announced recently that it is investigating robotic surgery devices in response to a number of reports of accidents and adverse outcomes. The FDA has received reports of at least five deaths involving robotic surgery since early 2010, but a statement from the FDA says the agency does not yet know if there is any trend or if robotic surgery is responsible for the deaths or other problems. “Since it is difficult to know why the reports have increased, the FDA has elected to talk with surgeons to better understand the factors that may be contributing to the rise in report numbers,” the statement says.

The FDA database of problems related to medical devices includes 500 reports since Jan. 1, 2012. Some are duplicates, reported by the hospital and the manufacturer, and there is no evidence that any of the problems were caused by the robot. Many of the reports did not involve a patient injury.

Hospitals and device makers are required to report adverse outcomes related to medical devices, but the increase in reports could reflect only wider use. Intuitive Surgical in Sunnyvale, CA, which makes the popular da Vinci surgical arm, reports that in 2012 there were 367,000 robot surgeries versus 114,000 in 2008. The da Vinci is the only robotic system cleared for soft-tissue surgery by the FDA, but other robotic devices are approved for neurosurgery, orthopedics, and other procedures. (See the story on p. 65 for the manufacturer’s response to the FDA concerns.)

The Denver hospital is entangled in the Porter case partly because it knew of problems with Porter’s robotic outcomes, explains Daniel P. Slayden, JD, a partner with the law firm of Hinshaw & Culbertson in Joliet, IL, which handles medical malpractice. The hospital issued a statement confirming that it suspended Kortz’s robotic-surgery privileges for three months in 2010. The medical board’s complaint states that the hospital reported Kortz had complications with 11 surgeries using a hospital robot.

Slayden notes that many of the patient complaints against Kortz related to informed consent, with some claiming that he did not properly explain the risks of the robotic procedure or offer a traditional surgery option. That issue is one for the physician rather than the hospital, he says. “It could become a hospital issue, though, if the plaintiff shows when the doctor started having too many accidents, too many poor outcomes, a higher return-to-surgery rate and asks why the hospital didn’t suspend him until 2010,” Slayden says. “If the data show that his rates were higher than the average, and especially if they were higher when using the robotic arm, someone is going to argue that you should have suspended him in 2009. That’s when it becomes a hospital risk management issue.” (See the story below for more on how hospitals can manage risks that come with cutting-edge technology.)

**Executive Summary**

A doctor’s performance with robotic surgery is being questioned, and the hospital is entangled because it knew of the problems. The case shows how cutting-edge technology might affect how a hospital supervises physicians.

- The Colorado Board of Medical Examiners has charged the doctor with unprofessional conduct.
- The hospital suspended the doctor’s privileges at one point.
- Risk managers should ensure surgery with high-tech devices receives the same oversight as any other procedure.

**Sources**

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## Hospital’s oversight of robotic surgery could be a critical issue, lawyer says

In the case involving allegations of unprofessional conduct against Warren Kortz, MD, of Denver, the use of a robotic surgery arm might be only a distraction, say two malpractice attorneys. No matter what equipment was used, the real issue might be whether the hospital adequately credentialed him and required him to meet the same performance standards as any other surgeon, with or without the robot.

Porter Adventist Hospital in Denver could be held liable if the plaintiff shows that the surgeon was insufficiently trained or skilled on the robotic device, because the hospital allowed him to operate there, explains Daniel P. Slayden, JD, a partner with the law firm of Hinshaw & Culbertson in Joliet, IL.

Moreover, the hospital marketed the robotic surgery and included Kortz in the marketing efforts. A plaintiff could claim that the hospital gave the doctor a pass on surgical outcomes that would raise a red flag with other doctors because he was generating significant revenue for the hospital, Slayden explains.
The hospital is more likely to be drawn into such a case when the state has no liability cap, explains Rodney K. Adams, JD, a shareholder with the law firm of LeClairRyan in Richmond, VA. The plaintiff will look to the deeper pockets of the hospital and allege negligent credentialing, failure to have a safe environment and similar issues. “In Virginia, for instance, most physicians are insured to the cap, and so the plaintiff doesn’t need four or five defendants,” he says.

Although some facts are not known about the Denver case, Slayden notes that it does highlight a particular risk of working with new technology. Like lasers 20 years ago, robotic surgery is now a cutting-edge, high-tech treatment option that can draw in more patients to the hospital, but Slayden cautions that risk managers must apply the same patient safety standards. “Patients with choices will decide where they want to be treated based on marketing that shows the latest, most up-to-date technology in use,” Slayden says. “But what standards are you setting for your physicians so you can be comfortable that they are properly trained and skilled?”

Adams notes that patients can drive the use of such technology and physicians will want to respond. The equipment can cost millions of dollars, so hospitals sometimes are heavily incentivized to market the technology and look the other way if outcomes are not good, he says.

Risk managers must watch for any tendency among administrators and clinical leaders to accept lower quality or more threats to patient safety when cutting-edge technology is used, Slayden says. “Those temptations will always come up with any new technology. That’s the nature of the beast,” he says. “Your job has to be to hold the line on what is an acceptable record and not change that because your doctor or your hospital really wants to use this device.”

But expect some push back on that, Adams cautions. “That’s going to create some tension with the marketing department. We saw the same thing with bariatric surgery, when so many hospitals wanted to get into that field because it is very lucrative and there’s a big demand for it,” Adams says. “A lot of hospitals have since gotten out of it because bariatric surgery requires a lot of training and brings some real challenges for the facility and a high complication rate. The marketing department and the accountants might have wanted to keep it, but someone had to step in and say ‘this isn’t the best thing for us to offer.’”

Da Vinci maker says incident increase is just statistical

In response to the Food and Drug Administration’s (FDA’s) announcement that it is investigating a possible increase in surgical problems related to the da Vinci robot, the device’s maker issued a statement saying the increase is only in the number of reports rather than the number of incidents.

Intuitive Surgical in Sunnyvale, CA, which makes the da Vinci surgical robot, confirms that it has filed more medical device reports (MDR) in recent years. However, the noted rise does not reflect a change in product performance but rather a change in MDR reporting practices, the company says.

In September 2012, Intuitive Surgical revised its MDR practices, which resulted in increased reports of device malfunction MDRs, the vast majority of which were related to instruments and not to systems. None of these device malfunction MDRs involved reportable injuries or deaths, the company says. “We self-identified the reporting issue, notified the FDA, and revised our practices,” Dave Rosa, senior vice president for emerging procedures and technologies, said in the statement.

MDRs can be found in the FDA database, which is updated regularly. (The database is accessible online at http://tinyurl.com/maudedatabase.) The most common type of report filed under the company’s revised MDR practices involves instrument cable breaks. These cable breaks render the instrument non-functional and require an instrument change, which can be accomplished quickly, the company says.

The company also made an administrative change in how MDRs previously reported as adverse events were subcategorized. This change has not increased the total number of adverse event reports, but it does result in an increase in events in the “serious injury” subcategory and a corresponding decrease in the “other” subcategory. Total adverse event rates have remained low and in line with historical trends, the company says.