CONTINUAL READINESS FOR DT CERTIFICATION

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Medtronic
Further, Together

DISCLOSURE

- Medtronic Employee

OUTLINE

- Why care about certification
- History and background of certification
- The Joint Commission (TJC) and DNV-GL Healthcare
- General quality principles
- TJC Disease-Specific Care (DSC) categories and standards
- Standards/elements pertinent to your role
- Standards/elements that are challenging for VAD programs
- What TJC reviewers are focusing on

WHY CARE ABOUT CERTIFICATION

Safety - Quality

- It is a measure of the quality of care being provided
- Demonstrates the commitment to excellence
- Promotes VAD services in a comprehensive manner

- Benefits:
  - Organized and consistent approach to care
  - Continual improvement – striving for the best care
  - Validation of team efforts
  - Providing the highest quality services
  - Fulfilling reimbursement requirements

HISTORY OF VAD PROGRAM CERTIFICATION FOR DESTINATION THERAPY (DT)

March 27, 2007 — CMS made changes to the national coverage decision (NCD)

- Certification by The Joint Commission (TJC) is required for Medicare reimbursement for VAD implant services for DT

March 27, 2009 — Deadline for VAD programs to become certified

- The Joint Commission under the Disease-Specific Certification Program for Ventricular Assist Device
- 75 VAD programs certified

October 30, 2013 — CMS made changes to the NCD

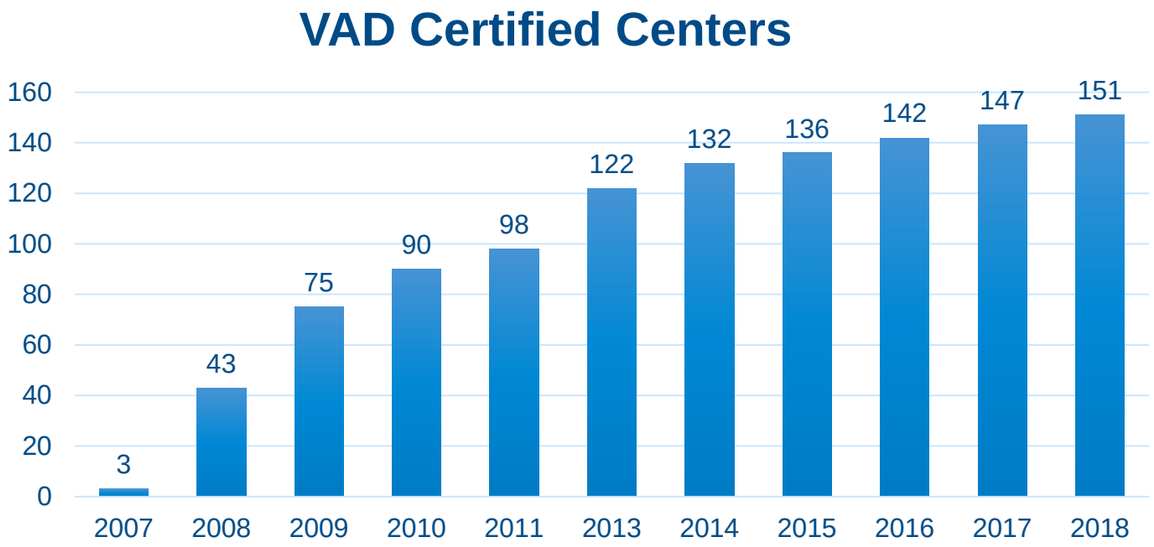
- Allowing other organizations to apply to CMS to be designated as a credentialing organization for VAD DT certification

January 17, 2014 — TJC updated VAD standard requirements

- Changes in the area of interdisciplinary team, patient selection/criteria, informed consent, outpatient management, data management, palliative care/end of life, surgeon training

TJC DISEASE SPECIFIC CARE CERTIFICATION

- Certification program established in 2002
- > 4,200 certified disease specific clinical care programs nationwide
- Currently 151 VAD centers TJC certified



- Designed to evaluate:
  - the overall quality and safety of the program services
  - the scope of a specific disease, condition or service across the continuum of care
  - compliance with a set of standards

https://www.qualitycheck.org/data-download/certification-data/

DNV GL HEALTHCARE

- Worldwide company in certification, standards development and risk management in a wide range of industries
- CMS approved hospital accreditation agency since 2008
- CMS approved credentialing agency, October 2014
- Programs certified: primary stroke center, comprehensive stroke center, acute stroke ready, heart failure, palliative care, hip and knee replacement and managing infection risk
- Recertification every 3 yrs with onsite review annually
- A few VAD programs certified to date

- Objective to:
  - determine the center's compliance with certification requirements through observations, interviews, and document review
  - provide quality driven clinical excellence certification

TJC ADVANCED DSC VAD CERTIFICATION

- The DSC Certification program has three key elements:
  - The requirement for compliance with 27 consensus-based national standards and additional VAD specific elements
  - The effective integration of established Clinical Practice Guidelines (CPGs) within the program to manage and optimize care
  - The requirement that the program collects and analyzes performance measure data to drive improvement activities
- On site recertification is every 2 yrs
- Intracycle call is 1 yr after cert/recert date

TJC ON-SITE VAD REVIEW AGENDA

Consider attending

	Day 1
Time	Reviewer
8:00 – 9:00 a.m.	Opening Conference and Orientation to Program
9:00 – 10:00 a.m.	Reviewer Planning Session
10:00 – 12:30 p.m.	Individual Tracer Activity *(three patients minimum—active patients desirable; if no active patients, most recently discharged patients will be selected)* Includes visiting the units/ dept. that VAD patients are housed and receive services: • Surgical Intensive Care Unit • Step-down Units • Emergency Room • Cardiopulmonary Function Testing • Pre-op, OR, PACU • Radiology • Procedure Units • Physical Therapy
12:30 – 1:00 p.m.	Reviewer Lunch
1:00 – 2:30 p.m.	Individual Tracer Activity…continued
2:30 – 3:30 p.m.	System Tracer – Data Use
3:30 – 4:00 p.m.	Issue Resolution
4:00 – 4:30 p.m.	Day 2 -- Reviewer Planning Session
	Day 2
8:00 – 9:00 a.m.	Competence Assessment & Credentialing Process
9:00 – 10:30 a.m.	Individual Tracer Activity…continued
10:30 – 11:30 a.m.	Reviewer Report Preparation
11:30 – 12:00 p.m.	Program Exit Conference

- The tracer methodology follows a patient's course of care, treatment, and services (inpatient and outpatient)
- Speaking with staff in all the areas and services involved in the patient's encounter
- HR files:
  - current license (primary verification)
  - job description (reflects current job duties)
  - current evaluation
  - current BLS and/or ACLS (if required)
  - current immunizations (if required)

Consider attending

DSC STANDARD CHAPTERS

DSC STANDARDS

Program Management

- Defining program leadership roles
- Conducting the program in an ethical manner
- Providing adequate access to care
- Supplying reference resources to staff
- Evaluating the program

Delivering or Facilitating Clinical Care

- Using qualified, competent practitioners
- Facilitating the delivery of care using evidence-based CPGs
- Individualizing care to meet the participant's needs
- Managing and coordinating continuum of care

DSC STANDARDS

Supporting Self-Management

- Assessing patients' self-management capabilities
- Providing support in self-management activities
- Addressing the patient's education needs

Clinical Information Management

- Preserving patient confidentiality
- Proactively gathering and sharing information across the continuum to coordinate care across settings and over time
- Providing easy access to patient-related information

Performance Measurement

- Having an organized, comprehensive approach to performance improvement
- Maintaining data quality and integrity
- Trending and comparing data to evaluate processes and outcomes
- Using information from measurement data to improve or validate clinical practice
- Evaluating the patient satisfaction with the quality of clinical care

AUDIT READY EVERYDAY

- *General Principles:*
  - Understand and follow guidelines, policies and procedures
    - Assure patient care is provided according to guidelines and patient condition
    - Standardize care across disciplines (i.e. VAD orders and policies)
  - Comprehensive plan of care is multidisciplinary approach and patient participative
    - Individualized and meets the patient's needs (clinical and educational)
    - Focuses on supporting the self-management activities of the patient
  - Ensure documentation is complete and accurate in the medical records
    - "If it is not documented, it didn't happen"
    - Assure all assessments, interventions and treatment are clearly documented in the record
  - Ensure your training is appropriate and documented
    - Qualified and competent
    - Licensure, privileges, evaluation etc. in HR file
  - Have an organized and comprehensive approach to performance improvement

PROGRAM MANAGEMENT (DSPR)

- DSPR.6 – The program has current reference and resource materials
  - Practitioners have access to reference materials
  - Reference materials and resources are current and evidence based

- DSPR.7 – The program's facilities are safe and accessible
  - The program develops and implements its medical equipment management plan
  - The program has a process for maintaining the most up-to-date device information, including recalls and warnings

https://www.jcrinc.com, 2017 Comprehensive Certification Manual for Disease-Specific Care Including Advanced Programs for DSC Certification

DELIVERING OR FACILITATING CLINICAL CARE (DSDF)

- DSDF.1 – Practitioners are qualified and competent
  - Practitioner competency is assessed at time of hire and on an ongoing basis
  - Orientation training is provided pertinent to the practitioner's responsibilities

- DSDF.4 – The program develops a plan of care that is based on the patient's assessed needs
  - The program demonstrates an interdisciplinary approach for outpatient VAD patient management
  - The plan of care is individualized for each patient and based on the patient's goals/needs

- DSDF.6 – The program initiates discharge planning and facilitates arrangements for subsequent care, treatment, and services to achieve mutually agreed upon patient goals
  - Outpatient management plan includes ongoing education based on patient and family needs

https://www.jcrinc.com, 2017 Comprehensive Certification Manual for Disease-Specific Care Including Advanced Programs for DSC Certification

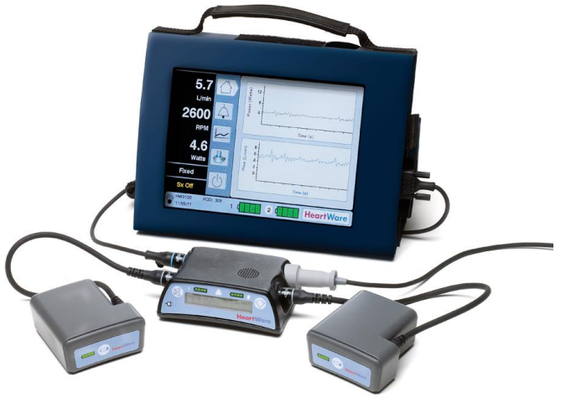
PERFORMANCE MEASUREMENT (DSPM)

- DSPM.3 – The program collects measurement data to evaluate processes and outcomes
  - Collect and analyze data on four performance measures
  - Monitors the occurrence of bleeding, infection, stroke, readmission and device malfunction
  - Monitors survival rate, functional capacity and data from Intermacs (national registry)
  - Evaluates VAD patient's perception of their quality of life
  - Evaluates VAD patient's satisfaction with the quality of care

https://www.jcrinc.com, 2017 Comprehensive Certification Manual for Disease-Specific Care Including Advanced Programs for DSC Certification

EXAMPLE QUESTIONS A REVIEWER MIGHT ASK YOU

- What is your role? What is your role with VAD patients?
  - What was the VAD training you received?
  - Whom do you contact if you have a VAD related question?
  - What VAD resources do you have?
- What CPGs or order sets are used for the VAD patient?
- What performance initiatives is the VAD Program doing?
- How is VAD equipment handled? What is your equipment management plan?
  - Where is VAD equipment stored? How do you get equipment after hours?
  - How do you know that the equipment is safe and ready to be used on a patient?
  - What is your system for tracking equipment and maintenance?
  - Does a patient who has been re-admitted use his/her own equipment from home? If so, how is that managed?
  - How do you know when preventative maintenance is due for VAD equipment?
  - How do you hear about VAD manufacturer recalls and warnings?
- Who does the pump prep in the OR? What training do they receive for pump prep?
- How are VAD parameters documented intra-operatively and postoperatively?



ELEMENTS CHALLENGING FOR VAD PROGRAMS

- Policies
  - Not following own policies or guidelines
  - Not following program's patient selection criteria
  - VAD Implant inclusion/exclusion criteria not evident in medical records
- Consents
  - Date and/or time missing
  - Missing key content
  - Consent/contract not signed before implant
- Medical Record Documentation (according to orders)
  - Missing
    - Daily weight and vital signs
    - Antibiotics
    - Driveline exit site dressing
  - Old orders still active in electronic medical record
  - Not using VAD order sets
  - Lack of transparency/documentation of evaluation process (i.e. tests needed, current plan, device)

ELEMENTS CHALLENGING FOR VAD PROGRAMS CONT.

- Education
  - Lack of documentation of ongoing education/competency assessment in healthcare providers file
  - Lack of biomedical training certificate for equipment preventative maintenance
  - Reference material outdated
- Clinical Management
  - Not consistently notifying community of patient being discharged
  - Lack of assessment of intervention/med
  - Lack of individualized or complete care plan
- Program Management
  - No clear scope of service
    - Interdisciplinary team composition and accountability
    - Mission and defined treatment and services provided
  - Limited CPGs
    - Device monitoring and management, anticoagulation therapy, driveline exit site care, emergency procedures, emergency management, equipment management, education plan
  - Lack of provider's privileges (i.e. surgeon/cardiologist)

RECENT REVIEWER FOCUS

- Equipment Management
  - Maintenance record
  - Program database – entering all equipment serial numbers
  - Medical device reporting (MDR) and device recall process
- Documentation
  - Transparency of plan of care in patient medical record
  - Evaluation, device, indication, inclusion/exclusion criteria, decisions
  - Pump parameters documented in the OR
  - Vital signs/parameters documented while off the unit (implant procedures and OR)
  - Device trained staff with patient during procedures/OR, according to institutions policy
    - A focus on non-cardiac OR procedures
  - Concomitant procedures (i.e. RV support, Valve repair, PFO) part of consent
  - Team composition and accountability listed in a document
  - Education/competency of staff (initial & ongoing)
    - Anyone that has direct VAD patient care
    - APN, Intensivist, Social Worker, PT/OT
- Performance Improvement
  - Data analysis and interventions/action plans

INDICATIONS, SAFETY AND WARNINGS

- **Brief Statement: HeartWare™ HVAD™ System**
- **Indications for Use**
- The HeartWare™ HVAD™ System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned.

- **Contraindications**
- The HeartWare System is contraindicated in patients who cannot tolerate anticoagulation therapy.

- **Warnings/Precautions**
- Proper usage and maintenance of the HVAD™ System is critical for the functioning of the device. Serious and life threatening adverse events, including stroke, have been associated with use of this device. Blood pressure management may reduce the risk of stroke. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not disconnect the driveline from the controller or the pump will stop. Avoid devices and conditions that may induce strong static discharges as this may cause the VAD to perform improperly or stop. Magnetic resonance imaging (MRI) could cause harm to the patient or could cause the pump to stop. The HVAD™ Pump may cause interference with automatic implantable cardioverter-defibrillators (AICDs), which may lead to inappropriate shocks, arrhythmia and death. Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta - use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD Pump post CPR.

- **Potential Complications**
- Implantation of a VAD is an invasive procedure requiring general anesthesia and entry into the thoracic cavity. There are numerous known risks associated with this surgical procedure and the therapy including, but not limited to, death, stroke, neurological dysfunction, device malfunction, peripheral and device-related thromboembolic events, bleeding, right ventricular failure, infection, hemolysis and sepsis.

- Refer to the “Instructions for Use” for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions and potential adverse events prior to using this device. The IFU can be found at www.heartware.com/clinicians/instructions-use.

- **Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.