

Clinical Statement on the Requirements for Surgeon Certification for Implantation of Durable Ventricular Assist Devices (VADs)

Francis D. Pagani, MD, PhD (Chairperson), Michael A. Acker, MD, Margarita T. Camacho, MD, Todd M. Dewey, MD, Seth D. Force, MD, Edwin C. McGee, MD, Michael F. McGrath, MD, Bryan F. Meyers, MD, Nahush A. Mokadam, MD, Nicholas G. Smedira, MD, Yoshida Toyoda, MD, Africa F. Wallace, MD, and Michael J. Weyant, MD

University of Michigan, Ann Arbor, Michigan (FDP); University of Pennsylvania, Philadelphia, Pennsylvania (MAA); St. Barnabas Heart Center at Newark Beth Israel Medical Center, Newark, New Jersey (MTC); Medical City Dallas Hospital, Dallas, Texas (TMD); Emory University, Atlanta, Georgia (SDF); Northwestern University, Chicago, Illinois (ECM); Mid-Atlantic Cardiothoracic Surgeons, Ltd, Norfolk, Virginia (MFM); Washington University at St. Louis, St. Louis, Missouri (BFM); University of Washington, Seattle, Washington (NAM); Cleveland Clinical Foundation, Cleveland, Ohio (NGS); University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania (YT and AFW); and University of Colorado, Denver, Colorado (MJW)

Background

Current Centers for Medicare and Medicaid (CMS) requirement for surgeon qualifications for implantation of durable, long-term ventricular assist devices (VADs) for destination therapy requires “placement of 10 ventricular assist devices in the last 36 months with current activity in the last 12 months and with volume requirement met by including artificial heart placements for no more than 50% of the total volume.”

The Joint Commission currently oversees the process of certification of centers to perform VAD implants for destination therapy through its Advanced Certification in Ventricular Assist Device Therapy as part of a mandate from CMS.

Rationale for Development of Surgeon Criteria

Current Limitations of the CMS Certification Requirements and Interpretation by Joint Commission

1. Current criteria for certification of surgeons for implantation of VADs require only a volume criterion and do not require documentation of other aspects of training and experience that are essential to the overall qualifications of a VAD Surgeon.
2. Although not specifically excluded by CMS criteria, a pathway for surgeon certification from foreign education and training is currently not recognized by the Joint Commission.
3. Although not specifically excluded by CMS criteria, a pathway for surgeon certification from residency

or fellowship experiences is not currently recognized by the Joint Commission. A precedent for recognition of residency and fellowship experiences currently exists for heart transplantation (a procedure of similar complexity to the VAD implant procedure) through United Network for Organ Sharing.

4. Although not specifically excluded by CMS criteria, the Joint Commission defines the primary surgeon as the surgeon appearing on the operative consent and submitting an operative record for reimbursement. This narrow interpretation of the primary surgeon limits educational opportunities for cardiothoracic residents, fellows, and surgeons in clinical practice to provide experiences that count toward VAD Surgeon certification.
5. Although not specifically excluded by CMS criteria, the Joint Commission has interpreted the CMS requirement on VAD cases to include at least one implant be performed for destination therapy.

Goal and Overview of Proposed Criteria

The goal of the proposed criteria for surgeon certification is to demonstrate competency in both the technical aspects of VAD implantation and competency in VAD patient management and to establish a minimum standard of training and experience as recognized by CMS to

Prepared by The Society of Thoracic Surgeons Workforce on the Surgical Treatment of End-Stage Cardiopulmonary Disease.

The International Society for Heart & Lung Transplantation (ISHLT) has endorsed this clinical statement.

Address correspondence to Dr Pagani, Department of Cardiac Surgery, Cardiovascular Center, University of Michigan, 1500 E Medical Center Dr, Ann Arbor, MI 48109; e-mail: fpagani@umich.edu.

For authors' disclosure of industry relationships, go to: <http://www.sts.org/annals-thoracic-surgery/auxiliary-annals> and search for Appendix for Pagani FD, et al. Clinical Statement on the Requirements for Surgeon Certification for Implantation of Durable Ventricular Assist Devices (VADs) (<http://www.sts.org/auxiliaryannals/Pagani-2013-95-5-1834-Appendix.pdf>).

permit safe VAD implantation and care of patients receiving durable VADs.

This document does not address criteria pertinent to temporary, emergency circulatory support circumstances (see III, E, 1, a, viii). These criteria apply only to the surgeon as the basis for performing VAD implants.

Proposed Criteria for Surgeon Certification for Implantation of a Ventricular Assist Device

Terminology

I. Definition of Primary Surgeon and First Assistant for Purposes of Obtaining VAD Surgeon Certification

A. For the purposes of VAD surgeon certification, the designation of primary surgeon on a cardiothoracic surgery resident's or fellow's operative log will be permitted for supervised operative experiences by a certified VAD Surgeon in a teaching setting when the following criteria are met:

1. The resident or fellow participated in the diagnosis, preoperative planning, and selection of the appropriate operation under the supervision of a certified VAD Surgeon. Documentation from the medical record supports the participation of the resident or fellow in the preoperative and postoperative care of the patient.
2. The resident or fellow performed those technical manipulations that constituted the essential parts of the procedure itself under the supervision of a certified VAD Surgeon.
3. The resident or fellow was substantially involved in the postoperative management, including critical care, under the supervision of a certified VAD Surgeon.
4. The guidelines to assign the designation of primary surgeon should follow those guidelines established by the American Board of Thoracic Surgery (ABTS).

B. For the purposes of surgeon certification, the designation of primary surgeon on a surgeon's operative log (eg, a surgeon in clinical practice performing a VAD implant procedure outside the setting of a residency or fellowship experience who is board certified or holds an equivalent foreign certification recognized by the applicant's hospital or organization) will be allowed for:

1. Operative cases that are performed by the surgeon under the appropriate supervision of a certified VAD Surgeon in a teaching setting, and the surgeon is performing those technical manipulations that constituted the essential parts of the procedure itself.
2. Operative cases in which the surgeon is operating independently, is listed as the surgeon of record as the primary surgeon on the medical and operative record, and is submitting the operative record for reimbursement.

3. In both cases above, the surgeon provides documentation of participation in the diagnosis, preoperative planning, and selection of the appropriate operation, as well as documentation of involvement in the postoperative management including critical care.

C. First assistant designation will apply when the cardiothoracic surgery resident, fellow, or board certified surgeon has an active role in the operation with direct assistance to the operative surgeon of record but the above criteria are not met. The first assistant role should be identified in both the operative note and medical record to distinguish this role from second assistant or observational roles.

D. Second assistant or observational roles during the operation do not count toward surgeon certification numbers.

II. Foreign Training and Equivalency

The medical center, hospital, or organization that is responsible for the credentialing process of the surgeon will be the final arbiter of determining equivalency of foreign training experiences.

III. Requirements for Obtaining VAD Surgeon Certification

A. The VAD Surgeon shall be a physician with an MD or DO degree or equivalent degree from another country who is licensed to practice medicine in his/her state in the United States or political jurisdiction and has been accepted onto the medical staff of the applicant's hospital or organization.

B. The VAD Surgeon shall have current certification by the ABTS or its foreign equivalent. Pediatric Cardiac Surgeons should similarly have ABTS congenital subspecialty certification or its foreign equivalent. If board certification in thoracic surgery is pending (as in the case of an applicant just finishing training), conditional approval may be granted for a 24-month period.

C. The VAD Surgeon shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

D. If a person is certified by the ABTS or its foreign equivalent, then the person must maintain his/her certification in the ABTS or its foreign equivalent.

E. To certify as a VAD Surgeon, the training/experience requirements will be met if the following conditions of (1), (2), or (3) are met:

1. The certification requirements for VAD Surgeon can be met during the applicant's cardiothoracic surgery residency if the following conditions are met:

- a. The surgeon performed as primary surgeon or first assistant a total of 10 or more VAD implants by the completion of the cardiothoracic surgery residency (maximum of 3

years) with five VAD implants occurring with the surgeon as the primary surgeon.

- i. Cases must be documented in an operative log.
 - ii. Documentation in the operative log includes the date of VAD implant, medical record number of the patient, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure as well as indication for procedure.
 - iii. The operative log must be signed or verified in writing by both the director of the residency training program and certified VAD Surgeon confirming the role of the surgeon in each case.
 - iv. For cases claimed as primary surgeon, supporting documentation from the medical record must demonstrate that the surgeon participated in the diagnosis, preoperative planning, surgical indications, selection of the appropriate operation, and postoperative management including critical care.
 - v. Primary surgeon role cannot be claimed by more than one surgeon.
 - vi. A minimum of three implants occur within the previous 12 months.
 - vii. The VAD implant procedures performed for bridge to transplant or destination therapy indications are equally acceptable as contributing toward the surgeon's total number of VAD implant procedures.
 - viii. Temporary mechanical circulatory assist devices, including extracorporeal or paracorporeal VADs, do not count toward the total number of VAD implants. This document refers to devices recognized as durable, implantable devices by INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) or in the setting of an investigational device that permits patient discharge to home with untethered mobility by a Food and Drug Administration (FDA)-approved investigational protocol. A maximum of five total artificial heart implantations may be credited toward the total number of VAD implant procedures. Experience with implantation of biventricular assist support is recommended.
- b. If the surgeon has obtained the requisite number of implants by completion of the cardiothoracic residency:
- i. The surgeon has a letter from the director of that cardiothoracic residency training program verifying that the surgeon has met the above require-

ments and that the surgeon is qualified to perform a VAD implant and care for a patient on VAD support.

- ii. The surgeon has a letter of recommendation from the person(s) named as the certified VAD Surgeon and/or VAD program director at the cardiothoracic residency training program attesting to the surgeon's overall qualifications to act as a certified VAD Surgeon, addressing the person's personal integrity, honesty, familiarity with and experience in adhering to compliance protocols, and other matters as deemed appropriate.
 - c. The above training was at a medical center with a cardiothoracic training program that is approved by the Accreditation Council for Graduate Medical Education or, in the case of foreign training, accepted as the equivalent training by the hospital's credentialing committee to which the applicant is applying.
2. For VAD implantation, when the certification requirements for VAD Surgeon have not been met during the surgeon's cardiothoracic surgery residency, they can be met by the completion of a fellowship experience if all the following conditions are met:
- a. The surgeon performed as primary surgeon or first assistant a total of 10 or more VAD implants by the completion of the fellowship experience (maximum of 3 years) with five VAD implants occurring with the surgeon as the primary surgeon.
 - i. Cases must be documented in an operative log.
 - ii. Documentation in the operative log includes the date of VAD implant, medical record number of the patient, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure as well as indication for procedure.
 - iii. The operative log must be signed or verified in writing by both the director of the fellowship training program and certified VAD Surgeon confirming the role of the surgeon in each case.
 - iv. For cases claimed as primary surgeon, supporting documentation from the medical record must demonstrate that the surgeon participated in the diagnosis, preoperative planning, surgical indications, selection of the appropriate operation, and postoperative management including critical care.
 - v. Primary surgeon role cannot be claimed by more than one surgeon.

- vi. A minimum of three implants occur within the previous 12 months.
 - vii. The VAD implant procedures performed during board qualifying cardiothoracic surgical residency will count toward this number if performed within the preceding 3 years and if performed while meeting the criteria for primary surgeon or first assistant designation.
 - viii. The VAD implant procedures performed for bridge to transplant or destination therapy indications are equally acceptable as contributing toward the surgeon's total number of VAD implant procedures.
 - ix. Temporary mechanical circulatory assist devices including extracorporeal or paracorporeal VADs do not count toward the total number of VAD implants. This document refers to durable, implantable devices by INTERMACS or in the setting of an investigational device that permits patient discharge to home with untethered mobility by an FDA-approved investigational protocol. A maximum of five total artificial heart implantations may be credited toward the total number of VAD implant procedures. Experience with implantation of biventricular assist device support is recommended.
- b. If the surgeon has obtained the requisite number of cases by completion of the fellowship experience:
 - i. The surgeon has a letter from the director of that fellowship program verifying that the surgeon has met the above requirements, and that the surgeon is qualified to implant a VAD and care for a patient on VAD support.
 - ii. The surgeon has a letter of recommendation from the person(s) named as certified VAD Surgeon, and the VAD program director at the fellowship training program attesting to the surgeon's overall qualifications to act as a certified VAD Surgeon, addressing the person's personal integrity, honesty, familiarity with and experience in adhering to compliance protocols, and other matters as deemed appropriate.
3. For VAD Surgeon certification, if the requirements have not been met as outlined above in a cardiothoracic residency or fellowship training experience, the requirement can be met by experience in clinical practice if the following conditions are met:
 - a. The surgeon performed as primary surgeon or first assistant a total of 10 or more VAD implants within a maximum of 3 years) with five VAD implants occurring with the surgeon as the primary surgeon.
 - i. Cases must be documented in an operative log.
 - ii. Documentation includes the date of VAD implant, medical record number of the patient, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure and indication for procedure.
 - iii. The operative log must be signed or verified in writing by the surgeon's appropriate supervisor named as VAD program director, division chief, department chair, or chief of staff confirming the role of the surgeon in each case.
 - iv. For cases claimed as primary surgeon, supporting documentation from the medical record must demonstrate that the surgeon participated in the diagnosis, preoperative planning, surgical indications, selection of the appropriate operation, and postoperative management including critical care.
 - v. The VAD implant procedures performed during board-qualifying surgical residency or fellowship will count toward this number if performed within the preceding 3 years and if performed while meeting the criteria for primary surgeon or first assistant designation.
 - vi. Primary surgeon role cannot be claimed by more than one surgeon.
 - vii. Three implants must occur within the previous 12 months.
 - viii. The VAD implant procedures performed for bridge to transplant or destination therapy indications are equally acceptable as contributing toward the surgeon's total number of VAD implant procedures.
 - ix. Temporary mechanical circulatory assist devices including extracorporeal or paracorporeal VADs do not count toward the total number of VAD implants. This document refers to devices recognized as durable, implantable devices by INTERMACS or in the setting of an investigational device that permit patient discharge to home with untethered mobility by an FDA-approved investigational protocol. A maximum of five total artificial heart implantations may be credited toward the total number of VAD implant procedures. Experience with implantation

of biventricular assist device support is recommended.

- x. The surgeon must receive and provide documentation of device-specific training from the manufacturer of all VADs that the VAD Surgeon has implanted.
- xi. The surgeon has a letter of recommendation from the person(s) named as VAD program director, division chief, department chair, or chief of staff from the program where the experience was gained attesting to the person's overall qualifications to act as a certified VAD Surgeon, addressing the person's integrity, honesty, familiarity with and experience in adhering to compliance protocols, and other matters as deemed appropriate.

IV. Requirements for Maintaining VAD Surgeon Certification

To maintain certification as a VAD Surgeon, the certification requirements will be met if the following conditions of either (A) or (B) are met.

- A. The surgeon performs as primary surgeon or first assistant, over a maximum of 3 years, 10 or more VAD implant procedures. The surgeon must perform at least five of these cases as the primary surgeon unless performed in the role of the proctor or teaching physician.
 - 1. Cases must be documented in an operative log.
 - 2. Documentation includes the date of VAD implant, medical record number of the patient, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure and indication for operation.
 - 3. For cases claimed as primary surgeon, supporting documentation from the medical record must demonstrate that the surgeon participated in the diagnosis, preoperative planning, surgical indications, selection of the appropriate operation and postoperative management including critical care.
 - 4. If the surgeon is credentialed at more than one hospital, VAD implant procedures performed at institutions at which the surgeon is credentialed may count in the surgeon's total number of VAD implant cases. These cases must be documented in an operative log. Documentation should include the date of VAD implant, medical record number of the patient, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure. This log should be signed by the VAD program director, division chief, or department chair from the program where the experience was gained.
 - 5. Three implants must occur within the previous 12 months.
 - 6. Cases performed during the surgeon's cardiothoracic residency or fellowship training experience

will count if performed within the preceding 3 years and if performed while meeting the criteria for primary surgeon or first assistant designation.

- 7. Primary surgeon role cannot be claimed by more than one surgeon.
 - 8. The VAD implant procedures performed for bridge to transplant or destination therapy indications are equally acceptable as contributing toward the surgeon's total number of VAD implant procedures.
 - 9. Temporary mechanical circulatory assist devices including extracorporeal or paracorporeal VADs do not count toward the total number of VAD implants. This document refers to devices recognized as durable, implantable devices by INTERMACS or in the setting of an investigational device that permit patient discharge to home with untethered mobility by an FDA-approved investigational protocol. A maximum of five total artificial heart implantations may be credited toward the total number of VAD implant procedures. Experience with implantation of biventricular assist device support is recommended.
 - 10. The surgeon must receive and provide documentation of device-specific training from the manufacturer of all VADs that the surgeon has implanted.
 - 11. The surgeon has a letter of recommendation from the person(s) named as VAD program director, division chief, department chair, or chief of staff from the program where the experience was gained attesting to the person's overall qualifications to act as a certified VAD Surgeon, addressing the person's integrity, honesty, familiarity with and experience in adhering to compliance protocols, and other matters as deemed appropriate.
- B. The surgeon has a lifetime experience of 100 or more VAD implantations with activity in each of the previous 3 years.
 - 1. Cases must be documented in an operative log.
 - 2. Documentation includes the date of VAD implant, medical record number of the patient, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure and indication for operation.
 - 3. For cases claimed as primary surgeon, the supporting documentation from the medical record must demonstrate that the surgeon participated in the diagnosis, preoperative planning, surgical indications, selection of the appropriate operation, and postoperative management including critical care.
 - 4. The VAD implant procedures performed for bridge to transplant or destination therapy indications are equally acceptable as contributing

uting toward the surgeon's total number of VAD implant procedures.

5. Temporary mechanical circulatory assist devices including extracorporeal or paracorporeal VADs do not count toward the total number of VAD implants. This document refer to devices recognized as durable, implantable devices by INTERMACS or in the setting of an investigational device that permit patient discharge to home with untethered mobility by an FDA-approved investigational protocol. A maximum of five total artificial heart implantations may be credited toward the total number of VAD implant procedures. Experience with implantation of biventricular assist device support is recommended.
6. The surgeon must receive and provide documentation of device-specific training from the manufacturer of all VADs that the surgeon has implanted.
7. The surgeon has a letter of recommendation from the person(s) named as VAD program director, division chief, department chair, or chief of staff from the program where the experience was gained attesting to the person's overall qualifications to act as a certified VAD Surgeon, addressing the person's integrity, honesty, familiarity with and experience in adhering to compliance protocols, and other matters as deemed appropriate.

V. Requirements for VAD Certification for Pediatric Cardiac Surgeons

For the purposes of this document, a Pediatric Cardiac Surgeon will be defined as ABTS congenital subspecialty certified or its foreign equivalent surgeon whose practice is entirely restricted to the treatment of congenital heart disease or to children under the age of 21 years.

- A. The surgeon performs as primary surgeon or first assistant, over a maximum of 3 years, five or more VAD implant procedures. The surgeon must perform at least three of these cases as the primary surgeon.
 1. Cases must be documented in an operative log.
 2. Documentation includes the date of VAD implant, medical record number of the patient, and the role of the surgeon (primary surgeon

or first assistant) in the operative procedure and indication for operation.

3. For cases claimed as primary surgeon, supporting documentation from the medical record must demonstrate that the surgeon participated in the diagnosis, preoperative planning, surgical indications, selection of the appropriate operation, and postoperative management including critical care.
4. Planned VAD implant procedures performed for bridge to recover, transplant or destination therapy indications are equally acceptable as contributing toward the surgeon's total number of VAD implant procedures.
5. Temporary mechanical circulatory assist devices, including extracorporeal or paracorporeal VADs, will count toward the total number of VAD implants. Devices must be recognized in PediMACS (pediatric registry component of INTERMACS) as a pediatric VAD device. Extracorporeal membrane oxygenation or extracorporeal life support will not count toward VAD implant numbers. Implantation of an investigational VAD will count toward VAD implant numbers if performed under an FDA-approved investigational protocol. Experience with implantation of biventricular assist device support is recommended.
6. Experiences obtained with adult patients and documented as required in this document will be counted toward the surgeon's total number.
7. The surgeon must receive and provide documentation of device-specific training from the manufacturer of all VADs that the surgeon has implanted.
8. The surgeon has a letter of recommendation from the person(s) named as VAD program director, division chief, department chair, or chief of staff from the program where the experience was gained attesting to the person's overall qualifications to act as a certified VAD Surgeon, addressing the person's integrity, honesty, familiarity with and experience in adhering to compliance protocols, and other matters as deemed appropriate.

(Adopted by the STS Executive Committee: February 10, 2013)