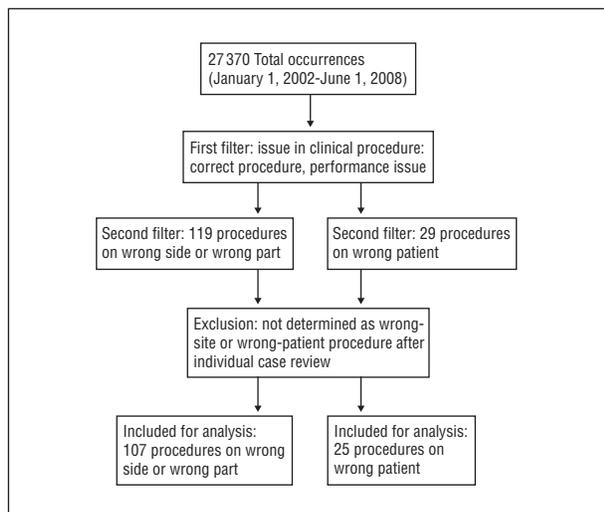
Characteristic	No. (%)	
	Wrong Patient (n=25)	Wrong Site (n=107)
<b>Nonsurgical specialty</b>		
Dermatology, nonprocedural	1 (4.0)	4 (3.7)
Emergency medicine	0	2 (1.9)
Family or general practice	2 (8.0)	4 (3.7)
Internal medicine	6 (24.0)	8 (7.5)
Neurology	0	1 (0.9)
Ophthalmology, nonprocedural	0	1 (0.9)
Pathology	2 (8.0)	1 (0.9)
Pediatrics	2 (8.0)	1 (0.9)
Radiation oncology	0	3 (2.8)
Radiology	1 (4.0)	4 (3.7)
<b>Surgical</b>		
Anesthesiology	0	13 (12.1)
Dermatology, procedural	0	2 (1.9)
Otorhinolaryngology	1 (4.0)	1 (0.9)
General surgery	0	18 (16.8)
Obstetrics-gynecology	2 (8.0)	1 (0.9)
Ophthalmology, procedural	0	1 (0.9)
Orthopedic surgery	0	24 (22.4)
Neurosurgery	0	2 (1.9)
Urology	2 (8.0)	4 (3.7)
Other	6 (24.0)	12 (11.2)
<b>Sex</b>		
Female	6 (24.0)	14 (13.1)
Male	11 (44.0)	80 (74.8)
Unknown	8 (32.0)	13 (12.1)
<b>Practice type</b>		
Ambulatory surgery center	2 (8.0)	24 (22.4)
Hospital	8 (32.0)	62 (57.9)
Office	9 (36.0)	13 (12.1)
Nursing home	1 (4.0)	0
Other	5 (20.0)	8 (7.5)

**Table 2. Occurrences Reported to the Colorado Physician Insurance Company Database That Resulted in a Claim or Lawsuit**

Report Year	Occurrences, No.	Claims or Lawsuits, No. (%)
2002	3586	712 (19.9)
2003	3905	685 (17.5)
2004	4180	684 (16.4)
2005	4088	716 (17.5)
2006	3781	909 (24.0)
2007	3749	985 (26.3)
2008 <sup>a</sup>	4081	831 (20.4)
<b>Total</b>	<b>27 370</b>	<b>5873 (21.5)</b>

<sup>a</sup>Numbers for 2008 are shown for the full calendar year, whereas the data analyzed in the present study only include the first 5 months of 2008 (January 1 to June 1, 2008).

tives. When the narratives alone were deemed ambiguous or insufficient, the complete patient dossiers were obtained and analyzed in detail. Cases that were classified as not being a factual wrong site (n=12) or wrong patient (n=4) after individual case analysis were excluded from the study. A total of 107 wrong-site and 25 wrong-patient cases were included in the final analysis (Figure 1).



**Figure 1.** Flowchart of case selection in the Colorado Physician Insurance Company database.

1. Root cause analysis	D. Error in judgment
A. Error in diagnosis	D1. Wrong indication for procedure
A1. Delayed diagnosis	D2. Violation of guideline or protocol
A2. Failure to diagnose or misdiagnosis	D3. Inadequate planning of procedure
A3. Failure to perform diagnostic tests	D4. Other judgment issue
A4. Misinterpretation of diagnostic test results	E. System issue
A5. Other diagnostic issue	E1. Time-out not performed
B. Error in treatment	E2. Error in credentialing or competency
B1. Wrong treatment concept	E3. Error in supervision or staffing
B2. Technical error	E4. Environmental safety or security issue
B3. Delayed treatment	E5. Inadequate resources
B4. Failure to treat	E6. Other system issue
B5. Unnecessary treatment	F. Root cause equivocal or not determined
B6. Medication error	
B7. Other treatment issue	
C. Error in communication	2. Outcome
C1. Error in verbal communication	G. Patient death
C2. Error in written communication	H. Significant harm or impairment
C3. Error in information handover	I. Minimal harm or impairment
C4. Other communication issue	J. No-harm event
	K. Outcome equivocal or not determined

**Figure 2.** Standardized adverse event classification form for evaluation of root causes and outcomes of wrong-patient and wrong-site procedures. In the root cause analysis, multiple selections within and across categories were permitted. Outcomes were restricted to a single selection.

## OUTCOME VARIABLES

All patient narratives were reviewed independently by the first author (P.F.S.) and the senior author (P.S.M.), according to evaluation criteria that were defined a priori. These data were recorded on standardized adverse event classification forms (**Figure 2**). Disagreements were resolved by a face-to-face, detailed consensus review. The root cause analysis was stratified by error in diagnosis, error in treatment, error in communication, error in judgment, and system issue, with defined subgroups in each category. Multiple selections within and across categories were permitted. For example, a wrong-patient procedure resulting from a mislabeled biopsy specimen in the laboratory was concomitantly classified as an *error in diagnosis* (because the correct diagnosis was not established) and as an *error in communication* owing to written and/or verbal communication breakdown that led to the incorrect labeling or mix-up of samples. The definition of *unnecessary treatment* was applied to all cases in which a full surgical procedure was accomplished at the wrong site or in a wrong patient. In all other situations, the procedure was aborted in time, thus resulting in a

*no-harm* event (eg, a pure surgical approach on the wrong side, which was recognized and aborted in time). Patient outcome was furthermore evaluated in 5 distinct categories: death, significant harm, minimal harm, no harm, or equivocal/undetermined. The definition of *death* was applied exclusively to patients who died as a direct consequence of the erroneous procedure. *Significant harm* was applied to occurrences in which a procedure performed at the wrong site (eg, vitrectomy in which a procedure performed at the wrong patient (eg, prostatectomy in a healthy patient) led to a long-term functional or structural impairment. *Minimal harm* was applied to incidents in which a procedure was initiated but aborted (eg, skin incision at the wrong site) or completed without inducing a significant harm (eg, diagnostic arthroscopy on the wrong side). A *no-harm* event was defined as an occurrence in which an invasive procedure was not actually initiated (eg, preparing and draping of the wrong site or wrong patient, local or regional anesthesia at the wrong site, or vaccination of the wrong patient). Unclear root causes and outcomes were coded as *equivocal* or *not determined*.

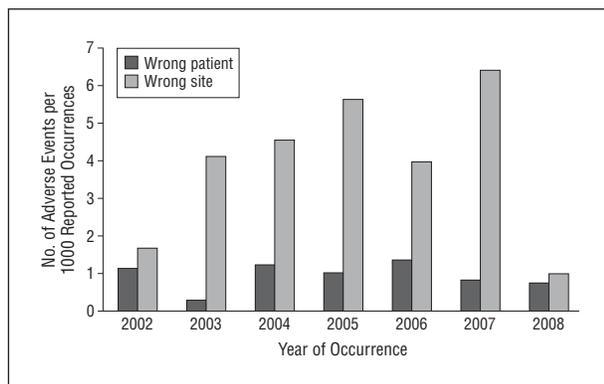
## STATISTICAL ANALYSIS

Descriptive statistics were generated to examine the characteristics of the insured physicians who reported the occurrences, the root cause analyses of adverse events, and the patient outcomes. Pearson  $\chi^2$  and Fisher exact tests were used to determine whether there were significant differences between root causes in the 2 categories (wrong patient and wrong site) and to analyze the relationship between outcome and root cause or outcome and physician specialty in surgical vs nonsurgical disciplines. Data were analyzed using SPSS statistical software, version 17.0 (SPSS Inc, Chicago, Illinois). All tests were 2-sided, and statistical significance was set a priori at  $P < .05$ .

## RESULTS

### ADVERSE OCCURRENCES

The screening of 27 370 consecutive adverse occurrences reported to the COPIC database during the study period from January 1, 2002, to June 1, 2008, revealed 119 wrong-site and 29 wrong-patient procedures. After individual case review, cases that were not classified as involving a wrong-site (12 [10.1%]) or wrong-patient (4 [13.8%]) procedure were excluded because those reports had been miscoded in the taxonomy of the COPIC database. A total of 107 and 25 occurrences were included in the 2 respective groups for final analysis (**Figure 1**). The frequency of occurrences per year is shown in **Figure 3**, with the numbers for 2008 reflecting the first 5 months only (ie, until June 1, 2008). Peak occurrences were detected in 2004 and 2006 for wrong-patient cases (5 for each year) and in 2005 and 2007 for wrong-site cases (23 and 24, respectively). Physician specialty, sex, and practice type are indicated in Table 1. The most frequent specialties involved in wrong-patient procedures were internal medicine (24.0%), family or general practice, pathology, urology, obstetrics-gynecology and pediatrics (each 8.0%). For wrong-site occurrences, the most frequently involved specialties were orthopedic surgery (22.4%), general surgery (16.8%), and anesthesiology (12.1%). Physician specialty was stratified into nonsurgical vs surgical disciplines, as outlined in Table 1.



**Figure 3.** Occurrence of wrong-patient and wrong-site procedures in the Colorado Physician Insurance Company database from January 1, 2002, to June 1, 2008. Bars are the relative numbers per 1000 reported occurrences per year.

### PATIENT COMPENSATION

In 48.0% (wrong site) and 70.0% (wrong patient) of cases, there was no monetary demand. Compensation was offered in 25.0% and 10.0%, respectively, before a monetary demand. A monetary demand was made in 19.0% and 17.0% of cases that did not proceed to a lawsuit. These cases were resolved at an average cost of \$47 216 (wrong site) and \$2813 (wrong patient). Only 7.0% and 3.0% of cases proceeded to a lawsuit, with an average cost of \$80 041 and \$46 172, respectively.

### ROOT CAUSE ANALYSIS

The root causes of the adverse occurrences are listed in **Table 3**. Errors in diagnosis were significantly more frequent as a root cause for wrong-patient (56.0%) than wrong-site (12.1%) procedures ( $P < .001$ , Pearson  $\chi^2$  test). Similarly, errors in communication were more frequent as a root cause for wrong-patient (100%) than wrong-site (48.6%) occurrences ( $P < .001$ ). Errors in judgment were the leading root cause of wrong-site (85.0%) compared with wrong-patient (8.0%) procedures ( $P < .001$ ). The 85.0% of wrong-site cases related to errors in judgment were invariably captured by the subcategory inadequate planning of procedure (Table 3). Errors in treatment (88.0% vs 92.5%) and system issues (84.0% vs 72.9%) were in a similar range as a root cause for wrong-patient and wrong-site occurrences ( $P = .44$  and  $.25$ , respectively). However, medication errors were significantly more common in wrong-patient cases (24.0% vs 0%), whereas unnecessary treatment was significantly more frequent in wrong-site procedures (86.9% vs 68.0%). A significant difference was seen in the time-out not performed subgroup as a root cause for wrong-site (72.0%) vs wrong-patient (0%) procedures, which constituted 98.8% of all system issues leading to wrong-site occurrences ( $P = .005$ ). No case was classified as root cause equivocal or not determined (Figure 2).

### OUTCOMES

The incident-related outcomes in both categories are given in **Table 4**. No patient died as a result of a wrong-patient procedure. In contrast, 1 patient (0.9%) died sec-

**Table 3. Root Causes of Adverse Occurrences<sup>a</sup>**

Root Cause	No. (%)		P Value <sup>b</sup>
	Wrong Patient (n=25)	Wrong Site (n=107)	
Error in diagnosis	14 (56.0)	13 (12.1)	<.001
Misinterpretation of diagnostic test results	12 (48.0)	6 (5.6)	
Failure to diagnose or misdiagnosis	7 (28.0)	7 (6.5)	
Delayed diagnosis	4 (16.0)	2 (1.9)	
Failure to perform diagnostic tests	1 (4.0)	2 (1.9)	
Other diagnostic issue	2 (8.0)	2 (1.9)	
Error in treatment	22 (88.0)	99 (92.5)	.44
Unnecessary treatment	17 (68.0)	93 (86.9)	
Medication error	6 (24.0)	0	
Delayed treatment	2 (8.0)	10 (9.3)	
Technical error	2 (8.0)	19 (17.8)	
Wrong treatment concept	2 (8.0)	1 (0.9)	
Failure to treat	1 (4.0)	7 (6.5)	<.001
Other treatment issue	4 (16.0)	0	
Error in communication	25 (100)	52 (48.6)	
Error in written communication	21 (84.0)	13 (12.1)	
Error in verbal communication	15 (60.0)	11 (10.3)	
Error in information handover	2 (8.0)	8 (7.5)	
Other communication issue	17 (68.0)	34 (31.8)	<.001
Error in judgment	2 (8.0)	91 (85.0)	
Inadequate planning of procedure	1 (4.0)	91 (85.0)	
Wrong indication for procedure	1 (4.0)	0	
Violation of guideline or protocol	0	2 (1.9)	
Other judgment issue	0	0	
System issue	21 (84.0)	78 (72.9)	.25
Time-out not performed	0	77 (72.0)	
Environmental safety or security issue	1 (4.0)	0	
Error in credentialing or competency	0	0	
Error in supervision or staffing	0	1 (0.9)	
Inadequate resources	0	0	
Other system issue	20 (80.0)	4 (3.7)	<.01

<sup>a</sup>The percentages do not total 100 among the categories and the respective subcategories because of the option of multiple selections in the assessment process.

<sup>b</sup>For wrong patient vs wrong site, the Pearson  $\chi^2$  test was used except for error in treatment, for which the Fisher exact test was used.

**Table 4. Incident-Related Outcomes of Wrong-Patient and Wrong-Site Procedures**

Outcome	No. (%)	
	Wrong-Patient Cases (n=25)	Wrong-Site Cases (n=107)
Death	0	1 (0.9)
Significant harm or functional impairment	5 (20.0)	38 (35.5)
Minimal harm or functional impairment	8 (32.0)	65 (60.7)
No-harm event	9 (36.0)	3 (2.8)
Outcome equivocal or not determined	3 (12.0)	0

ondary to a wrong-site procedure from acute respiratory failure after a wrong-sided placement of a chest tube. A significant harm was inflicted in 5 patients (20.0%) in

**Table 5. Physician Specialty and Incident-Related Patient Outcomes**

Specialty	No. (%)					P Value <sup>a</sup>
	Death	Significant Harm or Impairment	Minimal Harm or Impairment	No-Harm Event	Outcome Not Determined	
Wrong patient						
Nonsurgical <sup>b</sup>	0	1 (5.3)	7 (36.8)	8 (42.1)	3 (15.8)	.01
Surgical <sup>c</sup>	0	3 (75.0)	1 (25.0)	0	0	
Wrong site						
Nonsurgical <sup>b</sup>	1 (3.1)	10 (31.2)	20 (62.5)	1 (3.1)	0	.67
Surgical <sup>c</sup>	0	20 (30.8)	43 (66.2)	2 (3.1)	0	

<sup>a</sup>Fisher exact test.

<sup>b</sup>Nonsurgical disciplines were defined as emergency medicine, family or general practice, internal medicine, neurology, pathology, pediatrics, radiation oncology, and radiology. Dermatologists, ophthalmologists, and other specialties were categorized based on whether a procedure was discussed in the narrative.

<sup>c</sup>Surgical disciplines were defined as anesthesiology, obstetrics-gynecology, otorhinolaryngology, general surgery, orthopedic surgery, neurosurgery, and urology. Dermatologists, ophthalmologists, and other specialties were categorized based on whether a procedure was discussed in the narrative. Cases with undetermined physician specialty (Table 1) were removed from this analysis.

the wrong-patient category and in 38 patients (35.5%) in the wrong-site group. The 5 occurrences that led to significant harm in the wrong-patient category were attributed to prostatectomies performed on wrong patients secondary to mislabeling of biopsy samples (n=3), a vitrectomy on the wrong patient owing to the coincidental presence of 2 patients with identical names in the ophthalmologist's office, and a myringotomy in a child scheduled for an adenoidectomy, secondary to bringing the wrong patient to the operating room. The 38 occurrences that led to significant harm in the wrong-site group were attributed to wrong-level spine surgery (n=5), wrong-sided chest tube placement (n=4), wrong-site vascular procedure (n=4), wrong-part enterocolic resection (n=4), wrong-organ resection (n=4), wrong-site upper extremity surgery (hand and elbow; n=3), wrong-sided lower extremity surgery (knee and foot; n=3), wrong-sided ovariectomy (n=2), wrong-sided eye surgery (n=2), wrong-sided craniotomy (n=2), wrong-sided ureteric procedure (n=2), wrong-sided maxillofacial surgery (n=1), and unintentional irradiation of an untargeted organ outside the oncologic radiation field (n=2). A minimal harm was inflicted in 32.0% and 60.7% of all patients in the 2 respective groups. No-harm events occurred in 36.0% of wrong-patient and 2.8% of wrong-site cases. The occurrence-related patient outcomes could not be determined in 3 cases of wrong-patient procedures (Table 4).

The medical specialties of the insured physicians were compared with regard to the incident-related outcome (Table 5). Cases with undetermined physician specialty (Table 1) were excluded from analysis. In the wrong patient group, the physician specialty was significantly related to the patient outcome (P=.01). No significant differences were found in outcome related to physician specialty in the wrong-site category (P=.67).

**COMMENT**

In this study, we document a high frequency of surgical never events, with 25 wrong-patient and 107 wrong-site procedures in a 6½-year study period (Figure 3). These numbers are considerably higher than previously

reported in the peer-reviewed literature based on a study that identified 25 cases of nonspine wrong-site surgery in a closed-claims database from 1985 to 2004, which extrapolated a rare incidence of 1 occurrence in 112 994 operations.<sup>19</sup> The adverse occurrences in the present study led to significant patient harm in up to 35.5% of cases and to patient death in 1 case (Table 4). The root cause analysis (Table 3) revealed a high incidence of errors in diagnosis in more than half of all occurrences leading to a wrong-patient procedure (56.0%). This observation is confirmed by the finding that a mix-up of patients' medical records, radiographs, and laboratory or biopsy samples represented the proximate reason leading to wrong-patient procedures in 16 of 25 cases. A mix-up of tissue specimen samples in the pathology laboratory occurred on 6 occasions, which led to the unnecessary prostatectomy in a healthy patient in 3 distinct cases, which contributed to the significant harm occurrences in the outcome analysis (Table 4). These data support the recent notion that errors in diagnosis represent an underestimated source of preventable patient morbidity.<sup>24</sup>

In contrast to these severe complications related to errors in diagnosis owing to the mislabeling of pathology samples, the mix-up of medical records and x-ray films was associated with minimal-harm or no-harm events. The 2 other instances of significant-harm outcome in the wrong-patient category were attributed to a mix-up of 2 patients with identical first and last names who were present at the physician's office at the same time and the calling for a wrong child to the operating room. Both of these incidents could have been avoided by implementation of a formal preoperative reverification of identity, as recommended in the Universal Protocol. Furthermore, errors in communication were identified as contributing root causes in 100% of all wrong-patient procedure cases. Written errors in communication (84.0%) were mainly attributed to a mix-up of patient's medical records and mislabeling of biopsy samples. These data are in concordance with previous studies<sup>25</sup> that have identified communication breakdown as a leading cause of wrong-site surgery. Notably, the 60.0% incidence of verbal communication breakdown detected in the present

study may again have been prevented by implementation of formal “readbacks” within the surgical team, which are a basic tenet of aviation safety and represent a current national patient safety goal defined by the Joint Commission.<sup>26</sup>

Finally, we determined that surgical specialties were responsible for significant patient harm in the wrong-patient category but not in the wrong-site group (Table 5). These findings confirm the notion that once a patient has been subjected to a mix-up of identity, major harm is induced by surgical specialties owing to unnecessary procedures being performed on healthy patients, as exemplified by 3 distinct cases of radical prostatectomy in patients without pathological findings in their tissue biopsy specimens. The observation of a similar distribution of significant-harm (31.2% vs 30.8%) and minimal-harm (62.5% vs 66.2%) outcomes in nonsurgical and surgical specialties is highly surprising, suggesting that patients are equally susceptible to a wrong-site procedure outside the operating room, even in the office of a nonsurgical specialist. This notion is supported by the fact that the only patient who died from a wrong-site procedure was treated by an internist who placed a wrong-sided chest tube, leading to fatal pulmonary decompensation. In addition, internal medicine was the top-ranked specialty involved in wrong-patient occurrences (Table 1). The confluence of these findings strongly emphasizes that surgical never events are also a nonsurgical domain, necessitating that the Universal Protocol should be universally implemented and not limited to the classic procedural or operative disciplines.<sup>7,27</sup> Although there has been recent debate about the need to differentiate preventable from inevitable harm,<sup>28</sup> the events reported in the present study were indeed preventable with adequate vigilance.

Limitations of our study include the restricted coverage of the COPIC database to approximately 6000 practicing physicians in Colorado. Thus, our data may underestimate the statewide frequency of wrong-patient and wrong-site procedures. Another weakness of the study is represented by the potential for subjective bias in the determination of root causes assigned by the responsible investigators. Also, the designation of inadequate planning of procedure represents a generic category. A further limitation is the lack of a denominator because the overall number of surgical procedures performed in relation to the reported 27 370 adverse events is masked in the COPIC database. Our data therefore preclude any conclusions on the incidence and prevalence of wrong-site surgery. However, we strongly believe that relevant discussions on the topic should not focus on how to reduce the incidence but on how to completely avoid never events from occurring. This notion entails implementing surgical patient safety as a core value as opposed to just a priority.<sup>29</sup>

The findings from the present study emphasize a continuing and concerning occurrence of wrong-site and wrong-patient procedures in the current era of the Universal Protocol, leading to frequent patient harm and, rarely, patient death. Shockingly, nonsurgical disciplines equally contribute to patient injuries related to wrong-site procedures. Inadequate planning of proce-

dures and the lack of adherence to the time-out concept are the major determinants of adverse outcome. On the basis of these findings, a strict adherence to the Universal Protocol must be expanded to nonsurgical specialties to achieve a zero-tolerance philosophy for these preventable incidents.

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## The Hazard of More Reporting in Quality Measurement

**T**he US health care system is truly spectacular. Patients travel from other countries to get our state-of-the-art care. And our research is the envy of the world. Yet this same health care system leaves sponges in patients, amputates the wrong limbs, and overdoses children by issuing prescriptions with sloppy handwriting. This study alerts us, yet again, to the alarming problem of preventable errors—a systems issue that should have been engineered from surgical care long ago. Instead, we are only now beginning to realize the magnitude of the problem.

The authors would likely agree with me that the real rate of wrong-site surgery is still higher than their article reports. The reason is that nonanonymous, self-reported data understate the true incidence of any event. This reporting bias is particularly magnified when the event is associated with a stigma.

We should also avoid the trap of concluding that these are rates of events when in fact they are rates of reporting. Take, for example, the misleading Joint Commission data that wrong-site surgery is increasing. These data actually describe an increase in *reports* of events—not events.

The best proxy of error rates we have now is the National Surgical Quality Improvement Program (NSQIP)

complication rates and safety culture scores. Safety culture surveys of hospital employees ask respondents to anonymously indicate whether they feel comfortable speaking up if they see a safety concern, as well as to respond to other questions about quality care. Hospitals should publicly report their NSQIP outcomes and culture scores, which could lead to improved public reporting and benchmarking, as seen in cardiac surgery mortality reporting in New York State.

Finally, in an era of dissecting hospital systems, we must not let up on teaching individual responsibility. The moral hazard of the Universal Protocol is that we can rely on it *in place of* ourselves. Although I would agree that Universal Protocol compliance is important, it is not the magic wand of Merlin.

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