Flight plan for robotic surgery credentialing: New AAGL guidelines

By emulating the aviation industry, the ObGyn specialty can establish credentialing standards likely to enhance, rather than hinder, patient safety

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IN THIS ARTICLE

The AAGL, formerly the American Association of Gynecologic Laparoscopists, has approved the first-ever set of privileging and credentialing guidelines for robotic surgery.[1]

Why has this prestigious minimally invasive surgery organization done that?

Maybe you've seen the Internet and TV ads and billboard trucks driving outside of many major medical society meetings recently, advertising "1-800-BAD-Robot."[2] You also are probably aware of recent articles in the headlines of national periodicals like the *Wall Street Journal* claiming that robotic surgery can be harmful.[3]

And yet, robotic gynecologic surgery has grown at an unprecedented rate since its approval by the US Food and Drug Administration (FDA) in April 2005. Recent data from the Nationwide Inpatient Sample from the Agency for Healthcare Research and Quality indicate that robot-assisted hysterectomies have increased at a dramatic rate.[4] In a recent study of the FDA's MAUDE (Manufacturer and User Facility Device Experience) database, investigators found that more than 30% of injuries during robotic surgery are related to operator error or robot failure, but the majority of problems are not associated with the technology.[5]

In this article, I use the aviation industry as an example of a sector that has gotten safety right. By emulating many of its standards, our specialty can make great strides toward patient safety and improved outcomes. I also outline the main points of the new AAGL guidelines and the rationale behind them.[1] See, for example, the summary box on page 46.

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A "shining example"

The robot clearly is an enabling technology. With its high-definition 3D vision and scaled motion with wristed instruments, surgeons are more comfortable performing many complex gynecologic procedures that previously would have required open surgery to safely accomplish … but the da Vinci Robot does not make a poor surgeon a great surgeon.

Hospitals now are being sued for allowing surgeons to perform robotic surgery on patients without documenting adequate surgeon training or providing consistent oversight.[6] This new technology has outpaced the

ability of hospital medical staffs to establish practice guidelines and rules to ensure patient safety.

The aviation industry is a shining example of a highly reliable industry. Each day, thousands of commercial aircraft fly all over the world with amazing safety. Most of the time, the pilot and copilot have never flown together. However, each crew member knows his or her role precisely and clearly understands what is expected. Crew members must meet standards that transcend all airlines and all aircraft.[7] They all practice communication and undergo standardized training, including simulation, prior to taking off with live passengers on board.

In addition, all pilots must demonstrate their proficiency and competence on a regular basis—by exhibiting actual safe flight performance (over multiple takeoffs and landings) and undergoing check rides with flight examiners and practicing routine and emergency procedures on flight simulators. Airline passengers have come to expect that all pilots are equally proficient and safe. Shouldn't patients be able to expect the same from their surgeons and hospitals? And yet there is no national or local organization that ensures that all surgeons are equally safe in the operating room. That responsibility is too often left up to the courts.

Three requirements of robotic credentialing

In 2008, the MultiCare Health System in the Pacific Northwest adopted a unique system of robotic credentialing that was based on the aviation model.[8] This model has three main components, which are identical to the guidelines imposed on pilots:

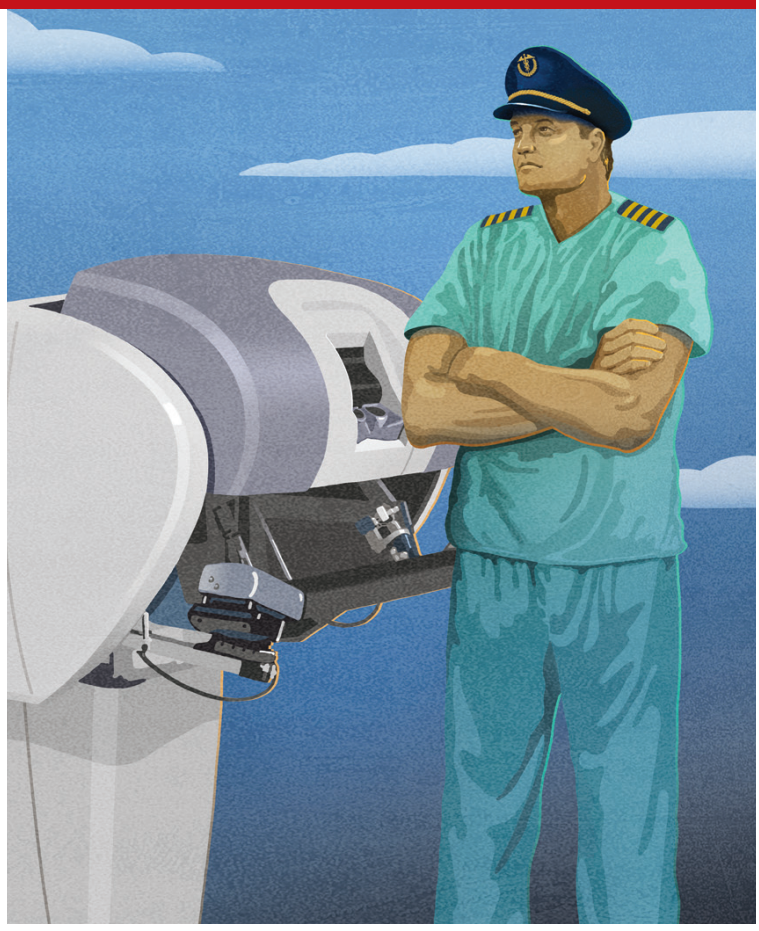
1. Surgeons selected for training should be likely to be successful in performing robotic surgeries safely and efficiently.
2. Practice makes perfect. There should be a minimum number of procedures performed on a regular basis to ensure that the surgeon maintains his or her psychomotor (hand-eye coordination) skills. The aviation world calls this concept "currency."
3. Surgeons, like pilots, should be required to demonstrate their competency in operating the robot on a regular basis.

Adoption of these tried-and-true safety principles would ensure that hospitals exercise their responsibility to protect patients who undergo robotic surgeries in their systems.

The AAGL's Robotics Special Interest Group, formed in 2010, is now the largest special interest group in the organization. The group was initially tasked to develop evidence-based guidelines for robotic surgery training and credentialing. Using the aviation industry's model, the group developed a basic template of robotic surgery credentialing and privileging guidelines that can be used anywhere in the world. This proposal is not meant to be a standard-of-care definition; rather, it is intended simply as a starting point.

Initial training involves a long learning curve

There is a long learning curve for surgeons to become competent in robotic surgery. In initial studies of experienced advanced



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There is no national or local organization that ensures that all surgeons perform equally safely in the operating room

ILLUSTRATION: MICHAEL GIBBS FOR OBG MANAGEMENT

Key components of new AAGL robotic surgery credentialing and privileging guidelines[1]

Initial training

- Train only surgeons who have an adequate case volume to get through the learning curve. Recommended: at least 20 major cases per year.
- Current training pathways include computer-based learning, case observations, pig labs, simulation, and proctored cases. More intense validated simulation training could replace pig labs.
- Surgeons should initially perform only simple, basic procedures with surgeon first-assists until they develop the necessary skills to safely operate the robotic console and start performing more complex cases.

Annual currency

- Surgeons should perform at least 20 major cases per year, with at least one case every 8 weeks.
- If surgeons operate less frequently, proficiency should be verified on a simulator before operation on a live patient.

Annual recertification

- All surgeons should demonstrate competency annually on a simulator, regardless of case volume.

laparoscopic surgeons, investigators found that learning curves could involve 50 cases or more.[9,10] In a recent study of gynecologic oncologists and urogynecologists at the Mayo Clinic, researchers found that it took 91 cases for experienced surgeons to become proficient on the robot.[11]

ObGyns in the United States are doing fewer hysterectomies than they used to.[12] Many surgeons now perform fewer than 10 hysterectomies per year. These surgeons clearly have worse outcomes than surgeons who operate more frequently.[13–15] Therefore, **these new guidelines suggest that hospitals should choose to train only surgeons who have a case volume that will allow them to get through their learning curve in a short time and continue to have enough surgeries to maintain their skills.** These guidelines recommend that surgeons who are candidates for robotic surgery training already perform a minimum of 20 major gynecologic operations per year.

It is important to learn to walk before you run. New student pilots start out with single-engine propeller planes before graduating to multi-engine props, jets, and commercial aircraft. Similarly, new medical students start out with easy surgical tasks before training for more complex procedures. This approach seems like common sense, although many surgeons may feel that, after orienting on the robot, they can start doing complex cases right away, as the robot enables them to do better and more precise surgery. Nothing could be further from the truth.

It is very important that new robotic surgeons start with easy, basic cases to completely familiarize themselves with the operation of the robot console before attempting more complex and difficult cases.

There is no absolute number of cases that ensures competency with the robot; the number depends on the surgeon's case load, surgical prowess, and psychomotor skills. A surgeon should be restricted to simple cases initially, and should have an experienced robot-credentialed surgeon operating with him or her during this initial learning period.

Practice makes perfect

Musicians will tell you that the more often you practice, the more skilled you become. This is true for anyone whose job requires special training. It would be naïve to assume that surgeons can maintain optimal skills for robotic surgery by performing only a few cases each year.

Psychomotor skill degradation has been explored in relation to various surgical skills. The more complex the skill, the more likely that skill set will deteriorate without use. In recent studies, investigators have shown that robotic surgery skills begin to decline significantly after only 2 weeks of inactivity, and that skills continue to degrade without use.[16,17]

Based on this information, **the currency requirement for surgeons to maintain privileges was set at 20 cases per year—**fewer than two cases per month. Although the members of the Robotics Special Interest Group strongly agree that

maintenance of privileges should not be based entirely on an arbitrary currency number, as Tracy and colleagues also argue in a recent publication,[18] it is clear that frequent performance of robotic surgery by high-volume surgeons clearly is more efficient and safer, with lower total operative times and complication rates, than robotic surgery performed by lower-volume surgeons.[8]

Currency is a well-accepted safety standard in aviation, and pilots know the importance of frequent practice and repetition in the cockpit under real-world conditions.

Ensure annual competency

Although a pilot must accomplish a minimum number of flying hours each year to maintain certification, this does not ensure that passengers will be safe. Pilots also must prove their competence by undergoing periodic check rides and demonstrating their skills on flight simulators.

Surgeons also can use these models to verify competency. Proctors who are independently certified by the FDA or another government agency as examiners could observe and evaluate surgeons performing robotic surgery using standardized checklists and grading forms. If done locally, care must be taken to assure standardization, as local hospital politics could interfere.

The only other methods currently available to verify surgeon competency are to demonstrate proficiency on simulation and to review outcomes data, looking for outliers in important areas such as complications, robotic console times, total operative times, length of stay, etc.

Simulation offers a standardized, independent method to monitor competency.[19] A passing test score on a robotic simulator exercise could be a way for a surgeon to prove his or her competency. Basic robotic skills such as camera control and clutching, energy use, and sewing and needle control can be practiced on a robotic simulator.

Virtual cases such as hysterectomy and myomectomy are not yet available on the simulator, nor are cases involving typical complications. These are being developed, however, and will be available shortly.

Several gynecologic resident and fellowship training programs are using simulation to train novice surgeons, and some community hospitals are using simulation as an annual requirement for all practicing surgeons to demonstrate proficiency, similar to pilots.[8] Some newer validated training protocols require a surgeon to demonstrate mastery of a particular robotic skill by achieving passing scores at least five times, with at least two consecutive passing scores.[20,21]

As simulators evolve, they will continue to be incorporated into training, used for surgeon warm-up before surgery, as refreshers for surgeons after a period of robotic inactivity, and for annual recertification.

A word to the wise

If hospital departments really want to ensure that they are doing all that they can to make robotic surgeries safe for their patients, they

Instant Poll

For credentialing and privileging of robotic gynecologic surgery, do you agree that the following points are essential components of the process?

- Surgeons should be selected for training who are most likely to be successful in performing robotic surgeries safely and efficiently.
- There should be a minimum number of procedures performed on a regular basis to ensure that the surgeon maintains his or her psychomotor (hand-eye coordination) skills.
- Surgeons, like pilots, should be required to demonstrate their competency in operating the robot on a regular basis.

Answer:

a. Yes, I agree.

b. No, I believe this approach is too restrictive.

c. No, I believe this approach is not restrictive enough.

To vote, please visit **obgmanagement.com** and look for "Quick Poll" on the right side of the homepage.

When robotic surgery leads to legal trouble

A recent medical malpractice case highlights the importance of having guidelines in place to protect patients. In Bremerton, Washington, in 2008,[1] a urologist performed his first nonproctored robotic prostatectomy. The challenging and difficult procedure took more than 13 hours; he converted to an open procedure after 7 hours. The patient developed significant postoperative complications and died.[1]

In the litigation that followed, the surgeon was sued for negligence and for failing to disclose that this was his first solo robot-assisted surgery. The surgeon settled, as did the hospital, which was sued for not supervising the surgeon and failing to ensure that he could use the robot safely. The family also sued Intuitive Surgical, the manufacturer of the da Vinci Robot, for failing to provide adequate training to the surgeon.[2]

The jury ruled in favor of the manufacturer, stating that the verification of adequate surgeon training was the responsibility of the hospital and specialty medical societies, not the industry.

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Some surgeons may believe it is unfair to restrict their ability to perform surgery just because of low volumes or a failure to demonstrate mastery on a simulator

will utilize the recent guidelines approved by AAGL. In order for these guidelines to work, hospital systems need to commit resources for medical staff oversight, including a robotics peer-review committee with a physician chairman and adequate medical staff support to monitor physicians and manage those who cannot meet these goals.

There clearly will be push-back from surgeons who feel that it is unfair to restrict their ability to perform surgery just because their volumes are low or they can't master the simulation exercises. However, in the final analysis, would we want the airlines to employ pilots who fly only a couple of times a year or who can't master the required simulation skills to safely operate a commercial passenger jet?

The important question is, what is our focus? Is it to be "fair" to all surgeons, or is it to provide the best and safest outcomes for our patients? As surgeons, we each need to remember the oath we took when we became physicians to "First, do no harm." By following these new AAGL robotic surgery guidelines, we will reassure our patients that we, as physicians, do take that oath seriously.

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