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Robotic surgical system under scrutiny

After more than a decade of spectacular growth, bulging profits and an expanding presence in US operating rooms, the world's most popular robotic surgical system has come under scrutiny.

Intuitive Surgical, Inc., maker of the da Vinci Surgical System, is facing questions about their marketing practices and lawsuits alleging injuries. The company has also received attention from the US Food and Drug Administration (FDA) about reports of alleged adverse events. As of Nov. 3, the FDA had received 3697 reports this year involving the da Vinci system, up from 1595 in 2012.

"A recent rise in MDRs [medical device reports] does not necessarily represent a recent spike in adverse events — all it means is that Intuitive Surgical was recently informed of a number of adverse events that could have occurred at any time in the past," says Lauren Burch, an Intuitive corporate communications representative.

The FDA agrees that the increase is partly the result of more physicians reporting but is still taking a closer look at how surgeons are using the system. In July, it warned the company to correct alleged violations or face equipment seizures or fines after an April inspection report found the company had not adequately reported adverse events and product corrections.

On Nov. 8, the FDA released the results of a survey of a small sample of surgeons about the safety and performance of the da Vinci system. Eleven surgeons responded and indicated that they thought robotic surgery benefitted patients in many ways, including reductions in bleeding, complications, recovery times, pain and lengths of hospital stay. But they also reported that "learning how to use the da Vinci Surgical System is the biggest challenge because of the device's complex user-interface."

Physicians and hospitals are required to report suspected medical device-related injuries or deaths to the FDA and the manufacturer. Manufacturers are required to report to the FDA when a malfunctioning device poses a threat or when a device may have caused or contributed to a death or injury.

But this self-reporting system is "haphazard and inconsistent" and the law enforcing it has "no teeth," says Dr. Martin Makary, an associate professor of surgery at Johns Hopkins University School of Medicine in Baltimore, Maryland.

Makary contributed to a recent review of nearly 12 years of FDA data concerning adverse reports involving robot-assisted laparoscopic surgery, finding 245 adverse incidents, including 71 deaths and 174 serious injuries (*J Healthc Qual* 2013 Aug 27. doi: 10.1111/jhq.12036).

"It's highly representative of a larger problem in health care," he says. "We lack standardized monitoring of new technology to properly evaluate it for safety and efficacy."

Robotic surgical technology is beneficial for certain types of surgeries — such as neck, throat and rectal operations — but has been "broadly adopted not based on good science but rather on patient demand and physician interests to attract patients," says Makary.

Getting accurate information to the public is essential as more Americans opt for the high-tech choice, Makary says. According to the study, the number of da Vinci systems in the US increased from 800 in 2007 to 1400 in 2011.

Canada has only 22 da Vinci systems, according to an Intuitive representative. More Canadian surgeons, however, are undergoing training at Canadian Surgical Technologies and Advanced Robotics, London Health Sciences Centre in Ontario, which has two da Vinci robotic systems.

Hospitals and surgeons considering the purchase of a system should view the promotional material that accompanies it with a degree of skepticism, warns Makary. In an earlier analysis of US hospital websites, he found that a third claimed robotic surgery improved cancer outcomes — a finding "unsupported by medical literature," says Makary.

"None of the informational material had any mention of risks," he says. "People tend to view this as the doctor's voice, when, in many cases, we found the manufacturer authored much of the unsupported claims."

Makary also found that 73 of the websites used wording taken directly from Intuitive's resource material. Intuitive said in an email that it can't control how hospitals market the da Vinci device, and that the informational material it provides is "fair and balanced."

Another emerging criticism of robotic surgery is that it may not be the cost-effective solution hospitals were hoping it would be. For example, robotic surgery does not substantially reduce complication rates, transfusion requirements or rate of discharge to nursing facilities for hysterectomies, according to a recent study (*JAMA* 2013;309:689-98). Although less likely to result in hospital stays longer than two days,

the robotic procedures cost $2189 more than traditional laparoscopic hysterectomies. — Patricia Guthrie, Seattle, WA.

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