"Never" Events Occur 4,000 Times Every Year

After a cautious and rigorous analysis of national malpractice claims, Johns Hopkins patient safety researchers estimate that a surgeon in the United States leaves a foreign object such as a sponge or a towel inside a patient's body after an operation 39 times a week, performs the wrong procedure on a patient 20 times a week and operates on the wrong body site 20 times a week. The researchers, reporting online in the journal *Surgery*, say they estimate that 80,000 of these so-called "never events" occurred in American hospitals between 1990 and 2010, and believe their estimates are likely on the low side.

Documenting the magnitude of the problem, the researchers say, is an important step in developing better systems to ensure never events live up to their name. "There are mistakes in healthcare that are not preventable. Infection rates will likely never get down to zero even if everyone does everything right, for example," says study leader Marty Makary, M.D., M.P.H., an associate professor of surgery at the Johns Hopkins University School of Medicine. "But the events we've estimated are totally preventable. This study highlights that we are nowhere near where we should be and there's a lot of work to be done."

For the study, Makary and his colleagues used the National Practitioner Data Bank (NPDB), a federal repository of medical malpractice claims, to identify malpractice judgments and out-of-court settlements related to retained-foreign-body, wrong-site, wrong-procedure and wrong-patient surgeries. They identified 9,744 paid malpractice judgments and claims over those 20 years, with payments totaling $1.3 billion. Death occurred in 6.6 percent of patients, permanent injury in 32.9 percent and temporary injury in 59.2 percent.

Using published rates of surgical adverse events resulting in a malpractice claim, the researchers estimate that 4,044 surgical never events occur in the United States each year. The more serious the outcome, the more the patient (or his family) was paid. Makary says the NPDB is the best source of information about malpractice claims for never events because these are not the sort of claims for which frivolous lawsuits are filed or settlements made to avoid jury trials. "There's good reason to believe these were all legitimate claims," he says. "A claim of a sponge left behind, for example, can be proven by taking an X-ray."

By law, hospitals are required to report never events that result in a settlement or judgment to the NPDB. If anything, he says, his team's estimates of never events are low because not all items left behind after surgery are discovered. Typically, they are found only when a patient experiences a complication after surgery and efforts are made to find out why, Makary says. In their study, never events occurred most often among patients between the ages of 40 and 49, and surgeons in this same age group were responsible for more than one-third of the events, compared to 14.4 percent for surgeons over the age of 60. Sixty-two percent of the surgeons were cited in more than one separate malpractice report, and 12.4 percent were

named in separate surgical never events.

Makary notes that at many medical centers, patient safety procedures have long been in place to prevent never events, including mandatory "timeouts" in the operating room before operations begin to make sure medical records and surgical plans match the patient on the table. Other steps include using indelible ink to mark the site of the surgery before the patient goes under anesthesia. Procedures have long been in place to count sponges, towels and other surgical items before and after surgery, but these efforts are not foolproof, Makary notes. Many hospitals are moving toward electronic bar codes on instruments and materials to enable precise counts and prevent human error. Surgical checklists, pioneered at The Johns Hopkins Hospital, are also often in place.

Along with better procedures to prevent never events, better reporting systems are needed to speed up safety efforts, says Makary. He advocates public reporting of never events, an action that would give consumers the information to make more informed choices about where to undergo surgery, as well as "put hospitals under the gun to make things safer."

Currently, he notes, hospitals are supposed to voluntarily share never event information with the Joint Commission that assesses hospital safety and practice standards, but that doesn't always happen.

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