# MEDCAC - Management of Heart Failure with the Use of Ventricular Assist Devices

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# Patient Criteria That Predicts Improved Health Outcomes

- ACC/AHA Guidelines for the Management of Heart Failure suggest that destination VAD therapy should be considered for patients with expected 1-year survival of < 50 % despite medical therapies
  - Does not define specific criteria other than overall mortality

# INTERMACS

- Patient profiles
  - Defines acuity and functional capacity but not specific "selection" criteria

**Table 3**  INTERMACS Patient Profiles and Timeframe for Initiating Mechanical Circulatory Support

| Profile # | Description | Time to MCS |
|---|---|---|
| 1 | "Crashing and burning"—critical cardiogenic shock. | Within hours |
| 2 | "Progressive decline"—inotrope dependence with continuing deterioration. | Within a few days |
| 3 | "Stable but inotrope dependent"—describes clinical stability on mild-to-moderate doses of intravenous inotropes (patients stable on temporary circulatory support without inotropes are within this profile). | Within a few weeks |
| 4 | "Recurrent advanced heart failure"—"recurrent" rather than "refractory" decompensation. | Within weeks to months |
| 5 | "Exertion intolerant"—describes patients who are comfortable at rest but are exercise intolerant. | Variable |
| 6 | "Exertion limited"—describes a patient who is able to do some mild activity but fatigue results within a few minutes of any meaningful physical exertion. | Variable |
| 7 | "Advanced NYHA III"—describes patients who are clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent. | Not a candidate for MCS |

IMTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; MCS, mechanical circulatory support; NYHA, New York Heart Association.
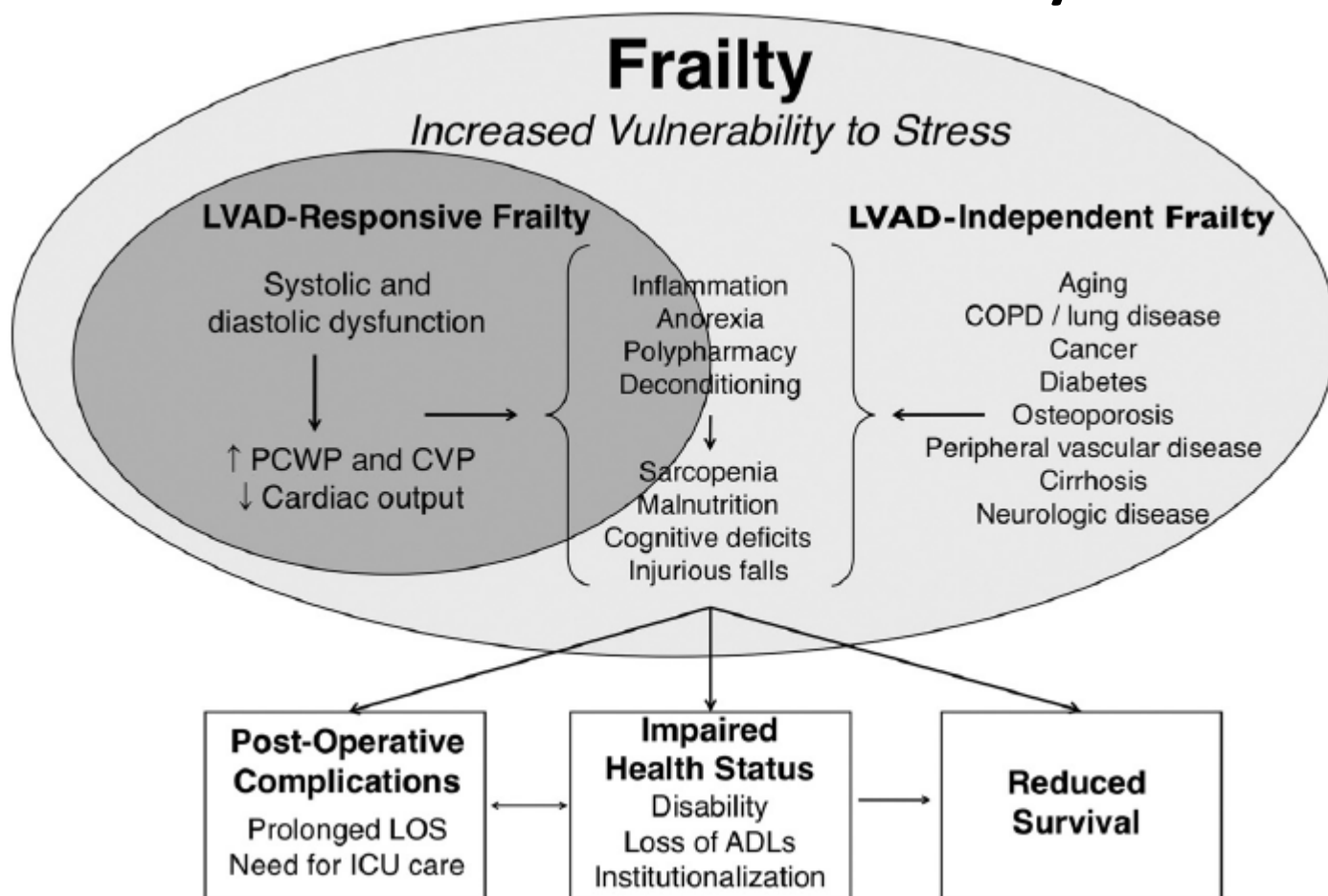
# Prediction Models

- Several models have been proposed to predict:
  - Heart Failure Survival (Seattle Heart Failure Score)
  - VAD Implant Survival (Leitz/Miller)

- No models have been developed to predict both survival and improved quality of life

- No standardized "evaluation" procedure for potential candidates for VAD therapy across programs to allow for collection of model covariates and subsequent outcomes

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# Factors Impacting Outcomes - Much More Than Hemodynamics

# Facility and Operator Characteristics Impact Outcomes

- Facility and Operator Characteristics impact the outcomes and cost of many surgical and cardiovascular procedures including VADs

- ACC supports the concept of Accreditation
  - JCAHO – VAD and Heart Failure Certifications – Programs and Heart Teams
  - CMS Minimum Volume Standards – Surgeons and Programs
  - ABIM Advanced Heart Failure and Cardiac Transplant Certification For Cardiologists

# Improved Survival with Experience

- Within the VAD Clinical Trials and the Intermacs registry there is clearly a "learning curve" both for individual providers and institutions

| Table 4 | Temporal Comparison of BTT Outcomes With the HM II LVAD | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **First Author (Ref. #)** | **Study** | **Enrollment Period** | **n** | **30-Day Operative Mortality** | **Transplantation, Recovery, or Ongoing Device Support at 180 Days** | **Kaplan-Meier Survival at 1 Yr** |
| Miller et al. (2) | HM II pivotal trial | 3/05–5/06 | 133 | 11% | 79% | 68% |
| Pagani et al. (3) | HM II pivotal trial | 3/05–3/07 | 281 | 8% | 84% | 74% |
| Current report | Post-approval INTERMACS registry study | 4/08–8/08 | 169 | 4% | 91% | 85% |

J Am Coll Cardiol 2011;57:1890–8

# Goals of Certification

- Insures that team members are experienced and competent within their discipline in the context of VAD patient selection, insertion, peri-operative, post-operative and long term management

- Availability of evidenced based care plans

- Evidence of data collection for quality measurement and improvement

- Adequate institutional commitment and resources

# Transplant

- Cardiac Transplant still provides the best long-term survival
  - Limited VAD survival data beyond two years
  - A mean two year survival for heart transplant would be considered unacceptable
- ACC supports the role of transplant centers in partnering with VAD centers to insure that candidates are appropriately screened for transplant before commitment to destination VAD therapy

# Heart Team

- <span style="color:red">The ACC strongly supports the concept of the multidisciplinary heart team</span> to provide care for patients with advanced heart failure including those being evaluated for and receiving ventricular assist devices.

- Physicians, nurses, social workers, nutritionists, pharmacists, physical therapists, psychologists and other sub-specialists all play critical roles in the assessment and management of VAD patients.

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# Generalizability To The Medicare Population

- Limited data in those over the age of 70

- Unique challenges
  - Caregivers
  - Living alone with a VAD
  - Comorbidities that may impact survival, quality of life or ability to manage the VAD

- Limited Assessment of "Frailty"

- Cost of outpatient supplies and equipment

# Evidentiary Gaps

- Utility and criteria for "Bridge to Decision" category

- Utilization of VAD technology in "less sick populations – NYHA Class 3(B)

- Multidisciplinary research on end-organ function and recovery

- End of life planning and care for VAD patients

- Management of arrhythmias/Devices
  - ICD and BiV Pacers
  - Ablations

# Evidentiary Gaps

- Factors allowing for successful bridge to heart transplant or recovery
- Role of anticoagulation strategies
  - GI bleeding/AVM
  - Age related risks
- Risk factors for pump thrombosis
  - Mechanical
  - Inflammatory
  - Genetic
  - Comorbidities – cancer, auto-immune, etc.

# Evidentiary Gaps

- Role of pharmacologic therapy for patients on VAD's
  - Neurohormonal blockade
  - Antiarrhythmics
  - Antibiotics
- Psychosocial impact
  - Care givers and wider support group
  - Depression and cognitive deficits
- Right Ventricular Failure
  - Predictors
  - Treatment – pulmonary vasodilators

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# Conclusion

- The ACC supports the need for supported VAD and advanced heart failure registry data to pool data across centers, allow for analysis of outcomes, identify factors for risk models and provide evidence for best practices