VAD Certification Program
The Joint Commission

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The Joint Commission
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Furthermore, each of the previously named speakers has also attested that their discussions will not include any unapproved or off-label use of products.
Learning Objectives

- At the conclusion of this presentation, the participant will be able to:
  - Describe the value of The Joint Commissions certification programs.
  - Identify the benefits of obtaining VAD certification through The Joint Commission.
  - Discuss the ability of customers to work with subject matter experts for their program in a transparent and collaborative manner.

Wendi Roberts, Executive Director, TJC, presented on 10.2.2015
An Update: Our Current Program Volumes

The Joint Commission is the original VAD program certifying body and currently certifies 138 programs nationally.

We accredit and certify nearly 21,000 healthcare organizations and programs in the United States.

We are the oldest and largest national accrediting/certifying body setting standards for safe, high quality healthcare for patients nationally and internationally.
Currently over 100 certified VAD centers in 35 states.
Providing Value for our Customers

We are committed to assuring subject matter experts review your program.

Our VAD reviewers currently work in a VAD program in a healthcare organization.

This assures they are current, contemporary and relevant.

Wendi Roberts, Executive Director, TJC, presented on 10.2.2015
Providing Value to our Customers

- Reviewers are trained to make the on-site review as transparent as possible.
- No surprises at the end of the review.
Providing Value to our Customers

- We will acknowledge staff for their contributions to the process and the program.
- Collaboration, engagement and sharing of best practices allows you to continually improve your program.
Providing Value to our Customers

- Improvements in our programs are made based on customer feedback.
- We are committed to you as our customer. We will review all feedback and, as appropriate, share it with the reviewer.
New and Revised Resources for Customers

- Revised the Review Process Guide. (RPG)
- Updated the agenda in the RPG for on-site events.
- Updated the ICM questions and process.

Wendi Roberts, Executive Director, TJC, presented on 10.2.2015
Revised and Improved Resources for Customers

- Developing and plan to launch a NEW DSC Certification website in 2015.

- Site features will provide easy access to customers for standards, e-app connections, eligibility requirements and program descriptions.

Wendi Roberts, Executive Director, TJC, presented on 10.2.2015
DSC Neurological

Applicable Neurological Certifications
The information below applies to all applicable certifications listed here.

- Acquired Brain Injury
- Alzheimer’s Disease
- Amyotrophic Lateral Sclerosis
- Epilepsy
- Head Injury
- Migraine Headache
- Multiple Sclerosis
- Parkinson’s Disease
- Traumatic Brain Injury

Why Joint Commission
- Benefits of Certification
- DSC Q&A Guide
- Fact About DSC Certification

Process
- Review Process Guide
- Application Process

Requirements/Performance Measurement
- Identify Performance Measures
- Standard Revisions
- Review Clinical Practice Guidelines

Eligibility
- Evaluation criteria for Disease-Specific Care Certification
New and Revised Resources for Customers

New E-dition with **free access** to TJC standards for new and currently accredited and certified healthcare organizations.

Wendi Roberts, Executive Director, TJC, presented on 10.2.2015
2014 NCD Bridge-to-Transplant and Destination Therapy Modifications

**MODIFIED:** Ventricular Assist Device Destination Therapy Requirements

Enhanced Requirements Align with Final NCD Memo

In late fall The Joint Commission announced revisions to requirements for the *disease-specific care* (DSC) advanced certification program for Ventricular Assist Device (VAD) for Destination Therapy (see November 2013 Perspectives, pages 6 and 13). Since that time the Centers for Medicare & Medicaid Services (CMS) has published its final National Coverage Decision (NCD) memorandum for VADs for Bridge-to-Transplant and Destination Therapy.

To align its requirements with the final NCD, The Joint Commission made the following modifications:

- Added a palliative care representative to the core interdisciplinary team
- Deleted the board certification requirement for the cardiologist
- Deleted the board certification requirement for the cardiovascular surgeon
- Clarified the volume requirements for surgeons in training
- Modified the requirements related to the use of a nationally audited registry
  - Please note that the addition of the palliative care representative to the interdisciplinary team will not be required until October 30, 2014.
  - The revised VAD program requirements, which are effective March 23, 2014, are available on The Joint Commission website at http://www.jointcommission.org/standards_information/prepublication_standards.aspx and will be published in both the spring 2014 E-dition® update and the 2014 Disease-Specific Care Certification Manual. The box below displays the revisions; new text is *underlined* and deleted text is shown in *strikethrough.*

For more information, please contact Kathleen Mika, MSN, RN, associate director, Department of Standards and Survey Methods, at kmika@jointcommission.org.
2014 NCD Bridge-to-Transplant and Destination Therapy Modifications

To align our requirements with the final NCD, The Joint Commission made the following modifications in 2014:

- Added a palliative care representative to the core interdisciplinary team
- Deleted the board certification requirement for the cardiologist
- Deleted the board certification requirement for the cardiovascular surgeon
- Clarified the volume requirements for surgeons in training
- Modified the requirements related to the use of a Nationally audited registry
• Improves the quality of patient care by reducing variation in clinical processes
• Provides a framework for program structure and management
• Provides an objective assessment of clinical excellence
• Creates a loyal, cohesive clinical team
• Facilitates marketing, contracting and reimbursement
• Strengthens community confidence in the quality and safety of care, treatment and services
Kathleen Mika, MSN, RN
Associate Director
Department of Standards and Survey Methods
Division of Healthcare Quality Evaluation
Learning Objectives

At the conclusion of this presentation, the participant will be able to:

1. Identify the most frequently scored standards in the VAD certification program for 2014 and the first half of 2015.

2. Identify strategies to comply with these standards.

3. Develop a plan to discuss these standards and other challenging standards with VAD program team to assure compliance.
Joint Commission VAD Certification

MOST FREQUENTLY SCORED STANDARDS
Top 10 Standards Scored for VAD
First Half Year of 2015

Kathleen Mika, Associate Director, TJC, presented on 10.2.2015
Top 10 Standards Scored for VAD
Full Year of 2014
Reviewer Experience with the VAD DT Standards

Standard DSDF.1

Practitioners are qualified and competent. EP 1 Practitioners have education, experience, training, and/or certification consistent with the program’s scope of services, goals and objectives, and the care provided.

Requirement(s) Specific to Ventricular Assist Device Destination Therapy

a. The interdisciplinary team has at least the following experience and expertise: (cont.)
Reviewer Experience with the VAD DT Standards

Standard DSDF.1 (cont.)
One or more cardiologists, each of whom:

i. Is trained and experienced in advanced heart failure therapies

ii. Has had recent experience managing patients who have had ventricular assist devices placed or heart transplants

iii. Has sufficient competency in evaluating patients for transplant as evidenced by having worked in or trained in a transplant center

(cont.)
Reviewer Experience with the VAD DT Standards

Standard DSDF.1 EP 1 (cont.)
One or more cardiac surgeons, each of whom has successfully placed 10 ventricular assist devices in the last 36 months with current activity occurring in the last year.

Note 1: Acceptable ventricular assist device procedures include placement of long-term devices and devices that are part of studies for U.S. Food and Drug Administration approval.

(cont.)
Reviewer Experience with the VAD DT Standards

Standard DSDF.1 EP 1 (cont.)
Note 2: If a surgeon on the team has not place 10 ventricular assist devices during the required time period, the volume requirement can include artificial heart placements for no more than 50% of the total volume within the 36-month period.

(cont.)
Standard DSDF.1 EP 1 (cont.)

Note 3: The 10 ventricular assist devices implanted by a surgeon-in-training could have occurred during a training program if the following are met.

- There is evidence that the surgeon-in-training physically implanted each ventricular assist device under the supervision of a cardiac surgeon. An example would be a procedure log with supporting documentation from the supervising surgeon.

(cont.)
Reviewer Experience with the VAD DT Standards

Standard DSDF.1 EP 1 (cont.)

- The surgeon in-training participated in the preoperative planning and postoperative management of the patient.
- A VAD coordinator who has experience and expertise in the complete course of treatment of a VAD patient
  Note: Examples of a VAD coordinator include registered nurse, perfusionist.
- A social worker who has experience in the assessment and evaluation of a VAD patient and his or her family
- A palliative care representative who has experience with the VAD patient population (cont.)
Reviewer Experience with the VAD DT Standards

Standard DSDF.1 (cont.)

**EP2** The program verifies each practitioner’s licensure using a primary source verification process upon hire and at licensure expiration.

**EP 3** The program assesses practitioner competency at time of hire. This assessment is documented.

**Requirements Specific to Ventricular Assist Device Destination Therapy**

a. The cardiac surgeon is privileged by the organization for VAD implantation. (cont.)

Kathleen Mika, Associate Director, TJC, presented on 10.2.2015
Reviewer Experience with the VAD DT Standards

Standard DSDF.1 (cont.)

b. One or more cardiologists, including the heart failure specialist, are privileged by the organization to care for the VAD patient population.

**EP 4** Orientation provides information and necessary training pertinent to the practitioner’s responsibilities. Completion of the orientation is documented.

**EP 5** The program assesses practitioner competence on an ongoing basis. This assessment is documented. (cont.)
Reviewer Experience with the VAD DT Standards

Standard DSDF.1 (cont.)

**EP 6** The program identifies and responds to each practitioner’s program-specific learning needs.

**EP 7** Ongoing in-service and other education and training activities are relevant to the program’s scope of services.
Reviewer Experience with the VAD DT Standards

Standard DSSE.2
The program addresses the patient's self-management plan.

EP1 The program promotes lifestyle changes that support self-management activities.

EP 2 The program evaluates barriers to lifestyle changes.

(cont.)
Reviewer Experience with the VAD DT Standards

Standard DSSE.2 EP 2 (cont.)

Requirements Specific to Ventricular Assist Device Destination Therapy

a. The program determines that the patient’s home environment can support safe and reliable functioning of a VAD device.

Note: Any valid method for making a determination on the home environment can be used. The program does not have to visit the patient’s home.

b. The program evaluates the home environment as part of its decision-making process for implantation of a VAD device. (cont.)
Reviewer Experience with the VAD DT Standards

Standard DSSE.2 (cont.)
EP 3 The program engages family and community support structures in the patient’s self-management plan, as directed by the patient.

Requirements Specific to Ventricular Assist Device Destination Therapy
a. The hospital ascertains, through the home assessment, that the patient’s home environment is satisfactory and that the patient has an adequate and reliable power supply and telephone service. (cont.)
Reviewer Experience with the VAD DT Standards

Standard DSSE.2 (cont.)

b. Communication is sent from the hospital to the power company informing it that a ventricular assist device patient lives in the vicinity.
Reviewer Experience with the VAD DT Standards

Standard DSSE.2 (cont.)

**EP 4** The program assesses and documents the patient’s response to recommended lifestyle changes.

**EP 5** The program addresses the education needs of the patient regarding disease progression and health promotion.

**EP 6** The program revises the self-management plan according to the patient’s assessed needs.
Reviewer Experience with the VAD DT Standards

Standard DSDF.2
The program develops a standardized process originating in clinical practice guidelines (CPGs) or evidence-based practice to facilitate the delivery of clinical care.

EP 1 The selected clinical practice guidelines are evaluated for their relevance to the target population.

EP 2 The selected clinical practice guidelines are based on evidence that is determined to be current by the clinical leaders.  (cont.)
Reviewer Experience with the VAD DT Standards

Standard DSDF.2 (cont.)

EP 3 The program leader(s) and practitioners review and approve clinical practice guidelines prior to implementation.

EP 4 Practitioners are educated about clinical practice guidelines and their use.

EP 5 The program demonstrates evidence that it is following the clinical practice guidelines when providing care, treatment and services.

(continues...)

Kathleen Mika, Associate Director, TJC, presented on 10.2.2015
Reviewer Experience with the VAD DT Standards

Standard DSDF.2—EP 5 (cont.)

Requirement Specific to Ventricular Assist Device Destination Therapy

a. Inclusion criteria for VAD implant are as follows:
- Patients who have an anticipated survival benefit
- Patients with New York Heart Association Functional Classification Class IV heart failure symptoms who have failed to respond to optimal medical management
- Patients with a demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min (cont.)
Reviewer Experience with the VAD DT Standards

Standard DSDF.2 (cont.)
Patients with a continued need for intravenous inotropic therapy
Patients who have been evaluated for heart transplant and were not selected as candidates
Note: To receive CMS reimbursement, patients must meet current CMS patient selection and coverage criteria. (cont.)
Reviewer Experience with the VAD DT Standards

Standard DSDF.2 (cont.)

**EP 6** The program implements modifications to clinical practice guidelines based on current evidence-based practice.
Reviewer Experience with the VAD DT Standards

Standard DSSE.1
The program involves patients in making decisions about managing their disease or condition.

EP 1 The program involves patients in decisions about their care, treatment, and services.

(cont.)
Reviewer Experience with the VAD DT Standards

Standard DSSE.1 (cont.)

Requirements Specific to Ventricular Assist Device Destination Therapy

a. Informed surgical consent reflects the patient’s understanding of the following:
- Preoperative, intraoperative, and postoperative plan of care, treatment, and services
- Current survival and functional expectations after VAD implant
- Alternative courses of treatment (cont.)
Reviewer Experience with the VAD DT Standards

Standard DSSE.1 (cont.)

b. As part of facilitating patient decision-making, the interdisciplinary team members discuss the following with the patient and family:
- Anticipated outpatient management plan
- Quality of life factors such as physical function, psychosocial effect, symptoms, costs, caregiver burden
- Patient expectations
- Rehabilitation plan

c. The informed surgical consent and all decision making discussions are documented.
Reviewer Experience with the VAD DT Standards

Standard DSDF.3
The program is implemented through the use of clinical practice guidelines selected to meet the patient's needs.

EP 1 The program establishes an interdisciplinary team based on the patient's assessed needs and direction from clinical practice guidelines.

(cont.)
Reviewer Experience with the VAD DT Standards

Standard DSDF.3
The program is implemented through the use of clinical practice guidelines selected to meet the patient's needs.

EP 2 The assessment(s) and reassessment(s) are completed according to the patient's needs and clinical practice guidelines.

Requirement Specific to Ventricular Assist Device Destination Therapy

a. The VAD patient is evaluated for post-implant clinical improvement to determine further treatment options.
Reviewer Experience with the VAD DT Standards

Standard DSDF.3 (cont.)

EP 3 The program implements care, treatment, and services based on the patient's assessed needs.

Requirement Specific to Ventricular Assist Device Destination Therapy

a. The program has the ability to perform diagnostic tests to assess the VAD patient pre-implant or post-implant. These may include electrocardiography, echocardiography with device implant, exercise testing, nuclear cardiology, electrophysiology, cardiovascular MRI, pacing, diagnostic catheterization of right- and left-sided heart, and interventional catheterization.
Your VAD Program’s Experience with the VAD DT Standards

- Other requirements that are problematic?
- Other requirements/issues to discuss with VAD team?
- Does your team have an ongoing “gap analysis” process?
ADDITIONAL RESOURCES

- Clinical Statement on the Requirements for Surgeon Certification for Implantation of Durable Ventricular Assist Devices (VADs) Prepared by The Society of Thoracic Surgeons Workforce on the Surgical Treatment of End-Stage Cardiopulmonary Disease-February 16, 2013

- The 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support
ADDITIONAL RESOURCES

Serious Adverse Events with Implantable Left Ventricular Assist Devices (LVADs): FDA Safety Communication
- Serious events with both FDA approved implantable LVADs

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm457327.htm
Summary:

Today, we have begun to do the following:

✓ Identify the most frequently scored standards in the VAD certification program for 2014 and the first half of 2015.

✓ Identify strategies to comply with these standards.

✓ Initiate development of a plan to discuss these standards and other challenging standards with VAD program team to assure compliance.
QUESTIONS?
Joint Commission Mission

To continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.

Vision: All people always experience the safest, highest quality, best-value health care across all settings.
Contact Us

To learn more about Certification and how to prepare to submit your application, please contact our team at (630) 792-5291 or email certification@jointcommission.org.
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