Patient Safety in North America: Beyond "Operate Through Your Initials" and "Sign Your Site"

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Patient Safety in North America: Beyond "Operate Through Your Initials" and "Sign Your Site"*

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Orthopaedic surgeons in Canada and the United States have been leaders in the patient safety movement[1-8]. Early efforts addressed wrong-site surgery. Both the "Operate Through Your Initials" program[9], introduced in 1993 by the Canadian Orthopaedic Association (COA), and the "Sign Your Site" initiative[10,11], introduced in 1998 by the American Academy of Orthopaedic Surgeons (AAOS), predate the 2000 publication of *To Err is Human: Building a Safer Health System* by the Institute of Medicine[12]. That report estimated that between 44,000 and 98,000 patient deaths from medical errors occurred in the United States each year. Following that report and the associated media attention, there has been more widespread interest in patient safety and medical errors.

In the more focused context of orthopaedic medical errors, patient deaths are rare. However, there are lessons to be learned in terms of the systems and human engineering issues identified in the two papers that were the basis for the Institute of Medicine report[13,14]. The first of these was from a study of New York hospitals. The second was a combined study from Utah and Colorado. One of the coauthors of the latter study was Dr. K. Mason Howard, an orthopaedic surgeon and past chairman of Colorado Physicians Insurance Corporation, the physician-owned professional liability carrier in Colorado.

The American Orthopaedic Association (AOA) and the COA have had prior discussions concerning patient safety in the two countries. A previous symposium took place at the Combined Meeting of the AOA and the COA in Victoria, British Columbia, Canada, in 2002[15]. Subsequent to that meeting,

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there have been notable developments regarding patient safety on national and world levels. These include a member survey on patient safety by the AAOS Patient Safety Committee[16], introduction of the Universal Protocol by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)[17,18], and the launch of a major operating-room safety initiative by the United Nations World Health Organization (WHO)[19].

The Patient Safety Symposium described in this paper was presented at the 2008 Combined Meeting of the AOA and the COA in Quebec City, Quebec, Canada, in June 2008. The symposium provided an opportunity to update orthopaedic surgeons on the evolution of patient safety in both organizations and countries.

Patient Safety—The Canadian Initiatives

In Canada, the issue of wrong-site surgery was first addressed in a white paper by the Committee on Orthopaedic Practice and Economics of the COA. Dr. Paul Wright was the chairman, and the report was issued in 1994[20]. The program that was recommended to reduce wrong-site surgery was the "Operate Through Your Initials" initiative. In 1995, the program was highlighted at the COA Annual Meeting, and a training program was instituted to expose all orthopaedic residents to the protocol. A subsequent review of wrong-site-surgery data from the Canadian Medical Protective Association (CMPA) in 2001 suggested that implementation of the program was associated with a downward trend in the number of lawsuits from wrong-site surgery[9].

Orthopaedic Patient Safety—Present Status in Canada

Most physicians in Canada—over 73,000 in 2007—are members of the CMPA[21], a not-for-profit mutual medical defense organization. In 2007, orthopaedic surgeons represented approximately 2% of the CMPA membership. CMPA members are eligible to receive a broad spectrum of assistance related to medicolegal difficulties arising from their professional work.

Open and closed medicolegal cases occurring between 1995 and 2006, in which wrong surgery (defined as wrong procedure, wrong body part, wrong patient, or wrong level) was the documented clinical issue, were identified. The closed cases, i.e., cases that had concluded by 2006, were further subdivided into cases involving orthopaedic surgeons and cases involving all other types of work.

A total of 279 cases of wrong surgery were identified, with eighty-six (30.8%) of the 279 events involving orthopaedic surgeons. Wrong surgery cases are largely indefensible and pose a high risk to members, with unfavorable judgments against the surgeon recorded in 231 (89.2%) of the 259 closed cases. Monetary reserves must be established to cover the liability risk of wrong-site surgery. Thus, occurrences are closely tied to the rates paid by orthopaedic surgeons for professional liability insurance.

For the years 2005 and 2006, the number of orthopaedic cases of wrong-site surgery that were reported was lower than average. However, past experience has shown that there can be up to a two-year delay in reporting cases of wrong surgery. Thus, further monitoring is needed to determine if the decrease in cases is an actual trend.

JCAHO Safety Initiative—The Universal Protocol

Surgical site-marking has evolved into a multifaceted quality assurance endeavor involving multiple professional medical societies and regulatory agencies. So-called systems interventions, rather than a focus on individual errors, have become the dominant quality assurance strategy. A prime example of an evolved systems intervention is the Universal Protocol[17,18]. The JCAHO has mandated compliance with the Universal Protocol in U.S. hospitals since July 2005. This patient-safety systems intervention has three major components: patient identification, surgical site-marking, and a time-out. The three elements address issues initially identified from the JCAHO Sentinel Event program. An analysis of wrong-site-surgery events in U.S. hospitals in 2006 showed that 17% of wrong-site surgeries in fact involved the wrong patient. Thus, a verification of patient identity became a component. Surgical site-marking primarily addressed the 56% of the wrong-site surgeries that involved the wrong side. In pilot tests, institutions adding a time-out to the patient identification and site-marking elements had no incidents of wrong-site surgery. Thus, the time-out was added as a module in the Universal Protocol.

Additional data in support of the Universal Protocol derived from several forums. The JCAHO, the AAOS, and the American College of Surgeons (ACS) cosponsored a Wrong Site Surgery Summit in May 2003. A second summit was convened in 2006. Data from the root cause analyses of wrong-site surgery from the JCAHO Sentinel Event program were reviewed by representatives of over forty professional medical associations at the summits[22,23]. The North American Spine Society (NASS) was also represented at both summits. NASS has a site-marking protocol specifically for the spine ("Sign, Mark and X-Ray")[24], which has been incorporated into the Universal Protocol. For spine procedures, the back is marked with the surgeon's initials and with the segments to be operated on, and an intraoperative radiograph is made to confirm the proper level.

While the COA and AAOS site-marking programs have been primarily directed toward the issue of wrong-side surgery, the JCAHO Sentinel Event program included several other (somewhat surprising) categories of medical error under the umbrella of wrong-site surgery[22]. For 2006 data (Fig. 1), these included other wrong-site errors (e.g., surgery on the wrong toe but the correct foot; 19%), wrong-procedure errors (e.g., carpal tunnel release done when an ulnar tunnel release was supposed to be performed; 8%), as well as wrong-patient surgery (17%). Wrong-side surgery continued to be the most frequent adverse event (56%). From an

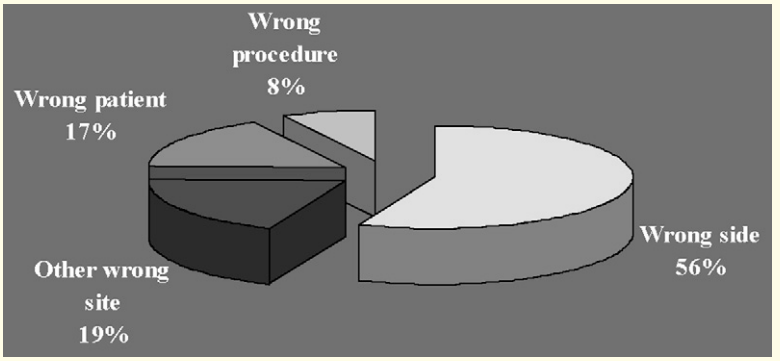

Fig. 1

Breakdown of incidents of wrong-site surgery from the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) Sentinel Event program of 2006. (Image courtesy of Dr. R. Croteau, JCAHO.)

analysis of these data, it was evident that a systems protocol to help to eliminate wrong-site surgery would need more elements than site-marking alone. A check of patient identity was clearly required. To this end, the JCAHO conducted several field trials of alternate protocols. The three interventions that combined to eliminate all categories of wrong-site surgery in the trials (patient identification, surgical site-marking, and time-out) became the basis for the three elements of the preoperative process ultimately designated the Universal Protocol by the JCAHO.

For the first six months after implementation of the Universal Protocol, there was a small decrease in the occurrence of wrong-site surgery. Subsequently, however, there was a slight increase in the number of incidents of wrong-site surgery[25]. The question is whether the increase truly represents a larger number of occurrences of wrong-site surgery or is a reflection of better reporting. The overall consensus at the second Wrong Site Surgery Summit was that the data likely reflected better reporting[22]. An analysis of longer-term data holds the key to answering this question. The other issue that stood out in the root cause analysis of wrong-site surgery occurring after the introduction of the Universal Protocol was the problem of inattention. Despite so-called lip service compliance with the steps of the Universal Protocol, it was apparent that incidents of wrong-site surgery continued to occur in some cases because of the inattention to or the lack of concentration on the specific details of the Universal Protocol. For example, in one of the orthopaedic incidents, the surgeon marked his initials on the patient's knee and the time-out was performed, but arthroscopy was performed on the wrong knee (which had been prepared and draped in error before the surgeon entered the operating room). There was clearly a breakdown in communication between the members of the team performing the time-out and inattention to the details of the Universal Protocol. With proper attention to and concentration on the details, this incident could have been prevented.

The conclusion of the second Wrong Site Surgery Summit was that the Universal Protocol was a good quality-assurance instrument. However, efforts needed to be redoubled to ensure compliance with full attention to the details of the Universal Protocol[22]. This principle also applies to the next patient safety initiative of the AAOS Patient Safety Committee determined after analysis of the data from the AAOS Member Survey.

AAOS Member Survey—Lessons Learned and a Basis for Future Directions

A survey of the members of the AAOS was conducted in 2005 by the AAOS Patient Safety Committee[16]. The purpose of the AAOS Member Survey was to identify issues of patient safety, specifically adverse events and errors experienced by orthopaedic surgeons. With the generally low response rates to surveys, the findings do not reach a level of significance. The appropriate use of the AAOS survey (and the audience responses in this paper) is as a quality-assurance instrument to serve as a guide for focused quality-assurance efforts. The Committee thought it was important to document the types of medical and surgical errors that occur in orthopaedic surgery in order to understand the types of errors, to classify the errors, and to inform the membership about common adverse events. With this knowledge, orthopaedic surgeons can make improvements in their practice to minimize the recurrence of the errors.

The definition of *medical error* used in the AAOS survey was that given by Dovey et al.[26]. This is generally considered a broad, very inclusive definition based on the principle of "I don't want this to happen again." This definition was also used in the study by Shah et al.[27] from the ear, nose, and throat surgeons. The definition is consistent in the AAOS study so that reasonable comparisons could be made with the study by Shah et al. The same criteria were used for the AOA-COA audience survey that follows.

The AAOS Member Survey was sent to 5540 members of the AAOS, and 917 (16.6%) responded. Four hundred and sixty-one (50.3%) of the 917 members stated that they had observed a medical or surgical error in the past six months of their practice. Fifty-one percent of this group indicated that they had noted more than one incident in the past six months. Among sixteen categories analyzed, the six most frequent types of errors and the percent of their occurrence were equipment (30%), communications (26%), technical problems (13%), medications (9%), wrong-site surgery (9%), and imaging problems (6%).

With the broad definition of medical errors used, not all events are

primarily under the control of the orthopaedic surgeon. The categories more directly relating to the orthopaedist (but generally still having a systems component) are communication errors, technical errors, and wrong-site surgery.

While communication error (as a primary cause of an adverse event) is a separate category, communication was a frequent secondary contributing factor to errors in other categories. A similar effect was found in the root cause analysis of sentinel events by the JCAHO[22,23]. The importance and value of clear, complete, and timely communication is apparent.

These errors occurred in many locations throughout the health-care system, but the majority (81.9%) occurred in the hospital; 11.8%, in the office; 1.6%, in surgery centers; and 4.7%, in rehabilitation or nursing home facilities. In the hospital, the most common location of medical errors was in the operating-room environment (36.5%). The next most common site was on the patient floors (30.7%). However, errors occurred throughout the system, including the intensive care units, radiology, and the laboratory.

It was surprising that the majority of errors experienced by orthopaedic surgeons were related to equipment—obviously a systems issue. Equipment errors were subdivided into thirteen equipment-error categories. In terms of the categories of errors that occurred at a higher frequency, the majority of errors were related to instrumentation (63.2%). Implant-related errors were involved in 31.6% of the incidents and bone allograft-related errors, in 2.9%. The top four reasons for instrument errors included missing parts, technical problems, broken implants in the operating room, and problems with sterility. Interestingly, wrong instrument sets were common at 6.1%. Broken implants preoperatively were also frequent at 5.1%. On careful review of the implant problems, the most common error was that some portion or all of the implant was missing (42.9%). The wrong implants for a patient were in the operating room in 28.6% of the incidents. Other issues included late arrival, implants broken preoperatively, and implants broken intraoperatively. In terms of the impact of equipment problems at the patient level, surgery was cancelled in 12% of the incidents and a reoperation was required for 8.4% of the incidents. As many equipment issues only came to light during the procedure, it was calculated that a time-out, including an equipment check, would have prevented problems in only 17% of the cases.

Communication errors were the second most common type of errors that orthopaedic surgeons reported. These included written and protocol communication errors, followed by verbal errors. Examples of written errors included the wrong dosage of a medication and poor handwriting leading to confusion about the route of drug administration (intravenous or intramuscular). Protocol errors comprised situations such as having a protocol in place to ensure that imaging studies are made ready for all surgeries by the radiology department, but none of the studies arriving by the start of an operation.

Medication errors occurred in forty-eight patients. Most errors had minimal adverse effects on the patients. However, five patients sustained temporary harm and nine patients sustained harm that required a prolonged hospital stay. Permanent harm was seen in two patients. Interventions to sustain life occurred on four occasions, and the error contributed to the death of two patients.

This AAOS Member Survey is the first of its kind in orthopaedic surgery to document on a voluntary basis the types and rates of medical and/or surgical errors experienced by orthopaedic surgeons in their practices. This kind of information is invaluable and needs to be expanded so that our profession has an accurate database of adverse event information. Such data will allow surgeons and the Academy to analyze why these errors occur but, most importantly, will allow changes to be made to avoid additional occurrences. It is apparent from this initial brief survey that systems issues are a major problem. Wrong-site surgery, surprisingly, still occurred in 9% of the errors reported. Wrong-side surgery (47%) was the most frequent, followed by other wrong-site (28%, e.g., wrong digit on the correct side), wrong-procedure (14%), and wrong-patient (11%) events.

The location of high frequency errors (operating room), combined with the etiology (communication and equipment) and the persistent reports of wrong-site surgery, have led the AAOS Patient Safety Committee and the AAOS leadership to direct the next major patient safety effort of the Academy toward the "Highly Reliable Operating Room."

AAOS Patient Safety Initiative—The Highly Reliable Operating Room

The results of the AAOS Member Survey and data analysis at the Wrong Site Surgery summits clearly indicated that there is additional work to be done to improve orthopaedic patient safety. At this point, the "Sign Your Site" program is well established. To move patient safety efforts to a higher level, the AAOS Patient Safety Committee will begin in the near future a new initiative called the "Highly Reliable Operating Room." This program will incorporate other AAOS areas of interest including communication and patient-centered care[28,29]. Some specific issues to be addressed include:

- Moving away from "name, blame, and shame" of individuals toward the concept of a team and team responsibility[30]. This is key to enabling a systems approach and systems solutions.
- Crew resource managementa-san intervention to flatten hierarchy[31,32]. This concept allows any member of the team to speak up concerning a quality or safety issue they have identified in a nonpunitive culture, thus helping to reduce errors occurring because a team member has felt too intimidated to communicate a recognized error.

- Team training models such as simulation.
- Team communication, e.g., the SBAR (situation, background, assessment, and recommendations) situation briefing model.
- Use of the WHO operating-room checklist including preoperative and postoperative briefings.

This program was the topic of a recent *AAOS Now* article by the Chair of the AAOS Patient Safety Committee[33].

WHO Second Patient Safety Challenge—Safe Surgery Saves Lives

The United Nations WHO has also begun a large-scale patient safety effort under the recently formed WHO World Alliance for Patient Safety. The alliance has thus far issued two "Global Patient Safety Challenges." The first, named "Clean Care is Safer Care," emphasized hand-washing hygiene and has led to the incorporation of bedside alcohol-based hand sanitizers now seen commonly in hospitals throughout North America and around the world[34]. Through intervention by the WHO at the health minister level of governments of U.N. countries, approximately 80% of the world population is covered by pledges to apply national hand-washing protocols.

The second WHO Patient Safety Challenge entitled "Safe Surgery Saves Lives"[19] was launched in June 2008 in Washington, D.C. The focus of the Safe Surgery Saves Lives initiative is an operating-room checklist. The instrument includes three sections (sign-in, time-out, and sign-out). The sign-in is done prior to the induction of anesthesia and includes confirmation of patient identification, consent, and site-marking as well as checks for allergies, difficult airway, and anticipated blood loss. Time-out (prior to the skin incision) is expanded to confirm the patient, site, procedure, position, and a category of "other checks" that would cover venous thrombosis prophylaxis in orthopaedics. In addition, the antibiotic prophylaxis and presence of imaging is checked, and anticipated critical events are disclosed. Prior to the removal of the drapes, the sign-out confirms the procedure performed and the instrument and sponge counts as well as the management plans for important surgical and anesthesia events. The WHO checklist expands on issues addressed in the JCAHO Universal Protocol and also allows an opportunity for the surgical team to consider strategies for improvement during the sign-out.

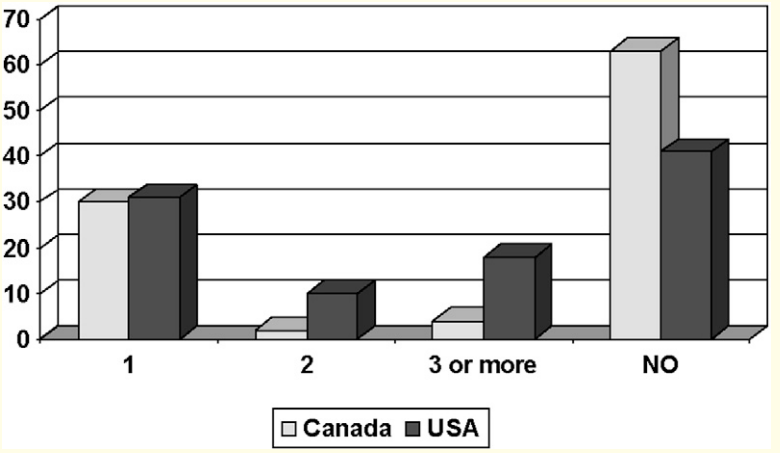

Fig. 2

The percentage of responses at the Patient Safety Symposium to the question: Are you aware of a medical error occurring in your sphere of practice in the last six months?

Participation at the AOA-COA Combined Meeting—Results of the Orthopaedic Patient Safety Audience Response Survey

The Patient Safety Symposium at the AOA-COA Combined Meeting in Quebec in 2008 offered a unique opportunity to obtain an audience response survey of leaders in orthopaedics in both the United States and Canada. The results of the audience survey could be contrasted between the two countries and also compared with the AAOS Member Survey.

The audience responses to safety questions were taken from the AAOS survey so that reasonable comparisons could be made. Demographic data (practicing in the United States compared with Canada) were also obtained. The audience response system allowed tracking and reporting of responses on the basis of the initial question of the country of present practice (fifty were from Canada and sixty-five were from the United States for a total of 115 respondents). Overall, almost 50% of the respondents were aware of a medical error (Fig. 2) in their sphere of practice in the previous six months (30% of the Canadian respondents had been aware of one error; 2%, two errors; and 4%, three or more errors; 31% of the U.S. respondents had been aware of one error; 10%, two errors; and 18%, three or more).

With regard to the location of an incident, the hospital had the highest frequency in both countries (84% for the Canadian respondents and 64% for the U.S. respondents). In the United States, an ambulatory care or surgery center accounted for 17% of the incidents (compared with 12% for Canada), and the office accounted for 9% (compared with 4% for Canada). If the incident occurred in the hospital, the operating room had the highest number of incidents in both countries (64% for Canada and 74% for the United States). The patient room and/or nursing unit was the next most frequent location (16% for Canada and 17% for the United States) followed by the emergency room (8% for Canada and 6% for the United States).

In terms of who was primarily involved in the adverse event, the reporting orthopaedic surgeon was in-

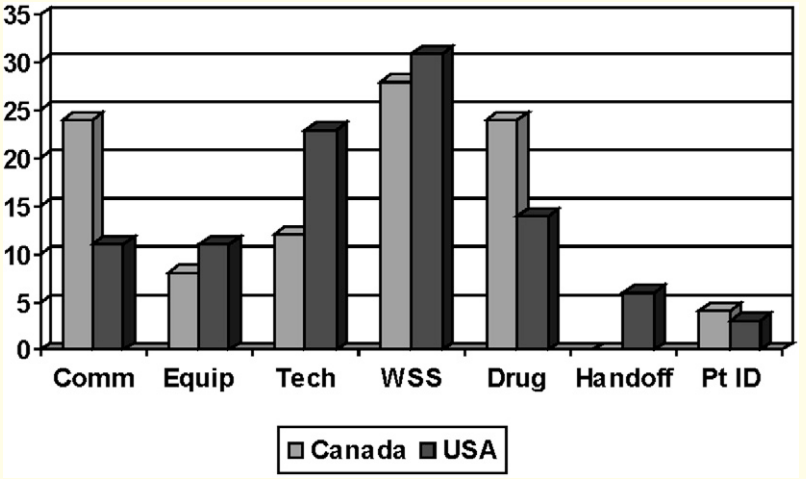

Fig. 3

The percentage of responses at the Patient Safety Symposium to the question: How would you classify this event? Comm = communication, Equip = equipment, Tech = technique, WSS = wrong-site surgery, and Pt ID = patient identification.

volved about equally in both countries (11% of the incidents in Canada and 12% in the United States). However, other parties varied considerably. Nursing staff involvement ranged from 33% in Canada to 12% in the United States. Other orthopaedic surgeons were primarily involved in 30% of the incidents in Canada and almost twice that number (59%) in the United States. Other physicians (such as internal medicine or emergency room physicians) represented 22% of the incidents in Canada and 15% in the United States. Interestingly, house staff (interns, residents, and fellows) were primarily involved in none of the incidents in Canada but in approximately 9% of the incidents in the United States.

Participants classified the error (Fig. 3) most commonly as a wrong-site surgery event (28% of those in Canada and 31% of those in the United States). In Canada, events were categorized as communication failures and medication errors (24% for each), improper technique (12%), and equipment and/or instrument problems in the operating room (8%). In the United States, other common categories were improper technique (23%), medication errors (14%), and communication failures and equipment and/or instrument problems in the operating room (11% for each).

The outcome of the medical error was most commonly short-term morbidity (35% for Canada and 44% for the United States), in which the patient had symptoms or physical changes develop but without a long-term effect (e.g., administration of a double dose of anticoagulants resulting in a wound hematoma that resolved without a long-term problem). No adverse effect (an error that reached the patient level but resulted in no physical effect, e.g., an extra dose of antibiotic was given but with no adverse effect) was next in frequency (23% for Canada and 24% for the United States). A near miss (the error was detected before reaching the patient level, e.g., a medication that the patient was allergic to was ordered, but the error was identified in the pharmacy and the drug was never administered to the patient) was involved in 15% of the events in Canada and in 12% in the United States. Serious effects that occurred included permanent morbidity (19% of the events in Canada and 15% in the United States) and death (8% in Canada and 6% in the United States).

In the subanalysis of wrong-site surgery, the audience response results can be compared with the AAOS survey data and the JCAHO Sentinel Events figures. The most frequent error in Canada was wrong-side surgery (77% for Canada and 39% for the United States) with 47% reported in the AAOS survey and 56% according to the JCAHO). The most frequent issue in the United States was other wrong-site surgery such as the wrong joint on the correct finger (50% for the United States and 8% for Canada, with 28% reported in the AAOS survey and 19% according to the JCAHO). Incidents involving the wrong patient (8% for Canada, 0% for the United States, 11% for the AAOS survey, and 17% for the JCAHO) and wrong procedure (8% for Canada, 11% for the United States, 14% for the AAOS survey, and 8% for the JCAHO) were also noted.

Discussion

Both the AAOS Member Survey and the AOA-COA audience response survey indicate that medical errors (including wrong-site surgery) continue to be an ongoing issue.

Both the AAOS Member Survey and the COA-AOA audience response survey are useful tools for quality assurance purposes but have methodology limitations. Both survey a small percentage of orthopaedic surgeons. Selection biases may operate both in the group who responds to a mailed survey as well as in the segment who attends an annual scientific meeting and are in the audience to respond to a specific topic.

The surveys have identified several high-risk venues in both Canada and the United States. Patient safety strategies directed toward these spheres can serve to improve safety.

Hospital operating rooms appear to be the highest-risk venue. The JCAHO Universal Protocol addresses many of the adverse events with the highest risk, such as wrong-site, wrong-patient, and wrong-procedure surgery. However, the expanded surgical checklist (including sign-in, time-out, and sign-out instruments) proposed by the WHO Safe Surgery

Saves Lives initiative addresses more specific orthopaedic issues such as equipment and implant problems. Another initiative, the AAOS Highly Reliable Operating Room, focuses on communication, teamwork, issue resolution strategies, and breaking down barriers of hierarchy.

At this point, compliance and attention to details of the Universal Protocol appear to be necessary to reduce wrong-site surgery. Orthopaedic surgeons in Canada and the United States are positioned to be thought leaders and facilitators in the quest to completely eliminate wrong-site surgery.

Questions have been raised as to whether medicine is ready for patient safety interventions[35]. Clearly, "to err is human," and it is unlikely that any systems intervention can completely eliminate medical errors. Nevertheless, it is our patients who remain at risk. Solutions must be found.

Overview

Patient safety issues demand our constant attention.

An orthopaedic surgeon has a measure of control and can become a thought leader in the patient safety effort with regard to the following specific issues.

- Pay attention to the details of the JCAHO Universal Protocol to prevent wrong-patient, wrong-procedure, and wrong-site surgery[17].
- Enhance communication and team building in the operating room as a systems intervention to prevent error[33].
- Consider attending or having your residents attend one of the AAOS communications education programs[36].
- Become involved in the Agency for Healthcare Research and Quality's Crew Resource Management for medicine initiative and training courses[37].
- Foster a patient safety culture in your orthopaedic department and operating room.

As leaders in organized medicine and in our roles as orthopaedic educators for future generations of surgeons, we must actively promote attention to patient safety in our practices, residency programs, and fellowships.

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