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Policy Forum

The Universal Protocol

The Joint Commission on Accreditation of Healthcare Organizations has implemented patient safety initiatives to help decrease the number of medical errors in surgery.

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This past July, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) formally implemented a Universal Protocol for the Prevention of Wrong Site, Wrong Procedure, and Wrong Person Surgery[1]. This occurred amidst the fanfare of a National Time-Out Day sponsored by the Association of Operating Room Nurses and with the formal endorsement and backing of more than 50 professional organizations, including almost all of the major surgical professional societies. How could a problem that required so much professional investment have arisen?

In the fast-paced, high-tech, and increasingly complex health care delivery environment, human errors—and the adverse events that all too often ensue—are seemingly inevitable. Indeed, there appears to be a certain fatalism about the occurrence of medication errors, surgical complications, and health care-associated infections, even where the most stringent error-prevention procedures are in place. Certain adverse events, however, simply should never happen. The performance of a surgical procedure on the wrong part of a patient's body, the performance of the wrong procedure on a patient, and the performance of surgery on the wrong patient rank at the top of such a list.

It is unlikely that the admonition of the Hippocratic Oath, "First do no harm," anticipated the potential occurrence of wrong site, wrong procedure, or wrong patient surgery. Indeed, available epidemiological patient safety data—whether sought in the refereed clinical literature or elsewhere—suggests that this problem arose *de novo* in the 1990s. Such an interpretation is simply not tenable. The absence of earlier data suggests a high level of professional and organizational denial in our health care system and reflects the ability of the delivery system and its participants to hide seemingly obvious mistakes.

The first highly visible case of wrong site surgery—involving the amputation of the wrong leg of a patient at a Florida hospital—was a major 1995 news media event and became the initial case in what would become the Joint Commission's Sentinel Event Database. Over the next 3 years, several additional cases of wrong site surgery became known to the Joint Commission and led to the issuance of one of its first Sentinel Event Alerts. This initial Sentinel Event Alert on wrong site surgery emphasized the need for pre-operative verification of the intended performance of a specific procedure on a specific patient; the desirability of marking the planned site of the surgery on the patient's body; and the conduct of a "time out" in the operating room to assure agreement among the surgeon and the other members of the operating room team as to patient, procedure, and surgical site.

What happened next surprised all of us. Following the issuance of the alert, the numbers of reported cases of wrong site surgery grew and then grew some more. By 2001, when the Joint Commission decided to issue a second Sentinel Event Alert on this subject, the number of these cases in the database was well over 100 and included 14 instances of surgery on the wrong patient, resulting in the death of 2 patients. Despite a concurrent initiative to encourage patient involvement in surgical site marking, the second alert seemingly also had little impact on surgical preparations: the number of reported cases continued to rise.

With concern about this problem beginning to grow in the surgery community, the Joint Commission—in

promulgating its 2003 National Patient Safety Goals—codified the performance expectations first suggested in the 1998 alert. A year later, the Joint Commission convened a national summit of professional leadership organizations which recommended the creation of the Universal Protocol. Adopted by the Joint Commission's Board of Commissioners and endorsed by virtually all of the key professional organizations that have an interest in surgery, the Universal Protocol is unambiguous in its expectations. In step-wise fashion, it outlines requirements for the pre-operative verification process, surgical site marking, and the conduct of an operating room team "time-out" immediately before the actual surgery is to commence. Compliance with the Universal Protocol is an accreditation requirement—any identifiable pattern of non-compliance can lead to loss of Joint Commission accreditation.

We might think this is the end of the story, but it is only the beginning of another chapter. We now have over 300 cases of wrong site, wrong procedure, or wrong person surgery in our database, and more continue to be reported. We do not know the frequency of these occurrences because the increased reporting could reflect either increased frequency of incidents or a higher rate of reporting. We do know, however, that we are dealing with a stubborn problem.

No surgeon willfully performs surgery on the wrong body site or wrong patient. Most surgeons believe they are careful, conscientious, and technically competent; have the results to back up those suppositions; and are certain that they themselves will never perform the wrong procedure on a patient or perform the intended procedure on the wrong body site or patient…until it actually happens. This is not a matter of maleficence, but it is a matter of denial and lack of awareness.

Why aren't they aware of the risks? As noted, the actual frequency of wrong site, wrong procedure, and wrong person surgery is not known, but it is certainly greater than the frequency with which it is reported to the Joint Commission. Although these are rare events, each year there are individual hospitals which report 4-6 new cases of wrong site surgery, often in the same surgical specialty. While occurrences have been reported in all surgical specialties, some have inherently greater risk exposure than others. In orthopaedic surgery for example, where the potential for right/left confusion is almost an occupational hazard, the American Academy of Orthopaedic Surgeons has estimated that the typical orthopaedic surgeon has a 25 percent risk of performing wrong site surgery during his or her career [2]. Other risk factors are also known. The rapid sequential performance of similar procedures in multiple patients, eg, cataract surgery, is a known risk factor. So too are complex procedures, patients with deformities or morbid obesity, and procedures that require special positioning of the patient on the operating room table. Any or all of the above considerations should provide ample basis to create at least a yellow alert mindset (to borrow from the terrorism alert warning system) for the typical surgeon.

The need for increased awareness is not limited to the frequency of and risk factors for surgical error. Most physicians also have little knowledge about organizational systems and the critical links between system integrity and patient safety. Nor have most surgeons been trained as team players with individuals from other disciplines or made aware of the rich knowledge base identifying the circumstances in which human error is more likely to occur. These are just a couple of the most dramatic examples of areas in which our medical education and post-graduate training programs are failing us.

The Universal Protocol describes a series of organizational systems. These systems are, like all good health care systems, designed to prevent human error from reaching and affecting the patient. The salutory potential effect of system design, however, is a function of the actual execution of system requirements. Effectively executing the system requires the surgeon and the rest of the operating room team—not the Joint Commission—to own the system, to own the Universal Protocol. It also means that the surgeon, as the "captain of the ship," must be aware of the capabilities and potential foibles of each team member and work with them to achieve successful outcomes.

Today, there are more hospitals and ambulatory surgery centers and surgeons who reflect the professional values embodied in the Universal Protocol than ever before. Further, by endorsing the Universal Protocol and affirming the professional expectation of their members, the leaders of the American College of Surgeons and the surgery specialty societies, have reinforced the importance of this message. Nonetheless, serious challenges remain, including the need for change in the organizational culture, the alignment of behavioral incentives, and health professions education and training reform. We simply have more to do before this "scourge" can be eliminated from health care.

References

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