

# The Joint Commission's disease-specific care certification for destination therapy ventricular assist devices

The Centers for Medicare and Medicaid Services announced that all hospitals implanting ventricular assist devices are required to have certification from the The Joint Commission for disease-specific care destination therapy with a ventricular assist device effective March 27, 2009, in order to receive Medicare reimbursement for services rendered to patients who have devices implanted for destination therapy. On February 23, 2007, The Joint Commission released the certification requirements for ventricular assist devices implanted for destination therapy in an 8-page document so that hospitals could prepare to meet the 2009 certification deadline. The Artificial Heart Program of the University of Pittsburgh Medical Center undertook a multidisciplinary project, under the guidance of the nurse coordinator, to prepare the hospital and program for a precertification survey by The Joint Commission for disease-specific destination therapy ventricular assist device certification. The Presbyterian Hospital Artificial Heart Program was awarded The Joint Commission's device-specific certification for destination therapy with ventricular assist devices in June 2008. (*Progress in Transplantation*. 2010;20:155-162)

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Approximately 300 hospitals in the United States are implanting ventricular assist devices (VADs). Initial hospitalization and follow-up care of patients having a VAD implanted is costly, and in order to ensure that services rendered to Medicare recipients are high quality, safe, and cost-effective, Medicare requested that The Joint Commission (TJC) establish guidelines and standards of care for patients having a VAD implanted as permanent (or "destination") therapy.<sup>1</sup> TJC has many programs with disease-specific care certifications such as primary stroke, heart failure, joint replacement, chronic kidney disease, inpatient

diabetes management, lung volume reduction surgery, and chronic obstructive pulmonary disease. The final recommendations for the VAD destination therapy certification were released by TJC in February 2007. Medicare's release stated that "effective March 27, 2009 . . . hospitals must now receive certification from The Joint Commission . . . under their Disease-Specific Certification Program for VADs."<sup>2</sup>

If the certification process were not achieved by the March 2009 date, VAD centers would lose reimbursement for destination therapy VADs implanted in Medicare patients.<sup>3</sup> After a year-long journey, the

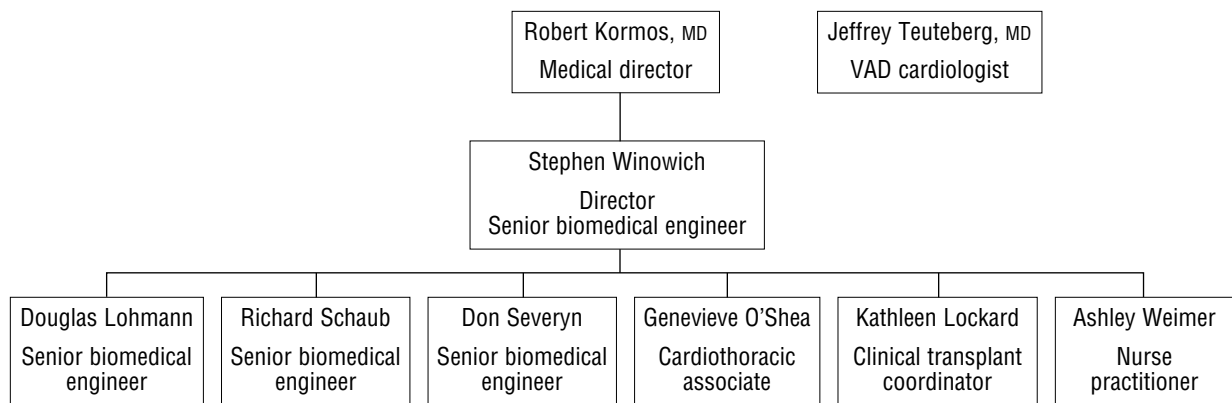


Figure Organizational tree for the Artificial Heart Program at the University of Pittsburgh Medical Center.

University of Pittsburgh Medical Center (UPMC) successfully achieved TJC VAD destination therapy certification. The collaboration of many disciplines involved in the care of VAD patients, led by the VAD nurse coordinator, permitted us to effectively present a comprehensive picture of our program and the processes in place to implant VADs successfully. Some of the details of our efforts in preparing for TJC VAD destination therapy certification are described in the following paragraphs.

### Disease-Specific Eligibility Criteria

The program director of the Artificial Heart Program (AHP) met with the director of the Regulatory Compliance Office and the VAD nurse coordinator to review TJC's VAD certification requirements<sup>3</sup> and to establish a time line to apply for and receive TJC certification for the destination therapy arm of our program. We downloaded and reviewed the VAD certification requirements with respect to our program. The first step was to review the eligibility criteria, which stated that the hospital must have the infrastructure to support VAD placements, as evidenced by adequate staffing and a facility where VADs can be implanted and VAD patients can recover. UPMC has been implanting VADs for more than 25 years, and the AHP is led by an experienced, board-certified cardiac surgeon. The AHP's organizational tree is provided in the Figure.

The second eligibility criterion addresses the hospital's membership in a nationally audited registry of VADs. The Interagency Registry of Mechanical Circulatory Support (INTERMACs) registry was established as a database of recipients of mechanical circulatory support devices. The registry collects and analyzes clinical and laboratory data from eligible, participating hospitals throughout the United States, on patients receiving mechanical circulatory support devices as destination therapy for end-stage heart failure. The registry collects data from new patients annually

for 5 years.<sup>4</sup> UPMC's AHP has been an active member of INTERMACS since its inception in 2006.

### Delivering or Facilitating Clinical Care

#### 1. Staff Training and Competency

This requirement addresses the qualifications and competencies of program staff.<sup>3</sup> Each practitioner's qualifications and competency skill level as required by the DSC criteria were assessed. UPMC has 1 board-certified cardiac surgeon who had successfully placed more than 10 VADs in the preceding 36 months and had been active in the preceding year (as required). A report was generated from the internal UPMC transplant database listing the surgeon, patients' initials, device implanted, date of implantation, date of explantation and outcome, and information was submitted to Medicare as required by Medicare guidelines. Medicare and TJC require 1 or more board-certified cardiac surgeons to have successfully placed at least 10 VADs in the past 36 months with current activity in the past year. UPMC has more than 1 board-certified cardiologist, each of whom is trained and experienced in treating advanced heart failure. The cardiologists have recent experience managing patients with VADs placed before heart transplantation and sufficient competency in evaluation of patients for transplantation; they have worked in or trained in a transplant center.

The hospital personnel in charge of physician credentialing verified that physicians' credentials were accurate and reflected their educational preparation and competencies based on their field of study. The program's certified registered nurse practitioner and registered nurses had current licensure verified by primary sources, documented annual assessments of VAD competency, current job descriptions, and corresponding job performance appraisals. The AHP's 5 full-time biomedical engineers had relevant education, training, and experience with a variety of VADs, documented annual assessments of competency, current

job descriptions, and corresponding job performance appraisals. The 27 part-time biomedical engineers had relevant education and experience, job descriptions, and corresponding annual appraisals. All documentation was placed in a binder for TJC review.

The nurse coordinator met with the human resource department and all AHP employee files were reviewed for current licensure, primary source verification, current job descriptions, appraisals, and proof of annual VAD competencies as required by the AHP department. The nursing staff maintained individual binders with proof of continuing education courses and applicable certifications (cardiopulmonary resuscitation, Advanced Cardiac Life Support, National Institute of Health Stroke Scale training, neurocognitive testing certificates). The human resource department generated employee lists for the cardiothoracic intensive care unit, step-down unit, and the physical therapy, occupational therapy, and cardiac rehabilitation departments, and each employee's file was reviewed for completeness before the survey.

## 2. Clinical Practice Guidelines

This requirement addresses the clinical practice guidelines (CPGs) used for the VAD program, which were based on evidence that has been evaluated as current by clinical leaders.<sup>3</sup> The CPGs used at UPMC were based on Medicare CPGs,<sup>5</sup> American Heart Association CPGs,<sup>6</sup> and the Thoratec CPG for Heartmate II LVAS.<sup>7</sup> Assessment of patients for VAD selection as destination therapy was based on the Medicare guidelines for patient selection criteria as follows:

VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years), are not candidates for heart transplantation, and meet all of the following conditions: A) The patient's Class IV heart failure symptoms have failed to respond to optimal medical management, including dietary salt restriction, diuretics, digitalis, beta-blockers, and ACH inhibitors (if tolerated) for at least 60 of the last 90 days; B) The patient has a left ventricular ejection fraction (LVEF) <25%; C) The patient had demonstrated functional limitation with a peak oxygen consumption of  $\leq 12$  mg/kg/min; or the patient has a continued need for intravenous inotropic therapy owing to the symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion; and D) The patient has the appropriate body size ( $>1.5$  m<sup>2</sup>) to support the VAD implantation.<sup>5</sup>

The CPGs are printed and placed in the AHP binder, and they are reviewed annually by the program's medical director to ensure that they remain current and appropriate for their intended use.

## 3. Assessment of Patients and Plan of Care

This requirement addressed how the program defined the patient assessment process and used the assessment to develop a plan of care.<sup>3</sup> UPMC used a mechanical circulatory support screening form to check prospective device recipients' medical status and to ascertain if they met implant criteria. The plan of care was developed and based on the patients' medical conditions and anticipated outcomes.

## 4. Concomitant Conditions

This criterion addresses how concurrently occurring conditions are managed. UPMC has a multidisciplinary group meeting weekly, composed of a board-certified surgeon, a board-certified heart failure physician, heart transplant/VAD fellows, a social worker, a clinical sociologist, biomedical engineers, certified registered nurse practitioners, physician assistants, registered nurses, and palliative care staff to discuss each patient's plan of care. The weekly VAD meeting attendance and minutes are recorded and kept in a binder for review. A variety of specialists are consulted, depending on the pertinent medical condition, including staff from endocrinology, thoracic surgery, general surgery, pain management, and other services.

## 5. Performance Measurement and Improvement

This criterion addresses the collection and review of data, variance tracking, and evaluation of the VAD program in relation to the CPGs; basically, "How are we doing compared with our goals?" The VAD program had to demonstrate an organized, comprehensive approach to performance improvement. According to TJC,

performance measurement in health care is the systematic process of data collection, repeated over time or at a single point of time. A performance measure is a quantitative tool that is calculated from a group of data elements.<sup>8</sup>

Four areas of patient care that affect outcomes were selected for our "wish list" of things we would like to improve:

1. Decrease length of stay for implantation of VAD
2. Decrease infection rate of VAD pocket/driveline
3. Monitor and record prealbumin levels of VAD patients, note levels <18 mg/dL preoperatively, and weekly for 1 month, and then monthly and intervene with patient education, nutrition consultation, and protein supplements

#### 4. Consult physical therapist within 48 hours of VAD implantation

Items 1, 2, and 3 were tracked via the UPMC transplant database. The physical therapy consultation and progress notes were manually collected and recorded by part-time biomedical engineers. A monthly report was produced, reviewed, and modified as needed to improve performance measurement items.

### Performance Measures

#### 1. Length of Stay for VAD Implantation

The goal of this performance measure was to provide safe, efficient, quality care to VAD patients and enable them to return home as soon as safe and practicable postoperatively. Part of this aim was to minimize patients' exposure to hospital-acquired infections. The length of stay report for VAD implantation was generated from the transplant database, and the mean length of stay for VAD implantation was well above the national average of 35.3 days.<sup>9</sup>

We began a concerted effort to begin VAD teaching sessions as soon as the patient was transferred from the cardiothoracic intensive care unit to the step-down unit and was medically ready. The physical therapy department was consulted within 48 hours of implantation, and therapy was initiated twice per day on the step-down unit, if the patient's medical condition permitted it.

#### 2. Infection Rate of VAD Pocket/Driveline

Device infections can be life threatening to VAD patients, and ongoing assessment of wound healing and formation of adherent tissue around the driveline is necessary. Sterile driveline dressing changes by educated and trained staff caring for VAD patients across the implant spectrum (intensive care unit, general care unit, home/external facility) were essential to minimizing driveline infection. Percutaneous driveline immobilization with the Telfa Island dressing (Covidien, Mansfield, Massachusetts), Hollister tube holder (Hollister, Libertyville, Illinois), and an abdominal binder was implemented to assist in tissue growth and wound healing, in order to prevent infections at the driveline exit site.<sup>10</sup>

#### 3. Record Prealbumin Levels and Treat Levels Less Than 18 mg/dL

Postoperative prealbumin levels are directly correlated with patients' outcomes and are an accurate indicator of patients' recovery. Monitoring of prealbumin levels is a cost-effective and objective method of assessing severity of illness in patients who are critically ill or have chronic disease.<sup>11,12</sup> The performance goal was to identify patients with prealbumin levels less than 18 (normal range, 18-38 mg/dL), to educate the patient about prealbumin levels and protein intake

for wound healing, and to consult the nutritionists for high-protein diets, protein supplements, and tube feedings if necessary.

#### 4. Physical Therapy Consultation Within 48 Hours of VAD Implantation

The target for physical therapy is that 90% of VAD patients be seen by physical therapy staff within 48 hours of consultation. Early physical therapy enables early assessment and development of a plan of care to promote the patient's strength and mobilization.<sup>13,14</sup> Many patients with end-stage heart failure have limited tolerance to activity, muscle weakness, and wasting before VAD implantation and require aggressive physical therapy to regain and improve their physical condition, increase stamina, and return to normal activities with a VAD.

### Supporting Self-Management

This requirement addresses how VAD patients are supported and encouraged to participate in their own care, disease management, and decision making.<sup>3</sup> All prospective device recipients are involved in making decisions about their clinical care, beginning with the preoperative education and consent process. Signed consent forms document the patients' understanding of the procedure, associated risks, and postoperative course as explained to them by the physicians.

Once potential VAD patients were identified, artificial heart nurse coordinators visited to educate them about their current medical condition, the proposed device to be implanted, and living life while supported by a VAD. The nurse coordinators also provided written information pertaining to heart failure and VAD therapy. All questions from patients and their families were addressed and documented in the medical record as well as in database progress notes.

The detailed discharge plan encompassed patient, family, and community education about VADs and the care of patients supported by VADs. Postoperatively, patients were encouraged to become personally involved in management of their device as soon as possible. Daily physical therapy provided the opportunity for device engineers to demonstrate and reinforce device management concepts, and to allow patients to begin hands-on involvement under supervision. This also permitted identification of learning barriers that could then be addressed (eg, reduction in grip strength requiring occupational therapy).

### Discharge Planning

Discharge planning is necessary to educate patients and their family members for a safe and comfortable discharge. Patients and families are given a discharge worksheet to complete with their contact information. This information includes current home address, home

and cell phone numbers, number of the next of kin or significant other, and other family contacts. The patient's pharmacy name and phone number is recorded in order to call in prescriptions. The patient provides the name and account number of their electricity provider, so that nurse coordinators can notify the patient's electricity service provider of the patient's discharge with a life-support device. If the electricity is voluntarily interrupted for elective repairs, the patient must be notified in order to relocate for the day. Names were obtained for the patient's local emergency department, emergency medical service provider; and local home care nursing agency willing to accept a VAD patient.

Nurse coordinators then set a date to go into the patient's community to educate the local health care providers about VAD function, power requirements, management issues of pulsatile pumps versus nonpulsatile pumps, driveline location, and care of the driveline site. Home care staff were provided a detailed demonstration of driveline dressing changes to minimize the driveline infection rate, as well as a list of dressing supplies and Healthcare Common Procedure Coding System numbers (HCPCS codes) necessary to obtain dressing supplies. They were provided a PowerPoint presentation that included a brief history of mechanical circulatory support devices, a list of available VAD types, descriptions of patient care and potential complications such as infection, thromboembolism, stroke, and device failure. Device manuals were left on site with the patient's local emergency department, emergency medical services provider, and homecare providers.

The patient and the patient's family identified all interested parties who were willing to be taught about the device and to take hands-on and written tests to verify their competency. The VAD educational process was explained to the family and caregivers, and a written statement about our educational sessions and what patients and family members should expect from these sessions, was provided. A minimum of 4 education sessions were provided to each patient/family: the first session presented by the VAD coordinator addressed the medical aspects of the ventricular assist pump, and sessions 2 through 4 were provided by the a biomedical engineer on the device components, function, alarms, and emergency procedures.

### **Ventricular Assist Device Program Leadership and Mission Statement**

The VAD certification requirement for program management addressed the leadership roles in the program that must be clearly identified.<sup>3</sup> The medical director of the AHP developed the following mission statements for the program:

1. To relieve patients' suffering and to provide a cost-effective alternative to death from end-stage con-

gestive heart failure through the use of therapies and technologies that promote recovery and repair of the heart, and when necessary to provide a replacement alternative through mechanical cardiac support.

2. To act as a regional and national resource in the field of cardiac recovery and replacement through the development of unified program of evaluation and therapy provided by a team of leading experts from cardiology, surgery, nursing, and engineering.

3. To assist in the development of satellite programs through educational initiatives thereby establishing a network of community and regional liaisons.

4. To interact in multidisciplinary projects with basic scientists in the fields of molecular cardiology, regenerative medicine, genetics and engineering to develop new technologies and therapies.

5. To investigate the safety, efficacy, and clinical utility of new therapies and technologies for end-stage congestive heart failure through participation and leadership of multicenter trials.

The medical director's accountability is clearly defined; he participates in designing and evaluating care, treatment, and services. He coordinates the weekly multidisciplinary meeting, as well as twice-weekly bedside patient rounds. The medical director and heart failure physicians are available 24 hours a day, 7 days a week to address patient care issues or concerns.

### **Certification Requirement: Clinical Information**

This criterion addressed the confidentiality and security of participants' information.<sup>3</sup> UPMC has a secure transplant database that houses electronic data on patients' demographics, medical history, diagnostic procedure results, VAD implant and device tracking information, and engineering and nursing notes. Patients complete an 8-page consent preoperatively, which permits entry of their data to share among their health care team providers. Data can be retrieved quickly and securely by all members of the health care team.

Preparing for TJC's disease-specific care certification process was a very large, time-consuming project for our organization. We are in the business of providing a service (health care) to our patients and are very adept at documenting our care in the medical record. We were required to step back and review our program on the basis of TJC's criteria, which was an enlightening experience for all parties involved. We were forced to look at our program and gather all necessary documents in one place for a detailed review by a TJC surveyor. We recorded our performance measures monthly, reviewed them, and implemented changes to our plan of care based on our findings (Table 1).

We found our goal to decrease the length of stay for VAD implantation to be realistic, provided that discharge planning was proactive, patients' nutrition was improved for wound healing and recovery, and physical

Table 1 Performance measures tracked from 2004 to 2009

Performance measure	2004	2005	2006	2007	2008	2009
No. of VAD patients supported by audited VADs	32	34	34	32	36	48
Length of stay for VAD implantation, days	50	51	42	38	43	37
Prealbumin levels <18 mg/dL, %	NA	NA	NA	34	94	75
Infection rate, %	25	9	21	12	17	15
Physical therapy consulted within 48 hours, %	NA	NA	NA	86	90	89

Abbreviations: NA, not applicable; VAD, ventricular assist device.

therapy and cardiac rehabilitation were started early to improve patients' mobility and strength. Relationships have been formed with specific rehabilitation and skilled nursing facilities for those VAD patients unable to return to their homes because of their chronic heart failure state or lack of caregiver support. UPMC is a tertiary hospital with high-acuity patients; many require additional procedures or surgeries that extend their length of stay. The mean length of stay for VAD implantation in a teaching hospital in 2007 was 42.5 days.<sup>9</sup>

Preoperative and then intensive postoperative monitoring of prealbumin levels allowed early targeted intervention with good results in several patients. Interventions were focused on patient education about the need for high-protein diets, including foods with high protein content and protein drink supplements, and tube feedings if necessary in cachectic patients. The AHP discharge packet contained information on prealbumin testing and several pages listing various foods and their protein content. Patients were notified of their progressive prealbumin levels, and their involvement to improve these levels was encouraged. Program nutritionists met with the patients to review high-protein diet foods and high-protein supplements available in shakes, pudding, and protein bars.

Device-related local infection rates have improved, perhaps because of strict adherence to VAD dressing procedures by staff in the cardiothoracic intensive care unit, on the specialty floor, and in home care agencies. We worked with home care agencies to develop a policy and procedure for VAD dressings for all home care nurses. Staff from the AHP and the cardiothoracic intensive care unit collaborated on the development of a detailed protocol for VAD dressing changes for the cardiothoracic intensive care unit and the step-down unit. External staff visited the AHP to observe and demonstrate VAD dressings in order to achieve proficiency as determined by AHP nurses.

Expediting a physical therapy consultation within 48 hours after surgery permitted earlier assessment and intervention in order to overcome patient deficits and enable them to improve balance, endurance, standing, sitting, and stair-climbing with the aim of early and safe discharge to home. Artificial heart performance

measures are reviewed monthly and shared with team members, and we discuss possible areas of improvement during our weekly AHP meetings.

The director of the regulatory compliance office continues to work with the AHP nurse coordinator to prepare for the next certification visit by TJC. The 2008 national patient safety goals, TJC requirements, and requirements regarding proper storage of supplies and equipment were reviewed and distributed to AHP staff. The VAD storage laboratory holds logs of inventory receipt and maintenance, as well as proper storage and electrical safety for all VAD-related items. A separate dirty utility room is used for equipment cleaning, and once cleaned, items are tagged with date and initials, then returned to the laboratory where maintenance logs are completed. Device electrical safety testing is completed by the hospital's clinical engineering staff, and device-related equipment logs are maintained by AHP engineers.

We met with unit directors from the emergency department, the coronary care unit, the cardiothoracic intensive care unit, and specialty units. We reviewed employee files identifying nurses' VAD competencies and checked that appropriate documentation was in each employee's file. Each unit ensured that they had a binder with all VAD manuals at the nursing station as a resource, and that staff were aware of how to contact AHP team members 24 hours a day 7 days a week. A mock survey was completed in each unit, and we noted areas for improvement based on the results.

Resource binders were provided to each rehabilitation unit and skilled nursing facility that had staff trained and educated on VADs. These binders contained sign-in sheets from the education sessions and completed/graded device tests. Staff from external facilities such as community emergency departments, emergency medical services, skilled nursing facilities, rehabilitation units, and home care agencies who have been VAD trained are documented in our electronic outpatient trained facility log. Our patient safety manager worked with the medical records department and pulled several of our patients' charts and reviewed all patients' charts for items such as the operative record, "Time Out" record, orders, and consultations. We

Table 2 Staff reviewed by The Joint Commission

Person interviewed	Topics
Coronary care unit: bedside nurse	Care of VAD patients in coronary care unit
Coronary care unit: nurse manager	Care of VAD patients in coronary care unit
Operating room: director	VAD implantation procedures and operative records
Operating room: nurse manager	VAD nurse education and training; how to contact the VAD team; how to respond to device failure; national patient safety goals
Step-down unit: bedside nurse	Medication administration; VAD knowledge; adequacy of VAD training
Step-down unit: VAD patient	Patient's satisfaction with the Artificial Heart Program team; perceived quality of care
Artificial Heart Program, cardiothoracic intensive care unit, and step-down unit staff	Employee file, training, and competencies
Physical therapy department staff	Employee file, training, and competencies
Artificial Heart Program clinical director	Employee file, training, and competencies
Physicians	Employee file, training, and competencies

Abbreviation: VAD, ventricular assist device.

printed off our outpatient clinic calendar, the nursing staff calendar, the on-call schedule, the call schedule for heart failure physicians, the on-call schedule for cardiac/VAD surgeons, and the on-call schedule for the cardiothoracic intensive care unit for the past year and placed all those items in a binder for review.

### Review Day

The Joint Commission disease-specific care certification review for destination therapy VADs took place for 1.5 days in June 2008. We opened the session with a brief PowerPoint presentation that provided an overview of the facility, program, and AHP performance measures. The TJC surveyor reviewed our program description, CPGs, orders, schedules, on-call schedules, employee files, and physician files for several hours. The surveyor then did a walkthrough of the hospital and interviewed several staff and reviewed files (Table 2).

The surveyor started in the coronary care unit and interviewed a bedside nurse and the charge nurse about the care of VAD patients. We then proceeded to the operating room, where the director and charge nurse were interviewed about VAD implantation procedures and several VAD-related operative records were requested and reviewed. We proceeded to the bedside of a current VAD patient on the cardiothoracic intensive care unit. The surveyor interviewed the bedside nurse about her VAD education and training, about the device, how to contact the VAD team, how to respond to a device failure, and the national patient safety goals. Next we went to the specialty unit, where the surveyor chose a staff member and began to ask questions about administering medications, device

knowledge, device training provided, and whether it met the staff member's needs. She then interviewed a VAD patient about his stay, perceived quality of care, and his satisfaction with the AHP staff.

We returned to the conference room, and the surveyor reviewed several VAD charts, with all questions answered by our patient safety manager and the VAD coordinator. Next a staff member from the human resource department arrived with a box full of employee files and the surveyor requested specific employee files to review. She noted whether the employee's job description criteria had been met for the employee to be in the position held, for example, whether the AHP nurse had achieved certification as a clinical transplant coordinator within 2 years of accepting the position. She requested to see all continuing education courses attended and recent cards indicating current certification in cardiopulmonary resuscitation and Advanced Cardiovascular Life Support by medical staff. She did note that one certified registered nurse practitioner on the specialty unit did not have a current cardiopulmonary resuscitation card, but it was not required in the job description. The surveyor interviewed the physical therapy staff and reviewed their credentials and employee files. She reviewed the AHP clinical director's employee file and had no questions about his education, skills, or competencies. Next a member of the physician credential department arrived with physicians' files, which were reviewed for device training and education. The surveyor noted that the physician credential file did not address VAD-specific credentials, and we stated that the process was underway and the files would reflect the physicians' VAD education and training. Finally the surveyor called a

meeting with the director, cardiologist, nursing administration, patient safety office, VAD coordinator, and biomedical engineering staff to state that we had passed TJC's disease-specific care certification process and would be required to enter our performance measures monthly and quarterly and to have an intracycle review in 1 year.

### Conclusion

A sustained and intensive effort by a multidisciplinary team, led by the AHP nurse coordinator, was necessary to achieve the "gold seal" approval of TJC's device-specific certification for destination therapy VADs, which was obtained initially in June 2008. The process underscores the necessity of a strong and comprehensive infrastructure to support implantation of VADs for permanent therapy.

### Financial Disclosures

None reported.

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