Potential risks of robotic surgery

Issue:
Robotic surgery (also called minimally invasive surgery, laparoscopic surgery or a closed procedure) is becoming more prevalent, especially for gynecologic or urologic procedures, and The Joint Commission is receiving increasing numbers of reports to our Sentinel Event database associated with robotic procedures. Of 34 reports that affected 36 patients, 27 are related to unintended retained foreign objects (URFOs), and seven are related to operative or postoperative complications. The complications are usually due to hemorrhage caused by laceration. Other reported complications include injury to surrounding tissue, and serious injury (including blindness) related to prolonged surgery. These complications are consistent with the risks of this new technology as reported in current literature. Of the seven operative/postoperative complication reports, two resulted in death. The two deaths were related to excessive blood loss (one report was also related to delay in treatment), which is consistent with current literature for most serious events involving robotic surgery.

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.

Robotic surgery is a relatively new technology that requires advanced operator skill not usually learned in residency. 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, and are not harmed.

Safety Actions to Consider:
Health care institutions that employ surgical robots in clinical practice should:
- Develop and follow credentialing guidelines.
- 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.

Legal disclaimer: This material is meant as an information piece only; it is not a standard or a Sentinel Event Alert. The intent of Quick Safety is to raise awareness and to be helpful to Joint Commission-accredited organizations. The information in this publication is derived from actual events that occur in health care.

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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:

- The American Congress of Obstetricians and Gynecologists: Statement on Robotic Surgery by ACOG President James T. Breeden, M.D., March 14, 2013
- The International Society for Minimally Invasive Cardiothoracic Surgery: Robotic-Assisted Surgery: Proposed Credentialing Guidelines
- The Joint Commission: Preventing unintended retained foreign objects, Sentinel Event Alert #51, October 17, 2013

Note: This is not an all-inclusive list.