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A Consensus Document on Robotic Surgery: Prepared by the SAGES-MIRA Robotic Surgery Consensus Group

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Introduction

Robotic surgical devices have developed beyond the investigational stage and are now routinely used in minimally invasive general surgery, pediatric surgery, gynecology, urology, cardiothoracic surgery and otorhinolaryngology. Robotic devices continue to evolve and – as they become less expensive and more widely disseminated – will likely become more frequently utilized in surgical procedures. The leadership of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Minimally Invasive Robotic Association (MIRA) felt that guidelines for the usage of robots in surgery were lacking, and that the surgical community would benefit from a consensus statement on robotic surgery including guidelines for training and credentialing.

To accomplish this task, SAGES and MIRA assembled an international multidisciplinary consensus group to draft a consensus statement. The SAGES-MIRA Robotics Consensus Conference was convened at Mount Sinai Medical Center in New York City on June 2-3, 2006. The task force addressed four distinct questions it felt were central to the use of robots in surgery:

- **Training and credentialing:** How should training for robotic surgery be accomplished? What is the appropriate process for credentialing robotic surgery?
- **Clinical applications of robots in surgery:** What are the appropriate clinical applications for robotic surgery; has efficacy been demonstrated for these applications?
- **Risks of Surgery and Cost-Benefit Analysis:** What are the physical risks of robotic surgery to the patient? What financial costs are involved in robotic surgery and are these costs justified?
- **Research:** What are the important unanswered questions in robotic surgery? What direction should future research take?

After meeting and presenting data regarding these issues in a didactic forum, the Robotic Task Force faculty was divided into 4 working groups to address these issues separately. The faculty then reconvened to review the working groups' conclusions and arrive at a generalized consensus. The results of these proceedings are presented in this document.

Definitions

“Robotic surgery” is an imprecise term, but it has been widely used by both the medical and lay press and is now generally accepted. The term refers to surgical technology that places a computer-assisted electromechanical device in the path between the surgeon and the patient. A more scientifically accurate term for current devices would be “remote tele-presence manipulators” since available technology does not generally function without the explicit and direct control of a human operator. For the purposes of the document, we define robotic surgery as a surgical procedure or technology that adds a computer technology enhanced device to the interaction between a surgeon and a patient during a surgical operation and assumes some degree of control heretofore completely reserved for the surgeon.

As an example, in laparoscopic surgery the surgeon directly controls and manipulates tissue, albeit at some distance from the patient and through a fulcrum point in the abdominal wall. This differs from current robotic devices, where the surgeon sits at a console – typically in the operating room but outside the sterile field – directing and controlling the movements of one or more robotic arms. While the surgeon still maintains control over the operation, the control is indirect and is effected from an increased distance.

This definition of robotic surgery encompasses micromanipulators as well as remotely-controlled endoscopes in addition to console-manipulator devices. The key elements are enhancements of the surgeon’s abilities, be they vision, tissue manipulation, or tissue sensing, and alteration of the traditional direct local contact between surgeon and patient.

Clinical Environment

Surgical robots are considerably more complex, both electrically and mechanically, than traditional devices used in the operating room environment. In addition, they involve direct contact with the patient, both externally and internally. These important features differentiate surgical robots from other equipment such as operating microscopes, intraoperative imaging devices and traditional operating room instruments.

In addition to the surgeon and surgical assistant, all personnel in the operating room must be appropriately trained to handle this equipment. There are currently no standard criteria set forth for registered nurses, operating room technicians, or surgeons with respect to appropriate training for managing these instruments in the operating room. However, at a minimum, operating room personnel should be trained according to the manufacturer’s training guidelines, and should have the opportunity to be “doubled up” with an experienced nurse or operating room technician during their early experience.

It is highly recommended that teams using such instruments – surgeons, technicians, nurses, and possibly manufacturing representative – meet on a periodic basis to stay current in their training and to learn of updates or changes to the hardware or software. In this way, emerging problems may be quickly identified and addressed.

I. Surgeon Training and Credentialing

In order to maintain the highest levels of patient care today and in the future, we must ensure that surgeons are adequately trained in the use of surgical robots prior to clinical use. Training and credentialing are separate but intimately related issues. Credentialing can only be granted by the individual institutions where surgeons work. We have included formal guidelines for credentialing in Appendix I of this document and guidelines for robotic surgery training in Appendix II.

There are two broad aspects to training with robotic systems. The first is technical training and capability. The

surgeon must have both a knowledge base and a practical working familiarity with these complex devices before clinical use. In addition to all standard operating procedures, this training must include how to safely and rapidly remove the device in an emergency, what to do if the system stops responding, and how to respond if the system makes movements that are potentially unsafe to the patient. All such reasonably foreseeable situations must be anticipated, practiced and understood. Currently, the FDA has in place a mandate that companies provide at least some of this training. Thus, at a minimum, surgeons must be trained to meet these FDA standards.

The second aspect of training involves the use of the robot for specific operations. The simplest situation exists when a fully trained and competent laparoscopic surgeon begins to use a robotic system clinically. In this case, it is merely a matter of adding the specific knowledge of robotic technology to an existing set of clinical skills. A more complex situation is presented by the surgeon who elects to begin his or her minimally invasive endeavors using the robot. In this situation, the amount of learning required may be substantially greater. Full credentialing guidelines that address these situations are presented in Appendix I.

SAGES and MIRA recognize that surgical simulators may play an increasingly large role in surgical training in the future. However, at present there are no simulators that provide training equivalent to that obtained in a formal clinical setting. Thus, at present, simulators must remain an adjunct in the training of robotic surgeons.

II. Clinical Applications

The goal of the Clinical Applications subgroup was to focus on the status of robotic surgery applications as of June, 2006. Although robotic surgery has shown great promise across a broad range of surgical disciplines, no level I data exist at this time to strongly support robotic surgery; conversely, no studies or anecdotal reports exist to suggest any increase in complication rates compared to conventional open or laparoscopic surgery.

In general, the literature regarding robotic surgery lags behind the clinical experience by several years. Current literature suggests that the primary clinical advantages of currently available robotic systems, compared to conventional open or laparoscopic surgery, include:

- Superior visualization including 3-dimensional imaging of the operative field
- Stabilization of instruments within the surgical field
- Mechanical advantages over traditional laparoscopy
- Improved ergonomics for the operating surgeon

Across multiple surgical specialties, robotic surgery was felt to offer the greatest advantage in complex reconstructive processes.

Limitations of current robotic technology include, among other technical constraints, lack of haptics (force feedback), size of the devices, instrumentation limitations (both size and variety), lack of flexibility of certain energy devices, and problems with multi-quadrant surgery (current devices are deployed typically for single quadrant application).

Overall, the technically exceptional laparoscopic surgeon may derive little benefit from robotic surgery. However, surgical robots may serve as an “enabling technology” for many surgeons, allowing them to provide complex minimally invasive procedures to a broad range of patients. The potential advantages of robotic surgery extend across many different surgical subspecialties.

Pediatric Surgery: Over 50 different types of abdominal and thoracic procedures have been performed in pediatric patients. Neonates and infants have also undergone robotic procedures safely and with excellent results. In particular, robotic surgery may present advantages for the Kasai procedure, choledochal cyst repair, and thoracic tumor excision. It may also be beneficial in abdominal and thoracic procedures requiring reconstruction. The major limitation is the size of the robotic instruments in relation to the pediatric patient.

Gynecology: Robotic surgery has shown promise in hysterectomy for both benign and malignant disease, as well as myomectomy. In myomectomy, the robot may provide substantial benefit by allowing minimally invasive fertility sparing options. It is also beneficial for tubal reconstruction. The robot may provide potential advantages for pelvic reconstructive surgery.

General Surgery: With present technology, robotic surgery is best suited to procedures limited to one quadrant of the abdomen that present challenging access: specifically those requiring fine dissection, micro-suturing or reconstruction. Reports have been published with use for cholecystectomy, but with no findings of improved outcomes nor safety. Reports for solid organ surgery, as adrenalectomy, have not found particular advantage, noted increased cost, but did prove feasibility. Procedures where it may be of particular value include Heller myotomy, paraesophageal hernia repair, gastric bypass, gastric resection for neoplasm, biliary reconstructive surgery, transhiatal esophagectomy, transthoracic esophageal surgery, distal pancreatectomy with splenic preservation, and selected colorectal procedures. It may hold promise for pancreatic head resection and hepatectomy, but experience to date is limited. In resections for neoplasm, robotic surgery may help to enhance the completeness of lymph node dissection.

Although there is a substantial cost disadvantage to using the robot for simple procedures such as cholecystectomy and fundoplication, these procedure may present an excellent opportunity for surgeons early in their robotic learning curve to acquire increasingly more advanced skills.

Urology: Robotic surgery has been shown to offer substantial advantages over conventional minimally invasive surgery in several urological procedures. While the most mature outcomes data in the field of robotics are for radical prostatectomy, robotics may also offer advantages for cystectomy, pyeloplasty, nephrectomy (partial, complete and donor) and ureteral reimplantation. Resection of bladder neoplasm may also be approached robotically with a lower incidence of postoperative ileus. Robotic surgery may ultimately replace open surgery for some complex urological procedures.

Thoracic Surgery: Robotic surgery offers clear benefits in the resection of solid thoracic tumors, particularly those located in the apex of the chest. Esophageal tumors such as leiomyomas may also be resected robotically.

Otorhinolaryngology/Head and Neck Surgery: Transoral robotic surgery is presently under study. Preliminary data indicate utility for transoral resections of benign and malignant lesions of the pharynx and larynx. Oncologic resections of the supraglottis, tonsil and tongue base have been shown to be feasible with potential advantages compared to traditional approaches. Preliminary evidence indicates that these advantages may include avoidance of mandibulotomy, avoidance of tracheostomy, decreased operative time, reduced requirements for complex reconstructions, and avoidance of external excisions.

Limitations of the present technology preclude transnasal and otologic procedures because of instrument size and functionality. Current otorhinolaryngology procedures are performed under IRB approval as FDA approval is still pending. Further use of robotic surgery in the head and neck will await the development of smaller instruments and more flexible robotic tools.

Limitations across specialties: Overall, the Clinical Applications subgroup felt that the 3 major impediments to

the clinical use of robots are cost, training issues and lack of outcomes data. Among the previously mentioned technical limitations, the primary technical limitation of robotic surgery is the difficulty in performing procedures that extend over a large area, such as multiquadrant abdominal surgery. These limitations will likely ease as robotic devices evolve.

The use of surgical registries will be important in future studies of robotic surgery, particularly those evaluating short- and long-term surgical outcomes.

III. Cost/Benefit Analysis of Robotic Surgery

The cost/benefit analysis of robotic surgery involves a complex combination of numerous variables. Costs of the surgical robot include capital acquisition, limited use instruments, team training expenses, equipment maintenance, equipment repair, and operating room setup time. At present it is unknown whether robotic surgery will affect complication rate, length of stay, or length of patients' convalescence. Any analysis of robotic surgery must ensure that an appropriate comparison to alternative therapies is being made. In some cases robotic surgery should be compared to open surgery while in others to laparoscopic or alternative minimally invasive techniques.

Capital Acquisition Cost

The treatment of the capital acquisition cost will vary across institutions. In some cases the cost analysis will not include the capital purchase cost, while in others the allocation of this investment and depreciation will be assessed on a per case basis. Donations, institutional technology investment decisions, or marketing programs may or may not enter the cost analysis. Multidisciplinary team training is an up front investment that can be capitalized and requires inclusion in the initial analysis.

Instrumentation

The number of different robotic instruments utilized varies from case to case. Current instruments are limited to a fixed number of uses, unrelated to instrument wear. Since repeated reuse of instruments lowers the per case cost, an important future goal should be indefinitely reusable instruments.

Equipment Maintenance and Repair

The cost of maintaining, servicing, and repairing these highly complex devices represents a significant portion of the yearly cost. We estimate that the sum of these costs each year is approximately 10% of the capital acquisition cost. Reducing this expense should be an important goal of future device development.

Operating Room Time

The cost analysis of operating room time includes multiple variables: room setup time, time for draping and docking the robot, skin to skin procedure time, undocking/storage time, and room turnover time. These factors are improved by effective team training, attention to efficient procedures, surgeon and team experience, and initial patient selection. Small increases in overall operating room time become significant only when additional personnel are required, overtime is paid, or fewer cases per shift can be accomplished.

Complication Rates

Complications have been shown to have a significant impact on the cost of care. It is generally felt that the use of robotics shortens the learning curve for acquiring complex minimally surgical skills. At present, there are no studies suggesting that robotic procedures performed by experienced robotic surgeons have different complication rates either better or worse than other comparable techniques.

Length of Stay

Comparison of robotic surgery to alternative techniques requires procedure by procedure analysis since there will be instances where robotic surgery is appropriately compared to minimally invasive techniques and others where it is compared to open techniques. Also, it should be remembered that length of stay affects cost centers outside the operating room. Decreased length of stay will counterbalance some of the increased operating room expenses associated with all forms of MIS. Length of stay may be affected by postoperative pain, intraoperative blood loss and complication rates. The differences between robotic and conventional surgery in these categories has not yet been adequately studied.

General Benefits

The desirable characteristics of current therapeutic robotic systems include platform stability, motion scaling, tremor reduction, excellent visualization, and articulating end effectors. Taken in combination these characteristics create a highly effective therapeutic system for performing surgical procedures. Robotics have made minimally invasive techniques accessible to patients in whom the procedures could not be performed using conventional laparoscopic techniques. Furthermore, enhancements in precision may aid in the conduct of a variety of advanced MIS procedures.

Ergonomics

Both open and laparoscopic surgical procedures may be physically strenuous and have been associated with surgeon morbidity from repetitive use injury. Since the robotic surgeon sits comfortably in an ergonomically-designed workstation, the conduct of robotically-controlled procedures is generally more ergonomic for the operating surgeon. However, this benefit may not apply to the patient-side assistant. Such ergonomic differences will be magnified for lengthier procedures.

Learning Curve

Technically complex surgical tasks such as suturing present a substantial learning curve. These may be facilitated by the additional degrees of freedom inherent in articulated-arm robotic operating systems. Thus, articulated arm robots will potentially reduce technical skill acquisition time. They may enable surgeons to access difficult anatomic regions more easily, potentially speeding the introduction and clinical adoption of new MIS techniques.

Patient Return to Usual Activity

Some robotic surgical procedures may have better patient outcomes than their open or standard minimally invasive counterparts. Return to work benefits will vary based on the type of procedure and the population served

Risks of Robotic Surgery

Current surgical robots are continuously controlled by the surgeon and do not move autonomously. They

possess neither artificial intelligence nor independent functioning. The robot remains a high-level, sophisticated tool used by the surgeon in the conduct of an operative procedure. Risks of robotic surgery can be categorized into those pertaining directly to the use of the robotic system and the general risks of the operative procedure.

Theoretically, the lack of haptic feedback in current robotic systems could lead to an increased risk of inadvertent tissue injury. However, to date, robotically performed operations have not been associated with higher clinical complication rates than their standard laparoscopic or open counterparts in experienced hands. In certain instances evidence exists that robotically performed procedures may be associated with a lower complication rate.

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 will be dependent upon 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.

Mechanical Risks

All mechanical and electronic devices are subject to failure. Surgical robots – complex systems relying on a delicate interplay of hardware and software – are no exception. Current systems are designed with features intended to minimize the potentially deleterious effect of such failures on patients. Such features include system redundancy, so called “graceful” performance degradation or failure, fault tolerance, just-in-time maintenance, and system alerting. These are standards to which all high level systems should be held.

Institutional Risks

Healthcare institutions that employ high level technology as surgical robots in clinical practice need to develop and follow credentialing guidelines. The initiation of a robotic surgical program is similar to the introduction of any other novel, high-level, direct patient care technology, and should require appropriate training and credentialing (see Appendix I and II). In addition, each institution needs to develop a consistent policy concerning the nature of the procedures to be performed with regard to the need for IRB oversight. Such policy must take into account the nature of the proposed procedure itself. The institution also has an obligation to maintain the system consistent with manufacturer's guidelines.

IV. Research

Surgical robots are now in their infancy. At present, there is only 1 commercially available general surgery robot in the United States. The robot does not perform any independent actions, but rather serves as a direct extension of the surgeon's own hand. In this sense, current robots are more correctly described as electromechanical surgical actuators. These devices faithfully reproduce a surgeon's action, as a ‘mimic’, but with no artificial intelligence nor automated subroutines. Since the term “robot” has come into general use in both the lay press and professional literature, and it is certainly a less cumbersome descriptor, we have used it throughout this document.

The present paradigm for surgical robotics is a limited one. A surgeon sits at a console, and his or her physical motions are translated via an elaborate electromechanical linkup to surgical instruments in the operative field. This paradigm does provide certain advantages in manipulating tissue, such as motion scaling and elimination of hand tremor. Current technology also has disadvantages, such as loss of haptic feedback. There is a significant amount of research and development that is evolving to bring us smaller, cheaper, faster, and safer devices with

improved feature sets, such as haptic feedback. It is critical that future research in surgical robotics should not be tethered to the surgeon-at-a-console paradigm. Rather, research and development endeavors should address broader goals of a “grand vision” of computer/robotic assisted surgery. Some of these goals are enumerated below.

Instrumentation

Current robotic instruments have evolved to provide a miniaturized ‘endowrist’ with degrees of freedom rivaling human capability. Future instrumentation will evolve in size and variety to further expand surgical capability.

‘Smart instruments’ are evolving so that dissection instruments can be imbued with capability to provide the user not only with mechanical dissection and retraction capabilities, but with ‘smart sensing’ capabilities, to provide the surgeon with information about tissue oxygenation, blood flow, molecular information, even tumor margin information.

Visualization

Computer enhanced vision has already restored 3-dimensional vision. Additional visual enhancement systems can further enhance the operator’s vision, importing anatomic overlays, even ‘help’ heads-up displays. Visual system enhancements can also offer an array of ‘optical biopsy’ capabilities, as confocal microscopy, optical coherent tomography (OCT), and others, which can further enhance computer assisted visualization, enabling real-time microscopy, even molecular imaging.

Integrated Surgery

Robotic surgery presents an excellent opportunity to integrate anatomic and physiologic data into the operative field. Preoperative or even intraoperative imaging (e.g., CT, MRI, or ultrasound imaging) can reveal the three-dimensional topology of the operative field even before tissue is disturbed. Since the spatial coordinates (x, y, z axis) of the surgical instruments are “known” at all times by the surgical robot, the robotic interface provides an excellent platform through which this information can be integrated, registered, with the surgical device, so that the imaging information can be fused with the computer visual field, providing the potential for visual overlays of anatomy, function, even tumor mapping, such that the surgeon could ‘see into’ the tissues. Virtual barriers could be mapped into the operative field, identifying danger, or ‘no fly zones’, with the computer helping guide the surgeon away from potential hazard. This information could be used to guide surgical procedures intraoperatively, or even to simulate a proposed procedure before it is carried out. One of the more exciting potential areas of computer assisted interventional research relates to integrating imaging with interventional platforms.

Simulation

Robot workstations can serve as both consoles controlling robotic systems, but can also have potential to serve as simulator environments, with the capability to import patient specific information and allow rehearsal of patient specific procedures toward reduction in complications rates, learning curves, even development of new technical approaches.

In addition to providing input integration of imaging registered with an interventional robotic platform, robots can capture data regarding how a surgeon performs specific tasks. These ‘black box’ data could be used for quality control, teaching purposes, or even to “train” the computer to perform similar tasks independently.

Miniaturization

Future electromechanical technology may allow robots to be miniaturized to the point where they can enter the human body and perform surgery by remote control, or even autonomously. Such robots would potentially permit novel access paths to internal organs and could substantially decrease the invasiveness of surgical procedures. If such miniaturization is extended down to the level of “micro-machines”, then surgery could theoretically be performed at the cellular level. Such extreme miniaturization, while beyond current realization, would require extensive reworking of current surgical paradigms. However, the potential for new minimally invasive approaches is great.

In the near term, robotic platforms and instrumentation may evolve to enable single access port (SAP) surgery, with a device, that once deployed, provides, through a single port, a multi-capable platform providing vision and multiple effectors devices.

Improved Mobility

Current robots work best when the surgical field is limited to a relatively small area, such as a single quadrant of the abdomen. Future devices will need improved flexibility so that they can easily be deployed to access entire body cavities without reconfiguration. Mobility of the robotic device itself is also an issue – current devices are large and difficult to move, and do not lend themselves to use outside an operating room environment, such as in the battlefield. Mobility of robotic devices will improve as they miniaturization improves and the footprint of the devices becomes smaller.

True Independent / Autonomous Robotic Surgery

Current devices do not exercise independent logic or reason and do not even serve to automate repetitive tasks in the way that a sewing machine does. A first step in this direction for future robots would be the automation of routine tasks such as sewing; i.e. the surgeon indicates a start point and a finish point and the robot completes the suture line. Robots could use “artificial intelligence” to learn from the surgeon operating the device. Thus, robots could move from telemanipulators to skilled assistants in the future. If a robot acquired technical or cognitive knowledge from a large group of surgeons, it could ultimately serve as a computerized “colleague” to provide technical assistance in routine or unusual operative situations.

Safety and Documentation of Outcomes

Ultimately, all research in surgical robots must be undertaken with the goal of improving patient care and safety. Patient safety and clinical outcomes must remain foremost in future research efforts.

To adequately assess the risks and benefits of robotic surgery now and in the future, and to assist in guiding future research efforts, it will be essential to have outcomes registries for robotic surgery. Only through such registries will it be possible to accurately compare robotic surgery to traditional approaches, to document quality of outcomes, and to help identify needed no directions for development.

Surgical Team Robotic Augmentees

Just as current surgical robots can enhance human surgeon performance, devices already exist to enhance the surgical team. ‘Penelope’ is a commercially available robot to replace the scrub technicians. Next generation devices under development can enhance the work of scrub nurses, supply workers, among others. Future devices can further augment human capability, task performance, and enhance the surgical team.

Operating Room Integration

Just as an imaging system as a CT scanner is a computer with eyes, and a robot is a computer with arms, an operating room can become a computer system, with surgical robots integrated into perioperative workflow and process. Integrated computerized tracking of surgical activity, workflow, use of materials, devices, consumables, can enhance task performance, quality of care, and ultimately patient safety. Key will be standards development, 'plug and play' interoperability, modularity, and better understanding of human-system integration and limitations.

Enabling steps

To fully realize the future of computer assisted intervention/ robotics evolution, we will need transdisciplinary collaboration across not only surgical, interventional, and imaging disciplines, but with engineers and computer experts, backed with significant funding to realize the potential of the human-system interface. The prospects for enhancing patient care, quality, and safety are substantial. Further consensus efforts will be needed to define 'white papers' to serve as roadmaps for future research and development.

Appendix I: Guidelines for Institutions Granting Privileges in Therapeutic Robotic Procedures

Preamble

The International consensus group of 2006 of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Minimally Invasive Robotic Association (MIRA) recommend the following guidelines for privileging qualified surgeons in the performance of surgical procedures utilizing therapeutic robotic surgical devices alone or in a hybrid fashion. The basic premise is that the surgeon(s) must have the judgment and training to safely complete the procedure as intended, as well as have the capability of immediately proceeding to an alternative therapy when circumstances so indicate.

I. Principles of Privileging

A. Purpose

The purpose of this statement is to outline principles and provide practical suggestions to assist healthcare institutions when granting privileges to perform procedures utilizing these technologies. In conjunction with other organizations guidelines for granting hospital privileges, implementation of these methods should help hospital staffs ensure that surgery is performed in a manner assuring high quality patient care and proper procedure utilization.

B. Uniformity of Standards

Uniform standards should be developed which apply to all medical staff requesting privileges to perform procedures utilizing these technologies. Criteria must be established which are medically sound, but not unreasonably stringent, and which are universally applicable to all those wishing to obtain privileges. The goal must be the delivery of high quality patient care. Surgical proficiency should be assessed for every surgeon, and privileges should not be granted or denied solely based on the number of procedures performed. Ongoing review

of results and comparison to published data and/or recognized benchmarks is encouraged.

C. Responsibility for Privileging

The privileging structure and process remain the responsibility of the institution at which privileges are being sought. It should be the responsibility of the specialty department, through its chief to recommend privileges for individual surgeons to perform procedures. These recommendations should then be approved by the appropriate institutional committee, board, or governing body.

D. Definitions

Must/Shall - Mandatory recommendation

Should - Highly desirable recommendation

May/Could - Optional recommendation; alternatives may be appropriate

Documented Training and Experience

1. Case list that must specify the applicant's role (primary surgeon, co-surgeon, first assistant, chief resident, junior resident or observer). Complications, outcomes, and conversion to traditional techniques should be included if known. The applicant must specify if these details are not known.
2. Summary letter from preceptor and/or program director and/or chief of service (should state if applicant can independently and competently perform the procedure in question).

Privileging - The process whereby a specific scope and content of patient care services (that is, clinical privileges) are authorized for a health care practitioner by a health care organization based on evaluation of the individual's credentials and performance.

Competence or Competency - A determination of an individual's capability to perform up to defined expectations.

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

Complete Procedural Conduct - Competency of the applicant and/or institution regarding patient selection, peri-procedural care, conduct of the operation, technical skill and equipment necessary to safely complete a procedure and the ability to proceed immediately with the traditional open procedure.

Formal Course - A formal course alone is not appropriate training to begin performing a procedure independently. The course should be taught by instructors with appropriate clinical experience, and have a curriculum that includes didactic instruction as well as hands on experience utilizing inanimate and/or animate models. The course director and/or instructor should provide a written assessment of the participant's mastery of course objectives. Documentation for certain courses consisting of only didactic instruction may consist of verification of attendance.

Therapeutic Robotic Procedures - The spectrum of procedures utilizing a human controlled computer assisted electromechanical system which converts information to targeted therapeutic action.

II. Minimum Requirements for Granting Privileges

Part II A is mandatory, and *must* be accompanied by either part II B, or II C and at least one component of II D.

A. Formal Specialty Training

Prerequisite training *must* include satisfactory completion of an accredited surgical residency program, with subsequent certification by the applicable specialty board or an equivalent as required by the institution.

B. Formal Training in Residency and/or Fellowship Programs

For surgeons who successfully completed a residency and/or fellowship program that incorporated a structured curriculum in minimal access procedures and therapeutic robotic devices and their use. This should also include the science and the techniques of access to the body cavity and area of surgery. This includes adequate clinical experience. The applicant's program director, and if desired other faculty members, should supply the appropriate documentation of training and clinical experience.

C. No Formal Residency Training in Therapeutic Robotic Surgery

For those surgeons without residency and/or fellowship training which included structured experience in therapeutic robotic procedures, or without documented prior experience in these areas, a structured training curriculum is required. The curriculum should be defined by the institution, and should include a structured program. The curriculum should include didactic education on the specific technology and an educational program for the specialty specific approach to the organ systems. If the access is an intracavitary procedure then that experience and education should be a prerequisite to the training. Hands-on training, which includes experience with the device in a dry lab environment as well as a specialty-specific model which may include animate, cadaveric and /or virtual reality and simulation modeling, is necessary. Observation of live case(s) should be considered mandatory as well. Other teaching aids may include video review and interactive computer programs.

D. Practical Experience

1. Applicant's Experience – Documented experience that includes an appropriate volume of cases with satisfactory outcomes, equivalent to the procedure in question in terms of complexity. The chief of service should determine the appropriateness of this experience.
2. Initial clinical experience on the specific procedure must be undertaken under the review of an expert and may include assisting. An adequate number of cases to allow proficient completion of the procedure should be performed with this expert review.
3. Preceptor or proctor. - The specific role and qualifications of the expert must be determined by the institution. Criteria of *competency* for each procedure should be established in advance, and should include evaluation of: familiarity with instrumentation and equipment, *competence* in their use, appropriateness of patient selection, clarity of dissection, safety, and successful completion of the procedure. The criteria should be established by the chief of service in conjunction with the specific specialty chief where appropriate. It is essential that mentoring be provided in an unbiased, confidential, and objective manner.

E. Formal Assessment of Competency

When available, validated measures of competency should be used to further document the applicant's abilities. These may include knowledge, medical decision making, and/or technical skill assessments. This may include certificates of completion of training or validated assessment tools for competency or proficiency in a specific procedure, or set of similar procedures.

III. Institutional Support

It is necessary that the staff and technical support team undergo a similar formal technical training with the device before its use in a clinical scenario. Therapeutic robotic surgery requires technical support and must be approached with a team concept.

IV. Maintenance of Privileges

A. Provisional Privileges

Once competence has been determined, a period of provisional privileges may be appropriate. The time frame and/or number of cases during this period should be determined by the chief of service and/or the appropriate institutional committee, board, or governing body.

B. Monitoring of Performance

Once privileges have been granted, performance should be monitored through existing quality assurance mechanisms at the institution. These mechanisms may be modified as appropriate, and should evaluate outcomes, as well as competency in the complete patient care process.

C. Continuing Medical Education

Continuing medical education related to the field should be required as part of the periodic renewal of privileges. Attendance at appropriate local, national or international meetings and courses is encouraged.

D. Renewal

An appropriate level of continuing clinical activity should be required. This should include review of quality assurance data, as well as appropriate CME activity, in addition to existing mechanisms at the institution designed for this purpose.

E. Denial of Privileges

Institutions denying, withdrawing, or restricting privileges should have an appropriate mechanism for appeal in place. The procedural details of this should be developed by the institution, and must satisfy the institution's bylaws and institutional recommendations.

Appendix II. Guidelines for Training in Therapeutic Robotic Procedures

Purpose:

To define guidelines for practical education in therapeutic robotics and its application to surgical specialties. A defined course should provide the necessary information, skill training and familiarization with the technology to initiate a mentored clinical experience. The completion of a course should be considered only as preparation for the performance of a mentored clinical experience as determined by individual institutions

Expert Instructor:

Must have substantial practical experience with the specific advanced technology and have utilized this technology in clinical applications with reported results and review. The individuals should have specialty specific experience and expertise in the advanced technology.

Didactics:

The length of this portion of the educational experience should reflect the complexity of the technology and the specialty specific procedure and the underlying experience of the students, as well as the incremental increase in the procedure and technology. This should allow a complete understanding of the technology, device function, altered functional status, basic troubleshooting, other technical issues, device parameters and limitations. Technology and team interactions should be addressed as well.

Procedure specific information should include indications, workup patient selection, instrumentation, preop preparation, patient and system positioning, port placement, procedural steps, complications and management. Learning curve related issues should be presented. Reported outcomes and expected perioperative course should be included.

Live Case Observation:

The observation of a complete procedure is an important part of a total preclinical training program. The experience should include procedure preparation, system set up, patient positioning, review of case selection and intraoperative technical aspects.

Hands on experience:

Hands on experience should include non clinical simulation encompassing system set up, connections, operation, and troubleshooting. Initial skill training should include basic and advanced techniques to develop adequate proficiency necessary to complete the intended procedure. Clinical simulation should include procedure specific modeling with successful completion of the key components utilizing an appropriate model for the expected procedures. It is recommended that advanced simulation tools be used when available. The complexity of the procedure may dictate the length of the time necessary to complete the tasks.

Residency programs:

It is recommended that specialty training programs include exposure to therapeutic robotic interventions as part of their curriculum. A structured curriculum on therapeutic robotic procedures should be included in programs providing clinical experience to their trainees.

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