



American Urological Association

Education and Research, Inc.

STANDARD OPERATING PRACTICES (SOP'S) FOR UROLOGIC ROBOTIC SURGERY

1. PURPOSE:

Computer assisted surgery using remote tele-presence manipulators is widely referred to as robot assisted or robotic surgery. Since the term is used extensively in the press as well as medical journals, the term “robotic surgery” will be used in this document.

The purpose of this document is to formulate standard operating practices for institutions to use during the process of credentialing of urologists for privileges to perform robotic surgery. The robotic approach involves the application of robotic technology primarily during laparoscopic surgery. Requirements for granting privileges for laparoscopy and individual surgical procedures will not be included in these standard operating practices. Institutions must continue to evaluate evidence of the urologist’s competence for individual surgical procedures, since the surgeon must have the knowledge and the skills to perform the procedure using the appropriate approach: open, traditional laparoscopy (in some cases), or robotic.

The standard operating practices are primarily intended for urologists who are seeking privileges after January 2010.

2. RESPONSIBILITY:

Credentialing of physicians and granting privileges to perform surgeries is the responsibility of the individual institution. The chief of medical staff/medical staff offices/committees/operating room committee or other qualified individual or committee may formulate requirements for credentialing for robotic surgery. Credentialing for individual urologic procedures should involve the chief of the urology service or the clinical supervisor of the urologist.

3. DEFINITIONS:

Standard Operating Practices: A related set of generalizations derived from past experience arranged in a coherent structure to facilitate appropriate responses to specific situations. This set of standard operating practices has a broad base of acceptance among experts in the field.

Competency- The state or quality of being adequately or well qualified to perform up to defined expectations.

Must/shall- mandatory recommendation

Should: highly desirable recommendation

May/could: optional recommendation

Credentials: Documented evidence of licensure, education, training, experience or other qualifications.

4. MINIMUM REQUIREMENTS FOR GRANTING UROLOGIC ROBOTIC PRIVILEGES:

Part 4 A and Part B or C mandatory.

A. Training in Urology:

- i) Completion of an Accreditation Council for Graduate Medical Education (ACGME) accredited urology residency program and American Board of Urology eligibility or certification.
- ii) Training in urology that is recognized as equivalent to item i, by the institution may be adequate.

B. Robotic Surgical Training in Residency and/or Fellowship Programs:

- i) Robotic surgery is now included in the American Urological Association's (AUA) Core Curriculum for urology residencies. Several residencies in urology have adequate training in robotic surgery. The program director must provide credentials to document satisfactory training and confirm competence of the urologist to independently perform robotic surgery. This must be accompanied by evidence of experience with a minimum of 20 robotic cases during residency. Fellowship with training in robotic urologic surgery would also be acceptable. The fellowship director should provide credentials for evidence of competence in urologic robotic surgery, as described in Part 4Bi indicating a minimum of 20 robotic cases completed during fellowship training.

c. No Residency or Fellowship Training in Urologic Robotic Surgery

Several practicing urologists have had no formal training in robotic surgery as described in Part 4B. These physicians should complete a structured training program before being granted privileges. The curriculum/requirement may include the following:

- i) Completion of Intuitive Surgical's on-line Training Module at <http://www.intuitivesurgical.com/clinical/producttraining/index.aspx> & Review of the **Patient Preparation & Operating Room Setup for Laparoscopic and Robotic Surgery Chapter in the "Urologic Robotic Surgery Curriculum"**
- ii) Have granted privileges for the surgery via an open approach
- iii) Observation of robotic surgeries performed by an experienced robotic surgeon sufficient for familiarity of the differences between robotic and open approaches with written confirmation that the procedure was performed safely.
- iv) Hands-on experience using the surgical robotic system with instruction by an instructor. This may include,
 - a. System set-up and docking
 - b. Skills training using inanimate models
 - c. Animal lab experience when available
 - d. Familiarity of robotic setup and technique for either or both upper (renal) and lower tract (prostate) procedures depending on which the surgeon performs.
- v) Proctoring and written confirmation by the proctor that the surgeon is competent to utilize the robotic platform independently of a proctor.
- vi) Assistance by another urologist until the urologist is comfortable operating independently.
- vii) Presence of appropriate biomedical support until the urologist and the OR team are comfortable working with the robotic platform.
- viii) Review of surgical outcomes after the surgeon's initial experience by an unbiased group of peers at the same institution.

5. MAINTENANCE OF PRIVILEGES:

- A. **Provisional Privileges:** Provisional privileges may be appropriate for a surgeon's initial robotic surgical experience. The period of time and number of cases before unrestricted privileges may be granted may be determined by the medical staff committee, chief of service or appropriate committee.
- B. Once unrestricted privileges for robotic surgery have been granted the physician may perform surgeries different from the initial type of robotic surgery for which he/she was granted privileges provided: The urologist has privileges to perform the specific type of surgery via an open or laparoscopic approach without robotic assistance.
- C. **Monitoring of privileges:** After the initial privileges are granted, the surgeon's clinical performance, surgical volume and complications may be monitored by an appropriate peer review to ensure adequate surgical outcome and volume in robotic surgery.
- D. **Continuing Medical Education:** Adequate evidence of CME activity in urological robotic surgery may be beneficial.

- E. Denial of privileges: Institutions that deny, restrict, suspend or modify privileges granted to a physician should have written regulations to apply the rules of the institution and should have an unbiased mechanism for appeal with the inclusion of the opinion of experts in the field. An expert panel with three unbiased members may be formed to make appropriate recommendations to the institution. One expert may be recommended by the physician, the second by the institution and the third who is jointly chosen by the two experts.

6. INSTITUTIONAL SUPPORT:

Successful establishment of a urologic robotic program requires a commitment from the institution for resources including dedicated operating rooms, nursing team, a robotic surgical coordinator, regular maintenance, disposable instruments and training material.

Acknowledgements: Definitions and format adapted from “A consensus Document on Robotic Surgery” by the SAGES-MIRA Robotic Surgery Consensus Group.

Standard Operating Practices for Proctors during Robotic Surgery:

Proctors should have completed at least 50 robotic surgical cases overall with at least 20 cases similar to the one that is being proctored.

Informed consent must be obtained from the patient, about the presence and responsibility of the proctor.

Granting temporary privileges to the proctor to assist during surgery should that be required, may be considered.

The role and responsibility of the proctor should be clearly defined including his/her responsibility in the event of a complication.

The proctor should be present in the operating room for the entire surgery.

Legal liability of the proctor should be minimized after consulting with the local legal counsel and the institution must indemnify the proctor against possible legal action.

Acknowledgement: Adapted from the Recommendations of the Society of Urologic Robotic Surgeons (SURS). Training, credentialing, proctoring and medicolegal risks of robotic urological surgery: recommendations of the society of urologic robotic surgeons. Zorn KC, Gautam G, Shalhav AL, et al, J Urol. 2009 Sep;182(3):1126-32.

APPENDIX 1

SAMPLE PROCTORING FORM

Name of the Surgeon:

Name of Proctor:

Date of Surgery/Proctoring:

Procedure Performed:

Patient's name:

Was the surgery performed for an appropriate indication: Yes/No.

If no, discuss _____

Was the pre-operative work-up adequate? Yes/No.

If no, discuss _____

Please rate the surgeon's knowledge of the surgical anatomy and the steps of the surgery?

Poor/Satisfactory/Excellent. Comments, if any _____

Please rate the surgical competence during this surgery, for his/her level of experience with robotics: Poor/Satisfactory/Excellent. Comments, if any _____

Does the surgeon require proctoring for his/her cases in future: Yes/ No.
If yes, for how many more cases would proctoring be required? _____

Comments: If any _____

Signature: _____ Date: _____

Name: _____

Address: _____ City _____ State _____ Zip _____ Phone: _____
