Society of Thoracic Surgeons

Intermacs & Pedimacs User Group
Webinar

April 24, 2024
Agenda

- Welcome and introductions
- STS housekeeping
- New Data Manager (part II) presentation by Rebecca Harap, RN

Open Discussion

- Please use the Q&A Function
- We will answer as many questions as possible
- We encourage your feedback and want to hear from you!
Important Dates

- INTERMACS/PEDIMACS QUALITY ASSURANCE WEBINAR- APRIL 25\textsuperscript{TH} @ 2PM CT
- DATA ENTRY DEADLINE FOR Q1 - APRIL 30\textsuperscript{TH}

<table>
<thead>
<tr>
<th>Calendar Quarter</th>
<th>Data Entry Deadline</th>
<th>Coverage Stop Date</th>
<th>Distribution Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>April 30th</td>
<td>March 31st</td>
<td>June 30th</td>
</tr>
<tr>
<td>Q2</td>
<td>July 31st</td>
<td>June 30th</td>
<td>September 30th</td>
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<td>Q3</td>
<td>October 31st</td>
<td>September 30th</td>
<td>December 31st</td>
</tr>
<tr>
<td>Q4</td>
<td>January 31st</td>
<td>December 31st</td>
<td>March 31st</td>
</tr>
</tbody>
</table>
AQO 2024

- Registration is open!
- Wednesday, September 11th - Intermacs/Pedimacs
- In-person pricing and virtual pricing
  - Early bird discount through May 16th

**Schedule**

- Wednesday, September 11 - Intermacs/Pedimacs
- Wednesday, September 11 - General Thoracic
- Thursday, September 12 - Adult Cardiac
- Friday, September 13 - Congenital Heart
Contact Information

• Carole Krohn, MPH, BSN, RN, LSSGB, Director, STS National Database
  ckrohn@sts.org

• Patricia Potter, BSN, RN, Intermacs Data Warehouse Manager of Clinical Affairs
  patricia.potter@kirso.net
New Data Managers Session Part 2
Learning Objectives:

Upon completion of this session the participant will be able to

• Understand how to successfully enter a patient into the Intermacs database
• Calculate and understand Intermacs follow-up windows
• Assess patient charts to identify Intermacs adverse events
Screening a Patient

* Remember to fill out an early right heart failure AE if you have a LVAD and RVAD in the same OR.
<table>
<thead>
<tr>
<th>Demographic Form</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient's Home Zip Code</strong></td>
</tr>
<tr>
<td><strong>Health Insurance Claim Number (HICN):</strong></td>
</tr>
<tr>
<td><strong>ST= Unknown</strong></td>
</tr>
<tr>
<td><strong>Date of Birth</strong></td>
</tr>
<tr>
<td><strong>MM/DD/YYYY</strong></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
</tr>
<tr>
<td>○ Male</td>
</tr>
<tr>
<td>○ Female</td>
</tr>
<tr>
<td><strong>Ethnicity: Hispanic or Latino</strong></td>
</tr>
<tr>
<td>○ Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Race</strong></td>
</tr>
<tr>
<td>○ American Indian or Alaska Native</td>
</tr>
<tr>
<td>○ Asian</td>
</tr>
<tr>
<td>○ African-American or Black</td>
</tr>
<tr>
<td>○ Hawaiian or other Pacific Islander</td>
</tr>
<tr>
<td>○ White</td>
</tr>
<tr>
<td>○ Unknown / Undisclosed</td>
</tr>
<tr>
<td>○ Other / none of the above</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
</tr>
<tr>
<td><strong>Highest education level</strong></td>
</tr>
<tr>
<td><strong>Working for income</strong></td>
</tr>
<tr>
<td>○ Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Is patient involved in a VAD related study?</strong></td>
</tr>
<tr>
<td>○ Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>
Index Hospitalization Worksheet

Index Hospitalization Form

Patient name: Swift, Taylor
Surgeon: Jones
Implant date: 3/1/24
In/Out OR time: 0707-1604
60 d pre implant: 1/1/24
CPB: 1055-1233
Induction: 0723
Incision: 0842
Extubation: 
Inotropes off: 
Tx to stepdown: 
Surgery time: 
ICU: 
Stepdown: 
Dates of AEs/notes:
a fib 3/3/24
Re-intubated 3/2/24
Pre-implant Form

**Patient Information**

- Admission Date for This Hospitalization
  - ST: Not Applicable, Patient Still Hospitalized
  - ST: Unknown

- Height
  - Enter the height of the patient at the time of implantation in inches or centimeters.
  - ________ in
  - ________ cm

- Weight
  - Enter the weight of the patient at the time of implantation in the appropriate space, in pounds or kilograms.
  - ________ lbs
  - ________ kg

- BSA

- BMI

- BloodType
  - O
  - A
  - B
  - AB
  - Unknown

- Payer
  - Government Health Insurance
  - Commercial Health Insurance
  - Health Maintenance Organization
  - Non-U.S. Insurance
  - None / Self
  - Unknown

**Medical Support Status**

- Current Device Strategy at time of implant
  - Bridge to Recovery
  - Rescue Therapy
  - Bridge to Transplant (patient currently listed for transplant)
  - Possible Bridge to Transplant - Likely to be eligible
  - Possible Bridge to Transplant - Moderate likelihood of becoming eligible
  - Possible Bridge to Transplant - Unlikely to become eligible
  - Destination Therapy (patient definitely not eligible for transplant)
  - Other, specify

- List Date for Transplant
  - ________
  - ST: Unknown

- Enter UNOS waitlist ID number
  - ________
  - ST: Unknown

- Time since first cardiac diagnosis
  - < 1 month
  - 1 month - 1 year
  - 1-2 years
  - > 2 years
  - Unknown

- Number of cardiac hospitalizations in the last 12 months
  - 0-1
  - 2-3
  - 4 or more
  - Unknown
Pre-implant Form

| History of Cardiac Arrhythmia | □ Yes  
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>□ No</td>
</tr>
<tr>
<td></td>
<td>□ Unknown</td>
</tr>
</tbody>
</table>

| If yes, check all that apply | □ Atrial Fibrillation (paroxysmal or chronic)  
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>□ Atrial Flutter</td>
</tr>
<tr>
<td></td>
<td>□ Other Atrial</td>
</tr>
<tr>
<td></td>
<td>□ Ventricular Tachycardia</td>
</tr>
<tr>
<td></td>
<td>□ Ventricular Fibrillation</td>
</tr>
<tr>
<td></td>
<td>□ History of ICD discharge or history of sudden cardiac death</td>
</tr>
<tr>
<td></td>
<td>□ Other Ventricular</td>
</tr>
</tbody>
</table>

| Current ICD device in place? | □ Yes  
<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>□ No</td>
</tr>
<tr>
<td></td>
<td>□ Unknown</td>
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</tbody>
</table>

| If yes: | □ ICD Only  
<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>□ CRT Only</td>
</tr>
<tr>
<td></td>
<td>□ ICD/CRT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary Cardiac Diagnosis</th>
<th>Select primary reason for cardiac dysfunction</th>
</tr>
</thead>
</table>

| Prior Cardiovascular Intervention (non-surgical) | □ Percutaneous Coronary Intervention  
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>□ Permanent Pacemaker</td>
</tr>
</tbody>
</table>
|                                                | □ Prior medical history of ICD (if pt. currently has ICD in place, please document in question “Current ICD Device in place?” in medical support status section and do not duplicate here).  
|                                                | □ Prior medical history of CRT (if pt. currently on CRT, please document in question “Current ICD Device in place?” in medical support status section and do not duplicate here).  
|                                                | □ CardiacIEM/ES                                 |
|                                                | □ Mitraclip                                     |
|                                                | □ TAVR                                         |
|                                                | □ Other, Specify                                |
|                                                | □ Unknown                                      |
|                                                | □ None                                         |

| Prior medical history of dialysis? | □ Yes  
<table>
<thead>
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<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>□ No</td>
</tr>
<tr>
<td></td>
<td>□ Unknown</td>
</tr>
</tbody>
</table>

| Prior Cardiovascular Intervention (surgical) | □ None  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ CABG</td>
</tr>
<tr>
<td></td>
<td>□ Aneurysmectomy (DOR)</td>
</tr>
<tr>
<td></td>
<td>□ Aortic Valve replacement / repair</td>
</tr>
<tr>
<td></td>
<td>□ Mitral valve replacement / repair</td>
</tr>
<tr>
<td></td>
<td>□ Tricuspid replacement / repair</td>
</tr>
<tr>
<td></td>
<td>□ Congenital cardiac surgery</td>
</tr>
<tr>
<td></td>
<td>□ LVAD, Temporary</td>
</tr>
<tr>
<td></td>
<td>□ LVAD, Durable implantable</td>
</tr>
<tr>
<td></td>
<td>□ RVAD, Durable implantable</td>
</tr>
<tr>
<td></td>
<td>□ RVAD, Temporary</td>
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<tr>
<td></td>
<td>□ TAH</td>
</tr>
<tr>
<td></td>
<td>□ Previous heart transplant</td>
</tr>
<tr>
<td></td>
<td>□ Previous ECMO</td>
</tr>
<tr>
<td></td>
<td>□ Complex Aortic Surgery</td>
</tr>
<tr>
<td></td>
<td>□ Unknown</td>
</tr>
<tr>
<td></td>
<td>□ Other, specify (INCLUDE ONLY OPERATIONS ACTUALLY PERFORMED ON HEART OR GREAT VESSELS)</td>
</tr>
</tbody>
</table>
# Pre-implant Form

**Clinical Events and Interventions DURING Implant Hospitalization**

- Cardiac arrest
- Dialysis
- Intubation Ventilator
- Myocardial Infarction
- Positive blood cultures
- Major Infection
- IABP
- Ultrafiltration
- Feeding tube
- ECMO
- CABG
- Aortic Valve replacement / repair
- Mitral valve replacement / repair
- Congenital cardiac surgery
- LVAD, Temporary
- RVAD, Durable implantable
- TAH
- Percutaneous Coronary Intervention
- Permanent Pacemaker
- CardioMEMS
- Mitraclip
- TAVR
- Unknown
- None
- LVAO, Durable implantable
- RVAD, Temporary

**ECMO: Present at the time of durable MCS device implant**
- Yes
- No
- Unknown

**ECMO: Approach to Insertion**

**ECMO: Extracorporeal membrane oxygenation**

**ECMO: Inflow**

**ECMO: Outflow**

**Total Number of days on ECMO**

**ST:**
Pre-implant Form

Is this implant the primary MCSD (LVAD or TAH) for this patient?

- Yes
- No

INTERMACS® Patient Profile at time of implant

Select one. These profiles will provide a general clinical description of the patients receiving primary LVAD or TAH implants. If there is significant clinical change between the initial decision to implant and the actual implant procedure, then the profile closest to the time of implant should be recorded. Patients admitted electively for implant should be described by the profile just prior to admission.

1. "Critical cardiogenic shock" describes a patient who is "crashing and burning", in which a patient has life-threatening hypotension and rapidly escalating inotropic pressor support (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
2. "Progressive decline" describes a patient who has been demonstrated "dependent" on inotropic support but nonetheless shows signs of continuing deterioration (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
3. "Stable but inotropic dependent" describes a patient who is clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) after repeated documentation of failure to wean without symptoms (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
4. "Resting symptoms" describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with ADL (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
5. "Exertion Intolerant" describes a patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or household (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
6. "Exertion Limited" also describes a patient who is comfortable at rest without evidence of fluid overload, but who is able to do some mild activity (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
7. "Advanced NYHA Class 3" describes a patient who is clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
Pre-implant Form-Things to Remember

• The Pre-Implant Form should be collected
  • Closest to implant but must be within 60 days of implant
  • No data from the OR should be used in the Pre-Implant Form
  • The quality of life and trailmaking data needs to be collected within 30 days implant

• Hemodynamics
  • The general hemodynamics should be collected at the time of the Swan hemodynamics

---

**General Hemodynamics**
Closest to implant but not in OR. General hemodynamics optimally should be obtained at the same time as the Swan Hemodynamics.

**Echo Findings**
Closest to implant but not in OR.

**Swan Hemodynamics**
Closest to implant but not in OR. Swan Hemodynamics optimally should be obtained at the same time as the General hemodynamics.
Pre-implant Form-Labs

• All within 60 days of implant

• ‘Not done’ should be used if the lab was not drawn within the 60 days of implant

• ‘Unknown’ should be used if the reported value is outside of the parameters/range or contains a non-numeric component such as >

• Care Everywhere results are acceptable as long as they are within 60 days of implant

• Lupus Anticoagulant if this is positive continue to mark yes on every follow-up form

• HIT use the data from the current lab draw
Pre-implant Form - Medications

Currently using - At the time of VAD placement.

Known previous use within the past year - Intended to capture the adequacy of medical therapy prior to determining heart failure to be refractory. For instance, ACEI, beta blockers, and diuretics are considered standard necessary therapy for heart failure but may be stopped due to hypotension or renal failure during a hospitalization for severely decompensated heart failure. If patients are known to have received these agents within the past year, please check known previous use.

No (not being used) - If there is no reason to believe that they have taken those agents, and reasonable certainty that information is accurate, check No.

Unknown - If it is not known whether the patient has taken these agents within the previous year, check Unknown.

- Allopurinol
- Angiotensin receptor blocker drug
- Amiodarone
- ACE inhibitors
- Beta-blockers
- Aldosterone antagonist
- Warfarin (coumadin)
- Antiplatelet therapy drug

- ARNI (Entresto)
- Nitric oxide
- Loop diuretics
- Outpatient (prior to admission) inotrope infusion
- Is patient on Metalozone/Thiazide within 60 days of the implant date
- Is patient on Phosphodiesterase inhibitors?
- Is patient on direct oral anticoagulants (DOACs) or novel oral anticoagulants (NOACs)?

Such as: dabigatran (Pradaxa), rivaroxaban (Xarelto), apixaban (Eliquis), edoxaban (Savaysa), and betrixaban (Bevyxxa)
Pre-implant Form-Quality of Life (QOL)

- QOL forms can be found on https://intermacs.kirso.net/intermacs-documents/

- Make sure you are
  - Keeping hard copies of QOL forms
  - Scanning them into the medical record
## Exercise Function and Trailmaking Data

**6 minute walk**

| feet | ST= |

This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk behind the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here. NOTE: You may use the time from the first 15 feet of the 6 minute walk for the Gait speed test listed below. (please see instructions for the gait speed test below)

**Gait Speed (1st 15 foot walk)**

| seconds | ST= |

Instructions: Record the time (seconds) required for the patient to walk the first 15 feet of the 6 minute walk. The 'starting' line and the 15 foot line should be clearly marked. Record the time to the first footfall at 0 feet and ends with the first footfall at 15 feet in the nearest 0.1 sec with a stopwatch. NOTE: You may use the time from the first 15 feet of the 6 minute walk for the Gait speed test.

**Peak VO2 Max**

| mL/kg/min | ST= |

Maximum volume of oxygen the body can consume during exercise (mL/kg/min) is the mL/kg/min of oxygen consumed during symptom-limited exercise testing either on a bicycle or treadmill. The values recorded during the bicycle are usually 1-2 mL/min lower than for the treadmill, but it is assumed that most institutions will use only one instrument. If both are available, the bicycle is preferable as the mode easiest to standardize.

**R Value at peak**

| % | ST= |

R Value at peak is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort.
# Pre-implant Form - Comorbidities

## Severe Diabetes
- **Defined as** a Hemoglobin A1c greater than 8 mg/dl or associated with diabetic nephropathy, vasculopathy, oculopathy.

- **Options**:
  - Yes
  - No
  - Unknown

## Prior Sternotomy
- **Options**:
  - Yes
  - No
  - Unknown

## If yes, how many
- **Options**:
  - Enter number
  - Unknown

## Pulmonary Hypertension Definition
Indicate whether there is physician documentation of Pulmonary Hypertension as documented by:
- Right heart catheterization: mean pulmonary arterial pressure (PAP) > 25 mmHg at rest
- Echocardiographic diagnosis: PA systolic pressure (PASP) > 50 mmHg
- Mean Pulmonary Artery Pressure greater than 25mmHg obtained from most recent right heart catheterization of right ventricular systolic pressure greater than 50mmHg obtained from the most recent right heart catheterization or most recent echocardiogram.

## Psychosocial Issues
- **Options**:
  - Yes
  - No
  - Unknown

## Chronic Lung Disease Definition
Indicate whether the patient has chronic lung disease, and the severity level according to the following classification:
- **Mild**: FEV1 60% to 75% of predicted or on chronic inhaled or oral bronchodilator therapy.
- **Moderate**: FEV1 50% to 59% of predicted or on chronic oral/systemic steroid therapy aimed at lung disease.
- **Severe**: FEV1 < 50% or Room Air pCO2 > 60 or pCCO2 > 50.
- **CLD present, severity not documented.**
- **Unknown**

## Time Frame:
Do not use values obtained more than 12 months prior to the date of surgery. Spirometry results that have not been interpreted by a pulmonologist may be used to quantify chronic lung disease.

## Chronic Lung Disease
- **Options**:
  - Yes
  - No
  - Unknown

## Smoking
- **Options**:
  - Remote use (more than 3 months ago)
  - Recent use (within 3 months)
  - Unknown

## Alcohol Abuse
- **Options**:
  - Remote use (more than 3 months ago)
  - Recent use (within 3 months)
  - Unknown
Index Hospitalization Worksheet

Index Hospitalization Form

Patient name: Swift, Taylor
Surgeon: Jones
Implant date: 3/1/24
In/Out OR time: 0707-1604
60 d pre implant: 1/1/24
CPB: 1055-1233
Incision: 0842
Induction: 0723
Inotropes off:
Extubation:
Tx to stepdown:
ICU:
Stepdown:

Dates of AEs/notes:
a fib 3/3/24
Re-intubated 3/2/24
Surgery time:
Implant Form
# Implant Form

## Additional Operative Details

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was left ventricular thrombus present at operation?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>If you select Yes, you are confirming that the left ventricular thrombus</td>
<td>was removed</td>
</tr>
<tr>
<td>Was left atrial appendage clot present at operation?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Was palpable atherosclerotic plaque or calcified plaque present in the</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>ascending aorta or aortic arch at operation?</td>
<td>Unknown, Did not evaluate</td>
</tr>
<tr>
<td>Was a patent foramen ovale present at operation?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Were traction/stabilization sutures utilized to optimize (inlet cannula)</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>LVAD pump position?</td>
<td></td>
</tr>
<tr>
<td>Which deairing techniques were utilized at device implantation?</td>
<td>None, Use of CO2 to flood the operative field, Needle evacuation of air from the outflow graft, Aortic root vent, Left ventricular vent (Right superior pulmonary vein), Unknown, Other, specify</td>
</tr>
<tr>
<td>Was the LVAD procedure complicated by vasoplegia (MAP &lt;60 mmHg requiring</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>1 vasopressor to treat or unexpected ECMO) during or following</td>
<td></td>
</tr>
<tr>
<td>cardiopulmonary bypass in the operating room?</td>
<td></td>
</tr>
</tbody>
</table>

## Implant Hemodynamics

- **Heart rate**: Enter beats per min
- **Systolic blood pressure**: Enter mmHg
- **Diastolic blood pressure**: Enter mmHg

## Intraoperative Transfusions

Intraoperative transfusions are not counted as a major bleeding event

- **Were intraoperative blood products or clotting factors given to treat bleeding/coagulopathy?**
  - Yes, No, Unknown

**Check any transfusions or clotting factor replacements administered:**
- Packed RBC
- Prothrombin Complex concentrate
- Factor VII
- Platelets
- Cryoprecipitate
- Fresh frozen plasma
- Other
- Unknown
Follow-up Forms

- Once the implant form is complete the 1 Week Follow-up and the Implant Discharge Form will open
Follow-up Forms- 1 Week and 1 Month

• These forms collect the same variables
• Use all data from the previous visit to the current follow-up date
  • 1-Week-from the date/time the patients leaves the OR to date of follow-up
  • 1-Month-from the day after the 1-Week follow date to the date of the follow-up
Implant Discharge Form

During the implant hospitalization was the patient?  Discharged alive with a device in place

Patient discharged to  Rehabilitation Facility

Implant Discharge or LVAD Exchange Date

03/23/2024

Acute care (ICU / CCU) duration of post-implant stay

5 days

Intermediate / step-down care - duration of post-implant stay

12 days

Date of approximate discontinuation of inotropes

1-2 weeks

Since the VAD implant date has the patient tested positive for COVID-19?  Yes  No  Unknown

Interventions since implant

Surgical Procedures:

- Device Related Operation
- Surgical Procedure - Non Cardiac Surgical Procedure
- Surgical Procedure - Other Procedure
- Surgical Procedure - Unknown

Cardiac Surgical Procedures:

- Resumption for bleeding within 48 hours of implant
- Recovery for Bleeding and/or tamponade > 48 hours
- Surgical Drainage of pericardial effusion
- Aortic Valve Surgery - Replacement - Biological
- Aortic Valve Surgery - Replacement - Mechanical
- Aortic Valve Procedures
- Mitral Valve Surgery - Repair
- Mitral Valve Surgery - Replacement - Biological
- Mitral Valve Surgery - Replacement - Mechanical
- Tricuspid Valve Surgery - Repair - De Vega
- Tricuspid Valve Surgery - Repair - Other
- Tricuspid Valve Surgery - Exclusion
- Tricuspid Valve Surgery - Replacement - Biological
- Tricuspid Valve Surgery - Replacement - Mechanical
- Pulmonary Valve Surgery - Repair
- Pulmonary Valve Surgery - Replacement - Biological
- Pulmonary Valve Surgery - Replacement - Mechanical
- Arrhythmia Surgery (Ablation)
- Ligation of Left Atrial Appendage
- Aortic valve surgery
- Mitraclip
- TAVR
- Other Cardiac Surgical Procedure
- Cardiac Surgical Procedure - Unknown

Other Procedures:

- Implantation of LVAD
- Dialysis
- Bronchoscopy
- Ultrafiltration
- Other, specify:

Was ECMO initiated at any time after VAD implant?  Yes  No  Unknown

Console Change

Was there a Console Change? (For TAH or Berlin Heart Consoles)  Yes  No  Unknown
Follow-up Forms - 3 Month and all Subsequent Forms

- All forms from 3 mo., 6 mo., and every form thereafter will be the same

- How do we determine the window we are looking at?
  - Look at the follow-up prior to the current form and use all time from that date to the date of your current follow-up
    - Example 2yr 5/20/2023-06/26/2023 but look back to 01/10/2023
    - Example 2.5yr 11/20/2023-12/20/2023 but look back to 06/27/2023
Follow-up Forms-Non-Trigged Events

- With every follow-up form you will need to check
  - All LDH and plasma-free hemoglobin results from the previous visit to date of follow up (Example window 12/6/2023-7/22/2023)

- Was the patient admitted during this window?
  - If so, look for IV diuretic/IV inotropes $\geq 72$hrs or ECMO to assess for RHF

- Has the patient experienced a neurological AE post VAD?
  - If so, look for a documented MRS
  - Determine a MRS based off of clinical judgement from the available documentation
Follow-up Forms- 3 Month and all Subsequent Forms

- The patient’s current device strategy is asked on the 3-mo. form and all follow-up moving forward

![current_device_strategy]

- When you abstract Bridge to Transplant the following will open

![list_date_for_transplant]

- When you abstract anything other than Bridge to Transplant a comorbidity form will open within the follow-up form
Adverse Events-Hemolysis

- Use the search feature within your EMR to look at all LDH and plasma-free hemoglobin results during your current window
  - Plasma-free hemoglobin >20mg/dL
  - LDH > 2.5x the upper limit of your hospital’s normal range
    - 271 units/L is NM normal range
    - Look for a result of 677.5 units/L to meet this AE
  - Isolate LDH elevations should not be reported
- If the AE exists then determine if it is minor or major

**Minor Hemolysis**
A plasma-free hemoglobin value greater than 20 mg/dl or a serum LDH level greater than two and one-half times (2.5 x) the upper limits of the normal range at the implanting center occurring after the first 72 hours post-implant in the absence of clinical symptoms or findings of hemolysis or abnormal pump function (see Major Hemolysis for a list of symptoms and findings) and thought not attributable to laboratory error.

**Major Hemolysis**
A plasma-free hemoglobin value greater than 20 mg/dl or a serum LDH level greater than two and one-half times (2.5 x) the upper limits of the normal range at the implanting center occurring after the first 72 hours post-implant and associated with clinical symptoms or findings of hemolysis or abnormal pump function.

Major Hemolysis requires the presence of at least one of the following conditions:
- Hemoglobinuria (“tea-colored urine”)
- Anemia (decrease in hematocrit or hemoglobin level that is out of proportion to levels explainable by chronic illness or usual post-VAD state)
- Hyperbilirubinemia (total bilirubin above 2 mg/dl, with predominately indirect component)
- Pump malfunction and/or abnormal pump parameters as per section on device malfunction
Adverse Events-Late Right Heart Failure (RHF)

- Was your patient admitted at any time during the follow-up period?
  - If NO, then you cannot have a later RHF AE
  - If YES
    - Did the patient have IV diuretics or inotropes for greater than 72 hours? Was ECMO cannulated?
      - If YES, then do they meet the following criteria

Hospitalization that occurs greater than 30 days post-implant and which requires intravenous diuretics or inotropes support for at least 72 hours and is associated with:

The diagnosis of right heart failure is made by the presence of at least two of the following clinical findings:

- Ascites
- Functionally limiting peripheral edema (≥2+).
- Elevated estimated jugular venous pressure at least halfway up the neck in an upright patient.
- Elevated measured central venous pressure (>15 mm Hg).

Or is associated with at least one of the following manifestations:

- Renal failure with serum creatinine > 2 baseline value
- Liver injury with an elevation of at least 2 upper limit normal in AST/ALT or total bilirubin > 2.0
- A reduction in pump flow of > 30% from the previous baseline in the absence of tamponade
- SV02 < 50%
- Cardiac index < 2.2 liter/min/m²
- Elevated lactate > 3.0 mmol/liter
Adverse Events-Hepatic Function

• Any time after POD 14 a patient can meet definition for a hepatic AE

• Using the search function in the EMR look at all ALT, AST, and Total Bilirubin results during the window
  
  • Look for levels 3x the upper limit of normal for your hospital

<table>
<thead>
<tr>
<th>Test</th>
<th>Normal Range</th>
<th>74</th>
<th>25</th>
<th>22</th>
<th>12</th>
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<tbody>
<tr>
<td>ALT (SGPT)</td>
<td>0 - 52 units/L</td>
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<tr>
<td>Alkaline Phosphatase</td>
<td>34 - 104 units/L</td>
<td>69</td>
<td>32</td>
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<tr>
<td>AST (SGOT)</td>
<td>0 - 39 units/L</td>
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<td>94</td>
<td>91</td>
<td>64</td>
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<tr>
<td>Bilirubin Total</td>
<td>0.0 - 1.0 mg/dL</td>
<td>0.7</td>
<td>0.8</td>
<td>0.7</td>
<td>0.7</td>
</tr>
</tbody>
</table>

• Assess for this AE during every open window

• A patient may have multiple instances of hepatic AE if their labs stabilize and then again meet criteria
Adverse Event-Arrhythmias

- Any time after the patient leaves the OR
- This AE can be documented every 7 days
- ATP is included in this AE
Thank you

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