PATIENT SAFETY ALERT™
A quarterly supplement on best practices in safe patient care

Retained instruments: Rare error or safety concern?

Establish a strategy to make such errors less likely

A paper in the Jan. 16, 2003, *New England Journal of Medicine* has the safety community abuzz; are too many instruments and sponges being left inside patients after surgery?

The paper, widely regarded as the largest and most reliable to date on the subject, reported that such errors occur in approximately 1,500 out of 28 million patients each year. The research was conducted by staff at the Brigham and Women's Hospital in Boston.

The figure of 1,500 was projected from data in insurance records from about 800,000 operations in Massachusetts for 16 years ending in 2001. The researchers counted 61 forgotten pieces of surgical equipment in 54 patients, and calculated that this would translate into a national estimate of 1,500 cases yearly.

"First of all, I think the study was very well done," says **F. Dean Griffin,** MD, FACS, a practicing physician in Shreveport, LA, and chair of the patient safety / professional liability committee of the Chicago-based American College of Surgeons.

"The shortcoming is that all of the patients came from insurance company records, and only dealt with cases that became litigated. You and I know there are more patients [with similar experiences] that didn't sue."

Other observers also have suggested the real number may be higher because hospitals are not required to report such errors to public agencies.

This one shortcoming does not decrease the significance of the study, Griffin says. "It is one of many that come voluntarily from people in medicine that point out problems in quality, to educate our peers so we can do a better job."

Besides, he says, the exact number is not nearly as important as the fact that such errors are being made. "The thing is, one such error is one too many; having an exact number is not that important. We have to do a better job of controlling these errors."

Emergency department key

Perhaps one of the least surprising findings in the study was the fact that emergency department operations were nine times as likely to lead to such errors, given the press of time and the stressful nature of such procedures.

"Your goals may actually be in conflict with safety," notes **James A. Espinosa,** MD, FACEP, FAAFP, chairman of the emergency department at Overlook Hospital in Summit, NJ. "For example, you want to finish on time, so you might do a little less thorough exploration of the abdomen. At the same time, the nurse responsible for checking and counting instruments might be distracted."

Espinosa notes that a number of principles of human performance come into play with such errors. In addition to the aforementioned goal conflict with safety pressures, they include, among others, deviation from nominal work flow and poor coordination across silos. "The more complex the action, the more likely you are to have human performance problems," he notes. "The solution is to build in simplicity."

Complexity clearly is a key problem, adds **Tina Maund**, MS, RN, director of performance improvement at Overlook. "You have multiple technologies at work, very advanced kinds of physical technical procedures being applied, high levels of knowledge, and often high levels of experience being brought to the table," she notes.

"Carrying out a technical procedure at hand using instruments and applying learning and critical thinking [at the same time] is tough."

Griffin agrees. "Technology is growing so rapidly that what we're doing in medicine is increasingly dangerous," he says.

It's important when seeking to understand the causes of these errors that you look beyond the provider, asserts **Marilyn Sue Bogner**, PhD, head of the Institute for the Study of Human Error, LLC, in Bethesda, MD. "The paper examined what other factors there were [in addition to the providers]. That made me feel good," she says.

"We must take a systems approach to error," she continues. "In the context of care, a number of characteristics of defined systems provoke error on behalf of the care provider."

For example, the Boston researchers noted a higher degree of errors for patients with a higher body mass index (BMI). "People never consider the characteristics of the patient — we're always so busy looking at the provider," notes Bogner. "But with obese patients, you have to peel back several vertical inches of fat to get to the area you need to work on, and maybe your vision is obscured."

Even political, regulatory, and legal factors can work their effects down to the provider level, she adds.

Searching for solutions

Given these diverse pressures, how should one approach a strategy to reduce these errors? "First, you have to figure out why the errors happen," Bogner says. "Examine the characteristics of the situation, the patient, and other conditions. Then, what is it about the emergency department that contributes to these errors — time constraints or workloads?" Of course, you also need to talk to the care providers and ask them what the problems are. "Since people understandably don't want to admit to error, ask them about accidents that *almost* happened," she suggests.

"What was the circumstance: the type of surgery, time constraints, and so on? Had the surgeon had any rest, or were there back-to-back surgeries? What time of day was it performed?" Bogner asks.

From there, you can move to potential solutions, such as adjusting staffing or scheduling. Solutions become a bit more problematic if the error stems from the nature of the patient, but even there possible solutions exist. "The researchers talked about using X-rays," she notes. "Maybe that's not necessary for every patient, but you can target obese patients or make an extra special count on people who are larger than the run-of-the-mill patient."

This makes sense conceptually, Griffin says. "Consider the universal precautions we take, for example, in terms of AIDS or hepatitis. Originally, we thought we should treat those patients differently, but the facts are we treat everyone the same; we take the same maximal precaution with every case so as to not have to rely on patient confidentiality issues, and so on; we can just assume everyone has AIDS or hepatitis. In many ways, the universal precaution should apply to this issue; treat everybody maximally, even if the risk is lower. However, that may not be practical."

Since it may be impractical to X-ray the abdomen of every single emergency case after surgery, "you could maybe take a subset," Griffin suggests. However, he recalls a strategy employed by the Mayo Clinic that might be practical.

"In the operating room they built many years ago, there was an X-ray unit incorporated in the doorway, so as the patients were rolled out of the room, it automatically took a picture of them," he notes. "But it's not the standard of care [today]."

Despite the admitted challenges of technology, "this may be an event where technology is an utterly necessary adjunct," Espinosa suggests. "The fact that in the paper the counts were right indicates we may be exploring the limits of human performance." He notes human reliability research that shows people can have difficulty even with a series of simple math questions. "Your mind 'sees' the right answer," he explains. "You can be asked to subtract six from eight, you write down three but you see two."

In some situations, he continues, there is just no substitute for technology. "It would be helpful if there were some way to have a detection system, where all the instruments were tagged in such a way that you could have one sweep of that patient," he suggests. "That would not be the end of the problem, but another way of measuring."

Griffin agrees. "I would hope there would be technology that would provide some type of implantable device in these instruments that would be detected with a probe, but nothing is being done to my knowledge," he says.

Without such a development, Espinosa suggests, the progress that can be made in reducing these errors will be limited.

"Human performance without computer or machine guidance tends to be in errors of parts per hundreds of thousands," he notes. "It's hard

to get past that unless you use very strong technology. So, 50 errors per million is five per 100,000 — it's actually astonishing they can get that low with human performance. To get to parts of tens of millions, you would need much more robust technology."

"Nonetheless," concludes Griffin. "You have to remember to always work toward perfection."

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Pfizer to bar code drugs to reduce dispensing errors

Codes can be read by bar code readers

New York City-based Pharma company Pfizer, Inc. will use a new bar code technology on its hospital unit-dose products in an effort to help reduce dispensing errors at hospitals and pharmacies nationwide. The bar code system — developed in accordance with the new Reduced Space Symbology standards established by the Uniform Code Council (UCC) in Lawrenceville, NJ — allows for each unit of product to be identified by its national drug code, its expiration date, and its lot number in machine and human readable format.

"It is going to improve patient safety, especially dispensing errors, and if we can do it, we should be doing it," says **Rich Hollander,** Pfizer's senior director of packaging services. While the UCC only recently introduced its standards, Pfizer has been working on the problem for two years. "The initial push came through our CEO's office," he recalls. "He asked, 'Why are we not doing something about bar coding — especially on unit doses?' We thought that was a pretty good question, so we began to research what hospitals were looking for, whether there were industry standards, and what we could do about it."

For years, some companies, Merck among them, had been using scanning technology for a single element — the national drug code. So Pfizer began investigating that area, but in talking to hospitals, they found "they couldn't tell us what they wanted," Hollander reports. "The fact was, with very few exceptions, most people were not scanning, but said it would help, and they would love to do it."

Pfizer's due diligence revealed there were no standards governing bar coding. "At the same time, looking at standard linear bar code symbologies, we realized they required a lot of 'real estate,'" he notes. "We would have had to retool our products, which would in turn have decreased production rates. We were willing to do this, but it would have taken a long time."

A couple of key events helped speed the process along. Organizations such as the Food and Drug Administration (FDA) and the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) joined forces to look at preventing dispensing errors, and in August 2002, came out with a white paper calling for bar codes, not only for the drug code, but for the expiration date and lot number (the latter would help with traceability and, if needed, recalls).

"Both [of the new elements] were highly controversial," Hollander says. "After all, opponents asked, how often would you need them?"

However, the paper received a lot of attention. Then, Tommy Thompson, secretary of the Department of Health and Human Services, made a trip to a Veterans Affairs (VA) hospital and saw how they were using bar codes to prevent dispensing errors.

Although that was being done through repackaging rather than on the original product containers, Thompson said it should be considered a benchmark. At his urging, the FDA published a requirement in the Dec. 12, 2002, *Federal Register*.

"Most of the industry was pushing back against this, and saying you did not need the other two elements," Hollander notes. "You didn't have the technologies available to do it, and the size of the packages was also an issue."

At about the same time, the UCC developed its new Reduced Space Symbology standards, calling for the NDC (National Drug Code) to be put on very small packages. "However, you still could not go small enough for 3 cc or 5 cc vaccine vials, or ampules," he says. "With packages that small, nobody knew of a linear symbology that worked."

Pfizer challenged itself to develop one package

configuration that would work without the need to retool product lines, and without compromising the already crowded real estate on the package. "We realized it may be some years before hospital systems can adapt to read them, but we developed a standard we feel will work in any hospital," says Hollander. "We also wanted make sure the human readable quality was just as good." Pfizer introduced its first lot just before the end of 2002. The codes can be read by conventionally available bar code readers. "We've had a lot of favorable comments from hospitals, congratulating us for leading in this effort," he says. "There have been no complaints to date about the human readable aspect."

No data are in yet on error reduction, but Hollander says the NCC-MERP web site (www.ncc-merp.org) contains studies on the VA experience. Pfizer plans to be imprinting on all its hospital unit dose packages by the end of 2003, and on other types of packaging as technology permits. "Ultimately, this system will help reduce dispensing errors, and make sure you are using the right product, at the right strength, for the right patient," he predicts.

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AHRQ unveils web-based medical journal

Focus on medical errors in blame-free environment

The Agency for Healthcare Research and Quality (AHRQ) has launched a monthly peer-reviewed, web-based medical journal that showcases patient safety lessons drawn from actual cases of medical errors. Called *AHRQ WebM&M* (Morbidity and Mortality Rounds on the web), the web-based journal (webmm.ahrq.gov) was developed to educate health care providers about medical errors in a blame-free environment.

In hospitals across the country, clinicians routinely hold morbidity and mortality (M&M) conferences to discuss specific cases that raise issues regarding medical errors and quality improvement. Until now, there has been no comparable national or international forum to discuss and learn from medical errors. AHRQ saw the opportunity to use the web to host an ongoing national M&M conference aimed at improving patient safety by sharing information from anonymous cases.

"The AHRQ WebM&M web site offers the medical community a unique opportunity to learn about patient safety from the experiences of their colleagues across the country and around the world," says AHRQ director **Carolyn M. Clancy**, MD. "The anonymity safeguards will enable physicians to share their experiences without fear of reprisal. Their involvement will contribute to the education of other providers about how to prevent medical errors and improve patient safety."

Every month, five selected cases of medical errors and patient safety problems — one each in medicine, surgery / anesthesiology, obstetrics-gynecology, pediatrics, and other fields, including psychiatry, emergency medicine, and radiology — will be posted along with commentaries from distinguished experts and a forum for readers' comments. Each month, one case will be expanded into an interactive learning module ("Spotlight Case") featuring readers' polls, quizzes, and other multimedia elements and offering continuing medical education credits. Cases are limited to near misses or those that involve no permanent harm.

The web site was developed for AHRQ under a contract to an editorial team at the University of California, San Francisco. The editorial team is led by Robert M. Wachter, MD, associate chairman of UCSF's Department of Medicine and chief of the medical service at UCSF Medical Center. The editorial board and advisory panels include many of the nation's experts in patient safety.

Lucian Leape, MD, a leading patient safety researcher and a member of the AHRQ WebM&M advisory panel, praises the new journal. "To make real progress in patient safety, we have to engage physicians and break down the shame and silence surrounding errors. By presenting real-life cases of medical errors along with dynamic, systems-oriented expert commentaries, AHRQ WebM&M is an ideal way for physicians to learn more about and ultimately improve patient safety."

In its inaugural issue, the web-based journal features cases on a mix-up involving two patients with the same last name in the same hospital room; a mistaken drug administration causing a patient to stop breathing unexpectedly; a procedural mishap requiring emergency vascular surgery; an infusion pump flying into a magnetic resonance imaging machine, narrowly missing a child; and a misdiagnosis of delusions in a man later found to have metastatic brain and spine cancer. ■