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Best Practices for Robotic Surgery Programs

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ABSTRACT

Background and Objectives: Robotic surgical programs are increasing in number. Efficient methods by which to monitor and evaluate robotic surgery teams are needed.

Methods: Best practices for an academic university medical center were created and instituted in 2009 and continue to the present. These practices have led to programmatic development that has resulted in a process that effectively monitors leadership team members; attending, resident, fellow, and staff training; credentialing; safety metrics; efficiency; and case volume recommendations.

Results: Guidelines for hospitals and robotic directors that can be applied to one's own robotic surgical services are included with examples of management of all aspects of a multispecialty robotic surgery program.

Conclusion: The use of these best practices will ensure a robotic surgery program that is successful and well positioned for a safe and productive environment for current clinical practice.

Key Words: Best practices, Credentialing, Robot, Robotic assistance, Robotic surgery.

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INTRODUCTION

It is timely now to investigate the process of best practices for robotic surgery programs as the technology matures. Academic liaisons from industry are extending their presence, and residency and fellowship programs are considering educational requirements. Independent of these forces, robotic program creation and sustainability should be described when engaging surgeons to perform minimally invasive procedures in all fields. Our objective was to document and demonstrate programmatic development methods for a robotic surgery program.

HISTORY OF THE DEVELOPMENT OF A ROBOTICS PROGRAM

Our core robotic program started with the purchase of the first robotic system in 2009 (da Vinci Si, Intuitive Surgical, Sunnyvale, California). Our Reproductive Endocrinology/Infertility service completed the first case in October 2009 and then Urology followed shortly, with Otorhinolaryngology (Ear, Nose and Throat, or ENT) soon thereafter. Three further robotic systems were installed (da Vinci Si and Sie in 2012 and Xi in 2015). Robotic-trained surgeons encompass the specialties of general surgery, colorectal surgery, ENT, pediatric urology, adult urology, thoracic surgery, surgical oncology, gynecology, reproductive endocrinology, urogynecology, and gynecologic oncology (**Figure 1**). The total number of robotic surgeons has increased each year to our current volume of 27 surgeons (**Figure 2**). An Assistant Director of Robotic Surgery Program position was added in 2014. On December 22, 2015, our program acquired the Flex System (Medrobotics, Boston, Massachusetts) to translate our robotic experience into leadership in the field for a new flexible robotic system that has been approved by the U.S. Food and Drug Administration (FDA) for ENT.

The overarching goal is to expand and examine the use of a variety of minimally invasive techniques: robotic surgery is one example. Minimally invasive surgery is no stranger to the controversy surrounding various approaches to surgical intervention. With the first human laparoscopic case in 1911,[1] various instruments were then developed to allow for examination of the peritoneal cavity with

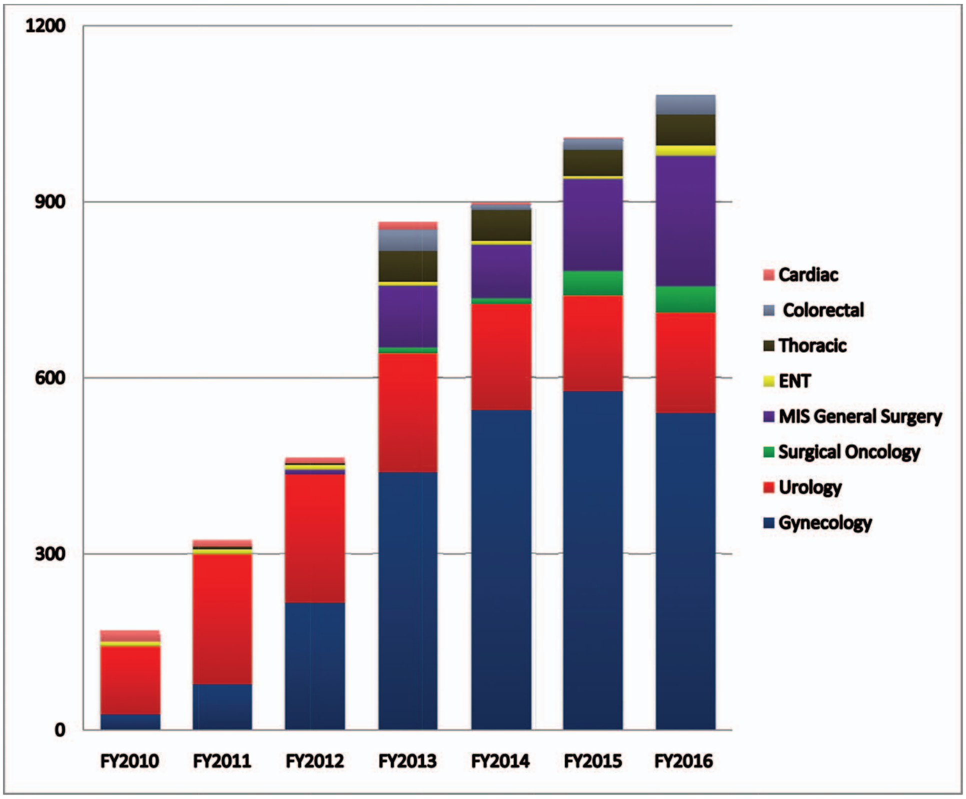

Figure 1. Case volume by specialty per fiscal year.

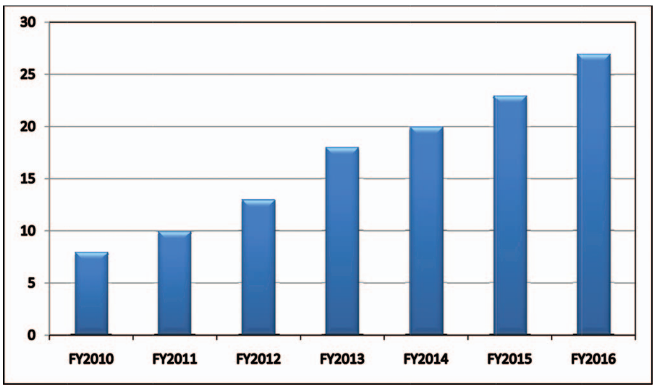

Figure 2. Number of robotic surgeons per fiscal year.

gynecologists increasing use in the 1960s and 1970s. Then, Dr. Kurt Semm, a pioneer in the field, performed the first laparoscopic appendectomy in 1983,[2] after which general surgeons expanded the use of the technique to multiple applications. The advantages of using a newly developed technology that will lead to improvements in patient care are often not realized until years or decades after the initial procedure is performed. It is fitting that gynecology and general surgery are again engaged in the examination of robotic surgery and its applications.

We present herein the experience of years of work with processes surrounding the development and implementation of a robotics program. The sharing of best practices will assist other institutions to develop their programs and to introduce additional robotic surgical devices and techniques. There are advantages and disadvantages to the scrutiny and training pathways for robotic surgery, but we can continue to modify these pathways. However, it is important to have a starting point for training, competency, and quality metrics at an institutional level.[3] The following description encompasses goals, safety standards, monitoring, credentialing, training methods, and documentation that can be built upon as we advance this technology.

GOALS AND VISION

Goals and a vision for the robotics program are critical first components and are essential for sustainability. The Penn State Hershey Robotics Program was envisioned as a structure that would provide unparalleled patient care in a multidisciplinary approach and was designed to advance the frontier of the use of robotic technology in multiple fields. As an academic institution, the goal is to have the experts teach others and to progress with new and innovative techniques through minimally invasive robotic surgery. Examples of strategic goals and objectives are provided and can be individualized to each institution.

STRATEGIC GOALS AND OBJECTIVES

- Become the primary referral center in the geographic area for both complex and routine robotic surgeries.
- Increase the number of minimally invasive surgeries performed.
- Support a collaborative approach between surgeons for complex cases.
- Maximize the expansion of women's health services.
- Be an integral part of educating the healthcare workforce of the future.
- Enhance patient satisfaction with surgical services, specifically robotics.
- Identify methods for advanced simulation training.
- Establish a collaboration (in our case with Penn State University, University Park, Pennsylvania, USA), for diversification of research endeavors (ie, engineering).
- Increase translational research.
- Inspire innovation.

LEADERSHIP TEAM

The development of a leadership team is critical to the success of a robotics program (**Table 1**). The individuals involved in this team should include a Director of Robotic Surgical Services and can include an Assistant Robotics Director as indicated by patient volume. The Director and Assistant Director are charged with continuing to advocate for the goals and vision of the program. They work closely with a Robotics Head Clinical Nurse which is a position that is dedicated to the robotics program. In addition, a perioperative staff member should be included to fulfill the role of Robotics Manager. Last, a Robotics Coordinator is an important component of a robotics program. The responsibilities of the coordinator are the following:

- Assure that each room has the correct robotic equipment and instrumentation. (This does not include setting up the entire room for the procedure, as all staff will be familiar with the robotics setup.)
- Review surgeon preference cards to potentially limit or expand what is included in the list of desired surgical instruments for each procedure.
- Play an integral role in training and providing step-by-step manuals for the scrub (nursing and surgical assistance) staff.
- Facilitate education of medical students, residents, fellows, and attending staff and be the point person for organization of simulator training.
- Maintain credentials of those who have completed available on-line courses.
- Investigate new robotics technology.
- Follow up with other organizations and robotics programs to keep abreast of outside information on new ideas to bring before the robotics team and the operating room staff.
- Encourage promotion of the robotics program through contact with the marketing arm of the institution.

Table 1.
Robotic Leadership Team Role Descriptions

Leadership Team Member	Role
Robotic Director	Provide leadership, vision, implementation of programmatic components, justification of equipment purchase, and monitoring of credentialing
Assistant Robotic Director	Provide leadership, assist Robotics Director with high-volume programs
Robotics Clinical Head Nurse	Monitor and assist with team training, supervise operating room staff, certify staff, and communicate with Robotic Director regarding any problem with robotic technology or robotics staff
Robotics Coordinator	Monitor equipment, instrumentation, staff training; preference card, inventory, and troubleshooting; maximize utilization,
Robotics Manager	Schedule and monitor utilization, collect metrics data, actively manage operating room coordination of robotic cases
Robotics Advisory Board	Holders of all positions described above, all robotic surgeons (anesthesia staff added when indicated)

- Issue a newsletter containing, for example, news of advances in robotics and changes in techniques and in-house processes.
- Encourage the efficient use of the robotic system to maximize its availability.

An Internal Robotics Advisory Board is beneficial; it should include all of the current active robotics surgeons, robotics directors, robotics nurse, the robotics coordinator, the robotics manager, anesthesia staff, and selected perioperative staff. This group has a varying schedule of meetings and can be subdivided as necessary to achieve various goals (ie, initiation of first robotic purchase versus subsequent equipment purchases). Robot user meetings (all members of the Internal Advisory Board) can convene as determined by need (ie, monthly versus quarterly versus yearly).

A collaboration was formed with the Anesthesia Department to create a Robotics Advisory form to communicate with Anesthesia about robotics surgical cases (Appendix 1). This advisory form was also emailed to all Anesthesia residents before their first robotics cases.

The expansion of robotics systems was based on case volume and the number of surgeons desiring to use the robotics system. At approximately 400 cases per year, we expanded to our second Si system. At this time, we also purchased a da Vinci Si-e system that would be dedicated to development of a cardiac and thoracic program. Our investment in the Xi platform was based more on the technology needed for our colorectal, surgical oncology, gynecologic oncology, thoracic, and general surgery minimally invasive specialties for multiquadrant surgery (**Figure 3**).

METRICS

The careful monitoring of the robotics program allows follow-up of patient outcomes and application of metrics to day-to-day practice, individual providers, and overall evaluation for planning for future program growth. Data management includes a practice pattern of monthly review prepared by the Perioperative Business Manager via Business Objects-Webi (SAP, Newtown Square, Pennsylvania, USA) sent automatically to the Robotics Director, quarterly review of utilization (for each surgeon, and also by service), and quarterly robotic statistics review prepared by our systems analyst via Business Objects—Launchpad (SAP) with data listed in tables and graphs routinely sent to the department chairs and Robotics Director. Monthly and quarterly metrics reports include multiple data points (**Table 2**).

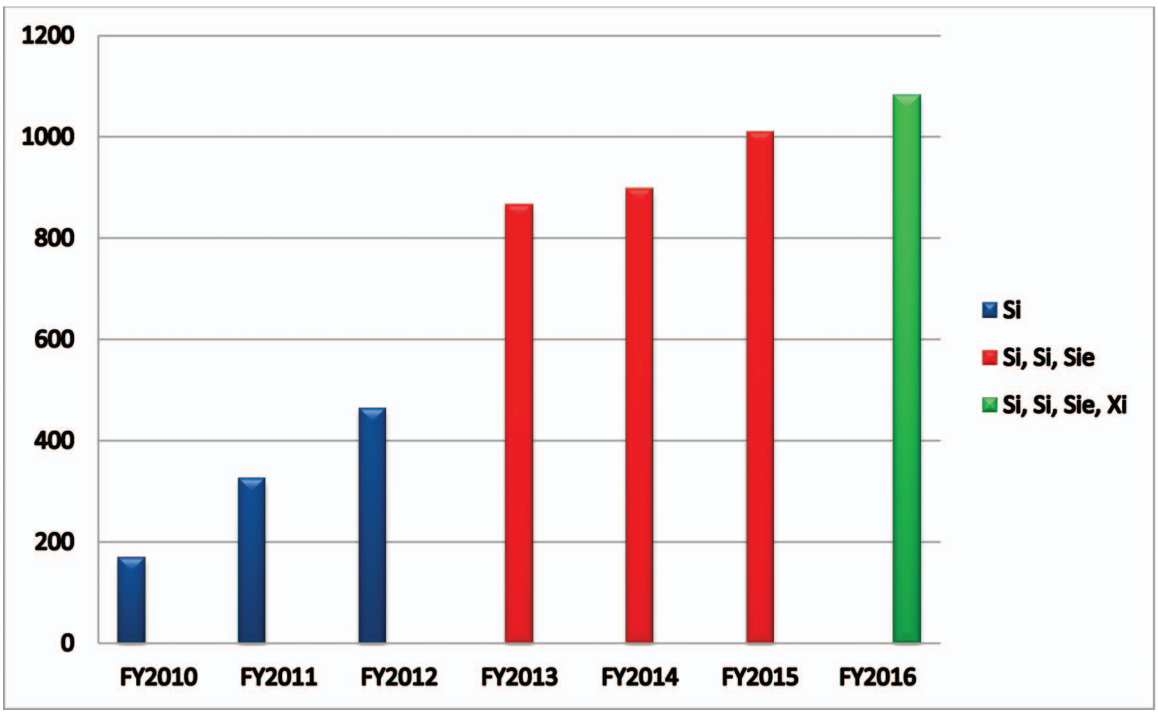

Figure 3. Case volume per number of robotic systems.

Table 2.
Metrics Data Collected

Monthly Metrics	Quarterly Metrics
Case volume summary	Overall number of cases
Per service total	Total
Per surgeon total	Per surgeon
Per month for each surgeon	Per case type
Per month for each service	Per day
	Per time of check-in
Utilization	Length of robotic surgery time in hours used per surgeon
Robotic procedures	Converted cases (planned robotic, but converted to open)
Total by type of case	
Total by case type per surgeon	
Procedure summary	Major and minor complications
Patient in to time out	Each case listed
Surgeon start to incision	Description of each complication
Patient in to incision	Percentage major complications/total robotic cases for the quarter
Incision to surgery end	Percentage minor complications/total robotic cases for the quarter
Surgeon stop to patient out of room	
Surgeon start to surgeon stop	
Minutes in room	
Length of stay	
Comparison of laparoscopic procedures with the same procedure summary data as robotics	Total (and %) readmissions
Length of stay by service	Total (and %) mortality listed per surgeon and case
Case length by service and surgeon	Total (and %) 90-day return to surgery listed per surgeon and case
Each surgeon has a tab with their cases listed under each surgeon name	EBL and total (and %) transfusions
Running count of cases	Delays
	Reasons
	How many
Robotic cases by date•	Financials chart
	Total charges
	Total payments to date
	Total cost
	Contribution margin

EBL, estimated blood loss.

CREDENTIALING

New users must submit responses to a questionnaire (**Appendix 2**) and approval for proceeding with robotic training is discussed and approved by the department chair.

Guidelines are in place for the minimum criteria necessary for credentialing (**Appendix 3**). All physicians must be board certified or board eligible or have equivalent competency within their surgical specialty. All must be privileged for the surgical procedure being performed on the da Vinci Surgical Platform. Physicians can then attest to one of the 3 following pathways:

The first pathway is for the new user. The physician must show evidence of successful completion of the Intuitive Clinical Pathway for the use of the da Vinci Surgical Platform and satisfactory proctoring of at least 2 surgical cases. The completed proctoring form (adapted from American Association of Gynecologic Laparoscopist [AAGL] guidelines, which had permission from MultiCare Health Systems, Tacoma, Washington, USA[4]) is reviewed by the Robotics Director. If any unsatisfactory component is identified, it is reviewed with the physician's division chair and department chair.

The second pathway is for current users who are transferring their credentials from another institution. The requirement is for review of a letter of prior credentials or 6-month case volume.

The third pathway is for residency- or fellowship-trained users. Residents and fellows must have a letter documenting proficiency from their residency or fellowship director and their 6-month case volume.

In addition, the first 5 robotic cases of every new surgeon are reviewed after the initial credentialing. Ongoing monitoring of competency and case volume requirements to support renewing of robotic privileges is completed per hospital policy by the department chair.

Other more rigorous privileging guidelines for robot-assisted gynecologic laparoscopy have been described.[4] As our program has multiple subspecialties with a range of surgeons performing various procedures that may not be as common as gynecologic or urologic procedures, we have instituted the above guidelines successfully for this diversity of practice.

Serious major complication such as bowel, bladder, ureter, or vascular injuries or significant internal bleeding have been <1.52%, and minor complications such as hernia, corneal abrasion, infection (wound, urinary, chest, vaginal), fever, urinary retention, and ileus have been consistently <2.27%. The percentage of patients undergoing conversion to laparotomy or transfusion is ~1%.

RESIDENT, FELLOW, AND BEDSIDE ASSISTANT TRAINING

As a teaching institution, we have developed general guidelines for residency and fellow training. These guidelines, in general, are:

- Eight hours of documented training on the robot, to include work on inanimate models, docking practice, time with the Intuitive representative, proctoring by upper level residents, and individual practice of techniques.
- Online training.
- Bedside assisting in at least 10 cases.

Once the first 3 requirements are completed, the resident or fellow can submit the above information to the residency and fellowship director and then sit at the robotic console at the discretion of the attending surgeon.

More specifically, residents and fellows must complete the online modules by Intuitive Surgical for the equipment that they will be using (Si or Xi System or both) at www.davincisurgerycommunity.com, including the post test. Certificates of completion are kept in the residents' files. Medical knowledge regarding robotic surgery is then enhanced by readings for application in the appropriate specialty, after which they complete an orientation session provided by an experienced instructor before assisting in the first case. The session includes hands-on focus regarding the equipment; setup; emergency protocols, troubleshooting, and fault management; configuration of the system components; and instruction on the preparation of the console and simulator. The online training and orientation session must be finished before the surgeon participates in the first robotic surgery. Residents and fellows send a notice to the appropriate supervising physician for sign-off in a tracking system for the robotics curriculum developed by New Innovations (Uniontown, Ohio, USA). The system is used to document completion of the online module, orientation session, bedside assistant cases, and console cases.

Next, trainees must have 8 hours of documented training on the robot simulator in combination with acting as a bedside assistant for at least 10 cases before sitting at the console. All cases are reviewed and submitted to New Innovations for the attending's signature. A focus on competency for robotic surgery training assessment and a Fundamental Skills of Robotic Surgery Curriculum have been proposed for surgical training.[5–7]

Once the above requirements are met, the resident or fellow can submit the information to the residency director and then sit at the robotic console at the discretion of the attending surgeon. Individual skills can be recorded by the trainee and submitted for verification to the attending participating in that case.

A residency or fellowship attestation letter can then be drafted to comment on the depth and breadth of each individual's experience, along with a case list to give to the graduate for his or her records that is useful for applying for credentialing at one's own institution or an outside institution (**Appendix 4**). One can now also submit a letter to the Intuitive Training Staff to receive a Training Equivalency Certificate with a residency/ fellowship director documenting participation in 10 cases as a patient-side assistant and in at least 20 cases as the console surgeon with documentation that this resident/fellow also "received training in port placement, patient cart setup, docking and undocking, instrument insertion and exchange, surgeon console settings, camera control, clutching, EndoWrist instrument manipulation, third-arm control, range of motion, retraction, dissection, suturing, applying energy, and troubleshooting and communication (Intuitive Surgical)."

We also have criteria for bedside assistant training that include the following, before an individual assists with any of the robotic components:

- Online training module (Intuitive Surgical website) with completion certificate.
- Robotic orientation session and hands-on system training, which include ~1–2 hours with a representative from Intuitive surgical, an attending physician who has robotic credentials, a qualified chief resident, or a fellow. This session consists of didactic and practical skills sessions covering the components and proper use of the da Vinci Surgical System and EndoWrist Instruments. On-site training highlights key da Vinci System features, system preparation, and management.

CASE VOLUME REQUIREMENTS

Because of the multiple subspecialties in our robotics program, the case volume requirements are 12 cases over 2 years with an average of 6 cases per year. In our experience, initial surgeon selection is critical in credentialing surgeons who are interested in robotic surgery and who will maintain competency. If this case volume minimum is not met, then case reviews by members of the Internal Advisory Board are completed with either a recommendation to continue privileges with an appropriate monitoring plan or a recommendation, presented to the department chair, to discontinue privileges. The learning curve varies by specialty.

FUTURE ENDEAVORS

As a program, we are reviewing recommendations brought forward from the Genesis Program (sponsored by Intuitive Surgical), a 2- to 3-day on-site review of the robotics program. The focus is on leadership, communication, task overlap, and standardization. Process review through evaluation of all aspects of the robotics program (including the sterile processing unit, evaluating par levels, assessing the components of trays) is a way in which to achieve additional efficiency and cost savings.

We are also incorporating robotics into our Physician Assistant (PA) Program. We have completed one training session and will assist in expanding the educational efforts of the PA Program in the area of exposure to robotic surgery. New patterns of practice may emerge with the integration of robotics into more surgical specialties.

We are examining the concept of an "innovation committee" that would enhance the incorporation of new robotic platforms into patient use by overseeing new instrument review and surgeon credentialing and by planning for additional devices that would allow robot-assisted surgical procedures.

CONCLUSION

Robotic surgery programs are an excellent microcosm of a surgical practice within which development of various protocols for training, credentialing, and monitoring are ideal. Best practices can be instituted without burdening the system by appropriate division of responsibilities and accountability within hospital systems. Adaptations to the approaches described are encouraged and processes will continue to change over time. Safe and effective patient care is the ultimate goal.

Appendix 1. Robotic Anesthesia Practice Advisory

Appendix 2. New Robot User Questionnaire

Appendix 3. Robotic Credentialing Form

Appendix 4. Residency/Fellowship Robotics Letter

Above appendices can be accessed at: http://jsls.sls.org/wp-content/uploads/2017/03/jls020163616sa.pdf.

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