Wrong-Side/Wrong-Site, Wrong-Procedure, and Wrong-Patient Adverse Events
Are They Preventable?

Samuel C. Seiden, MD; Paul Barach, MD, MPH

Hypothesis: Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events (WSPEs) are devastating, unacceptable, and often result in litigation, but their frequency and root causes are unknown. Wrong-side/wrong-site, wrong-procedure, and wrong-patient events are likely more common than realized, with little evidence that current prevention practice is adequate.

Design: Analysis of several databases demonstrates that WSPEs occur across all specialties, with high numbers noted in orthopedic and dental surgery. Databases analyzed included: (1) the National Practitioner Data Bank (NPDB), (2) the Florida Code 15 mandatory reporting system, (3) the American Society of Anesthesiologists (ASA) Closed Claims Project database, and (4) a novel Web-based system for collecting WSPE cases (http://www.wrong-side.org).

Results: The NPDB recorded 5940 WSPEs (2217 wrong-side surgical procedures and 3723 wrong-treatment/wrong-procedure errors) in 13 years. Florida Code 15 occurrences of WSPEs number 494 since 1991, averaging 75 events per year since 2000. The ASA Closed Claims Project has recorded 54 cases of WSPEs. Analysis of WSPE cases, including WSPE cases submitted to http://www.wrong-side.org, suggest several common causes of WSPEs and recurrent systemic failures. Based on these findings, we estimate that there are 1300 to 2700 WSPEs annually in the United States. Despite a significant number of cases, reporting of WSPEs is virtually nonexistent, with reports in the lay press far more common than reports in the medical literature. Our research suggests clear factors that contribute to the occurrence of WSPEs, as well as ways to reduce them.

Conclusions: Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events, although rare, are more common than health care providers and patients appreciate. Prevention of WSPEs requires new and innovative technologies, reporting of case occurrence, and learning from successful safety initiatives (such as in transfusion medicine and other high-risk nonmedical industries), while reducing the shame associated with these events.

Arch Surg. 2006;141:931-939

Performing a procedure on the wrong side of a patient’s body, performing a wrong procedure, or performing the correct procedure on the wrong patient constitute some of the worst medical errors that clinicians and patients experience. The Institute of Medicine report To Err Is Human painted a broad picture of the magnitude of medical errors in the United States and gave directions for safety improvements. Questions linger about ways to prevent errors such as wrong-side surgery. Although these events seem preventable, they continue to occur. We have few data on how often and why they occur and on why the safety mechanisms in place fail to prevent them. This report presents data demonstrating that there are many more wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events (WSPEs) than generally appreciated. The data indicate that current practices and guidelines for WSPE prevention are insufficient to prevent future events.

We define a WSPE as any procedure that has been performed on the opposite side, incorrect site, or incorrect level of the body; is performed on the wrong patient; or is the wrong procedure. Wrong-side/wrong-site surgery is the most infamous, but wrong-side anesthetic procedures also occur, and cases continue to occur outside the operating room (OR) in virtually all areas of health care. Wrong-procedure and wrong-patient errors might stem from different causes but often share a root error pathology related to ambiguous and imprecise identification. The similarity is often rooted in communication breakdowns or lack of safety systems that could have prevented these errors. However, other factors are unique to these different kinds of errors of action. Studies have suggested that the inability to maintain
right and left sidedness consistently (or confusion of right and left [apraxia]) probably stems from an underlying neurological challenge that seems to predispose humans to confuse left and right in wrong-side errors. A procedure performed on the wrong patient or wrong side is a wrong procedure, just as when procedure A is intended and procedure B is performed instead. Therefore, all such errors can appropriately be called WSPEs.

The exact incidence and prevalence of WSPEs remains unknown. We have identified many sources for finding cases of WSPEs using the following 3 different methodologies: (1) searching the medical literature, including lay and traditional peer-reviewed sources; (2) assessing national, state, and private adverse incident databases; and (3) reporting on a sample of cases we have collected using an anonymous Web-based reporting tool. Accurate estimates of incidence cannot be determined without mandatory reporting and true incidence of annual surgical procedures. Mandatory reporting is now becoming law in Florida, Indiana, Minnesota, and Pennsylvania.

The medical literature on WSPEs is quite limited. Several studies and databases document hundreds of cases. Some Swedish cases were reported as early as the 1970s, and other case reports have appeared sporadically. From 1995 through 2005, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sentinel event statistics database ranked wrong-side surgery as the second most frequently reported event (JCAHO) sentinel event statistics database ranked wrong-side surgery as the second most frequently reported event. The medical literature on WSPEs is quite limited. Several studies and databases document hundreds of cases. Some Swedish cases were reported as early as the 1970s, and other case reports have appeared sporadically. From 1995 through 2005, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sentinel event statistics database ranked wrong-side surgery as the second most frequently reported event. Some Swedish cases were reported as early as the 1970s, and other case reports have appeared sporadically. From 1995 through 2005, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sentinel event statistics database ranked wrong-side surgery as the second most frequently reported event. Some Swedish cases were reported as early as the 1970s, and other case reports have appeared sporadically.

We reviewed the following 4 databases pertaining to WSPEs: (1) the National Practitioner Data Bank (NPDB); (2) the Florida Code 15 mandatory reporting system; (3) the American Society of Anesthesiologists (ASA) Closed Claims Project database; and (4) our novel WSPE incident reporting tool. The NPDB Public Use Data File (PUDF), which collects malpractice-adjudicated data throughout the United States, was searched for WSPE occurrence. Data collected in the NPDB PUDF originate from malpractice cases after adjudication and do not include adverse events that did not lead to a malpractice claim or that were settled without a practitioner being named. However, because WSPEs are so obvious, they very often lead to claims and result in malpractice awards in 84% to 93% of cases. The Florida Comprehensive Medical Malpractice Act of 1985 mandated the reporting of adverse events to the Florida Agency for Health Care Administration. All WSPEs are required to be reported as the result of statute 395.0197, which states that the report should contain a “factual written statement about a particular adverse incident detailing particulars as to time, place, all persons directly involved (including professional titles and license numbers), and the nature of the event including a description of the damage or injury.” These reports must include a description of the cause of the event and the corrective or proactive actions taken. These reports must be recorded within 15 days of the event (known as Code 15 reports). The ASA Closed Claims Project database includes settled malpractice claims since 1988. We queried this database for cases of WSPE. Finally, we have been collecting WSPE cases using an anonymous Web-based incident-reporting tool (http://www.wrong-side.org).

### METHODS

**NATIONAL PRACTITIONER DATA BANK**

The NPDB PUDF contains 2217 cases (0.94% of all recorded cases) of “wrong-body-part surgery,” and 3723 cases (1.58% of all recorded cases) of “wrong-treatment/wrong-procedure performed” of 236 300 cases coded for malpractice reported from 1990 through 2003 (Table 1). Wrong-patient procedures are not coded separately and it is not possible to determine their frequency in the NPDB PUDF. The national incidence is likely higher, however, because a claim does not result from each WSPE occurrence, especially if minimal or no patient harm results. There is also growing evidence of health care facilities signing confidentiality agreements in which the plaintiffs agree to remove the names of the physicians involved, and thus only the hospital name appears in the sealed legal record. Annual frequencies of WSPE in the NPDB ranged from 359 to 457 cases from 1990 through 1998. The apparent decline in occurrence in the Figure may be owing to a mean delay of 3.9 years from the WPSE occurrence to closing of the legal case. We predict that WSPEs reported in the NPDB will continue to be in the range of 400 cases per year. Physicians, according to the NPDB, performed most of the events on the wrong body part (n=1721 [77.6%]), followed by dentists (n=402 [18.1%]) (Table 1).

In addition, prevalence of WSPEs address almost exclusively wrong-side surgery in the OR, ignoring the likely more common WSPEs outside the operating room and hospitals, where more than 90% of health care is delivered.

---

**Table 1. NPDB Occurrences of WSPE by Practitioner Type, 1990-2003**

<table>
<thead>
<tr>
<th>Practitioner Type</th>
<th>No. (%) of Cases</th>
<th>Wrong-Body Part Surgical Procedures</th>
<th>Wrong-Procedure/Wrong-Treatment Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>1721 (77.6)</td>
<td>2056 (55.2)</td>
<td></td>
</tr>
<tr>
<td>Intern or resident</td>
<td>12 (0.5)</td>
<td>23 (0.6)</td>
<td></td>
</tr>
<tr>
<td>Dentist</td>
<td>402 (18.1)</td>
<td>1529 (41.1)</td>
<td></td>
</tr>
<tr>
<td>Registered nurse</td>
<td>17 (0.8)</td>
<td>24 (0.6)</td>
<td></td>
</tr>
<tr>
<td>Podiatrist</td>
<td>58 (2.6)</td>
<td>54 (1.5)</td>
<td></td>
</tr>
<tr>
<td>Other health professional</td>
<td>7 (0.3)</td>
<td>37 (1.0)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2217 (100)</td>
<td>3723 (100)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: NPDB, National Practitioner Data Bank; WSPE, wrong-side/wrong site, wrong-procedure, and wrong-patient adverse event.

aThe data column headings are labeled with terms that are used by the NPDB. Percentages have been rounded and may not total 100.
In Florida, there have been 494 well-documented WSPE reports to the state since 1991, with an average of 75 events per year reported since 2000. Table 2. Florida Code 15 Adverse Event Data, 1990-2003*

<table>
<thead>
<tr>
<th>Years</th>
<th>Wrong Site</th>
<th>Wrong Patient</th>
<th>Wrong Procedure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000-2003</td>
<td>178 (61)</td>
<td>34 (12)</td>
<td>82 (28)</td>
<td>294 (100)</td>
</tr>
<tr>
<td>1996-1999</td>
<td>90 (63)</td>
<td>22 (15)</td>
<td>22 (22)</td>
<td>144 (100)</td>
</tr>
<tr>
<td>1991-1995</td>
<td>41 (73)</td>
<td>7 (13)</td>
<td>8 (14)</td>
<td>56 (100)</td>
</tr>
<tr>
<td>Total</td>
<td>309 (63)</td>
<td>63 (13)</td>
<td>122 (25)</td>
<td>494 (100)</td>
</tr>
</tbody>
</table>

*Table reprinted from Kellier and Barach. Florida state law requires incidents that are referred to as Code 15 to be reported to the Florida Agency for Health Care. A Code 15 event must be reported by the hospital within 15 days, except for more serious events, which must be reported within 24 hours. A Code 15 event is defined as "an adverse incident over which healthcare personnel could exercise control and the event was associated in whole or in part with a medical intervention rather than the condition for which the intervention occurred and which resulted in 1 or more of a list of serious preventable injuries."

†Percentages have been rounded and may not total 100.

Florida Code 15 MANDATORY REPORTING SYSTEM

In Florida, with an average of 75 WSPEs per year and 3,858,752 combined inpatient/outpatient surgical procedures (2,452,998 outpatient discharges and 1,405,754 inpatient discharges with surgical International Classification of Diseases, Ninth Revision codes in 2005) (Jeff Gregg, Bureau Chief, Agency for Healthcare Administration, Florida Department of Health, and Reprint Editor, Department of Health, Florida Department of Health, Florida Department of Health), mandatory reporting system is in place. The system underreports by roughly 1 order of magnitude, suggesting that an estimated incidence of 1321 cases per year may be an underestimate, since it is based on the Florida Code 15 incidence. In addition, our data and those of others suggest a higher incidence of wrong-site surgeries than that found by Kwaan et al (who did not report on wrong-patient or wrong-procedure events). Their retrospective chart review reported an incidence of 1 WSPE per 112,000 procedures, significantly noting that only two thirds of the cases they analyzed might have been prevented by the JCAHO universal protocol.
Florida, written communication, June 26, 2006), one would expect 1 WSPE per 51,540 surgical procedures—more than twice the rate reported by Kwaan et al. The National Center for Health Statistics reports 43.9 million inpatient surgical procedures in 2003 and 31.5 million outpatient surgical procedures in 1996. Using the calculated incidence rate of 1 WSPE for 51,540 surgical procedures in Florida, one might expect 1466 events in the United States per year.

It is further worth noting that a recent 2003-2004 review of WSPEs conducted at 17 Minnesota hospitals demonstrated an incidence rate of 36.6 cases per 1,000,000 procedures or 1 case for every 27,322 surgical procedures (Gordon Mosser, MD, written communication, May 15, 2006). This rate would suggest an annual incidence as high as 2760 WSPEs per year in the United States.

ASA CLOSED CLAIMS PROJECT DATABASE

The search of 5803 claims produced 54 WSPEs (0.93%) (Table 3). Wrong-side surgical adverse event errors provided the most detailed data and were the most common. An anesthesiologist was present in the OR during 35 (80%) of the wrong-side errors, but most of these errors were detected after induction of anesthesia. It was determined after evaluation that better preanesthetic evaluation would have prevented only 10 of these claims (Karen Posner, PhD, ASA Closed Claims Project, written communication, April 13, 2005).

WSPE INCIDENT-REPORTING TOOL

We developed an innovative anonymous Web-based reporting site for WSPEs. Our analysis of several dozen cases submitted to http://www.wrong-side.org is reinforced by our analysis of other cases in the literature of poorly resilient health care systems. These systems suffer from enabling conditions that predispose WSPE occurrence. These include lack of patient involvement, lack of knowledge about the procedure being performed, and failure of safety mechanisms to prevent the error from occurring (Table 4).

Data from the 4 sources of WSPE reports demonstrate that WSPEs are more common than generally accepted or than is reported in the literature. Although WSPEs are probably relatively rare events, we believe they are substantially underreported and totally preventable. The incidence of 1300 to 2700 WSPE cases per year out of more than 75 million surgical procedures performed annually in the United States is more than 5 to 10 times greater than that accepted by the manufacturing industry’s quality-defect standard Six Sigma.

Furthermore, although orthopedic surgery has received the most attention, WSPEs continue to occur in other disciplines (eg, anesthesiology [Table 3]) or during ambulatory procedures outside the OR (eg, radiology and dentistry [Table 1]). The increased use of conscious sedation for surgical procedures in ambulatory and free-standing surgery cen-

### Table 3. Classification of WSPE Reported Claims to the ASA Closed Claims Project Database

<table>
<thead>
<tr>
<th>Site of Error</th>
<th>No. (%) of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong-side procedure</td>
<td></td>
</tr>
<tr>
<td>Knee</td>
<td>20 (37)</td>
</tr>
<tr>
<td>Eye</td>
<td>5 (9)</td>
</tr>
<tr>
<td>Hip</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Foot/ankle</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Hernia</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Pain block</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Ear</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Laminectomy</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Craniotomy</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Nephrectomy</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Thumb</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Wrong-patient error</td>
<td></td>
</tr>
<tr>
<td>Patients with same name</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Patients looked similar</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Unknown cause</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Wrong procedure</td>
<td></td>
</tr>
<tr>
<td>Wrong site near correct site</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Total</td>
<td>54 (100)</td>
</tr>
</tbody>
</table>

**Abbreviations:** ASA, American Society of Anesthesiologists; WSPE, wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse event.

*Because of rounding, percentages may not total 100.

### Table 4. Factors Contributing to WSPE From Case Analyses

<table>
<thead>
<tr>
<th>Human factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>High workload environment</td>
</tr>
<tr>
<td>Fatigue</td>
</tr>
<tr>
<td>Multiple team members</td>
</tr>
<tr>
<td>Diffusion of authority/lack of accountability</td>
</tr>
<tr>
<td>Team communication</td>
</tr>
<tr>
<td>Change of personnel</td>
</tr>
<tr>
<td>Haste</td>
</tr>
<tr>
<td>Inexperience</td>
</tr>
<tr>
<td>Incompetence</td>
</tr>
<tr>
<td>Other cognitive factors</td>
</tr>
</tbody>
</table>

**Patient factors**

- Sedation or anesthesia
- Patient not consulted before block or anesthesia
- Patient confusion of side, site, or procedure
- Inability to engage patient (eg, young child or decreased competence)
- Patient ignorance
- Patient has common name or same name as another patient in hospital

**Procedure factors**

- Wrong side draped/prepped
- Similar or same procedures back to back in same room
- Patient position or room changed prior to initiating procedure
- Attempts to prevent WSPE
- Not observing marked site/marking wrong site
- Not cross-checking for consistency in consent form, patient chart, or OR booking form

**Abbreviations:** OR, operating room; WSPE, wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse event.

*These factors have been noted as occurrences in cases we have analyzed in the literature in addition to original cases submitted to http://www.wrong-side.org.

©2006 American Medical Association. All rights reserved.
ters will likely increase these numbers. Most states have little oversight of freestanding procedure facilities and thus have little means to record WSPEs in freestanding outpatient clinics.

WHAT IS THE NATURE AND CONSEQUENCE OF WSPE ERRORS?

Most studies have been descriptive studies limited to orthopedic surgery and its subspecialties (eg, hand surgery). No studies have examined the types of laterality errors or have included wrong-patient or wrong-procedure errors or wrong-side events (Table 5). Wrong-implant procedures have occurred in obstetrics (wrong-embryo implantation) and ophthalmology (wrong-lens implantation) and likely have occurred in other specialties. In addition, wrong-side events have been reported in corrective eye surgery (laser in situ keratomileusis), and the rapid growth of this procedure suggests that the number of such errors will increase. Data exist on the kinds of laterality errors that are most common (eg, wrong-knee and wrong-finger errors).

Wrong-patient procedures have been reported less frequently in the medical literature. The lay press, however, has been more active in discussing wrong-patient procedures, including, for example, reporting cases of termination of life support on the wrong patient, administration of radiation treatment to the wrong patient, cardiac catheterizations in the wrong patient, and, of course, the widely publicized ABO-incompatible heart-lung transplant at Duke Medical Center, Durham, NC, in 2003. When laterality errors occur, the nature of the error and the magnitude of the consequences lead to a decrease in widespread press coverage contributing to decreased public confidence in the safety of the healthcare system.

The consequences of WSPEs range considerably from increased hospitalization and pain to serious iatrogenic injury and death. In 1 case, the wrong hip was pinned and, during wound closure of a second operation, the patient experienced cardiac arrest and died. Another patient had his healthy right lung excised instead of the cancerous left lung. Even if there were little or no permanent harm to a patient, the event is an embarrassing one for the clinician, the hospital, and the entire healthcare domain. The public media almost always finds it difficult to argue that the clinician should not be blamed for the error. Moreover, in most of these events, there is permanent harm and resulting litigation. Consequently, WSPEs result in a high financial cost of malpractice, with an average payment of $96,032 per claim in the NPDB, with the largest recorded payment being $9 million.

WHY DO THESE ERRORS OCCUR?

The current healthcare system is not culturally or structurally organized for preventing WSPEs. Multiple systems and organizational factors lead to WSPE occurrence, including similarity of site, surgery, and patient names; breakdowns in communication and teamwork; patient and procedure factors; and failure of existing safety checks (Table 3). Fail-safe patient identification systems that would consistently ensure that the right patient and right side or site are undergoing the right procedure are still experimental. New surgical smart chips might offer help in reducing the impact of these medical errors. Wrong-side procedures almost certainly stem from the bilateral symmetry of the human body. There are unique cognitive challenges that occur partly because of bilateral symmetry and the ease with which people can confuse left and right. Some people are probably genetically incapable or predisposed to consistent error in distinguishing right from left in themselves and in others (apraxia).

Clinicians grow accustomed to their right side being their patient's left side when facing a patient. However, the opposite is not true if the patient and the clinician are facing the same direction. This can be especially challenging in the OR, where the patient is covered in sterile drapes or the patient's position is changed during the procedure, eg, from supine to prone, or the entire table is rotated 180°. If the patient is rotated onto one side and the limbs are flexed then, from some viewing angles, it requires significant mental effort to rotate the patient's body so that it is spatially congruent with that of the observer and its laterality is made clear. This rotational mental effort is required to allow direct mapping of the clinician's perspective onto the patient. This congruence is essential to ensure correct-sided procedures. It is not surprising that such a cognitively demanding process could be subject to error, especially in a distraction-rich environment like the OR. Other complexities include the standard practices of marking laterality on radiographs, computed tomograms, and magnetic resonance images. Each can be erroneously labeled, or the laterality can be misinterpreted even if labeled correctly. Poor viewing practices and lack of adequate facilities for viewing at the point of care can further predispose to a WSPE.
LESSONS FROM TRANSFUSION MEDICINE

The NPDB PUDF from 1990 through 2003 mentions 52 cases (0.02%) of wrong–blood type transfusions, including 14 fatalities, and the JCAHO sentinel event statistics database contains 94 occurrences (2.6%) of transfusion error.\(^24,20\) Fatal transfusion errors used to be common. In 1942, acute hemolytic reactions led to 1 death for every 935 transfusions.\(^64\) Furthermore, given the distribution of A and B blood types in the population, the number of errors may be much larger than reported because a large number of errors do not lead to adverse outcomes. The rate has steadily declined over time to an estimated 1 death out of 1 800 000 transfusions,\(^32\) or about 12 to 13 deaths per year in the United States—a nearly 2000-fold reduction in incidence.\(^21\) Although more than 222 articles on transfusion errors dating from the 1950s are referenced in PubMed, we found fewer than 10 articles on WSPEs in the medical literature. Most publications pertaining to WSPEs are case reports or descriptive case series.

The success of reducing transfusion errors has come through research on common causes, near-miss and adverse event reporting systems, safety policies, human factor engineering, and the development of error-free technologies (eg, bar-coded patient wristbands, wireless technologies, and computer-based patient identification systems).\(^21,65-67\) Learning about transfusion errors through mandatory no-fault reporting, including the classification, analysis, and monitoring of mistransfusions and near misses, has helped foster a more resilient and reliable safety culture in transfusion medicine.\(^68,69\) Reporting systems seem to enhance safety culture through more transparency, communication, and accountability.\(^70,71\)

HOW CAN THESE EVENTS BE PREVENTED?

Unfortunately, modern health care creates many opportunities for WSPEs to occur. Many medical interventions include procedures on organs and limbs that appear externally normal and offer no cues or site salience to indicate the correct side for intervention (eg, arthroscopy and nerve blocks). Paper checks and procedures such as site marking will decrease but not eliminate WSPEs. The American Academy of Orthopedic Surgeons has promoted a site-marking policy since 1997 and has publicized it extensively. However, only 70% of orthopedic hand surgeons were aware of the policy and, of those, only 45% had changed their practice habits as a result of this new policy.\(^26\)

In addition, error prevention depends on the individual’s ability and willingness to use prevention mechanisms. For instance, Gawande et al\(^10\) found that, in 88% of retained surgical instrument cases, an instrument count had been performed in the OR and had been found to be correct (indicating no missing instruments). Thus, the OR staff may have miscounted or may have reported the correct number of instruments without actually performing the count. Both options indicate possible opportunities for failure of checklists and safety policies.

Patient involvement and verification of operative site and procedure is an often recommended and appropriate protection tool. It is used in conjunction with built-in redundancies because the patient can be as much in error as the clinician. For instance, the Association of Perioperative Registered Nurses\(^72-74\) and the subsequent JCAHO universal protocol\(^75\) suggest preoperative confirmation of laterality and procedure by using documents such as the patient history, physical examination findings, preoperative assessment, review of the informed consent, and applicable imaging studies. We have reviewed several WSPE cases in our database in which the patient was awake and alert. The patients, including one physician, failed to alert or stop the surgical team from performing a WSPE. One patient had his sole functioning kidney removed after his incorrect indication of laterality, and a patient with aphasic stroke received a bilateral orchietomy instead of the planned circumcision because the team incorrectly understood his response to indicate that he was a different patient.\(^1\) Another patient, a physician, allowed an incorrect-sided anesthesia block to be placed while observing the procedure. In addition, encouragement of patient involvement by asking patients to mark their own operative site preoperatively is an important opportunity to empower patients but has met with low compliance.\(^20\) DiGiovanni et al found low compliance in patients marking their own operative site. Of the 100 patients included in the study, 59% correctly marked the procedure site, 37% did not mark the site, and 4% did not mark the site correctly.

The prevention of WSPEs is a prerequisite to safe patient care. A zero-tolerance policy is the only standard that can be ethically justified by providers or accepted by patients and the public. Mechanisms for prevention require specific attention to organizational and cultural barriers that affect patient safety strategies. One of the greatest barriers to eliminating WSPEs is that, paradoxically, WSPEs occur relatively infrequently. Health care providers usually believe that they are immune to these human errors until they are involved in a WSPE. Some have said that the rare frequency of such events is acceptable, given that most procedures are error free. Failure to attend to the organizational and cultural barriers to change will lead to significant physician resistance and recurring WSPEs.

On July 1, 2004, the JCAHO implemented the universal protocol for the prevention of WSPEs.\(^73\) The protocol aims to eliminate WSPEs by using (1) preoperative verification of patient, site, and procedure; (2) marking of the operative site; and (3) a time-out immediately before starting the procedure. The policies of the JCAHO, the American Academy of Orthopedic Surgeons, the Association of Perioperative Registered Nurses, and other relevant organizations\(^78,71-73,77-80\) do not require reporting or investigation of cases of WSPEs or near-miss WSPEs. An Association of Perioperative Registered Nurses position paper notes that “procedures for reporting and responding to wrong-site surgery or near misses” are “key points” of any WSPE policy and constitute an important step in reducing these events.\(^27\) Without the ability and data to evaluate the reporting of WSPE errors and near misses or an accurate estimate of the frequency of such errors before implementation of the universal protocol, it is impossible and premature to assess the effect of this policy on reducing WSPEs. Recent data
published in this journal suggest that one third of wrong-site surgery cases occurred even with careful site identification procedures similar to the JCAHO universal protocol. Although comprehensive data are lacking, WSPEs have occurred after implementation of the universal protocol. In 1 health care system experience, 14 cases of wrong-side and wrong-site surgery occurred from January 2003 through June 2004 in the presence of an institutional policy in concordance with the JCAHO universal protocol (Allison Haskins Page, MS, MHA, Fairview Health Systems, Minneapolis, Minn; written communication; April 26, 2005). This is an early indication that the JCAHO universal protocol may be insufficient to completely prevent WSPEs, and further underscores the need for robust research as to the protocol’s efficacy.

Careful review of the nationally promulgated policies for reducing wrong-side surgery suggests that these recommendations are supported by limited evidence. A Cochrane standard-of-evidence base assessment would barely amount to a level C, suggesting limited scientific validity of this protocol.

Systems redesign will significantly diminish WSPEs but will require a microsystem or team-based effort that requires focused training on preventing WSPEs. Reporting all errors—those that result in harm to the patient as well as near misses—is an essential element of developing a learning culture similar to the one that has led to the dramatic safety improvements in transfusion medicine and in other industries such as aviation and nuclear power. This will require creating conditions that help health care providers feel comfortable and safe to report these events without retribution. Every member of the health care team will view prevention of WSPEs as his or her responsibility, a position advocated by the Association of Perioperative Registered Nurses. A pre-procedure briefing (similar to a preflight briefing) is a valuable tool that has been used in commercial aviation and in the military. The preprocedure time-out (a final verification of correct patient, site, and procedure) recommended by the JCAHO guidelines is a step in the right direction but fails to address the complexity of WSPEs. A time-out suggests something separate and external rather than integral to the process, thus encouraging workarounds that undermine the effectiveness of these policies. The time-out policy falls short in addressing health care challenges such as unavailable equipment, varying roles, and unavailability of team members. Time-outs planned without consideration of work flow add more work and ultimately can lead to limited behavior change and pro forma acceptance. In addition, the occurrence of the time-out just before the surgical procedure is ineffective in preventing anesthesia-related WSPEs, which can occur both inside and outside the OR. Finally, as theory and research data become available on the mechanisms of WSPEs, such knowledge must be incorporated into the training of health care providers.

LIMITATIONS

We are unable to present a definitive prevalence and incidence of WSPEs in this report. Unfortunately, these data are not presently available in health care and have never been published. The shame factor associated with WSPEs has kept most clinicians from talking about and learning from their events, thus eliminating the learning opportunity. The data we have presented herein indicate that WSPEs occur at a rate more common than previously published and without sufficient attention from researchers, educators, or health care policy leaders. The lack of a national database and national reporting requirements prevents a realistic assessment of the frequency of WSPE occurrence or the efficacy of prevention efforts, such as the recent JCAHO universal protocol. Our attempts to use the NPDB, the Florida Code 15 mandatory reporting system, ASA Closed Claims Project database, and our anonymous reporting tools gave us convenience samples that indicate a high number of cases for which attention is warranted. It is widely believed that current reporting systems underreport occurrences of such errors by several magnitudes.

CONCLUSIONS

Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events are more common than previously reported. Based on the several available databases we have analyzed, WSPEs have been occurring steadily for years without significant attention or evidence of reduction in prevalence. The data support widespread underreporting of these adverse events. At a minimum, assuming 100% of cases are reported, our extrapolation of data from Florida predict that there would be 1321 cases in the United States annually. However, multiple studies have demonstrated that the compliance of physicians in reporting has ranged from 5% to 50% of events. Assuming that this frequency of reporting is true for WSPEs as well, the more cautious estimate of 50% underreporting indicates that annual US WSPE incidence may be at least 2-fold higher, thus predicting a WSPE incidence of 2600 events in the United States annually. Based on the available databases, extensive review of the literature, and discussion with regulators, an estimate of 1300 to 2700 WSPEs per year in the United States seems likely. Continued occurrence of WSPEs undermines the goal of health care by contributing to unnecessary deaths, disability, suffering, malpractice, and decreased public confidence in the health care system. The Institute of Medicine report has led to numerous efforts to improve the quality and safety of patient care. Unambiguous and reliable patient and procedure identification must be a priority in translating research gains into clinical practice. Although widespread policy efforts suggest that there might be some reduction in the incidence of WSPEs, no evidence at present supports this change in outcomes. We believe that WSPEs are completely preventable and that the recommendations outlined in the following sections will help to reduce the occurrence of WSPEs.

REPORTING

Health care professionals must acknowledge and report WSPEs and near misses and create safe ways to discuss the system- and performance-shaping factors that enable them...
to occur. For these lessons to become part of the culture of health care, they need to be integrated into the curriculum of all health care providers. Reporting of WSPEs will occur when health care providers feel safe to report them. Present punitive programs in a few states will likely not serve to enhance patient safety. Mandatory reporting of all WSPEs will help raise awareness of these events. Reducing the stigma and shame associated with these events, as well as addressing the regulatory reform, will help. After a near miss in clinical care, clinicians in Florida are at risk of paying significant fines and of performing community service. This practice has had a chilling effect on reporting and patient safety programs in the state (Laurie Davies, MD, Florida Board of Medicine, written communication, March 1, 2006). These events happen to well-trained and respected practitioners and we should acknowledge that. We have created a voluntary anonymous Web site for reporting cases of WSPE (viewable at http://www.wrong-side.org), and we invite health care providers to submit cases of WSPEs to this site.

TEAM PREVENTION APPROACH

All health care professionals involved in performing invasive procedures—as well as the patient—must be actively involved in ensuring correct surgical and intervention procedures. Team training—with its explicit knowledge, skills, and attitudes required of the full surgical team, including the clerical scheduling personnel, nurses, surgeons, and anesthesiologists—should be required in health care facilities.87

HUMAN FACTORS ANALYSIS

Human factors, failure mode effects, and root cause analyses should be performed after all WSPEs to better understand why our present systems are failing to stop these events.75

TECHNOLOGY

Technological development of robust patient identification systems such as barcoding or radiofrequency tagging should be developed and their use required by medical regulators.60-62 A best-practice evidence-based approach to prevent WSPEs should be applied to recommendations made before their dissemination and enforcement by regulatory agencies.

Accepted for Publication: November 30, 2005.

Correspondence: Paul Barach, MD, MPH, Departments of Anesthesiology, Medicine, and Epidemiology, University of Miami Miller School of Medicine, 1611 NW 12th Ave, Miami, FL 33136 (pbarach@med.miami.edu) or Samuel C. Seiden, MD, Department of Pediatrics, The University of Chicago Comer Children’s Hospital, 5721 S Maryland Ave, Mail Code 8016, Chicago, IL 60637 (seiden@uchicago.edu).

Acknowledgments: We thank Ming Wen, PhD, from the Department of Sociology, University of Utah, Salt Lake City, for statistical analysis of the NPDB data; John Senders, PhD, from the University of Toronto, for comments regarding human-factor error and analysis; Bill Rutherford, MD, from the University of Western Michigan, Julie Johnson, MSPH, PhD, from the Department of Medicine, University of Chicago, and Hal Kaplan, PhD, from Columbia University and NewYork-Presbyterian Hospital, for suggestions and review of the manuscript; Wrenn Levenberg, MD, from the Department of Emergency Medicine, Boston University Medical Center, for assistance in researching the transfusion literature; Karen Posner, PhD, from the ASA Closed Claims Project, for providing data; and Robert Oshel, PhD, Health Research Services Administration, for assistance in searching the NPDB PUDF.

REFERENCES
