



## Robotic-Assisted Surgery: Focus on Training and Credentialing

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### ABSTRACT

Since 2005, healthcare facilities have reported 722 safety events involving robotic-assisted surgery (RAS) to the Pennsylvania Patient Safety Authority. Five hundred forty-five (75.5%) were categorized as Incidents that did not result in patient harm. Of the 545 Incidents reported, 344 (63.1%) of the events were categorized as complications of a procedure/treatment/test or errors related to a procedure/treatment/test. One hundred seventy-seven (24.5%) were reported as Serious Events that resulted in patient injury, including 10 events that resulted in patient fatality. Complications of a procedure/treatment/test ( $n = 131$ ) and errors related to a procedure/treatment/test ( $n = 44$ ) comprised 98.9% of the Serious Events. Further review of these cases showed that the event type subcategories of unintended laceration/puncture, bleeding/hemorrhage, other events related to patient positioning complications, retained foreign body, and infection made up 75.1% of the Serious Events. The rapid growth of RAS has presented new challenges as this technology has emerged as an alternative treatment option to many laparoscopic and open procedures. Current literature supports that a steep learning curve exists as surgeons develop skills to perform robotic procedures. As professional organizations discuss developing and defining standards for training and credentialing, the responsibility falls on the individual hospital to develop programs to ensure that both the physician and the entire surgical team are proficient and competent to safely perform robotic procedures and that patient outcomes are monitored to ensure ongoing staff competency. (Pa Patient Saf Advis 2014 Sep; 11[3]:93-101.)

### INTRODUCTION

The use of robotic technology has escalated over the past four years, and the number of robotic-assisted surgeries (RASs) performed worldwide nearly tripled between 2007 and 2010, from 80,000 to 205,000.<sup>1</sup> Originally developed by the US Department of Defense for use in the battlefield in the 1990s, robotic surgical technology has rapidly changed the practice of minimally invasive surgery.<sup>2,3</sup> In 2000, the US Food and Drug Administration (FDA) cleared the da Vinci<sup>®</sup> Surgical System by Intuitive Surgical, Inc. for laparoscopic surgery, and as of this writing, it remains the only commercially available system. This system is currently FDA-cleared for many procedures, including general surgery, cardiac, colorectal, noncardiac thoracic, head and neck, urologic, and gynecologic procedures.<sup>4,5</sup> The benefits of robotic technology include three-dimensional magnified vision, enhanced ergonomics and tremor filtration, motion scaling, and improved manual dexterity.<sup>3,6,8</sup> Patient-centered potential advantages include reduced length of hospital stay, improved postoperative recovery time, decreased postoperative pain, and decreased blood loss.<sup>9</sup> The manufacturer reports the major benefits experienced by surgeons include greater surgical precision, increased range of motion, improved dexterity, enhanced visualization, and improved access.<sup>7</sup>

Limited valid data is currently available on complication rates or adverse events related to robotic surgery. FDA's Manufacturer and User Facility Device Experience (MAUDE) database collects medical device adverse event data, but this system has its limitations and states that information collected cannot be used to evaluate adverse outcome rates.<sup>10,11</sup>

The cost of implementing a robotic surgery program requires a substantial financial commitment from the hospital, as the cost of a robotic system runs in the range of \$1.5 million to \$2 million, with additional costs for maintenance of the system and purchase of limited-use instruments.<sup>12</sup> The cost of training the surgeons and the entire surgical team is estimated to be about \$10,000 per surgeon.<sup>8</sup> As the learning curve is steep, the hospital will also need to account for the increased operative costs during this period. The professional organizations have not reached a consensus on training or credentialing standards.<sup>7,12,13</sup> This leaves the individual hospital responsible to develop and implement training and credentialing processes that are medically sound, that promote patient safety, and that protect the organization from undue risk.

Implementing a robotic surgery program is challenging. The focus of this article is not to debate the efficacy of one surgical approach versus another but rather to identify organizational training and credentialing processes that may increase RAS safe patient outcomes within an organization as well as reduce organizational risk.

### COMPLICATIONS AND ADVERSE EVENTS RELATED TO ROBOTIC SURGERY

Valid data on complication rates and adverse patient events is limited and can be conflicting. No studies exist to support that RAS conducted by experienced robotic surgeons has complication rates that differ from other techniques.<sup>8</sup> Current sources of national adverse event data include FDA's MAUDE database and procedure-specific studies. In addition, the Pennsylvania Patient Safety Authority's Pennsylvania Patient Safety Reporting System (PA-PSRS) contains event reports that were reviewed following a query of the reporting system database that included the terms "robot" or "da Vinci." Additional like events may have been reported through PA-PSRS but not captured in this analysis if this terminology was not included in the event report.



## MAUDE

At the national level, manufacturers, importers, and device user facilities are required to report to FDA certain device-related adverse events involving serious patient injury and/or death as well as product problems.<sup>14</sup> Reports made to MAUDE include information that may identify patterns or problems or a failure mode with a particular device that organizations can review as part of their ongoing robotic patient safety program. MAUDE's system limitations are widely known, and FDA has indicated that the data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices, as many reports may be missing, duplicated, or incomplete.<sup>10</sup>

Dr. Martin Makary, Johns Hopkins University, was noted to say that MAUDE is a "haphazard reporting system that uses immature data and only the best experiences make it into the data."<sup>15</sup> On November 23, 2013, Intuitive Surgical, Inc. posted an analysis of the MAUDE database by date of event from 2010 to 2013. Its analysis showed a decrease in the overall adverse event rate. Included in its rate calculation explanation, Intuitive states, "Rate computed by dividing number of adverse events by number of surgical procedures completed worldwide through 31 October 2013. Q4 2013 procedures are an estimate."<sup>12</sup> The actual denominator of total robotic cases was not found to be reported in the literature reviewed, but the manufacturer approximated that 1.5 million procedures have been performed worldwide as of December 2013.<sup>7,16</sup>

Gupta et al. performed a study of the MAUDE database for the years 2009 and 2010 for which 741 events were identified that involved robotic surgery. The authors reported that of the cases reviewed, 27.3% were urology, 32.6% gynecology, 10.8% other, and 29.2% not specified. This study found that 43.4% of the cases were associated with use of an energy instrument, 19.3% with the surgical system,

and 11.7% with an instrument accessory. Gupta et al. opined that the number of adverse events was low, or about 0.1% over two years.<sup>17</sup>

Cooper et al. also studied the FDA MAUDE database for device-related robotic surgery complications, by specialty and procedure type, reported from January 1, 2000, to August 1, 2012. In addition, the authors searched LexisNexis and Public Access to Court Electronic Records (PACER) databases for any legal judgments to see if there was a corresponding report in MAUDE. Cooper et al. found that 245 cases had been reported, which included 71 deaths and 174 nonfatal injuries. Eight cases were found in LexisNexis and PACER in which the FDA report was inaccurate, filed late, or not filed. Of these eight, FDA did not receive a report on five, although several were in litigation and had been reported via the media. Cooper et al. recommended that a standardized mechanism be put in place to monitor device and patient safety. The authors opine that there are several reasons for underreporting of robotic surgical events, including difficulty in separating poor surgical skill from device-related injuries, little oversight regarding reporting, and little incentive to improve reporting.<sup>14</sup>

## Reviews in Literature

Tsao et al. at the University of Pittsburgh reviewed their first 100 patients having robotic-assisted laparoscopic prostatectomy from October 2004 to August 2007 performed by three attending surgeons. The variables reviewed included estimated blood loss, operative time (trocar placement to skin closure), margin status, length of stay, postoperative prostate-specific antigen level, and continence. The authors found that 99% of the surgeries were completed robotically and only one converted to an open case. No intraoperative complications were reported, and 23% of the surgeries had positive margins. Postoperative complications included

pulmonary emboli (n = 4), open conversion (n = 1), ileus (n = 5), infections (n = 4), myocardial infarction (n = 2), urine leaks (n = 7), fascial dehiscence (n = 1), extremity weakness (n = 3), abdominal bleed secondary to anticoagulation for pulmonary embolus (n = 1), death due to pulmonary embolus (n = 1), reoperation for fascial dehiscence (n = 1), readmission for pelvic abscesses (n = 2), and bladder neck contractures (n = 3). The most significant decrease in operative time was seen after the first 25 patients, and blood loss was noted to decrease after 50 patients. Their overall complication rate was 26%. Improvement of surgical outcomes and patient safety was present with ongoing surgical experience.<sup>18</sup>

Smith et al. at the University of North Carolina conducted a study of 250 robotic-assisted radical cystectomy cases. This study showed no definitive proof that the robotic approach decreased complications or improved patient outcomes as compared with open procedures. The authors found that patient selection was key when a surgeon was new to robotics and suggested that simple cases be done until the surgeon was past his or her learning curve. The authors found that use of perioperative care pathways, intraoperative techniques learned from increasing experience, and careful instrument selection helped avoid complications.<sup>19</sup>

Davis et al. performed a study utilizing a large database to assess the learning curve effect for robotic-assisted radical prostatectomies (RARPs) and to compare the outcomes of RARP with open radical prostatectomy (ORP). The database consisted of 71,312 reports of radical prostatectomies performed at more than 300 hospitals by more than 3,739 surgeons utilizing an open or robotic approach from 2004 to 2010. The key variables reviewed were conversion to open, surgical time, inpatient length of stay, and complications. The RARP results by surgeon experience showed

improvements in conversion rates (1.13% to 0.31%), surgery time (5.0 hours to 4.1 hours), hospital stay (2.4 days to 2.0 days), and complication rates (11.75% to 8.93%) within the initial 100 cases performed by the surgeon. The study also noted that there was continued improvement in conversion rates, surgery time, and hospital stay beyond the initial 100 cases. In comparing the two surgical approaches, the length of surgical time was greater for RARP than for ORP, but the length of the hospital stay and overall complication rate was lower for the robotic approach.<sup>20</sup>

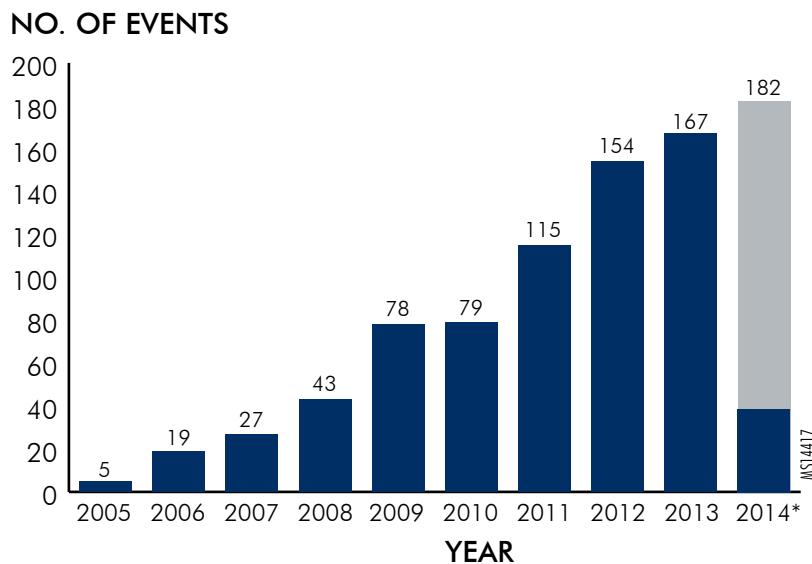
### PA-PSRS Reports

A query of PA-PSRS reports using the terms “robot” and “da Vinci” from June 2004 through March 2014 found 913 events. Of these reports, 722 events directly involved RAS. Figure 1 shows the distribution of reports by calendar year. It was noted that the Authority did not receive any reports involving RAS occurring in 2004.

Analyzing the event date by event type shows that complications of procedure/treatment/test, errors related to procedure/treatment/test, and equipment/supplies/devices events comprised 90.2% of all RAS events (see Figure 2). Five hundred forty-five reports (75.5%) were categorized as Incidents that may or may not have reached the patient and did not result in patient harm. Of the 545 Incidents reported, 131 (24.0%) were attributed to equipment/supplies/devices.

One hundred and seventy-seven (24.5%) of the PA-PSRS reports were reported as Serious Events that resulted in patient injury, including 10 events that resulted in a patient death. Ninety-nine percent of Serious Events were attributed to complications of procedure/treatment/test and errors related to procedure/treatment/test, with only one event attributed to equipment/supplies/devices. Five of the 10 patient events resulting in death

**Figure 1. Robotic-Assisted Surgery Events by Calendar Year 2005 to 2014, as Reported to the Pennsylvania Patient Safety Authority (N = 722 reports through March 2014)**



**\* The number of events for 2014 is a forecasted value. Forecast was calculated using formula  $a+bx$ , where  $a = \bar{y}-b\bar{x}$ ,  $b = \frac{\sum(x-\bar{x})(y-\bar{y})}{\sum(x-\bar{x})^2}$  and where  $x$  and  $y$  are the sample means of known calendar years and of known events reported for full calendar years, respectively. The forecast section of the stacked bar for 2014 represents the forecast total less the known number of events through first quarter 2014 ( $n = 35$ ).**

involved perforation or laceration of a vessel or bowel.

Further review was performed on the subcategories and narrative details of the Serious Events to gain a better understanding of the reports that resulted in patient harm. It was noted that errors related to procedure/treatment/test and complications of procedure/treatment/test totaled 98.9% of all Serious Events (see Figure 2).

In reviewing the reported complications and narrative details of the PA-PSRS RAS Serious Events, the most frequently occurring complications were unintended laceration/puncture (43.5%) and bleeding/hemorrhage (17.5%). Retained foreign body and infection each accounted for 4.0% of complications. Other complications were reported in 31.1% of the Serious Event reports, of

which 20.0% were related to positioning complications. See Figure 3.

Hospitals also provide information describing contributing factors and remedies to reduce reoccurrences. It was noted that two of the Serious Events identified inexperienced staff or issues of staff proficiency as a contributing factor. Fourteen Serious Events documented that further education and training of the staff and referral of these events to medical leadership, administration, and quality/risk management for further review were recommended to prevent reoccurrence.

The following are samples of events reported to the Authority.

#### Unintended Laceration/Puncture

*During robotic-assisted lobectomy, the patient's pulmonary artery was nicked. The procedure was converted*



to an open thoracotomy, resuscitation was not successful, and the patient died. Training and education of the staff was recommended as a remedial measure to prevent recurrence.

**Bleeding/Hemorrhage**

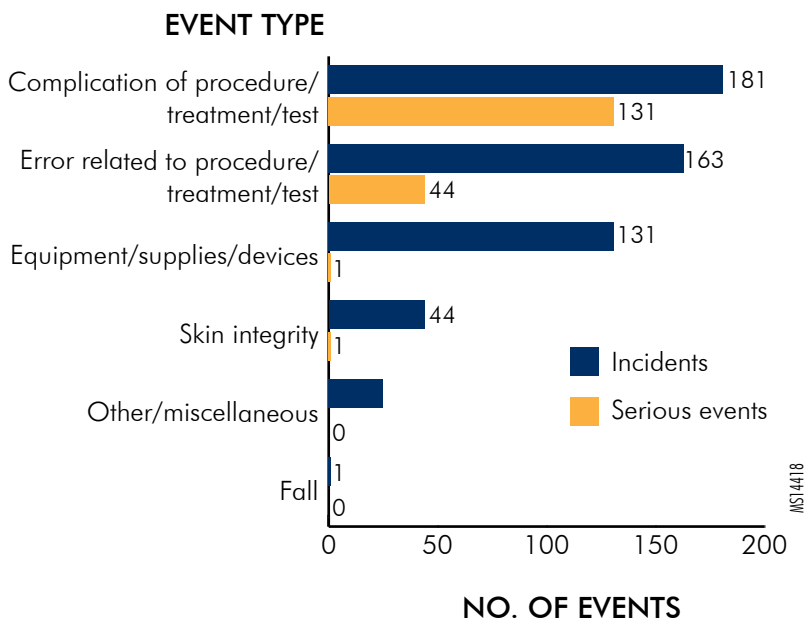
Patient underwent robotic-assisted laparoscopic partial left nephrectomy without incident. H/H [hemoglobin and hematocrit] dropped, and increased bleeding around the JP [Jackson-Pratt] drain was noted. Patient was taken back to the OR [operating room] for exploratory laparoscopy; evacuation of hematoma and cauterization of various bleeding points was performed. Patient was returned to unit stable; later, the patient was observed with increased blood in JP drain. The decision was made to take the patient back to the OR for open exploration. Nephrectomy was performed and adrenal gland found to be actively bleeding and also removed. Patient returned to unit in stable condition.

After a robotic TATA [transanal abdominal transanal proctosigmoidectomy with descending coloanal anastomosis] and diverting loop ileostomy procedure, the patient developed hypotension, tachycardia, and a drop in hemoglobin. The patient was returned to the OR for laparoscopic washout of intra-abdominal hematoma and vascular control of the inferior mesenteric artery.

**Positioning**

A patient underwent an elective nephrectomy via laparoscopic robotic procedure. Noted small bowel perforation in two separate areas. Severe adhesions noted from previous abdominal surgery. Surgery consulted. Repair performed. Proceeded with open nephrectomy. Time patient positioned on side in OR exceeded expected surgical time. Patient went to the ICU [intensive care unit]

**Figure 2. Robotic-Assisted Surgery by Event Report Types, 2005 through March 2014, as Reported to the Pennsylvania Patient Safety Authority (N = 722)**



postoperatively. [More than five hours later,] patient complained of flank pain on same side as positioned in OR. Symptoms of compartment syndrome noted. Return to OR for fasciotomy. Return to ICU. Condition deteriorated. Renal failure, comfort measures per family request/decision. Patient expired. Education and training of staff along with review/revision of policies and procedures and referral to medical and administrative leadership for further quality review were recommended.

**Retained Foreign Body**

A patient underwent a robotic transaxillary thyroid lobotomy. Midway through the robotic dissection, the electrical power was lost [on] three separate occasions [not exceeding 30 seconds]. The case was converted to open. During the robotic procedure, metallic clips were used and the instruments were entangled in a gauze sponge. The counts were correct and

the wound was closed. The staff was informed that this patient presented to another hospital for removal of a retained foreign body. Case referred to surgical and ENT [ear, nose, and throat] departments for further quality review.

**Infection**

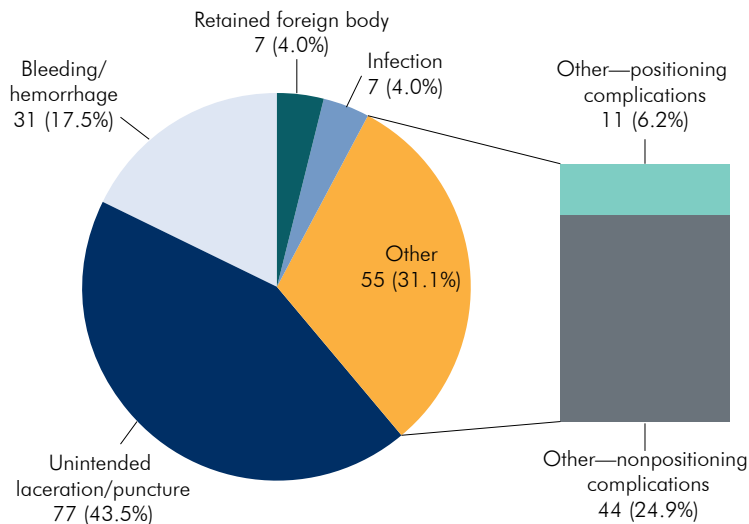
Debris left on robotic instrument and was introduced into the patient's abdominal cavity upon insertion of instrument through port. Area irrigated and patient received antibiotics postoperatively. Lack of staff proficiency noted as a contributing factor to the event.

**KEY STRATEGIES FOR IMPLEMENTING A ROBOTIC SURGERY PROGRAM**

**Training and Education**

As noted in several of the included event narratives, training and education, credentialing, and continuous quality

**Figure 3. Robotic-Assisted Surgery Serious Events by Reported Complications, 2005 through March 2014, as Reported to the Pennsylvania Patient Safety Authority (N = 177)**



**Note: Sum of percentages does not equal 100 due to rounding.**

reviews are necessary to ensure that a robotic surgery program functions safely and efficiently. Attention to the following issues will assist the hospital in ensuring optimal patient outcomes while mitigating RAS risks and complications.

Robotic surgical training provided by the manufacturer provides basic training but does not ensure that the surgeon is competent to perform RAS. Larson et al. reported that the learning curve for a physician starting robotic surgery is steep, and the credentialing plan must address the individual learning needs.<sup>21</sup> Steinberg et al. devised a theoretical model to determine the operative costs during the learning curve for robotic-assisted prostatectomy and compared the costs with an actual series of robotic-assisted prostatectomies. The most expensive learning curve involved 360 cases with operative and anesthesia costs totaling \$1.3 million, and the least expensive learning curve involved 24 cases and totaled \$95,000.<sup>8,22</sup>

In general, RASs performed by inexperienced surgeons result in longer OR times and increased complications. When the necessary training time, increased procedure times, and increased risks are taken into account, overall RAS results increased costs to the medical system during the learning curve period.

The University of California, Irvine (UC Irvine) developed a successful robotic training program utilizing a three-phase approach to learning and the guidance of an experienced mentor.<sup>23</sup> In 2003, McDougall et al. presented a five-day comprehensive mini-residency program at UC Irvine to 21 urologists from four countries that included dry lab, animal/cadaver lab, and live demonstration in the OR.<sup>8,24</sup> Within 14 months of the course, 95% of the participants were safely performing RARP. All participants recommended this program to their colleagues. Follow-up studies showed that these participants were able to keep up safe practice in

both the short and the long term. This program was funded by a grant, but UC Irvine estimates that the cost of providing this type of training would be approximately \$10,000 per surgeon.

Another example of an organization's RAS training program (at Tacoma General Hospital in Tacoma, Washington) is discussed by Lenihan.<sup>2</sup> The military and aviation industries have a long history of requiring flight simulation training and strict regulations on licensing and maintenance of skills.<sup>25</sup> Lenihan likens operating a robotic surgical system, such as the da Vinci, to flying an airplane and believes that aviation safety standards can be employed. As part of a hospital's training program, the hospital can develop a system whereby the surgeons, like pilots, train and test to become credentialed, then must perform a certain number of procedures, get additional training, and take annual examinations to prove continued competency.<sup>2</sup>

Lenihan reports that Tacoma General Hospital's robotic surgical training and credentialing system is based on the aviation model, and other hospitals may consider this program as a template for establishing a robotic surgery program. The program identified training candidates as those surgeons who perform frequent major surgery, are comfortable with complex surgical procedures, and have laparoscopic experience. Consistent training was given to all, including didactic training, dry lab on a robotic platform or simulator, case observation, live animal model lab training, and proctored cases. More steps could be added for residency or fellowship programs. Each surgeon had a minimum of two cases proctored and mentoring by a skilled robotic surgeon when the surgeon started performing more complex cases or new procedures. A proctor was defined as a surgeon who has performed 40 RASs internally or externally, has done the procedure they are proctoring, and has a standardized



evaluation process to report back to both the surgeon and executive team at the hospital.<sup>2</sup>

Tacoma General Hospital required that 12 to 15 simple cases be done first before attempting complex cases. For the surgeon's first advanced case, a physician first assistant is utilized. If it is a new case, the physician is proctored. After completing training, the surgeon starts doing cases right away and no later than 60 days after completion of training. Tacoma General Hospital's Robotics Peer Review Committee does a focused review of the first five basic cases and first three advanced cases. The established minimum number of cases for a surgeon to maintain skills and privileges is set at 20 to 24 cases per year and at least one every eight weeks. If a surgeon does not meet their currency requirements, they can try to increase their volume of surgical procedures or they can retrain in the dry lab using a simulator and then have the next three cases proctored by a fully qualified robotic surgeon and reviewed.<sup>2</sup>

Although professional organizations have not reached consensus on a consistent training program, nor have they come to agreement on the definition of competency to perform the procedures, several have published recommendations.<sup>7,12,13</sup> In 2007, a consensus document prepared by the Society of American Gastrointestinal and Endoscopic Surgeons along with the Minimally Invasive Robotic Association presented guidelines for the level of training needed to perform robotic surgery and for granting privileges as part of the credentialing process. The guidelines include didactic training, live case observation of an experienced robotic surgical team, and simulation training in preparation for a mentored clinical experience at the hospital.<sup>26</sup> The Fundamentals of Robotic Surgery consensus conference brought together over 19 professional organizations and developed a list of 25 outcome measures to be mastered by

a surgeon seeking privileges in robotics: 8 preoperative, 15 intraoperative, and 2 postoperative tasks.<sup>27</sup>

### Team Training

Proper training of the entire team is critical to maintain patient safety. Staff need experience with the robotic system, cadaver training, observation of an experienced team, and simulation training. Simulation training studies show that it takes surgeons eight attempts to achieve proficiency in each step of a RAS process.<sup>28</sup> The entire team needs to practice together on the equipment prior to using it on patients.<sup>29</sup> The University of Iowa Hospitals and Clinics has developed staff competency forms and robotic suite setup diagrams for prostatectomy as good visual teaching aides for the clinical staff.<sup>30</sup>

Team training includes drills for any type of failure that might occur during robotic surgery—for example, drills addressing equipment failure, conversion to an open procedure, and removal of equipment from the surgical cavity.<sup>31</sup>

Because robotic equipment, particularly the robotic arm, necessitates unobstructed movement, patient positioning is more complex. And once the robot is docked, it is difficult to access positioning. Patients can experience position-related complications such as peripheral nerve injury and rhabdomyolysis. The deep Trendelenburg position, in which the patient is inclined at 45 degrees with the pelvis higher than the head, used in gynecologic and urologic surgeries, can increase intraocular pressure. If the patient's position is changed during the procedure, it may not be noticed, as the large robot obscures the patient. Elevating the patient's head or arm to make room for the robotic arm may lead to hyperabduction of the elevated arm and a potential neurologic injury.<sup>32</sup>

The team will need to adapt to the size of the robot in the operative suite and ensure that there is adequate space for

proper placement of the instruments and supplies needed for RAS, along with other instruments if the case converts to an open procedure. Rehearsed practice will allow the surgical team to refine their practice and evaluate what changes they will need to incorporate into their practice and communication patterns.<sup>33</sup> A second time-out occurs three to four hours after the start of RAS. This additional time-out is designed to assess patient safety and promote communication between the surgical, anesthesia, and nursing staff while addressing specialty concerns, such as proper patient positioning, that affect patients during robotic surgery.<sup>34</sup> In addition, use of a robotic surgical safety checklist may help reduce the risk of intraoperative complications.<sup>35</sup>

### Credentialing

The Society of Urologic Robotic Surgeons has published suggested recommendations for the safe implementation and credentialing of RARP at an institution. It stresses the need for a centralized certification authority that would not be the robotic industry. This authority would be responsible for identifying and promoting expert robotic surgeons who would be permitted to function as proctors for other physicians learning robotic skills. Among the other recommendations presented was the need to ensure that the novice urologist would have three to five cases proctored for review by the healthcare organization's credentialing committee. The credentialing committee would develop written guidelines to reduce liability exposure for the proctor as well as address informed consent. This process would include notifying the patient regarding the role of the proctor during the surgery. The organization further recommended that evaluation of the robotic surgeon be an ongoing process and that failure to perform at a satisfactory level would require a recommendation for further education or preceptoring.<sup>8</sup>

Lenihan describes competency-based credentialing for robotic surgery at Tacoma General Hospital. Outcome standards were developed that include review of total operative time, estimated blood loss, and major robotic complications such as injury or conversion to an open case. If the surgeon's performance does not meet the organization's established outcome standards, the Robotics Peer Review Committee reviews the surgeon's performance. Options to improve skills can be offered, such as working with a proctor on each case, obtaining advanced training, practicing on the simulator, continuing to do only basic cases, or referring cases to a more experienced surgeon. Use of simulators can be factored into competency evaluation or annual review of skills to document proficiency. If a case falls out due to a competency issue, the committee can recommend focused reviews, additional training, having an experienced robotic surgeon review all the cases, having a proctor in on every case, or limiting privileges.<sup>2</sup>

A robust credentialing process requires that an ongoing quality outcomes process be in place. Literature supports the need to study patient outcomes and the cost-effectiveness of using a robotic technique versus another modality. For radical prostatectomies, most of which are done robotically, oncologic outcomes and improved complication rates have not been proved.<sup>36</sup> Outcomes to be measured may include blood loss, complication rates, hospital lengths of stay, operating times, postoperative pain, and time to return to activities of daily living.<sup>30</sup>

Brown University Women and Infants' Hospital's Robotics Surgery Peer Review Committee consists of robotic surgeons and quality, risk management, and infection control professionals. This committee reviews the following cases: any conversion to open surgery, any patient seen in the emergency department within two weeks of surgery, any case referred for

review by risk management or any member of the surgical or clinical team, and all 20 cases of a surgeon in provisional status seeking advancement to full privileges.<sup>37</sup>

Martino et al. at Lehigh Valley Health Network studied 2,554 patients who underwent a hysterectomy between January 2008 and December 2012. Women undergoing robotic-assisted hysterectomy to treat benign disease had fewer readmissions within 30 days, less estimated blood loss, shorter lengths of stay, and a cost savings related to those readmissions when compared with laparoscopic, abdominal, and vaginal approaches. More prospective studies are recommended for all the surgical modalities so that surgeons can evaluate the outcome of robotic surgery and the benefit, or lack thereof, to the patient.<sup>38</sup>

### Patient Disclosure

Specific informed consent considerations will need to be addressed with an RAS program. Patients need to know more than just the general risks, benefits, and alternatives that are associated with the procedure. The risk of robot malfunction and the readiness to implement a contingency plan, such as converting to an open procedure, can also be addressed in the informed consent discussion. Surgeons will need to spend time with the patient explaining the pros and cons of selecting robotic surgery over other modalities.<sup>13,34</sup>

Plaintiff's attorneys are alleging insufficient training and credentialing against the hospitals in medical malpractice litigation. Surgeons may be charged with failing to obtain proper informed consent even if they have disclosed surgical risk but have not disclosed the surgeon's robotic training and where they are on the learning curve. The argument presented is that had the patient known that the surgeon lacked experience in robotic surgery, the patient would not have elected to have the procedure or would have selected a more experienced surgeon.<sup>39</sup>

## A PENNSYLVANIA HOSPITAL'S EXPERIENCE

Francine Miranda, director of OB/GYN quality and performance improvement at Lehigh Valley Hospital (LVH) and Authority editorial board member, shared in a telephone interview on May 22, 2014, the highlights of her organization's robotics program.<sup>40</sup> LVH implemented a robotics program in 2008 and currently has three robotic surgical systems. LVH performs between 800 and 900 RASs per year and has performed over 3,000 procedures since 2008.

Miranda stated that LVH adheres to a team approach and that training is a key component of the program. All members of the robotics team receive coordinated and intense training. The team recently attended the Fundamentals of Robotic Gynecologic Surgery Consensus Committee meeting. She reported that what is clear is that there is much discussion among the various surgical disciplines and that this group is working on coming to a consensus on generalized training and credentialing standards for all organizations to follow. LVH currently utilizes RAS in general surgery, urology, benign gynecology, gynecologic oncology, urogynecology, thoracic, colorectal, and surgical oncology procedures. Simulator training at LVH is part of the curriculum. The team also performs drills for all types of emergency situations, including converting to an open procedure. LVH utilized taped vignettes that show the correct and incorrect ways to handle emergency situations.

In regard to credentialing and privileging, every surgeon has to perform at least 25 cases—of which at least three to five are proctored by an experienced robotic privileged surgeon—before advancing to full privileges. Each physician has a scorecard that the quality/performance improvement department prepares. Indicators such as number of surgeries performed and complications are reviewed. In



addition, 100% of benign gynecologic, gynecologic oncology, and urogynecologic robotic cases are reviewed by Miranda's quality/performance improvement staff. She stated that not all organizations are able to do this, but she feels that by doing this, her organization knows exactly what issues need to be changed in order to improve practice. Miranda noted that the more proficient a surgeon becomes, the better outcomes he or she sees.

Miranda stated that the team also does an additional time-out at four hours, as they know that a prolonged operative time along with the position of the patient can lead to complications. During this second time-out, the surgeon, anesthesiologist, and entire OR staff review patient safety issues, including patient positioning and the need for additional antibiotics.

LVH has updated its gynecology/urogynecology and gynecology oncology hysterectomy/other procedures consent forms to address potential risks specifically

related to robotic surgery, such as nerve damage, lymphedema, facial swelling, and ear problems (LVH's gynecology oncology hysterectomy/other procedures form is available in the online version of this article). In addition, LVH educates the community on robotic surgery. Every year, the organization sponsors the Robotic Olympics, at which time it takes its robotic simulator out into the community and lets the general public get a chance to operate the robotic simulator.

**CONCLUSION**

RAS is rapidly being deployed in hospitals throughout the United States and abroad. The growth of robotics programs has outpaced the industry's ability to develop and implement clear, consistent standards for training and credentialing. Research is needed that evaluates outcomes, patient benefits, the ergonomics for the surgeon, and the costs related to RAS. The need for standardized training, consistent patient education, and outcome registries

with accurate data that surgeons can use to compare RAS with other surgical modalities is necessary.

Until clear, consistent standards have been established by the professional organizations, the responsibility rests with the hospital to develop training programs that adequately prepare the physician and the entire surgical team to safely perform robotic procedures. A documented steep learning curve for surgeons as they master the use of robotic systems may challenge hospitals to ensure that training and credentialing are done in a fashion that is both medically sound and consistent. Staff may utilize various forms of training, which may include simulation training, so that they are prepared to handle any emergency situation that may occur during a robotic procedure. In addition, the hospital can ensure optimum outcomes for patients and that appropriate policies and procedures are in place for training, privileging and credentialing, proctoring, informed consent, and equipment maintenance.

**NOTES**

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