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AN AOA CRITICAL ISSUE

MEDICAL ERRORS IN ORTHOPAEDICS: PRACTICAL POINTERS FOR PREVENTION^{*}

BY DAVID WONG, MD, MSc, FRCS(C), JAMES HERNDON, MD, AND TERRY CANALE, MD

The 1999 Institute of Medicine (IOM) report "To Err is Human"¹ focused the attention of the public and the media on adverse events occurring during the treatment of patients. Eye-catching newspaper headlines suggested that "at least 44,000" and possibly "as high as 98,000" patients died yearly in the United States as a consequence of "medical errors"¹. However, even prior to publication of the IOM report, a number of professional medical associations, including the American Academy of Orthopaedic Surgeons (AAOS) and the Canadian Orthopaedic Association (COA), had recognized the importance of medical errors and had initiated programs to help physicians to foster a culture of patient safety. The IOM report did serve to heighten

awareness of patient-safety issues in the minds of both patients and orthopaedic surgeons. Heretofore, prevention of medical errors had been considered a "worthy, but cheerless" matter deserving only limited time and resources in an era of ever-contracting medical finances. In the "To Err is Human" report, the IOM challenged professional medical organizations to make patient safety a priority item in their agendas, implored medical schools to include patient safety as part of their curricula, and urged regulatory agencies to monitor patient-safety data. In addition, patients were encouraged to be proactive in their own care and to be conscious of safety issues.

In this new environment of awareness, the initiation of patient-

safety programs has taken on a higher priority. Professional medical organizations such as the Canadian Orthopaedic Association and the American Academy of Orthopaedic Surgeons have been acknowledged for their foresight and willingness not only to take on but also to offer constructive solutions to a difficult and unpopular problem.

The Canadian Orthopaedic Association, the American Orthopaedic Association, and the American Academy of Orthopaedic Surgeons have embraced a commitment to patient safety for a number of years. The COA's "Sign Through Your Initials" program and the AAOS's "Sign Your Site" initiative have been lauded as examples of rational, systematic protocols that improve patient safety. This symposium dis-

^{*}This symposium was presented at the Combined Meeting of the Canadian Orthopaedic Association and the American Orthopaedic Association in Victoria, Canada, on June 4, 2002.

cusses the history of these strategies, guidelines for their implementation, and the future of patient-safety initiatives. Additional background information regarding the Institute of Medicine's "To Err is Human" report is presented, and some of the more contentious issues, such as mandatory versus voluntary reporting and punitive versus nonpunitive evaluation of patient-safety incidents, are raised.

The Institute of Medicine Report: "To Err is Human"

The Institute of Medicine is an arm of the National Academy of Sciences, an agency of the United States Federal Government that is similar in status to the Environmental Protection Agency. As part of its mandate to "advise the federal government . . . on scientific and technical matters,"¹ the IOM initiated the "Quality of Health Care in America" project. "To Err is Human," on the topic of medical errors, was the first report from this project. A subsequent publication, "Crossing the Quality Chasm,"² focused on the general organization of American health care.

Reflections on the Institute of Medicine Report

An unfortunate (and curious) corollary of the unpleasant headlines that followed the report was the lack of effective analysis before the provocative numbers were accepted by the media and published. In point of fact, the statements that between 44,000 and 98,000 patient deaths occur every year as a result of medical errors were based on only two studies (one from New York³ and the other from Colorado and Utah⁴). In both reviews, only a small, random sample of patient discharge records was examined (1.7% of discharges in New York in 1984 and 2.7% of discharges in Colorado and Utah in 1992).

The methodology by which "medical errors" were determined has also been criticized. Charts were initially reviewed by a nurse or medical records administrator to determine

whether an "adverse event" had occurred during the admission. An "adverse event" was deemed to have occurred when an "injury" had been caused by medical treatment (not by the disease process) and had resulted in either a longer hospital stay or disability at the time of discharge. Both studies used the same list of eighteen screening criteria in the first-level review. The criteria included such everyday events as transfer from a general-care unit to a specialty-care unit (e.g., an intensive-care unit, a coronary care unit, or a telemetry unit) and readmission to the hospital. A second-level review was then performed by a physician to determine *subjectively* whether the "adverse event" was a result of "negligent" or "non-negligent" care. Adverse events that were deemed to have resulted from negligent care were considered "medical errors." In the New York study, 3.7% of the reviewed admissions were associated with an adverse event and 13.6% of those were thought to have resulted in the patient's death. In the Colorado and Utah study, 2.9% of the admissions were associated with an adverse event and 6.6% of those were thought to have been related to the patient's death.

The calculation of the number of patient deaths due to "medical errors" was extrapolated with use of hospital discharge numbers from a year (1997) that was unrelated to either of the data-collection years (1984 and 1992). The upper estimate of 98,000 patient deaths due to medical errors was derived by extrapolating the New York numbers on the basis of the 33.6 million admissions recorded in 1997. The lower estimate of 44,000 patient deaths resulted from a similar computation using the lesser Colorado and Utah numbers.

McDonald et al.⁵ advanced a fairly compelling argument that the mortality numbers are overstated. They asserted that the screening criteria (e.g., transfer to the intensive-care unit) selects out a cadre of patients in whom the severity of illness is greater than that in the average patient population. This group of "severely ill" patients would be

expected to have a higher mortality rate even with faultless care. Thus, the true incidence of deaths from medical error would only be the *difference* between the observed mortality rate and the expected mortality rate for a cluster of more severely ill patients. McDonald et al. determined that the expected mortality rate for a group of severely ill patients using data from 1984 (the same year used in the New York study) was very close to the observed mortality rate. This finding suggests that the mortality figures published in the Institute of Medicine report are inflated.

History of "Operate Through Your Initials" and "Sign Your Site"

Arguments about the Institute of Medicine report aside, orthopaedic surgeons are acutely aware that medical error, particularly wrong-site surgery, is a legitimate patient-safety issue. Data concerning the problem were first documented in 1988 by the Medical Defence Union in the United Kingdom and in 1993 by the Canadian Medical Protective Association (CMPA) in Canada. Both organizations are the principal national malpractice insurance providers in their respective countries and thus are able to review nationwide statistics. The statistics generated by the Canadian Medical Protective Association and the distinct quality-of-care issues raised by the data led the Canadian Orthopaedic Association to review the situation and to publish a report in 1994. The primary author of this paper was Dr. Paul Wright, who proposed an "Operate Through Your Initials" program as a way to prevent wrong-site surgery. This initiative has been adopted by the Canadian Orthopaedic Association and has been used throughout Canada since 1994.

In the United States, an early survey of members of the Alamo Orthopaedic Society was performed by Drs. James Giles and Jesse DeLee in 1996. The American Academy of Orthopaedic Surgeons organized a task force to examine wrong-site surgery in 1997. The task force was chaired by Dr. S. Terry Canale, at that time an AAOS Vice Pres-

ident. The charges of the task force were to determine whether wrong-site surgery was a problem and to suggest solutions. To that end, the task force examined data from three malpractice insurance carriers in the United States. The largest, Physician Insurers Association of America, covered twenty-two states and insured approximately 110,000 physicians. Statistics were also provided by State Volunteer Mutual Insurance Company of Tennessee and Mutual Insurance Company of Georgia, both single-state malpractice-insurance providers.

From this information, it was clear that wrong-site surgery was a valid patient-safety issue. Physician Insurers Association of America had 331 claims on their books. State Volunteer Mutual Insurance Company reported thirty-seven incidents in Tennessee and further calculated that the cumulative probability that wrong-site surgery would occur at least once in an average orthopaedic surgeon's thirty-five-year career was 25%.

After careful examination of the wrong-site surgery question, the AAOS task force recommended the "Sign Your Site" plan⁶ as a way to reduce the number of incidents involving an incorrect surgical location. The major elements of the COA and AAOS programs are the same. Thus, orthopaedic surgeons throughout North America have been encouraged to use a similar patient-safety program for the prevention of wrong-site surgery since 1997. Both the COA and the AAOS initiated an active "awareness" campaign for their members. A survey by the AAOS in 2000 demonstrated that 78% of orthopaedic surgeons were aware of the "Sign Your Site" program. Just under half (46%) of the respondents were using "Sign Your Site" or a similar program on a day-to-day basis. Eighty-five percent of those surveyed thought that the "Sign Your Site" program would decrease wrong-site surgery and benefit patients.

Regulatory Agencies

The Joint Commission for the Accreditation of Hospital Organizations

(JCAHO) is the principal regulatory body for hospitals in the United States. Since 1998, the JCAHO has required tracking and a causal analysis for several unexpected occurrences. The JCAHO calls these incidents "sentinel events." Wrong-site surgery is considered a "sentinel event." In 1998, fifteen cases of wrong-site surgery were reported to the JCAHO. In a more recent survey from 2001, 150 of these incidents were noted. The root-cause analysis identified several contributing factors. The main problem was a breakdown of communication between the patient, the physician, and the members of the surgical team. Lack of a system to mark the surgical site, the absence of a preoperative checklist, and an incomplete preoperative assessment were also cited. In addition, the unavailability of pertinent information in the operating room (e.g., patient records, imaging studies, and so on), distraction factors (e.g., late starts), and staffing issues were identified as causal factors. To combat this problem, the JCAHO now recommends that the surgical site be marked, that a verification checklist be used, and that oral verification of the patient's identity, the surgical site, and the scheduled procedure be obtained. These recommendations are essentially identical to the measures in the "Sign Your Site" program.

Effectiveness of "Operate Through Your Initials"

The Canadian Orthopaedic Association and the Canadian Medical Protective Association (CMPA) have cooperated in monitoring the effectiveness of the "Operate Through Your Initials" program. With a single malpractice insurance carrier (CMPA) for the entire country, national data can be reliably and accurately compiled for Canada. Such statistics would be almost impossible to collect in the United States because of its decentralized system. Comparative data from the seven years prior to initiation of the program in 1994 were compared with data from the next seven years through the end of 2001. The review was summarized in the February-March 2002 issue of *COA Bulletin*⁷. The trending

graph in that report showed a steady decline in the number of wrong-site surgery cases reported to the malpractice insurer (CMPA). Overall, the rate of wrong-site surgery cases declined approximately 62%. That report was the first to confirm that implementation of this system effects an improvement in quality of care and patient safety.

Systems Issues

Root-cause analysis of medical errors generally indicates that multiple failures in a complex system result in an adverse event such as wrong-site surgery. The problem does not arise from a single error by a specific individual. One consequence of this discovery is to negate the traditional reaction of heaping blame on an individual physician or member of the surgical team. The conventional "name, blame, and shame" approach is clearly inappropriate in these circumstances⁸. Creative "systems solutions" such as "Sign Your Site" are required to address the multifactorial problems that can lead to failure in complex medical systems.

It has been suggested that medicine should borrow certain quality initiatives from industry. An example is the "six sigma" quality level⁹. "Six sigma" quality indicates a system in which the tolerated error or failure rate has been specified at six standard deviations (sigma) above the expected mean. This translates into a manufacturing error rate of 3.4 defects per million events or opportunities. In medical systems, medication errors run at about two sigma (308,000 errors per million opportunities). The specialty that comes closest to achieving six sigma quality is anesthesia. The rate of patient deaths from anesthesia has been improved to about five-sigma quality (5.4 deaths per million opportunities).

Future Initiatives

Patient safety will be a major focus of the American Academy of Orthopaedic Surgeons in 2003 and 2004. The AAOS Board of Directors has recently established a Patient Safety Committee to evaluate patient-safety initiatives to

date and to oversee future horizontal integration of patient safety measures into the AAOS infrastructure and programs. To help to disseminate the "Sign Your Site" program and to arrange other patient-safety initiatives, the AAOS will sponsor a meeting in the fall of 2002 to coordinate an Orthopaedic Patient Safety Coalition. This summit will bring together the major orthopaedic organizations in a cooperative effort to foster a culture of patient safety.

Practical Pointers for Prevention

Recognition of an issue is a major first step in its solution. The Canadian Orthopaedic Association and the American Academy of Orthopaedic Surgeons have been leaders among professional medical societies on the issue of patient safety. The COA's "Operate Through Your Initials" program and the AAOS's "Sign Your Site" program have been developed as practical systems-oriented initiatives to help to prevent medical errors, particularly wrong-site surgery.

The future goal of the COA and the AAOS is to decrease orthopaedic

medical errors with preventative, not punitive, programs. *All* orthopaedic surgeons can lead these efforts by mentoring and by example.

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