Robotic Surgery

Question
Our hospital purchased a robotic surgical system (RSS). We’re looking forward to using it for surgical procedures, but we’re also concerned about potential risks. What should we do to prepare?

Answer
When dealing with any new technology, including an RSS, it is always best to assess and examine the risks proactively, rather than after an adverse event. Currently, no standard consensus has been reached on appropriate training and credentialing for robotic surgery. Rather, healthcare organizations are responsible for determining their own standards for clinical training, proctoring and oversight, competency, and credentialing.

The Agency for Healthcare Research and Quality (AHRQ) recommends that, until well-validated credentialing and training models can be developed, hospitals should require a basic robotic safety curriculum for surgeons performing robotic surgery. AHRQ also recommends that hospitals require surgeons to provide case logs or undergo case proctoring before receiving robotic privileges.

If you plan to perform robotic surgery, you and your surgical team should consider — at a minimum — these basic risk strategies.

- For each type of procedure you plan to perform, document all physician and staff training and ongoing competency specific to the RSS. Because training from device manufacturers might not prove adequate, consider supplementing the manufacturer’s training and arranging mentorships.
• Work with your anesthesia team to develop screening criteria to identify the best candidates for robotic procedures. Criteria should specify exclusions for patients who might be at higher risk for surgical complications, nerve injuries, or other complications.

• For each potential candidate for a robotic procedure, work with the anesthesiologist to evaluate the patient’s medical history and physical exam to identify the risks and benefits of robotic surgery. Choose the conventional approach when indicated based on risk.

• Engage the patient in a thorough informed consent discussion, including a review of the risks, benefits, and alternative treatment options. Document the pertinent details of the informed consent discussion in the patient’s health record. The anesthesiologist also should conduct and document an informed consent discussion with the patient.

• Establish a contingency plan for converting from a robotic procedure to a laparoscopic or open procedure. Be cognizant of, and plan for, any risks that may occur during such a conversion.

• Document in the patient’s health record any special actions taken before, during, or after the procedure that specifically minimized the risks associated with robotic surgery (e.g., patient positioning or special monitoring).

**Resources**

• AUA BLUS Handbook of Laparoscopic and Robotic Fundamentals (American Urological Association)

• Computer-Assisted Surgical Systems (U.S. Food and Drug Administration)

• Guidelines for Privileging for Robotic-Assisted Gynecologic Laparoscopy (American Association of Gynecologic Laparoscopists)

• Is It Time for Safeguards in the Adoption of Robotic Surgery? (Journal of the American Medical Association)

• Rise of the Machines: Robotic Surgery, Patient Safety, and Liability (MedPro Group)

• Risk Q&A: Performing New Procedures and Adopting New Technologies (MedPro Group)
• Robotic Surgery (Urologic) Standard Operating Procedure (SOP) (American Urological Association)

• Robotic Surgery in Gynecology (American College of Obstetricians and Gynecologists)

• Robotic Surgery: Risks vs. Rewards (Agency for Healthcare Research and Quality)

• SAGES/MIRA Consensus Document on Robotic Surgery (Society of American Gastrointestinal and Endoscopic Surgeons and the Minimally Invasive Robotic Association)

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This document should not be construed as medical or legal advice. Because the facts applicable to your situation may vary, or the laws applicable in your jurisdiction may differ, please contact your attorney or other professional advisors if you have any questions related to your legal or medical obligations or rights, state or federal laws, contract interpretation, or other legal questions.

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