



An advisory on safety & quality issues

Issue Three

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Potential risks of robotic surgery

Issue:

Robotic surgery (also called minimally invasive surgery, laparoscopic surgery or a closed procedure) has seen exponential growth since its introduction into clinical practice and approval by the Food and Drug Administration (FDA) in 2000.¹ It also is becoming more prevalent across a broad range of common surgical procedures.¹ However, it also has potential risks. ECRI Institute included robotic surgery in its Top 10 Health Technology Hazards for 2020 – #5 Unproven Surgical Robotic Procedures May Put Patients at Risk. In addition, from 2017 through 2020, The Joint Commission received 33 reports to our Sentinel Event database involving robotic surgeries – all occurring in hospital settings. Of the 33 reports, 20 were related to unintended retained foreign objects (URFOs), five resulted in operative or postoperative complications, five involved wrong site surgery, one was a wrong procedure, and one involved a surgical fire.

Risks of robotic surgery can be categorized into those directly related to the use of the robotic system and the general risks of the operative procedure. According to a recent consensus statement, robotic telesurgery, in which the surgeon may be located at some distance from the patient, poses unique risks. For example, precise control of the robot depends on the quality of the data connection between the surgeon's console and the operating room robot. Issues pertaining to the quality and maintenance of such data connections may be beyond the control of the surgical team, but still represent a risk management challenge of which the organization must be mindful. All mechanical and electronic devices are subject to failure; surgical robots are no exception. Current systems are designed with features intended to minimize the potential for harm to the patient. Such features include system redundancy, fault tolerance, just-in-time maintenance, and system alerting.

To ensure safe surgical practice of new technologies, organizations are required to have specific credentialing policies in place.¹ In 2013, a small scale FDA survey indicated a lack of standardization in the credentialing process at the respective institutions.² A recent study of 42 U.S. hospital credentialing policies related to robotic surgery indicated inadequate guidelines to ensure surgeon proficiency. The creation and implementation of standardized credentialing guidelines was recommended to optimize patient safety outcomes.³

The FDA recommends that physicians, hospitals and facilities that use RAS (robotically assisted surgery) devices should ensure that proper training is completed and that surgeons have appropriate credentials to perform surgical procedures with these devices. Device users should ensure they maintain their credentialing. Hospitals and surgical facilities also should ensure that other surgical staff who use these devices complete proper training. If an organization suspects a problem or complications associated with the use of RAS devices, the FDA encourages filing a voluntary report through [MedWatch, the FDA Safety Information and Adverse Event Reporting program](#).²

The benefits of performing robotic surgery – when performed by a trained, competent and certified provider – include shorter recovery times, less blood loss, less chance of infection, and less scarring for the patient; as well as superior visualization and instrument range of motion for the provider. Organizations that invest in the equipment for robotic surgery should take actions to ensure that patients who decide on robotic surgery experience these benefits, as well as optimal outcomes.

(Cont.)



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The information in this publication is derived from actual events that occur in health care.

Safety Actions to Consider:

Health care institutions that employ surgical robots in clinical practice should:

- Develop and follow credentialing guidelines that are consistent with expert consensus for this rapidly evolving technology.
- Begin a focused and ongoing professional performance evaluation with specific triggers and measures related to robotic surgery.
- Ensure that staff are competent, trained, and credentialed and privileged to perform robotic surgery.
- Provide patient assessment to ensure that the planned procedure is appropriate for the patient.
- Improve OR team communication. For robotic surgery, the OR team must communicate in different ways, since the physician conducting the surgery is typically positioned at a console away from the operating table, and the OR team members cannot see what the physician sees at the console.
- Standardize processes in the OR, including the count process. The count process should:
 - Take into account sponges, needles and other supplies used (such as bulbs).
 - Include a check of tools and tool tips to ensure that they are secure and not broken, prior to ending the procedure.
- Monitor robotic procedures to ascertain the number of: URFOs discovered and number of counts that are off; and blood transfusions required. These are good indicators of the skill (or lack of skill) of the provider.
- Maintain robust quality review process(es) in which all cases are evaluated consistently and comprehensively to identify opportunities for improvement in patient safety for this new and evolving technology.

Resources:

1. Stefanidis D, Huffman EM, Collins JW, et al. "Expert Consensus Recommendations for Robotic Surgery Credentialing." *Annals of Surgery*, Nov. 17, 2020. doi: 10.1097/SLA.0000000000004531. Online ahead of print.
2. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH) Office of Surveillance and Biometrics (OSB) Medical Product Safety Network (MedSun) Small Sample Survey – Final Report Topic: da Vinci Surgical System. November 2013.
3. Huffman EM, Rosen SA, Levy JS, et al. [Are Current Credentialing Requirements for Robotic Surgery Adequate to Ensure Surgeon Proficiency?](#) *Surgical Endoscopy*, 2020.

Other resources:

- Society of Gastrointestinal and Endoscopic Surgeons: [A Consensus Document on Robotic Surgery](#). D.M. Herron, M.D. (chair), SAGES-Minimally Invasive Robotic Surgery (MIRA) Robotic Surgery Consensus Group
- The American Congress of Obstetricians and Gynecologists: [Statement on Robotic Surgery by ACOG President James T. Breeden, M.D.](#), March 14, 2013
- International Society for Minimally Invasive Cardiothoracic Surgery: [Robotic-Assisted Surgery: Proposed Credentialing Guidelines](#). Faiz Yahya Bhora, et al. *Innovation, Technologies, and Techniques in Cardiothoracic and Cardiovascular/Vascular Surgery*, May 2014
- *The Journal of Urology*: Best Practices for Robotic Surgery Training and Credentialing. Jason Y. Lee, et al. Volume 185, 1191-1197, April 2011
- *Annals of Surgery*: [Robotic Surgical Training in an Academic Institution](#). W. Randolph Chitwood, Jr., M.D., et al. 234(4)475-486, October 2001
- *NextMed*: [Fundamentals of Robotic Surgery: Outcomes Measures and Curriculum Development](#). Roger Smith, Ph.D., et al. February 20-23, 2013
- The Joint Commission: [Preventing unintended retained foreign objects](#). *Sentinel Event Alert* #51, October 17, 2013
- ECRI Institute: [Retained Foreign Objects: It's Not the Robot's Fault](#). *Patient Safety E-Alerts*, May 31, 2012

Note: This is not an all-inclusive list.



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