Clinical Statement for Surgeons and Programs Performing

Robot-Assisted Cardiac Surgery

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DEFINITION:

Robotic Cardiac Surgery is defined as any cardiac operation that is performed either completely or in part, using robot-assisted (i.e. telemanipulation) technology. At present for robot-assisted cardiac operations the Federal Drug Administration (FDA) has approved only one device, the da Vinci™ surgical system (Intuitive Surgical, Sunnyvale, CA).

PREAMBLE:

The da Vinci™ robotic surgical system was FDA approved for mitral valve surgery in 2002 after Phase I and Phase II investigative device exemption trials. In 2004 the system was FDA approved for coronary revascularization. Since then there has been slow adoption of this technology in cardiac surgery for many reasons including: 1) cost, 2) technical demands, 3) the need for significant institutional resources (i.e. dedicated operating room, nursing, anesthesia, and perfusion teams), and 4) more importantly, lack of proper training and for robotic mitral surgery the lack of prior experience in mitral valve repair and conventional minimally invasive techniques. This has resulted in only a few centers worldwide being able to establish successful and enduring da Vinci™ robotic cardiac surgical programs.

Cardiac surgeons receive appropriate training for conventional sternotomy-based cardiac surgical operations in either residency and/or postgraduate programs; however, only a few education programs offer training specifically in minimally invasive cardiac surgery. Moreover, these programs generally do not provide training in robotic-assisted cardiac surgery. In order for
surgeons to participate in this emerging field in a safe and efficacious manner, a new training paradigm with credentialing has become necessary. Many institutions desire more guidance from professional organizations when establishing robotic cardiac surgical programs.

This document establishes criteria, supported by the American Association for Thoracic Surgery (AATS) and The Society of Thoracic Surgeons (STS) that set minimum standards for both individual surgeons and surgical programs to begin and/or participate in robotic-assisted cardiac surgery. By adhering to these criteria cardiac surgeons can expect to follow minimum safety standards for implementation and independent conduct of robot-assisted cardiac surgical procedures. It is well recognized that a coordinated surgical team, which includes cardiac anesthesiologists, cardiac surgeons, operating room assistants, nurses, and perfusionists, is critical to establish a successful robot-assisted cardiac surgical program.

The intent of this document is not to delineate a training nor certification pathway, as we are not providing a certificate from any of the Societies. The purpose is to create a set of guidelines for surgeons and hospital administrators as a starting point to develop a robotic cardiac surgical program.

BACKGROUND:

Currently, robot-assisted tele-manipulation is used mainly for two cardiac surgical categories: *intra-cardiac operations* (mitral valve, tricuspid valve, atrial septal defect (ASD), cardiac tumors, and atrial fibrillation) and 2) *coronary*
revascularization. This document delineates credentialing criteria necessary to perform these operations independently and is endorsed by the STS and AATS.

CRITERIA:

Robotic Cardiac Surgical Team: Requirements

Institutional

To establish a successful robotic cardiac surgical program, there must be a strong commitment from the hospital, as well as from all team members, including cardiac anesthesiologists, cardiologists, cardiac surgeons, perfusionists, and operating room personnel. Individual surgeons should start programs only if this type of full commitment is apparent. In addition, the team must have had a substantial cardiac surgical experience as a unit. It cannot be overemphasized that transition from traditional sternotomy-based operations to a minimal invasive robotic-assisted platform requires an experienced and cohesive cardiac surgical team. Hospitals administrators and physician leaders should be aware of the necessity of surgeon and team learning curves, which in some complex procedures can reach 75 to 100 cases. Long operative times and technical difficulties, requiring conversion to sternotomy or thoracotomy, should be expected during the implementation phase.

Individual

A single cardiac surgeon should be designated to be the team leader. This person will coordinate the strategic action plan, when developing a robotic cardiac surgical program, as well as monitor program quality and safety. Initially,
one main robot-assisted application (i.e. an intra-cardiac procedure versus coronary revascularization) should be chosen based on the surgeon’s current practice. Simultaneous introduction of different procedures can be more challenging; however, such an approach may reduce the learning curve and help maintain adequate robotic procedure volumes. Surgeons selecting an intra-cardiac platform should be experienced in mitral/tricuspid valve operations as well as other open-heart procedures. If coronary revascularization is selected as the initial pathway, the surgeon should have solid coronary revascularization experience, which includes off-pump techniques and ideally mini-thoracotomy coronary revascularization approaches. Larger case volumes of conventional cardiac operations best prepare surgeons and teams for the initiation of a robotic cardiac surgical program.

The anesthesia team must have significant experience with cardiac surgery patients that have multiple co-morbidities. They should have a significant experience with intra-operative 2-D trans-esophageal echocardiography (TEE) and single lung ventilation, using double lumen intubation and bronchial blockers. For robotic mitral valve operations added expertise with 3-D TEE is desired, as a thorough understanding of the three-dimensional anatomy and pathophysiology is required. To gain maximal early experience, only one or two cardiac anesthesiologist should be involved in the first 20 robotic cardiac operations. It is best that the anesthesiologists or lead cardiac surgeon have prior experience in placing trans-jugular cannulas for cardiopulmonary perfusion, retrograde
coronary sinus cardioplegia administration, and intra-cardiac pressure monitoring.

If the program does not have anesthesiologists versed in intraoperative TEE, a dedicated cardiologist with experience in intraoperative imaging should perform TEE studies. TEE is also crucial for placement of monitoring lines, CPB cannula positioning, and weaning patients off-CPB. Therefore, the echocardiographer must also have this skill set.

It is critical that involved cardiac surgeon(s) and cardiologists define and agree which patients would benefit most from robot-assisted cardiac operations. Ideally, these decisions should be made in the setting of a multidisciplinary team case conference. In addition, they must monitor carefully intra- and postoperative quality outcomes and control. It is prudent to begin a robotic program by selecting low operative risk patients with simple pathology. This approach is extremely important and ensures sufficient physiologic reserve should initial learning curve cases become complicated, extensively long, or necessitate conversion to an alternate approach.

The perfusion team and cardiac surgeon should select one or two perfusionists who should perform the first 20 operations. They should have prior experience in managing peripheral arterio-venous perfusion with vacuum-assisted or kinetic venous drainage.

A small core group of operating room personnel must be dedicated to participate in each of these procedures. Surgical technicians and nurses must
become extremely familiar with the robotic system set-up, deployment, and intraoperative organization. It is crucial to have a single person (i.e. surgeon, physician assistant, or nurse assistant) selected to be the patient-side assistant for these early cases. Close synchrony between the patient-side assistant, surgeon, and scrub personnel is essential for maximizing temporal economy.

Due to the complexity of these procedures, reviewing a preoperative checklist for availability and function of all devices is recommended. Completion of this checklist should be part of the preoperative “time-out” protocol.

**Surgeon Experience: Requirements**

*Robotic Intra-cardiac Operations*

Surgeon expertise in performing both routine and high-risk cardiac procedures is essential. The surgeon should have completed an accredited thoracic surgical training program in which the surgical management of valve disease is a focal point. Ideally, this surgeon either should be eligible or certified by the appropriate cardiac surgical board according to his/her practice location. Surgeons with additional training in mitral valve surgery techniques and/or those who completed a minimally invasive/robotic fellowship training are best suited to develop an intracardiac robotic surgery program. However, the lead surgeon must hold an appropriate certification (e.g. board certification by the American Board of Thoracic Surgery or by the certifying institution at the country or region in which she/he practices cardiac surgery) to independently practice cardiac surgery. All available therapeutic alternatives must be conveyed, detailed and,
explained to potential robot-assisted surgical patients at consultation. These alternatives include traditional sternotomy-based, percutaneous, and other minimally invasive methods in addition to the robotic option. The surgeon must thoroughly discuss these different surgical approaches explaining the different relative risks and benefits of each alternative approach, and proper informed consent should be documented.

The console surgeon should be facile in performing sternotomy-based and/or minimally invasive intra-cardiac surgical operations. Within two years immediately preceding credentialing application, this surgeon should have performed a minimum of 60 cardiac surgical procedures that correspond to the type of operations that will be performed robotically. For robot-assisted mitral valve operations at least 25 of them should have been repairs. It is recommended that the surgeon have attained previously at least an 80% repair rate for degenerative/myxomatous mitral valve disease. It cannot be overemphasized that the surgeon must be facile in all aspects of mitral valve surgery and specifically repair, as these procedures will be prolonged during the initial learning curve. Tricuspid valve surgery, atrial septal defect closures, cardiac tumor extirpations, or atrial fibrillation procedures must not exceed ten aggregate cases (i.e. out of the 60 intracardiac cases recommended; in order to initiate the credentialing application, at least 50 cases must have been mitral valve operations). Aortic valve operations should not be included as part of the recommended 60 intracardiac procedures.
Alternatively, a surgeon may qualify to be credentialed if he/she has performed over 120 intra-cardiac operations after completing an approved cardiac surgery-training program. A minimum of 100 cases should be mitral valve operations of which at least 60 should be mitral repairs.

_Robotic Coronary Revascularization Operations_

Expertise in performing routine, complex, and high-risk coronary revascularization is essential. As above, the surgeon should have completed an accredited thoracic surgical training program in which the surgical management of coronary artery disease is a focal point. Ideally, this surgeon either should be eligible or certified by the appropriate cardiac surgical board. However, the lead surgeon must hold an appropriate certification to independently practice cardiac surgery. Again, all available therapeutic alternatives must be conveyed and detailed to potential robot-assisted surgical patients at consultation. These include traditional sternotomy-based, percutaneous, and other minimally invasive methods in addition to the robotic option. Again, the surgeon must thoroughly discuss these different surgical approaches explaining the different relative risks and benefits of each alternative approach, and proper informed consent should be documented.

The console surgeon should be facile in either sternotomy-based or minimally invasive coronary revascularization techniques. To be credentialed, this surgeon should have performed a minimum of 100 surgical coronary revascularization procedures two years immediately preceding an application. A minimum of 20 cases must have been off-pump coronary revascularizations.
Alternatively, a surgeon may qualify for the credentialing process if he/she has performed over 300 surgical coronary revascularization procedures after completing an approved cardiac surgery-training program. A minimum of 60 cases should have been coronary operations using off-pump techniques. However, extensive off pump surgery or minimal access experience is ideal as this could reduce dramatically conversion rates to an on-pump or sternotomy approach.

**Cardiopulmonary Bypass Skills**

For either robotic intra-cardiac or coronary operations, the surgeon must be able to institute and perform both routine and/or emergent peripheral cardiopulmonary bypass (CPB). Robotic coronary operations require peripheral CPB, not only when using arrested heart techniques, but also during off-pump revascularization, when immediate conversion to a pump operation becomes necessary. Therefore, to be credentialed, the lead surgeon should have performed at least 15 cardiac procedures, using peripheral arteriovenous cannulation and CPB, during the preceding two years. These may include peripheral cannulations (femoral or axillary arteries; femoral or jugular veins) done in patients undergoing any of the following: minimally invasive aortic, tricuspid, or mitral operations; minimally invasive atrial septal or other structural defect closures; aortic dissection surgery, or cannulation for extracorporeal membrane oxygenation (ECMO). Alternatively a surgeon should have a total experience of 30 cases with remote access (i.e. peripheral cannulation) for institution of cardiopulmonary bypass. In addition, robot-assisted operations for
structural heart disease require either vacuum-assisted or kinetic venous drainage, and the team must be well versed in using this technique.

It is imperative that the lead surgeon performs a complete clinical vascular examination. For any patient suspected of having vascular disease, preoperative aortic and aorto-iliac CT angiography is recommended before using peripheral cardiopulmonary bypass.

Using endo-balloon aortic occlusion with cardioplegia administration in robotic cardiac surgery requires a specific and complex skill set. Without prior advanced experience in using this technology, alternative-clamping techniques should be used during the early phases of this type of program. Only after the cardiac surgery team has attained accomplished endo-balloon skills should they be applied to robot-assisted operations.

**ADDITIONAL REQUIREMENTS:**

As stated earlier, robotic cardiac operations should be planned and performed only by a team of cardiologists and cardiac surgeons who have had a dedicated interest and demonstrated expertise. To develop a successful robotic program, clinicians with different strengths must be aligned and dedicated to operational success. This requires close collaboration between interventional cardiologists, cardiac surgeons, echocardiographers (technicians and cardiologists), cardiac anesthesiologists, perfusionists, operating room personnel, and cardiac intensive care staff. Absence of professional synergy usually leads to poor outcomes and programmatic demise. Moreover, the program must have enthusiastic support from the hospital administration and
chief medical officer. A multi-disciplinary team should evaluate patients jointly in a “Robotic Cardiac Surgical Clinic” or conference to select the best treatment algorithm for specific patients.

Well-organized logistic performance of these operations is crucial to optimizing patient safety. Currently, a hybrid operating room (OR) is not required to perform these types of robotic operations. Nevertheless, the hybrid OR does provide advantages in that high-resolution “catheterization-lab” imaging capabilities are available in a sterile environment. Using high-resolution X-ray imaging, especially when the endo-balloon technology is being used, may facilitate catheter/cannula placement. Moreover, high-resolution imaging is needed for hybrid coronary interventions (robotic surgical with percutaneous coronary stenting) and/or for post-operative imaging of robot-assisted coronary anastomoses. A minimum operating room requirement is access to an up-to-date C-arm X-ray machine. During a hybrid Robotic/PCI ‘same session’ procedure, it is advised that one of the following facilities/devices be available: a hybrid OR, C-arm x-ray equipment, or catheterization laboratories next to operating room facilities. Again, it is absolutely necessary to have TEE available for all intra-cardiac procedures.

Program Promotion:

Robotic surgical teams should be very careful in delivering promises to the patient. The possibility of an “open sternal conversion” or surgeon selection should be included always in discussions when obtaining the operative consent. Moreover, the surgeon should also explain an “open thoracotomy” as a second
intraoperative option. The patient should understand that conversion might be life saving should intraoperative technical difficulties arise. This is especially important during early program development. We cannot overemphasize the importance of obtaining proper informed consent prior to surgery.

Hospitals and individual surgeons should be careful and circumspect when marketing their programs. Advertising for a robotic program during the implementation phase is discouraged. Please refer to the STS advertising guidelines: http://www.sts.org/about-sts/policies/advertising-and-publicity-policy.

PROCEDURAL AND DEVICE-SPECIFIC EDUCATION

Surgeons seeking credentials to perform robot-assisted cardiac operations must show evidence of involvement in at least one initial training course, sponsored either by the STS or AATS. This includes robotic system as well as procedure specific training. Both formal didactic and hands-on courses help build the basic skills required to perform robotic cardiac operations safely. Training courses should include information regarding the preoperative work-up, technical nuances, advantages and disadvantages of the various devices, and the management of intra- and post-operative complications. This training should not only be for the operating surgeon but all team members must participate in these training courses. Moreover, they should provide opportunities for robust interactions between learning surgeons and experienced leaders. Surgeons starting a robotic cardiac surgery program must be proctored for at least 5 cases by a surgeon with extensive robotic experience. The proctor must discuss with
surgeon and his/her team after the case his/her observations of the case and recommendations for future cases. Proctoring is usually arranged via the robotic industry as they have developed training programs and pathways to maximize success.

Continuation of education should not end with the initial educational course attended by an individual surgeon. To build upon the basic knowledge obtained from introductory courses, additional expertise should be obtained through accredited continuing education programs. A program should perform at least 20 robotic cardiac surgical procedures per year in order to maintain proficiency. Every two years individual surgeons are expected to maintain credentials and privileges by participating in at least 10 hours of robotic cardiac surgical continuing education. For maintenance of a robotic cardiac surgical program, the dedicated group should have performed at least 40 successful robotic cardiac procedures during the previous two years. If these numbers are not achieved then it should be up to the discretion of the Institution to continue or not their robotic cardiac program. We strongly recommend that each Institution creates a “Robotic User Group” composed of both physicians and administrators who could actively examine the robotic program development, outcomes, and quality. This group could make decisions on whether or not to maintain a program that may no be maintaining proper competence.
In the event that a surgeon or institution feels that the patients’ outcomes are not as expected we strongly recommend that the institution brings a proctor back to evaluate the program and the potential of continuing with the program or not.

In addition, if a program is inactive for more than 6 months we recommend that an experienced proctor returns to get the program re-started.

It is recommended that surgeons performing robotic cardiac surgical operations should consider undergoing additional training as designated by the Joint Council on Thoracic Surgery Education (JCTSE). The length of “fellowships” may be modified in accordance with the minimally invasive cardiac surgical experience of the lead surgeon. These “fellowships” provide surgeon experience with intra-cardiac robotic procedures, robotic coronary revascularization, alternative cardiopulmonary perfusion techniques, and diagnostic techniques necessary to perform robotic cardiac operations optimally.

Surgeons and institutions, performing these operations, should monitor their outcomes through a comprehensive clinical database and make needed changes based on these data. This database can be associated with an institutional, state, or professional society national database (preferably the STS database). Frequent comprehensive analysis of morbidity and mortality (M & M) data should be directed toward continual improvement of clinical outcomes, patient safety and operational process. The robotic program must have a clear process to discuss complications. This could be done as part of an already established M & M conference as part of their ongoing cardiac surgery program or a new M & M conference (e.g. within a Robotic User Committee).
program outcomes should parallel benchmark STS outcomes (within 1 SD of the nation average) for each specific cardiac surgical procedure.

External review by an experience leader in robotic cardiac surgery should be consider in the event that the surgeon, Institution, or Robotic User Committee feels that the program outcomes are not as expected or as recommended in this document.

The position of this working group is that PATIENT SAFETY AND QUALITY OUTCOMES MUST BE FIRST PRIORITY FOR EVERY CARDIAC TEAM PERFORMING ROBOT-ASSISTED CARDIAC SURGERY.
TABLE 1.

PATHWAYS TO CREDENTIALING FOR ROBOTIC CARDIAC SURGICAL PROGRAM

I. SURGICAL EXPERIENCE / KNOWLEDGE BASE / DISEASE MANAGEMENT

A. Completion of an accredited cardiothoracic surgery residency for the primary operating surgeon.

B. Clinical experience of intra-cardiac pathology by a single surgeon:

1. Primary surgeon must have operated on 60 patients with intra-cardiac pathology (i.e. ASD, myxomas, tricuspid valve, and atrial fibrillation surgery) within the two years prior to credentialing as the attending of record. Aortic valve surgery could not be included as part of the 60 cases. In addition, 50 of these 60 intra-cardiac procedures must be mitral valve operations and 25 must be mitral valve repairs. The surgeon should have an 80% repair rate for degenerative mitral valve disease.

2. Alternatively, requirements are met if the primary surgeon has done 120 intra-cardiac procedures (i.e. ASD, myxomas, tricuspid valve, and atrial fibrillation surgery) during his/her career (as the attending surgeon), and 100 must be mitral valve operations with 60 of these being repairs. Aortic valve surgery could not be included as part of the 120 cases. This number of cases must be accumulated after completion of an accredited cardiac surgical training program. The surgeon should have an 80% repair rate for degenerative mitral valve disease.

C. Clinical management of coronary revascularization disease

1. Management of 100 coronary revascularization surgical procedures for the past two years immediately prior to application for credentialing as the attending surgeon. Twenty of
these operations must be off-pump coronary revascularization procedures. Observed mortality has to be lower than STS risk adjusted expected mortality.

2. Alternatively, requirements are met if the surgeon has done 300 coronary revascularization surgical procedures during their career, and 60 cases should be done using off-pump techniques. This may include experience gained during residency, fellowship, or independent surgical career. Observed mortality has to be lower than STS risk adjusted expected mortality.

D. Additional Requirements

1. Routine and/or emergent peripheral cardiopulmonary bypass (CPB) is required
   a. Performance of 15 procedures utilizing peripheral CPB via femoral or axillary arterial and venous cannulation within the two years prior to credentialing from any of the following:
      i. Minimally invasive aortic, tricuspid, or mitral surgery
      ii. Minimally invasive atrial septal or other structural heart defect surgery
      iii. Aortic dissection surgery
      iv. Initiation of extracorporeal membrane oxygenation or peripheral ventricular assist devices.
   b. The perfusion team must be facile with vacuum-assisted venous drainage.

II. ADJUNCTIVE REQUIREMENTS FOR CREDENTIALING OF ROBOTIC CARDIAC SURGICAL PROGRAMS

A. Designated cardiology associate as collaborating partner. Highly recommended that this cardiologist have an interest or expertise in structural heart disease. Two cardiologists may be necessary, one
with expertise in echocardiogram and valvular heart disease, and a second interventional cardiologist with expertise in coronary diseases.

B. Highly recommended that a Robotic Cardiac Surgical Program should include an organized, dedicated, institutionally recognized multidisciplinary clinic.

C. It is highly recommended that the institution provide the robotic cardiac surgery program with facilities enabling performance of these procedures including C-arm x-ray machine, audio-visual equipment and TEE (3-D TEE is preferred).

IV. PROCEDURAL AND DEVICE-SPECIFIC EDUCATION

A. Evidence of attendance of a procedure-based symposium completed at a STS/AATS sponsored credentialing robotic cardiac surgery training course if available.

B. Evidence of attendance of a device-specific training as recommended by the robotic manufacturer.

C. Participation in an approved institutional, state, or national clinical database (preferable the STS database).

D. Highly recommended participation in a JCTSE recognized robotic cardiac surgery training program

E. A program should perform at least 20 robotic cardiac surgical procedures per year in order to maintain proficiency. This requirement could be evaluated every two years and thus 40 cases should be recorded for the 2-year period.

F. Every two years individual surgeons are expected to maintain credentials and privileges by participating in at least 10 hours of robotic cardiac surgical continuing medical education.

AATS: American Association for Thoracic Surgery
CPB: Cardiopulmonary bypass
ECMO: Extracorporeal membrane oxygenation
JCTSE: Joint Council on Thoracic Surgery Education
STS: Society of Thoracic Surgeons
REFERENCES