Robotic surgery complications underreported

Robotic surgery has been widely adopted by hospitals during the past decade, but its safety is still unclear because of a haphazard system for reporting complications, Johns Hopkins researchers say.

A new study led by Martin Makary, MD, finds that of 1 million robotic procedures performed since 2000, only 245 adverse events were reported to the Food and Drug Administration (FDA), including 71 deaths. Several events were not reported to the FDA until after they were publicized in the national news media.

The number of events reported is very low for a complex technology that has been used more than a million times, Dr Makary says in a press release.

For the study, Dr Makary and colleagues reviewed the FDA device-related complication database (MAUDE) from January 1, 2000, to August 1, 2012. They also searched LexisNexis and PACER (Public Access to Court Electronic Records) to identify robotic surgery-related complications.

The researchers found that 8 cases were not appropriately reported to the FDA. In 5 of these cases, no FDA report was ever filed. In 1 case, the FDA report was filed 1 year after the patient’s death and 2 weeks after a Wall Street Journal article cited the case. In another case, despite an injury being reported to an Intuitive Da Vinci system representative, the Intuitive supervisor failed to file the FDA report.

Fatal, nonfatal injuries

The robotic procedures associated with reports of death were:

- gynecologic (22 deaths)
- urologic (15 deaths)
- cardiothoracic (12 deaths)
- otolaryngologic (10 deaths)
- colorectal (3 deaths)
- general surgical (3 deaths).

Six of the reported deaths had no procedure listed.

The cause of death was most often hemorrhage (21 patients). In 20 deaths the cause was not reported. Other causes of death included sepsis, cardiac arrest, multi-organ failure, and pulmonary embolus.

For those patients with nonfatal injuries, hysterectomy had the most complications (75 patients) followed by prostatectomy (30 patients).

Nearly half of nonfatal injuries (46.6%) resulted in permanent damage, 17.2% needed conversion to open surgery, and 15.5% required a second surgical procedure.

Reasons for underreporting

The authors cite several potential reasons for underreporting:

- It may be difficult to separate surgeon error from device-related injuries.
- There is little oversight regarding reporting.
- There is little incentive to improve reporting practices.

Dr Makary calls for a standardized reporting of adverse events related to robotic devices.

He suggests use of a database like the one maintained by the American College of
Surgeons in which independent nurses identify and track adverse events and complications of traditional surgical procedures.

The study was published online August 27 in the Journal for Healthcare Quality.