The American College of Surgeons’ Closed Claims Study: New Insights for Improving Care

F Dean Griffen, MD, FACS, Linda S Stephens, PhD, James B Alexander, MD, FACS, H Randolph Bailey, MD, FACS, Scott E Maizel, MD, FACS, Beth Howell Sutton, MD, FACS, Karen L Posner, PhD

BACKGROUND: All physicians must be vigilant in the pursuit of safe care for patients. While problems in care are identified, education that provides an understanding of these problems and guidelines for improvement can enhance patient safety. Our objective was to determine problematic aspects of surgical care, including care provided by surgeons before, during, after, and instead of surgery, that negatively affect patient safety.

STUDY DESIGN: Four hundred sixty malpractice claims against general surgeons were reviewed by surgeons (FACS). All claims were closed in 2003 or 2004. The data collection was completed at five medical liability companies representing a nationwide distribution of surgeons. Surgeons also dictated or wrote narratives for each case. The quantitative data and narratives were later analyzed to determine events responsible for unsafe care.

RESULTS: Surgeon-reviewers identified deficiencies in care that fell below accepted standards more often before and after operations than during them. These deficiencies were often the result of a failure to recognize surgical injuries, and many of these deficiencies were preventable. The quality of surgical care was satisfactorily met in 36% of cases. The most common procedures involving patient safety concerns were those involving the biliary tract, intestines, hernias, vascular system, esophagus, and stomach. The most frequent events leading to claims included delayed diagnosis, failure to diagnose, failure to order diagnostic tests, technical misadventure, delayed treatment, and failure to treat. Complications occurring most frequently were organ injuries, adult respiratory distress syndrome, and infection.

CONCLUSIONS: Closed claims reviews provide valuable data that may enhance provider performance through heightened awareness of common unsafe practices. Specifically, opportunities exist to improve surgical care provided during the preoperative and postoperative phases of treatment through continuing medical education to improve patient safety. (J Am Coll Surg 2007;204:561–569. © 2007 by the American College of Surgeons)

Reviewing the quality of health care in hospitals in the late 1980s and early 1990s, research teams collected data from hospital medical records for 15,000 and 30,000 patients, respectively, and found adverse events in 2.9% to 3.7% of cases. Competing Interests Declared: None.

This research was funded by grants from the American College of Surgeons. The opinions expressed here are those of the authors and do not necessarily reflect those of the American College of Surgeons or the University of Washington.

Received August 16, 2006; Revised November 3, 2006; Accepted January 4, 2007.

From the Committee on Patient Safety and Professional Liability, American College of Surgeons, Chicago, IL (Griffen, Alexander, Bailey, Maizel, Sutton) and the Department of Anesthesiology, University of Washington, Seattle, WA (Stephens, Posner).

Correspondence address: F Dean Griffen, MD, FACS, Highland Clinic, Department of Surgery, 1455 E Bert Kouns, Shreveport, LA 71105.

© 2007 by the American College of Surgeons

Published by Elsevier Inc.

27.4% and 32.6% of the adverse events were from negligence. To address these disturbing findings, the Institute of Medicine responded with reports, To Err Is Human and Crossing the Quality Chasm, recommending changes in the governance and delivery of health care to enhance patient safety. Policymakers, medical groups, insurance companies, and governing bodies have grappled with ways to effectively measure quality of care and improve patient safety by, among other things, analyzing outcomes.

Progress has been slow. In particular, reporting of adverse events, near misses, and errors is stifled by fear of litigation and censure. The American College of Surgeons (ACS) Patient Safety and Professional Liability Committee (PSPLC) reviewed a group of bad outcomes from a unique pro-
spective, conducting a study identified as the ACS Closed Claims Pilot Project. Fellows of the ACS collected data from closed files kept by liability insurance companies and involving legal actions against general surgeons. The fear of prosecution that can stymie both voluntary and mandatory reporting of errors is mitigated by this strategy. Conducted from April 2004 to February 2006, the pilot established a database from reviews of 460 closed claims from throughout the US.

The purpose of this study was to examine the various components of surgical care, including, but not limited to, technical operative knowledge and skills. In addition to care provided during operations, our aim was to assess care in the preoperative and postoperative periods, including ordinary tasks that are part of quality surgical care and communications patterns before, during, and after surgery. Our goal was to identify a wide array of potential areas in which care provided by individual surgeons at the point of service can be improved and strategies to correct the problems can be developed, enhancing patient safety.

METHODS
Standardized data were collected from closed general surgery liability claims from five professional liability insurers. One company provided national coverage, and the others provided regional coverage; companies were located in the midwest, northeast, southeast, and west coast regions of the country. The American Society of Anesthesiologists (ASA) Closed Claims Project,11 the study of adverse events in Colorado and Utah,1,6 and the ACS National Surgical Quality Improvement Program12,13 were used in the initial design of the data collection instrument. The eight-page data collection form was later revised through collaborative efforts of the PSPLC and the ASA Closed Claims Project at the University of Washington.

Study inclusion criteria were claim files involving general surgeon defendants that were closed in calendar years 2003 or 2004. Claim files typically included claim manager and attorney summaries, deposition transcripts or summaries, expert reviews, narratives of involved parties, claim evaluation and management correspondence, relevant medical records, and legal documents. Each claim file did not necessarily contain all documents, but all files contained documentation sufficient to reconstruct the sequence of events and the nature of the injury and to evaluate the defendant surgeon’s actions, conduct, and clinical care. Claims with no indemnity payment and associated loss expense less than $25,000 were excluded because such files frequently involve defendants dismissed at an early stage of the claim review process and contain insufficient information to reconstruct sequence of events and the nature of the injury. Project investigators worked with insurance company representatives to prescreen all potential cases to assure they met the inclusion criteria.

Data were collected at the insurance company offices. A total of 40 surgeons, all Fellows of the American College of Surgeons, participated in data collection. Faculty from the ASA Closed Claims Project at the University of Washington provided the initial closed claims data collection and coding training to the members of the Committee on Patient Safety and Professional Liability of the ACS. Other surgeon-reviewers received written guidelines for data collection in advance of their participation and in-person training at each of the data collection sites. To ensure consistency in coding and data collection, surgeons from the Committee on Patient Safety and Professional Liability and researchers from the University of Washington (mean = 4.1, range 2 to 7) traveled to each site to train new reviewers and assist in data collection.

Data recorded on the standardized data collection form included patient characteristics, patient health status, surgical procedure, clinical events leading to injury, complications (physical and psychological injuries, unplanned or prolonged care, reoperation), severity of injury, professional evaluations of care, and legal resolution. Each surgeon-reviewer also provided a detailed narrative describing the sequence of events and an evaluation of factors involved in each claim.

Members of a committee of six surgeons reviewed every claim in the data set for consistency of classification. Using the detailed claim narrative as their primary source of information, individual members of this committee reviewed assessments of quality of care. When the
second reviewer disagreed with the original assessment, the case was reviewed by a third surgeon for resolution. There was a high level of agreement between our first and second reviewers. For example, only 3 cases (0.07%) required a third reviewer to reach consensus on the severity of injury, 5 cases (1.1%) on the adequacy of preoperative care, 8 cases (1.7%) on the adequacy of postoperative care, 21 cases (4.5%) on the surgeons’ evaluation of all care, and 25 cases (5.4%) on whether the complication could have been prevented.

Definition of variables
Severity of injury was recorded on the National Association of Insurance Commissioners 10-point scale from 0 (no obvious injury) to 9 (death). For the purposes of analysis, severity was divided into the following groups: none to minor injury (0 to 3, temporary injuries that may require extra recovery time), major temporary (4, including injuries leading to temporary disability, prolonged hospitalization, or additional surgical procedures), permanent nonfatal (5 to 8, including disabling and nondisabling organ damage of a permanent nature, loss of limb, and injuries requiring lifelong care), and death (9). In defining complications, we included all complications for which there was clinical or physical evidence, regardless of whether or not the complication was the result of surgical care. Complications could be the result of care provided by other medical professionals, the patient’s underlying condition, or of undetermined origin.

Professional evaluations of quality of care included an evaluation of the adequacy of the surgeon’s preoperative care, operative skills (deficient, not deficient, impossible to judge), adequacy of postoperative care, whether violations in practice patterns of behavior had occurred, the clinical event representing the most deficient aspect of the surgeon’s care, and an assessment of the global quality of surgical care. Operative skills were defined narrowly to include only interventions a surgeon performed with his or her hands. The global quality of surgical care was assessed for each claim and defined as care that would be expected from a prudent and caring general surgeon under the same circumstances as determined by similarly qualified providers. It was possible that the quality of surgical care could be satisfactorily met even when a less-than-perfect technical performance occurred.

Surgeon-reviewers were asked the following open-ended question: “In evaluating this case as a surgeon-reviewer, for which event, if any, would you consider the surgeon’s involvement to be most deficient?” For the purpose of analysis, surgeon-reviewers’ identification of the most deficient aspect of care was classified as preoperative care (diagnosis and assessment, treatment, surgical plan, and care provided before surgery), intraoperative care (technical misadventures, intraoperative recognition and treatment of unanticipated findings or events), or postoperative care (diagnosis and treatment of complications). If deficiencies that occurred during multiple phases of care were assessed as having near-equal contributions, the category of “multiple care periods” was assigned. Cases could also have no deficiencies identified or be classified as impossible to judge (if reviewers could not decide whether surgical care was deficient).

Statistical analysis of nominal and ordinal level data was based on chi-square tests. Any result that did not meet the p < 0.05 level was not considered statistically significant.

RESULTS
Seventy percent of the patients in this study were older than 40 years old and three-fifths were women, as seen in Table 1. The most common comorbidity reported at the time of presentation was obesity, followed by smoking, hypertension, and diabetes. Comorbid conditions, however, are probably under-reported because not all of the patient files contained complete medical records. Three-fourths of the patients in the study were classified as relatively healthy, either an ASA 1 (normal healthy patient) or ASA 2 (a patient with mild systematic health issues). Less than 10% of the patients were seen for a trauma-related event, and one in five patients required an emergency procedure. Nine of 10 patients were considered functionally independent.

Patients in the review had undergone a wide range of different surgical procedures. Most common among the 460 cases was cholecystectomy (88, 20%). Almost all of these were initiated laparoscopically; 17% were converted to open procedures. Next in frequency were intestinal procedures that were predominately colorectal (58, 12%) followed by hernia repairs (38, 9%). Multiple procedures had been performed in many patients (8%). Vascular (7%) and gastric or esophageal procedures (6%) and procedures involving placement or removal of all types of central venous access devices (4%) were also sources of claims. Ten percent of claims in the review
involved care during which no surgical procedure was performed. For most of these cases, the surgeon evaluated the patient and either misdiagnosed or failed to diagnose a surgical problem. Given the frequency with which surgeons treat breast diseases,15 claims involving breast surgery appear under-represented (3%). All other procedures were less common sources of claims.

Table 2 provides insight into various areas of care (treatment, diagnosis, and other) that resulted in adverse events. Multiple events could be checked by surgeon-reviewers. In 94% of claims, at least one treatment issue was identified. At least one diagnostic issue was found in 54% of claims, and in 19%, other types of issues were identified, such as medications or medical devices. Most common among treatment issues were technical misadventure (50%), delayed treatment (35%), failure to treat (13%), and wrong treatment (9%). Frequent problems relating to diagnosis issues included delayed diagnosis (27%), failure to diagnose (22%), and failure to perform diagnostic tests (22%). Unnecessary tests were performed in less than 1% of all patients.

Complications resulting from real or perceived deficiencies in care were common among claims in this review (Table 3). At least one injury to an unintended organ occurred in 40% of claims. Injuries to the bile ducts (12%), bowel (9%), and blood vessels (9%) were especially common. Infection was a common complica-
Complications occurring at the surgical site in 6% and various other sites in 14% of patients. Common cardiopulmonary complications included adult respiratory distress syndrome and cardiac arrest. Pulmonary embolism occurred in 3% of claims, as did myocardial infarction. The injuries or complications were fatal in 37% of patients and permanent but not fatal in an additional 36% of patients. Patients had temporary but major injuries in 21% of cases. In 6% of patients, injuries were either temporary and minor or not evident to the surgeon-reviewer.

Reviewers compared measures of quality of surgical care in several different categories (Table 4). Care was assessed as inadequate for 17% of patients during preoperative care or during care involving only assessment and diagnosis when no surgical procedure was performed by the defendant-surgeon. Postoperative care was inadequate in 28%, and operative skills applied during operations were deficient in 12% of patients. The global quality of surgical care was satisfactorily met in 36% of claims and clearly not met in 50%. When re-
viewers were asked if the complication could have been prevented by the defendant-surgeon, they responded affirmatively for 51% of patients. Reviewers were reasonably confident that better preoperative care could have prevented the complication in 16% of patients, and better postoperative care could have prevented the complication in an additional 16% of patients. Better communications with patients or other providers could have prevented complications in 22% of the patients.

Even though many claims involved deficiencies in multiple areas of care, reviewers were able to identify a care period during which the surgeon’s care had been the most deficient for 348 of the patients (Table 5). Overall, the surgeon-reviewers found that the most deficient event occurred most frequently during postoperative care (31%). In 22% of patients, preoperative diagnosis and treatment were considered the most deficient aspects of the surgical care. A technical misadventure was considered the most deficient component of care in only 12% of patients. The severity of injury varied, depending on the event for which the care of surgeon-defendants was found most deficient. When injuries were fatal, postoperative care was considered most deficient in 36% of patients, preoperative care was considered the most deficient aspect of care in 28% of patients, and intraoperative care was considered the most deficient aspect of care in 4% of patients. When injuries were temporary and minor or not evident, preoperative care was the most deficient aspect of care in 18% of patients, and postoperative care was the most deficient aspect of care in only 12% of patients.

Also shown in Table 5, whether or not the global quality of surgical care was satisfactorily met varied with the event for which the surgeon’s care was most deficient. In 36% of the patients in whom the quality of care was not satisfactorily met, the most deficient care occurred in the postoperative period. Thirty-one percent of the time that the quality of care was not satisfactorily met, care was most deficient during the preoperative period. When the overall quality of surgical care was satisfactorily met, 83% of patients had no deficiencies identified.

**DISCUSSION**

It is noteworthy that deficiencies in care occurred most commonly during care provided outside of the operating

<table>
<thead>
<tr>
<th>Severity of injury*</th>
<th>Global quality of care†</th>
<th>Care most deficient‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>None to temporary minor</td>
<td>Temporary major</td>
<td>Permanent non-fatal</td>
</tr>
<tr>
<td>Preoperative care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intraoperative care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple care periods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No deficiencies identified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of cases, n</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Chi-square = 46.836, df = 12 (p < 0.000).
†Chi-square = 300.354, df = 8 (p < 0.000).
‡Cases in which it was impossible to determine the deficiency or the care period in which the most deficient care occurred were excluded. Because of rounding error, percentages may not sum to 100%.
room in the preoperative or postoperative periods. Care was most deficient in the preoperative period in 22% of patients. Even more profoundly, when the resulting injury was fatal, the most deficient care occurred postoperatively in 28% of patients. Thirty-one percent of the time that the required quality of surgical care was not achieved, the failure occurred during the preoperative period. Among preoperative failures, surgeon-reviewers identified signs, symptoms, laboratory results, x-ray findings, or other information related to the primary surgical problem, chief complaint, or comorbidities that should have led to earlier treatment, a different approach, or both, which were simply ignored or overlooked by defendants. Ironically, although our reviewers consisted of a group of thoughtful, caring surgeons who volunteered their time to work on this project because of their desire to improve surgical care, many of these same reviewers admitted that they had also occasionally been guilty of these same shortcomings in care. Fortunately, their lapses had not necessarily led to patient injury, but this admission, which was consistent with past quantitative findings, reveals the vulnerability we all have to error.

In addition to problems in the preoperative period, the most deficient event occurred postoperatively 31% of the time, and when the patient’s injury was fatal, the postoperative care was considered most deficient in 36% of patients. Similarly, 36% of the claims in which the quality of surgical care was not satisfactorily met were the result of deficiencies in postoperative care. In contrast, a surgical technical misadventure was the most deficient aspect of care provided by the surgeon in 12% of patients, even though organ injuries occurred in 40% of patients. Technical perfection is precluded and technical errors are engendered by patient, disease, institutional, and cultural factors that are in addition to the surgeon factors addressed in this review. In cases that involve impediments to success that fall outside of the surgeon’s control, perfection is not required to meet the legal standard of care. Unfortunately, the surgeons in this study too often failed to properly recognize and treat the complications of injuries that occurred as a result of antecedent technical misadventures, regardless of the cause. Too often these surgeons didn’t give enough attention to a patient’s complaints of discomfort, a family member’s concerns about changes in the patient, or inconsistent test results. In the opinion of reviewers, these errors were most often the result of a lack of diligence in performing ordinary tasks as opposed to a lack of extraordinary skills. These are errors to which we are all susceptible. Consequently, we must be vigilant in maintaining professionalism, communication, and other elements of surgical care that may require more time than skill.

In this review, we have defined a group of claims in which deficiencies in care occurred, even though the overall quality of surgical care was satisfactorily met. This delineation is consistent with earlier work that differentiated between “adverse events and negligence,” “adverse events and errors,” and “avoidable adverse events and negligent adverse events.” In this study, the term deficient care is used broadly to include not only diagnostic and operative events but also flawed professional behavior that does not necessarily contribute to the cause of the adverse event. In fact, these communication and practice pattern violations were the most common deficiency in care for one-third of the patients in whom the expected quality of surgical care was satisfactorily met. For example, a surgeon may be inattentive or supercilious, providing the patient with insufficient information with which to understand that the complication was inadvertent, thereby denying patient autonomy and provoking mistrust and litigation. Or a surgeon might fail to check a test result before discharging a patient, but the patient’s outcomes would not have changed even if the test had been checked. Deficient care that meets standards seems to be a paradox at first glance, but it does occur, even so, in some instances. Even though this care may technologically be adequate, the time and emotional energy invested in dealing with these nonmeritorious malpractice claims could be better used by surgeons to provide quality care for all patients. To the degree that these deficiencies can be attenuated, patient safety and satisfaction can be enhanced.

Because our sample was restricted to cases with payouts, defense costs in excess of $25,000, or both, our study is biased toward higher payments and more severe injuries. Also, closed claims research can be subject to outcomes bias. Additionally, closed claims reviews as tools for identifying unsafe practices are limited by their inability to identify the prevalence of errors committed by the defendant-surgeons. For example, technical misadventures occurred in 50% of claims, but reviewers were unable to evaluate the adequacy of the defendants’ surgical skills in 46% of the 414 claims that involved an operative procedure. By law, surgeons are not held to a standard of perfection. Prudent
and caring skillful surgeons make technical errors according to a predictable norm. For example, bile duct injury occurs, on average, in 1 to 5 per 1,000 laparoscopic cholecystectomies, with a greater probability of injury during a surgeon’s first 200 procedures.19-22 Only outcomes studies can provide the denominator required to determine any specific surgeon’s technical skill compared with benchmark practice. Surgeon-reviewers also often believed that they could not reliably evaluate technical skill without actually witnessing the surgeon’s performance given the operation’s confounding circumstances. Consequently, reviewers identified a clear lack of surgical skill only in the 12% of cases that involved obvious technical incompetence, lack of supervision, or failure to stay within a proper scope of practice. In addition, closed claims reviews cannot find for review the near misses or the seven of eight injured patients who never filed claims.16 Finally, the effectiveness of closed claims is limited by the absence of comprehensive medical records from files kept by insurance companies. But even when parts of the medical record were not included in the insurance company files, statements by the defendant, the plaintiff, other health care providers, and expert witnesses who had the original records provided extensive detail on each case.

This ACS Closed Claims Project is unique in that it involves only claims against general surgeons, and only Fellows of the ACS conducted reviews. Because closed claims give access to a large number of adverse events without the need for voluntary or mandatory reporting, the culture for under-reporting of errors to avoid the risk of legal discovery and action is avoided. Also advantageous is the availability of multiple reviews by claims managers and attorneys for the insurer, the plaintiff, and the defense, providing different perspectives and unique insights. The opportunity to see the events through the eyes of the patient or the family expressed in depositions is revealing. The data collected in this study are enhanced because they were collected from current cases, representing claims closed in 2003 and 2004, and because the data are drawn from a representative distribution of claims from academic and private practitioners nationwide.

There is another important aspect of this ACS project: it focuses on individual performance, not systems of care that hinge in large part on institutional and cultural human factors. Much has been made of flawed systems of care as causes for errors.3,8,23-27 Physicians, as required according to the ACGME competencies,28 are responsible for participating in development of safe systems of care in the institutions in which we work, but this study points out the frequent deficiency and critical importance of performance at the point of service, which has been somewhat underemphasized in recent years. If we surgeons focus either on systems of care or on individual performance, we create a false dichotomy because the two areas are almost entirely entangled with each other. Both are critical to addressing error. Certainly, there is need for improvement in both areas. Better systems of care can mitigate human error, but better performance at the point of service can mitigate flawed systems of care as well.8

This study and others have confirmed the value of closed claims as tools with which to identify unsafe practices (many of which apply to physicians in all medical specialties) in the delivery of general surgical care.6,7,9,29 The American College of Surgeons is currently embarking on the next step: education of surgeons in the identified problem areas. Some of these areas have been addressed many times in the past. Given the graphic emphasis these data bring to the reality of these problems along with newly identified permutations, the guidelines for care promulgated in the past may be refined and brought forward with new-found awareness of their importance. The newly quantified high frequency of problems occurring during the preoperative and postoperative periods will dictate added emphasis for education in these areas. The pilot having been completed, the project will now move forward with new disease-, procedure-, and complication-focused standardized data collection addressing each major problem more specifically.

Preventable adverse events in health care occur far too frequently. Medical organizations and health care policymakers have been vigorously addressing the issue, knowing that, although perfection can never be achieved, improvement is imperative.5 This closed claims initiative is a step toward that end.

Author Contributions
Study conception and design: Griffen, Alexander, Bailey, Maizel, Sutton, Posner
Acquisition of data: Griffen, Stephens, Alexander, Bailey, Maizel, Sutton, Posner
Analysis and interpretation of data: Griffen, Stephens
Drafting of manuscript: Griffen, Stephens, Posner
Critical revision: Griffen, Stephens, Posner
Statistical expertise: Stephens

Literature research: Griffen, Stephens, Alexander, Posner

Acknowledgment: We thank Ruth Shea (Administrative Assistant, ACS Professional Liability Program) and Barbara Cebuhar for administrative and site visit support; Cindy Brown (Division Director, ACS Division of Health Policy and Advocacy) for critical review of processes; Linn Meyer (ACS Director of Communications) for communications support; John Campos (Research Consultant, University of Washington) for technical support; and Lynn Akerlund (Program Coordinator, University of Washington) for administrative support. We also gratefully acknowledge the support of ACS PSPLC members: Drs John Daly, Hugh Gamble, and Susan Kaiser for review of processes and claims; and Drs Barry Manuel, Paul Nora, and Frank Spencer for sharing their wisdom, experiences and sage advice. Finally, this research would not have been possible without the assistance of more than 30 additional fellows of the ACS who volunteered their time to review claims in cities across the US.

REFERENCES

7. Cheney FW. The American Society of Anesthesiologists Closed Claims Project: what have we learned, how has it affected practice, and how will it affect practice in the future? Anesthesiology 1999;91:552–566.