Optimizing Patient Care with an Advanced Heart Failure Therapeutics Program: A Multidisciplinary Approach

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Kaufman Center for Heart Failure
Heart Failure Center
Heart & Vascular Institute

Cleveland Clinic
CURRENT CLINICAL NEEDS FOR HEART FAILURE PATIENTS ...........Facts and Gaps

• “Advanced heart failure” is poorly defined and represents a spectrum of illness
• High mortality rate...*need therapies to reduce*
• Utilize health care resources
• Poor quality of life….*need therapies to improve*
• Cardiac transplantation offers the best outcomes but is limited to 2100 per year and has limitations
• VADs have not provided the outcomes patients and clinicians desire…..UNTIL NOW
• Need for validated risk stratification tools for advanced heart failure to guide “best therapy at the best time”
What are the Components

- Heart failure evaluation and management: out patient, in-patient, and ICU care
  - Dedicated HF cardiologists and cardiac surgeons
  - Adjudication of treatment by committee of experts
- Cardiac transplantation
- Acute and chronic mechanical circulatory support
- Heart failure pharmacologic and non-pharmacologic clinical trials
- Heart failure disease management for local patients
Clinical Investigations

Contemporary Outcomes of Outpatients Referred for Cardiac Transplantation Evaluation to a Tertiary Heart Failure Center: Impact of Surgical Alternatives

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Cleveland, Ohio

Fig. 1. Disposition and outcomes of patients referred for cardiac transplant evaluation. Of 418 patients initially listed for transplantation, 32 were removed from the list and underwent alternative surgical treatments. Of patients who underwent alternative surgical treatments, 12 ultimately required cardiac transplantation.
Fig. 3. Kaplan-Meier survival from time of initial evaluation. For all groups the censoring endpoint is all-cause mortality only. NTS, nontransplant surgery; LVR, left ventricular reconstruction; PLV, posterolateral ventriculectomy.
Expertise for a Heart Failure and Transplant Cardiologist

**Table 1**

<table>
<thead>
<tr>
<th>Clinical Experience (Inpatient and Outpatient) and Proficiencies to Be Required for Eligibility for Secondary Subspecialty Certification in Advanced Heart Failure and Transplant Cardiology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart failure with dilated or nondilated LV</td>
</tr>
<tr>
<td>New-onset heart failure</td>
</tr>
<tr>
<td>Acute decompensation of chronic heart failure</td>
</tr>
<tr>
<td>Heart failure in a geriatric population</td>
</tr>
<tr>
<td>Heart failure associated with cancer chemotherapy</td>
</tr>
<tr>
<td>Heart failure patients who are pregnant or recently postpartum</td>
</tr>
<tr>
<td>Heart failure and congenital heart disease</td>
</tr>
<tr>
<td>Heart failure in patient from diverse ethnic groups, with attention to specific diagnostic and therapeutic issues within these groups</td>
</tr>
<tr>
<td>Heart failure in men and women</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
</tr>
<tr>
<td>Heart failure pre- and post-cardiac and noncardiac surgery</td>
</tr>
<tr>
<td>Inherited forms of cardiomyopathy</td>
</tr>
<tr>
<td>Hypertrophic cardiomyopathies</td>
</tr>
<tr>
<td>Infiltrative and inflammatory cardiomyopathies</td>
</tr>
<tr>
<td>Heart failure and arrhythmias</td>
</tr>
<tr>
<td>Heart failure in patients with other organs transplanted</td>
</tr>
<tr>
<td>Evaluation of patients for cardiac transplant or mechanical assist devices</td>
</tr>
<tr>
<td>Care of patients who have undergone cardiac transplant</td>
</tr>
<tr>
<td>Care of patients with mechanical assist devices</td>
</tr>
<tr>
<td>Evaluation of patients for ICDs and for CRT</td>
</tr>
<tr>
<td>Device interrogation and interpretation in patients with implanted ICD or ICD-CRT devices</td>
</tr>
<tr>
<td>Endomyocardial biopsies</td>
</tr>
</tbody>
</table>

**Note:** CRT = cardiac resynchronization therapy; ICD = implantable cardiac defibrillator; LV = left ventricle.
Section 10: Surgical Approaches to the Treatment of Heart Failure

Despite advances in medical management of HF, there remain circumstances in which surgical procedures are the only or the best treatment option. These include heart transplantation, the longest accepted surgical therapy, and procedures that (1) repair the heart, (2) reshape it, or (3) replace all or part of heart function.

10.1 It is recommended that the decision to undertake surgical intervention for severe HF be made in light of functional status and prognosis based on severity of underlying HF and comorbid conditions. Procedures should be done at centers with demonstrable expertise and multidisciplinary medical and surgical teams experienced in the selection, care, and perioperative and long-term management of high risk patients with severe HF. (Strength of Evidence =C)
**Table 4. Updates to Section 4.4. Patients With Refractory End-Stage Heart Failure (Stage D)**

### Class I

1. Meticulous identification and control of fluid retention is recommended in patients with refractory end-stage HF (209–216). *(Level of Evidence: B)*

2. Referral for cardiac transplantation in potentially eligible patients is recommended for patients with refractory HF.

3. Referral of patients with refractory end-stage HF to a HF program with expertise in the management of refractory HF is useful (218–221). *(Level of Evidence: A)*

4. Options for end-of-life care should be discussed with the patient and family when severe symptoms in patients with refractory end-stage HF persist despite application of all recommended therapies. *(Level of Evidence: C)*

5. Patients with refractory end-stage HF and implantable defibrillators should receive information about the option to inactivate the defibrillator. *(Level of Evidence: C)*

### Class IIA

1. Consideration of an LV assist device as permanent or "destination" therapy is reasonable in highly selected patients with refractory end-stage HF and an estimated 1-year mortality over 50% with medical therapy (222,223). *(Level of Evidence: B)*

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Jessup M et al. JACC Vol 53;2009
Goals

- Multi-disciplinary team: cardiology, cardiac surgery, nursing, immunology, ID, social services, bioethics
- Advanced heart failure therapeutics committee
- Expertise in surgical and medical therapies, transplantation and mechanical circulatory support devices
- Education and Research
Multi Disciplinary Team

….a critical component for success

Advanced Heart Failure Therapeutics Committee
# Section of Heart Failure & Cardiac Transplant Medicine Kaufman Center for Heart Failure

- **Heart Failure Cardiologists**
  - C. Bott Silverman, MD
  - M. Hazen, MD
  - R. Hobbs, MD
  - E. Hsich, MD
  - K. James, MD
  - M. Mountis, DO
  - G. Rincon, MD
  - R. Starling, MD, MPH
  - W. Tang, MD
  - D. Taylor, MD
  - J. Young, MD

- **Research**
  - C. Moravec, PhD
  - W. Sweet, MS
  - M. Baumann, BS
  - Dana Frank, BS

- **Nurse Practitioners**
  - Nancy Albert, PhD, RN, CCNS
  - Maureen O’Malley, CNP
  - Danielle Brown CNS

- **Nurse Clinicians**
  - C. Grobolsek, RN
  - L. Pekarski, RN
  - J. Clipps, LPN
  - J. Reese, RN

- **Advanced Fellows**
  - Eiran Gorodeski, MD
  - Bethany Austin, MD
  - Brian Hardaway MD
  - Mustafa Toma, MD
  - Vivana Navas, MD

- **Social Work**
  - K. Kendall, LSW

- **LVAD Team**
  - C. Gady, PA
  - K. Zeroske, RN
  - T. Buda, RN
  - C. Vacha, RN, APN
  - B. Loveland, APN
  - Marjorie Sturtz, CNP
  - Sheryl Hostutler, RN

- **Transplant Surgeons**
  - N. Smedira, MD
  - E. Soltesz MD
  - T. Mihaljevic, MD
  - G. Gonzalez-Stawinski, MD
Section of Heart Failure & Cardiac Transplant Medicine Kaufman Center for Heart Failure

Heart Failure Research Personnel
P. Bouscher, RN
B. Gus, RN-C
S. Moore, RN-C
C. Oblak, CCRN

Manager
M. Jarosz, RN

HFDM
M. O’Malley CNP

Heart Failure & Tx Research Database
E. Blackstone, MD
K. Hoercher RN

Heart Failure Database Network
P. Vargo
M. Henderson

Surgical laboratory
K. Fukamachi, MD, PhD

Heart TX Coordinators (PRE)
J. Campbell, RN
D. Hartman, RN CCTC
K. Ludrosky, RN CCTC

Heart Tx Coordinators (POST)
K. Kiefer, RN CCTC
D. Pelegrin, RN PA
A. Johnson, RN MBA
C. Haire, RN,CCTC
C. Zilka, RN
C. Kawczynski
Patient Care Metrics
NEWS FLASH
Cleveland Clinic Has Earned VAD Advanced Certification

Cleveland Clinic recently earned Ventricular Assist Device (VAD) Certification from The Joint Commission. Cleveland Clinic is one of only two healthcare organizations in the state of Ohio to earn advanced certification for VAD.

To earn this distinction, a multi-disciplinary team developed comprehensive program details and outlined four performance measures that will be reviewed by a team of Joint Commission surveyors every two years. The program is evaluated against Joint Commission standards through an assessment of a program’s processes, the program’s ability to evaluate and improve care within its own organization, and interviews with patients and staff.

News Archives...
Heart Failure Disease Management Metrics

- In patient JCAHO core measures
- Get with the Guidelines
- CMS 30 day mortality rates
- CMS 30 day HF readmission rates
  - Coming pay for performance
- UNOS/SRTS reports every 6 months
  - Outcomes closely monitored by UNOS
- CMS required INTERMACs data submission
  - No metrics for outcomes as yet
CMS: 30 Day Mortality Rates

Mortality - 95% Interval Estimates: 160 Ohio Hospitals

Acute MI  Heart Failure  Pneumonia

95% Interval Estimate for RSMR (%)

Your Hospital
Other State Hospitals
National Rate (11.5%)
CMS 30 Day Re-admission Rates

Readmissions - 95% Interval Estimates: 160 Ohio Hospitals

Acute MI

Heart Failure

Pneumonia

- Your Hospital
- Other State Hospitals
- National Rate (18.2%)

CCF
OPD IMPROVE HF REGISTRY
ACI-I / ARB

% of Indicated Patients Receiving Therapy

100
80
60
40
20
0
Baseline 6M 12M 18M 24M

Your site
National average
Top 10th percentile

Your site's performance over time compared to the national average and the top 10th percentile.
IMPROVE HF REGISTRY
ICD / CRT-D

% of Indicated Patients Receiving Therapy

- Your site
- National average
- Top 10th percentile
## National Programs
Scientific Registry of Transplant Recipients
7/01/2007 – 6/30/2008

<table>
<thead>
<tr>
<th></th>
<th>CCF</th>
<th>NE US</th>
<th>West</th>
<th>Pacific</th>
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</thead>
<tbody>
<tr>
<td>On list at start</td>
<td>29</td>
<td>136</td>
<td>172</td>
<td>32</td>
</tr>
<tr>
<td>New listings</td>
<td>82</td>
<td>147</td>
<td>111</td>
<td>23</td>
</tr>
<tr>
<td>Died waiting, %</td>
<td>10.3</td>
<td>14.0</td>
<td>6.4</td>
<td>6.3</td>
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<tr>
<td>Transplant</td>
<td>62</td>
<td>89</td>
<td>85</td>
<td>56</td>
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</tbody>
</table>

### 1 year survival

<table>
<thead>
<tr>
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<th>CCF</th>
<th>NE US</th>
<th>West</th>
<th>Pacific</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation*</td>
<td>91.3</td>
<td>85.2</td>
<td>87.0</td>
<td>86.5</td>
</tr>
<tr>
<td>Expected</td>
<td>86.7</td>
<td>83.1</td>
<td>89.1</td>
<td>89.6</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>CCF</th>
<th>NE US</th>
<th>West</th>
<th>Pacific</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waiting time, months*</td>
<td>1.8</td>
<td>4.4</td>
<td>2.2</td>
<td>1.6</td>
</tr>
<tr>
<td>Device</td>
<td>23%</td>
<td>33.7%</td>
<td>27.1%</td>
<td>5.4%</td>
</tr>
</tbody>
</table>

*For Patients Receiving their First Transplant of this type between 01/01/2005 and 06/30/2007 for 1 Year Cohorts
*4.8 mo in US
#13.2% nationwide
Device 30.2%

www.ustransplant.org
## Number of CCF Transplants Since 1998 - 2009

<table>
<thead>
<tr>
<th>Organ</th>
<th>No. of Transplants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart only</td>
<td>1425</td>
</tr>
<tr>
<td>Heart/kidney</td>
<td>3</td>
</tr>
<tr>
<td>Heart/lung</td>
<td>17</td>
</tr>
<tr>
<td>Heart/liver</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1449</strong></td>
</tr>
</tbody>
</table>
Survival Analysis

Patient Survival for 310 Primary Heart-only Transplants 2004 - 2008

Time | Survival, %
--- | ---
6 months | 94.1
1 Year | 92.6
2 Years | 86.5
## Evaluations in 2008

<table>
<thead>
<tr>
<th>Organ</th>
<th>No of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
<td>204</td>
</tr>
</tbody>
</table>
UNOS Status of Patients Transplanted in 2008

**At Listing**

<table>
<thead>
<tr>
<th>UNOS Status</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>21</td>
<td>35.0</td>
</tr>
<tr>
<td>1B</td>
<td>16</td>
<td>26.7</td>
</tr>
<tr>
<td>2</td>
<td>22</td>
<td>36.7</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>1.7</td>
</tr>
</tbody>
</table>

**At Transplant**

<table>
<thead>
<tr>
<th>UNOS Status</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>31</td>
<td>51.7</td>
</tr>
<tr>
<td>1B</td>
<td>21</td>
<td>35.0</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>13.3</td>
</tr>
</tbody>
</table>
### State of Residence of Heart Patients Transplanted in 2008

<table>
<thead>
<tr>
<th>State</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>OH</td>
<td>36</td>
<td>60.0</td>
</tr>
<tr>
<td>NY</td>
<td>6</td>
<td>10.0</td>
</tr>
<tr>
<td>MI</td>
<td>4</td>
<td>6.7</td>
</tr>
<tr>
<td>PA</td>
<td>4</td>
<td>6.7</td>
</tr>
<tr>
<td>IN</td>
<td>3</td>
<td>5.0</td>
</tr>
<tr>
<td>GA</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>KS</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>TN</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>VA</td>
<td>1</td>
<td>1.7</td>
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<tr>
<td>WI</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>WV</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>International</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>60</strong></td>
<td></td>
</tr>
</tbody>
</table>
Post Transplant CCF Patients being Followed in 2008

<table>
<thead>
<tr>
<th>Organ</th>
<th>No of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
<td>772</td>
</tr>
<tr>
<td>(includes 9 heart/lung, 3 kidney/heart, 1 liver/heart)</td>
<td></td>
</tr>
</tbody>
</table>

*Five dedicated full-time post heart transplant coordinators*
Is becoming a heart transplant center of excellence enough???

Is the future an Advanced Heart Failure Therapeutics Center of Excellence?
Features that define a Heart Failure Center of Excellence

- **Research** that has impacted the field
- **Top center** in the United States based on outcomes: HF care, transplant, and MCSD
- **Collective experience** of transplant cardiologists and surgeons
- **Provide training** for transplant cardiologists and cardiac surgeons and other team members
- **Leadership** positions in societies, education, industry advisory boards (all members of the team: physicians, nurses, ID, Admin, social workers)
Education
13th Year

571 attendees
74% national
PARIS 2009

international society for heart and lung transplantation

29th annual meeting and scientific sessions
april 22 - 25, 2009

preliminary program
registration
tours
housing forms

april in paris
palais des congres
paris, france
Advanced Fellowship
Heart Failure and Cardiac Transplant Medicine 1995 - 2009

- 46 fellows trained
- 30 in academic positions
- Cleveland Clinic, Ochsner Clinic, Stanford, CCF, Univ of Minnesota, Univ of Miami, Univ of Montreal, Rush, UAB, Henry Ford, Univ Coll Dublin, Univ New Zealand, Univ of Singapore, Univ of Utah, Univ of Maryland, Mayo Clinic, Allegheny General
- One Fulbright Scholar
Certification in Advanced Heart Failure and Transplant Cardiology, developed by the American Board of Internal Medicine (ABIM) for diplomates with certification in Cardiovascular Disease, is designed to recognize the qualifications of physicians who have met ABIM standards for specialists in advanced heart failure and transplant cardiology.

Advanced heart failure encompasses the special knowledge and skills required of cardiologists for evaluating and optimally managing patients with heart failure, particularly those with advanced heart failure, those with devices, including ventricular assist devices, and those who have undergone or are awaiting transplantation. Participation in the certification program is voluntary. Certification is not required of practitioners in this field, and the certificate does not confer privilege to practice.
Examples
Cleveland Clinic Staff Advisory Roles

- Member, Advisory Board on Solid Organ Transplantation, Aetna Ins. Co
- Member, Advisory Board on Solid Organ Transplantation, WellPoint
- Past Member, UNOS Membership and Professional Standards Committee
- Past Member, Advisory Committee on Organ Transplantation to the Secretary of HHS
- Member, Ohio Board of Solid Organ Transplantation
- INTERMACS: Interagency Registry for Mechanically Assisted Circulatory Support
CLEVELAND HEART
Protocol CTOT-05: NIH
Observational Study of Alloimmunity in Cardiac Transplant Recipients

- Measure alloimmunity
- IVUS: Cleveland Clinic Core Lab
- Tissue analysis
- Observational
Limitations of Cardiac Transplantation

- Donor availability
- Immune incompatibility (sensitized)
- Conditional half life about 10 years
- Post transplant complications
  - CAV
  - Malignancy
  - ESRD 10% at 5 years
  - Diabetes, hypertension, obesity, hyperlipidemia, osteoporosis
Patients who have marked symptoms at rest despite maximal medical therapy (e.g., those who are recurrently hospitalized or cannot be safely discharged from the hospital without specialized interventions)

Stage D
Refractory Heart Failure requiring specialized interventions

THERAPY*

GOALS
- Appropriate measures under Stages A, B, C
- Decision re: appropriate level of care

OPTIONS
- Compassionate end-of-life care/hospice
- Extraordinary measures
  - Heart transplant
  - Chronic inotropes
  - Permanent MCSD
  - Experimental surgery or drugs
Survival Among End-Stage Heart Failure Patients Discharged on Continuous Inotropes

CONTEMPORARY MEDICAL THERAPY; ICD NO BENEFIT

Survival at 6 months: 47% [95% CI, 38% to 56%]

INTERMACS
Interagency Registry for Mechanically Assisted Circulatory Support
“A critical and important resource to provide evidence based evolution of quality care”

www.intermacs.org
CCF LVADS Per Year (Indication)

- Destination Therapy
- Bridge to Transplantation
- Bridge to Decision

Implants

<table>
<thead>
<tr>
<th>Year</th>
<th>Destination Therapy</th>
<th>Bridge to Transplantation</th>
<th>Bridge to Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td></td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>1999</td>
<td></td>
<td>35</td>
<td>5</td>
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<tr>
<td>2001</td>
<td></td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>2003</td>
<td></td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>2005</td>
<td></td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>2008</td>
<td></td>
<td>10</td>
<td>15</td>
</tr>
</tbody>
</table>
Patient Survival Among Profiles

Event: Death (censored at transplant)

Levels 2-7: All Others, n=234, deaths=49
Level 1 (Critical Cardiogenic Shock), n=186, deaths=55

p = .002

Pagani F et al ISHLT Boston MA 2008
## Comparison of Pulsatile Flow and Continuous Flow LVADs

<table>
<thead>
<tr>
<th></th>
<th>PF LVAD</th>
<th>CF LVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (gm)</td>
<td>1250</td>
<td>390</td>
</tr>
<tr>
<td>Volume (ml)</td>
<td>450</td>
<td>63</td>
</tr>
<tr>
<td>Noise</td>
<td>Audible</td>
<td>Silent</td>
</tr>
<tr>
<td>Moving parts</td>
<td>Many</td>
<td>One</td>
</tr>
<tr>
<td>Maximal flow (l/min)*</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Clinical Durability (yr)</td>
<td>1.5</td>
<td>Est. &gt; 5 yrs</td>
</tr>
</tbody>
</table>

* at mean pressure=100 mm Hg
Improving LVAD Outcomes

Several months after implantation of a HeartMate II LVAD, patient survival is illustrated above. This plot shows survival rates at various time points for patients using the HM II device and the control group. The graph indicates that patients using the HM II device have a higher survival rate compared to the control group.

Time (Months):
- 0
- 1
- 3
- 6
- 9

Survival:
- 0.0
- 0.2
- 0.4
- 0.6
- 0.8
- 1.0

Remaining at Risk:
- 169
- 158
- 139
- 116
- 100
- 169

Starling RC et al. HFSA Annual Mtg Sept 14, 2009 Boston MA
Actuarial Survival vs REMATCH*  
HeartMate II Destination Therapy Trial

* N Engl J Med 2001; 345:1435-43
Left Ventricular Assist Devices (LVAD)

- Expanding market for bridge to transplant: 30% at least LVAD before transplant
- Steep growth curve for use of new axial flow pump with improved outcomes
- HeartMate II approved for chronic therapy (DT) January 2010
- Metrics and regulatory for LVAD?
“We’re seeing a transition in care for heart failure,” says Randall Starling
VADs Implanted per year at Cleveland Clinic

- 2001
- 2003
- 2005
- 2007
- 2009

n
- Referred for advanced therapies
- History of rectal ca and colostomy; <2 years since treatment
- Attempted to optimize
- Recurrent HF and admits
- Returned with newspaper in hand requesting LVAD
- INTERMACS level 4
- Elective surgery Jan 2010 FDA approved HM2 DT
- LOS 14 days
- Weekly VAD clinic appts