

## MedMal Matters > column



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## Automated surgery — a good idea?

**A**ccording to Intuitive Surgical Inc., the manufacturer of the da Vinci Robotic Surgery System, physicians have performed more than 1.5 million surgical procedures using the system. Intuitive says the da Vinci's magnified vision system and "tiny wristed instruments" enable a surgeon to operate with enhanced vision, precision, dexterity and control. As the company puts it, da Vinci is "taking surgery beyond the limits of the human hand." According to some critics, that may be a problem.

In April, Medscape reported that the U.S. Food and Drug Administration sent a survey to surgeons regarding their experience with the da Vinci system. The survey was prompted by a significant uptick in adverse event reports (AERs) involving da Vinci. Though some of the AERs filed with the FDA involved malfunctions that did not result in harm, other reports involve serious injuries and even deaths. In some cases, surgeons using the da Vinci system and various tools attached to it appeared to be at fault when they punctured bladders, transected nerves and damaged blood vessels. In other cases, Medscape reported, the da Vinci system "seemed to have a life of its own, at times inexplicably cauterizing a fallopian tube, damaging heart tissue or refusing to let go of a patient's tissue with its grasper." On its website, da Vinci's manufacturer states that the system "is not able to act on its own. Instead, the surgery is performed entirely by a doctor, who controls the system." In a manner vaguely but eerily reminiscent of unintended automobile acceleration cases, however, the AER for the latter incident stated: "We had to do a complete system shutdown to get the grasper to open its jaws."

In March, the Massachusetts Board of Registration in Medicine issued an Advisory on

Robot-Assisted Surgery in response to an increasing number of reports of patient injury. The board noted that while robot-assisted surgery has increased dramatically in the last decade, there are no large-scale, high-quality, prospective studies of the comparative risks and benefits of robotic-assisted surgery versus laparoscopic and open procedures. The single-institution, procedure-specific studies that have been done have discussed variable learning curves for surgeons, the need for significant mentoring and greater risks associated with longer and more complex cases.

Bloomberg News reports that at least 10 lawsuits involving the da Vinci system were filed between February 2012 and March 2013. Some of the reported injuries involved malfunction or design issues. For instance, a number of AERs reference burns and other heat-related injuries. CNBC reports that many sources attribute those injuries to the system's use of monopolar energy which can cause sparks or arcing. Intuitive responds that monopolar energy is used in other settings and claims that the system is safe and effective when used as indicated.

Many of the injuries and lawsuits, however, are related to user training and credentialing. According to Bloomberg, there is no universally accepted consensus on how to train surgeons to use robotic systems. That forces doctors and hospitals to rely on Intuitive's guidance, which has been criticized for rushing training to fuel revenue growth. Each da Vinci system costs about \$1.5 million and the more surgeons use them, the more machines are needed. Indeed, Bloomberg quotes several e-mails that came to light in a Washington state lawsuit. One message congratulated a company salesman for persuading a hospital that five supervised surgeries before granting privileges

were too many. Another e-mail told a sales team not to let "proctoring or credentialing get in the way" of increasing the number of robot-assisted surgeries.

Training currently consists of an online portion, a one-day training course and an experience with a simulator. According to Bloomberg, when the da Vinci system went on the market, a marketing official cut the on-site training to one day and reduced the certification test to 10 questions. Some critics argue that it is difficult to fail that test. According to Mayo Clinic researcher Joshua Woelk, it can take up to 90 operations to become proficient in robot-assisted gynecological procedures. Before that, there may be an increased rate of complications and injuries.

The Massachusetts medical registration board recommends that the risks for robot-assisted surgery should be thoroughly explained to the patient, including within the specific context of the clinical condition, the surgical options, the pathology and the anatomy. The board also specifically recommends advising the patient on the surgeon's experience with robotic procedures.

All surgeons must obtain informed consent before performing a procedure. Under Illinois law, informed consent means consent given after disclosure by the surgeon of those risks and benefits of, and alternatives to, the proposed treatment which a reasonably well-qualified surgeon would disclose under similar circumstances. In other words, tell patients the important facts so they can make an informed choice. Whether a surgeon has performed a surgery enough times to become "proficient" certainly is an important fact. Patient safety should always be paramount. ■

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