Wrong-patient, wrong-site procedures persist despite safety protocol

A new study found Joint Commission-required timeouts are skipped or rushed. Experts say a "zero tolerance" approach is needed to stop these tragic mistakes.


Performing surgery on the wrong body part -- or, worse yet, the wrong patient -- is the kind of mistake physicians agree should never happen.

A series of reports from hospitals documenting how these devastating errors slip through the cracks prompted the Joint Commission in 2004 to mandate a three-step protocol. It required physicians and other health professionals to perform a pre-procedure verification process, mark the correct site for the procedure and conduct a "timeout" discussion as a final check before the procedure begins.

Yet new evidence shows the commission's "universal protocol" has not stopped wrong procedures.

In fact, the number of wrong-patient and wrong-site procedure reports rose, according to a study of more than 27,370 adverse events self-reported by Colorado physicians and published in the October Archives of Surgery. The study found that 132 wrong-patient and wrong-site procedures were voluntarily reported to the Colorado Physician Insurance Co. from 2002 to 2008, with peak annual numbers of reports for both categories occurring after the commission's protocol was required.

"Everyone was under the assumption that when the so-called universal protocol was implemented in 2004, it would lead to a decrease in these 'never events,'" said study lead author Philip F. Stahel, MD, PhD, director of the Dept. of Orthopedic Surgery at the Denver Health Medical Center. "Not only did they not decrease, they increased. In the first few years, the universal protocol did not prevent these never events from happening."

The commission estimates that incorrect procedures happen about 40 times a week in the U.S. Lacking access to the total number of procedures performed during the six-year period examined, the study could not establish a wrong-procedure rate.

But Dr. Stahel and other experts said it is alarming that these tragic mistakes are still occurring.

"In aviation safety, we don't discuss whether we'll tolerate 50 jumbo jets crashing a year versus 100," said Dr. Stahel, associate professor in the orthopedic surgery and neurosurgery departments at the University of Colorado School of Medicine. "We want zero tolerance. The same is true of wrong-site and wrong-patient surgery, because every case is a pure catastrophe for the patient involved."

Effective January 2009, the Centers for Medicare & Medicaid Services no longer pays for procedures performed on the incorrect patient or site.

Joint Commission-accredited hospitals are complying with the protocol, or come into compliance soon after being surveyed, said Paul Schyve, MD, senior vice president at the commission. Yet the physician narrative reports analyzed in the new study showed that in 72% of wrong-site procedures, the required timeout was not performed.

Not sticking to protocol

Patient safety experts said the problem is not with the safety protocol, but with failure to follow it every time. Sometimes physicians and other health professionals rush through the checks, and in some places, the surgeon may not even be in the operating room when the timeout discussion is done.

"I'm not aware of a case we've ever had where the procedures were followed correctly and we still had an incorrect surgery," said James P. Bagian, MD, former chief patient safety officer at the Veterans Health Administration, an early leader in establishing presurgical safety checks.

Recently, the VA also has taken a tough line on the matter, launching administrative investigations of health professionals who have failed to follow the safety protocols -- even when no patient was harmed.

"In many cases where we had an incident, and the protocol was not executed correctly, if we gave the people involved a lie-detector test they'd tell you they did it all correctly, and the lie detector would indicate they were telling the truth," said Dr. Bagian, now director of the Center for Health Engineering at the University of Michigan. "They believed that they had done everything correctly but they actually did not. This represents a lack of diligence."

Analyses of wrong-procedure cases find that failure to comply with protocols is the No. 1 reason they occur, with poor communication and lack of physician leadership also frequently contributing, said LaMar McGinnis, MD, immediate past president of the American College of Surgeons. He also serves as the college's representative on the Joint Commission.

The commission's Center for Transforming Healthcare has launched a project with 10 participating hospitals devoted to coming up with better methods to prevent wrong-site surgeries.

"These institutions where this is being studied are advancing this to a whole new plane," Dr. McGinnis said. "They make our current protocol seem minor compared to what's being done and what's been done effectively."

Once these new protocols have been pilot-tested and proved effective, the commission will move forward to adjust its requirements, Dr. McGinnis said. In the meantime, he said, organizations should take a stronger stance on compliance.
"This is where top-down leadership comes in," he said. "The chief of surgery needs to make a stand that this will be done -- no ifs, ands or buts."

The universal protocol can add a few minutes to the total procedure time, but that should not be an excuse for skipping or rushing the process, Dr. McGinnis said. "It's almost a time to have reverence for what's about to happen. You're entering hallowed ground when you're entering someone's body."

Beyond the OR

The procedure problem is not limited to the operating room. A quarter of wrong-patient cases reported in the Archives of Surgery study involved internists, and 32% of all the incorrect procedures involved nonsurgical specialists such as radiologists and dermatologists. The one death reported was due to a chest tube being placed on the incorrect side, causing acute respiratory failure. Thirty-four patients were significantly harmed or impaired, the study said.

"What we have unearthed is evidence that wrong-site and wrong-patient events are certainly of concern for nonsurgical specialties," said Michael S. Victoroff, MD, a study co-author and risk management consultant at the Colorado Physician Insurance Co. "The family doctors, the pediatricians, the dermatologists, the endocrinologists, nurses, pharmacies -- all kinds of people are getting this wrong sometimes, and that means we have another entire patient safety analysis to do to prevent these mistakes."

The commission's universal protocol is supposed to be followed wherever a procedure occurs, not just the operating room. To prevent wrong procedures, physicians should exert the same caution before going forward, whether they are on the medical floor, the radiology lab, an exam room or the OR suite, said Dr. Victoroff, a family physician.


This content was published online only.

ADDITIONAL INFORMATION:

Mistakes in and out of the OR

A recent study showed that nonsurgeons, such as internists and family physicians, sometimes perform procedures on the wrong patient or wrong site. Here is a breakdown of wrong procedures self-reported by physicians in Colorado.

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Wrong patient</th>
<th>Wrong site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical specialists</td>
<td>11</td>
<td>78</td>
</tr>
<tr>
<td>Nonsurgical specialists</td>
<td>14</td>
<td>29</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>107</td>
</tr>
</tbody>
</table>

Source: "Wrong-Site and Wrong-Patient Procedures in the Universal Protocol Era," Archives of Surgery, October (archsurg.ama-assn.org/cgi/content/abstract/145/10/978)

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"Wrong-Site and Wrong-Patient Procedures in the Universal Protocol Era," Archives of Surgery, October (archsurg.ama-assn.org/cgi/content/abstract/145/10/978)


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