# 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 25TH @ 2PM CT
- DATA ENTRY DEADLINE FOR Q1- APRIL 30TH

**When are the reports distributed?**

| Calendar Quarter | Data Entry Deadline | Coverage Stop Date | Distribution Date |
|---|---|---|---|
| Q1 | April 30th | March 31st | June 30th |
| Q2 | July 31st | June 30th | September 30th |
| Q3 | October 31st | September 30th | December 31st |
| Q4 | January 31st | December 31st | March 31st |

# 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, Septemeber 13 - Congenital Heart

# Contact Information


- Carole Krohn, MPH, BSN, RN, LSSGB, Director, STS National Database
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- Patricia Potter, BSN, RN,  Intermacs Data Warehouse Manager of Clinical Affairs
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# 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

Intermacs

## Screening Log

**Implant Date**
MM/DD/YYYY

### Inclusion: Patient must meet all inclusion criteria:

If patient meets all inclusion criteria then check **ALL** inclusion reasons below.

- ☐ Patient receives a durable mechanical circulatory support device (MCSD) which is FDA approved
- ☐ Implanted on or after March 1, 2006 (The device does not need to be the first implant for the patient)

### Exclusion: Any exclusion will disqualify the patient for entry into INTERMACS®

If patient meets **ANY** exclusion criteria then check any of the appropriate exclusion reasons below (check all that apply).

- ☐ Patient receives a durable mechanical circulatory support device (MCSD) which is not FDA approved
- ☐ Patient is incarcerated (prisoner)

**Device type**

- ○ LVAD
- ○ RVAD
- ○ Both (LVAD + RVAD in the same OR visit)
- ○ Total Artificial Heart

**Device brand**

- ○ HeartMate IP
- ○ HeartMate VE
- ○ Novacor PC
- ○ Novacor PCq
- ○ HeartMate XVE
- ○ Abiomed BVS 5000
- ○ Biomedicus
- ○ SynCardia TAH - 70cc
- ○ AbioCor TAH
- ○ Thoratec IVAD
- ○ Medtronic HVAD
- ○ Abiomed AB5000
- ○ Abiomed Impella 2.5
- ○ TandemHeart
- ○ Thoratec Centrimag (Levitronix)
- ○ Berlin Heart EXCOR (paracorporeal)
- ○ Micromed DeBakey VAD - Child
- ○ Thoratec PVAD
- ○ HeartMate II LVAS
- ○ Sorin Revolution
- ○ Abiomed Impella 5.0
- ○ Abiomed Impella CP
- ○ Abiomed Impella RP
- ○ HeartMate III
- ○ SynCardia TAH - 50cc
- ○ Abiomed Impella 5.5
- ○ Other, Specify

* Remember to fill out an early right heart failure AE if you have a LVAD and RVAD in the same OR

# Demographic Form

Intermacs

## Demographics

**First Name**

**Middle Name**

**Last Name**

**Medical record number**

**SSN (last 5 digits)**

ST= ○ Not Assigned
○ Undisclosed

**Patient's Home Street Address**

ST= ○ Unknown
○ Undisclosed

**Patient's Home City**

ST= ○ Unknown
○ Undisclosed

**Patient's Home State/Territory/Province** ○ Alabama

**Patient's Home Zip Code**

ST= ○ Unknown

**Health Insurance Claim Number (HICN):**
Enter the HICN issued by CMS.

ST= ○ Unknown

**Date of Birth**
MM/DD/YYYY

**Gender**
○ Male
○ Female

**Ethnicity: Hispanic or Latino**
○ Yes
◉ No
○ Unknown

**Race**
Enter all race choices that apply

☐ American Indian or Alaska Native
☐ Asian
☐ African-American or Black
☐ Hawaiian or other Pacific Islander
☐ White
☐ Unknown / Undisclosed
☐ Other / none of the above

**Marital Status**

**Highest education level**

**Working for income**
○ Yes
○ No
○ Unknown

**Is patient involved in a VAD related study?**
○ Yes
◉ No
○ 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**

**Induction: 0723**

**Incision: 0842**

**Extubation:**

**Inotropes off:**

**Tx to stepdown:**

**ICU:**

**Surgery time:**

**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
○ 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

**Payor**

☐ 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**
This should be determined in conjunction with the heart failure cardiologist and surgeon at the time of the implant. This determination will be re-visited and recorded at 3 months, 6 months, and every 6 months thereafter.

○ 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**
The length of time that the patient had any known cardiac diagnosis. For example, the time since the patient had a myocardial infarction, congenital heart disease was noted or the patient was noted to have heart failure.

○ < 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
- ( ) No
- ( ) Unknown

**If yes, check all that apply**
- [ ] Atrial Fibrillation (paroxysmal or chronic)
- [ ] Atrial Flutter
- [ ] Other Atrial
- [ ] Ventricular Tachycardia
- [ ] Ventricular Fibrillation
- [ ] History of ICD discharge or history of sudden cardiac death
- [ ] Other Ventricular

**Current ICD device in place?**
- (●) Yes
- ( ) No
- ( ) Unknown

**If yes:**
- ( ) ICD Only
- ( ) CRT Only
- ( ) ICD/CRT

**Primary Cardiac Diagnosis**
Select primary reason for cardiac dysfunction

**Prior Cardiovascular Intervention (non-surgical)**
Select all non-surgical interventions that the patient has had prior to this implant hospitalization.
- [ ] Percutaneous Coronary Intervention
- [ ] Permanent Pacemaker
- [ ] 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).
- [ ] CardioMEMS
- [ ] Mitraclip
- [ ] TAVR
- [ ] Other, Specify
- [ ] Unknown
- [ ] None

**Prior medical history of dialysis?**
- ( ) Yes
- ( ) No
- ( ) Unknown

**Prior Cardiovascular Intervention (surgical)**
Select all cardiac operations that the patient has had prior to this implant hospitalization.
- [ ] None
- [ ] CABG
- [ ] Aneuryomectomy (DOR)
- [ ] Aortic Valve replacement / repair
- [ ] Mitral valve replacement / repair
- [ ] Triscuspid replacement /repair
- [ ] Congenital cardiac surgery
- [ ] LVAD, Temporary
- [ ] LVAD, Durable implantable
- [ ] RVAD, Durable implantable
- [ ] RVAD, Temporary
- [ ] TAH
- [ ] Previous heart transplant
- [ ] Previous ECMO
- [ ] Complex Aortic Surgery
- [ ] Unknown
- [ ] Other, specify (INCLUDE ONLY OPERATIONS ACTUALLY PERFORMED ON HEART OR GREAT VESSELS)

# Pre-implant Form

## Clinical Events and Interventions DURING Implant Hospitalization

**Clinical Events and Interventions this hospitalization (Pre-implant)**

Pertaining to this current hospitalization, select all events and interventions that occurred.

- [ ] Cardiac arrest
- [ ] Dialysis
- [ ] Intubation/Ventilator
- [ ] Myocardial Infarction
- [ ] Positive blood cultures
- [ ] Major Infection
- [ ] IABP
- [ ] Ultrafiltration
- [ ] Feeding tube
- [x] 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
- [ ] LVAD, 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

The INTERMACS® Patient Profiles are required at pre-implant and at all times when an implant occurs even if this is NOT the primary LVAD or TAH implant.

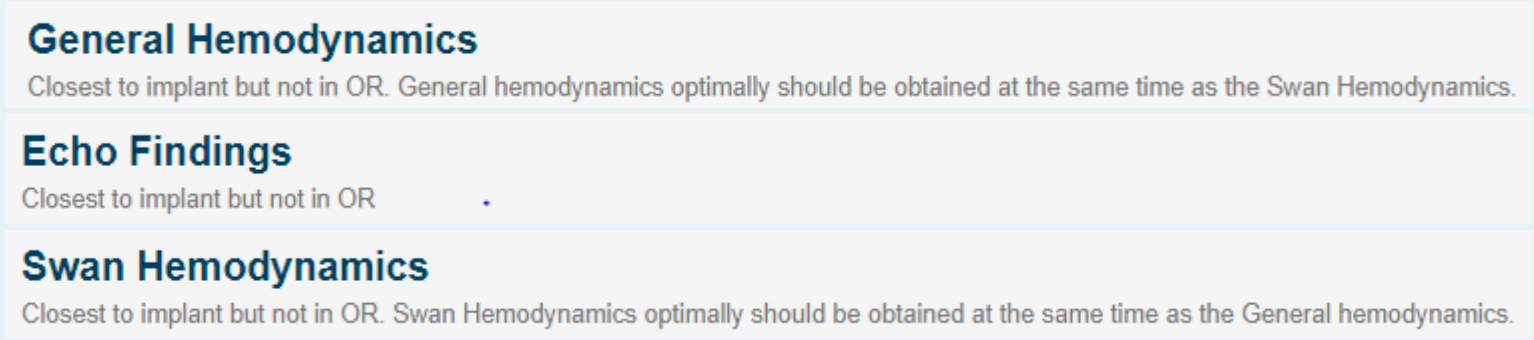
**INTERMACS® Patient Profile at time of implant**

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 rapdily 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 inotrope 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



# 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** - Is 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.

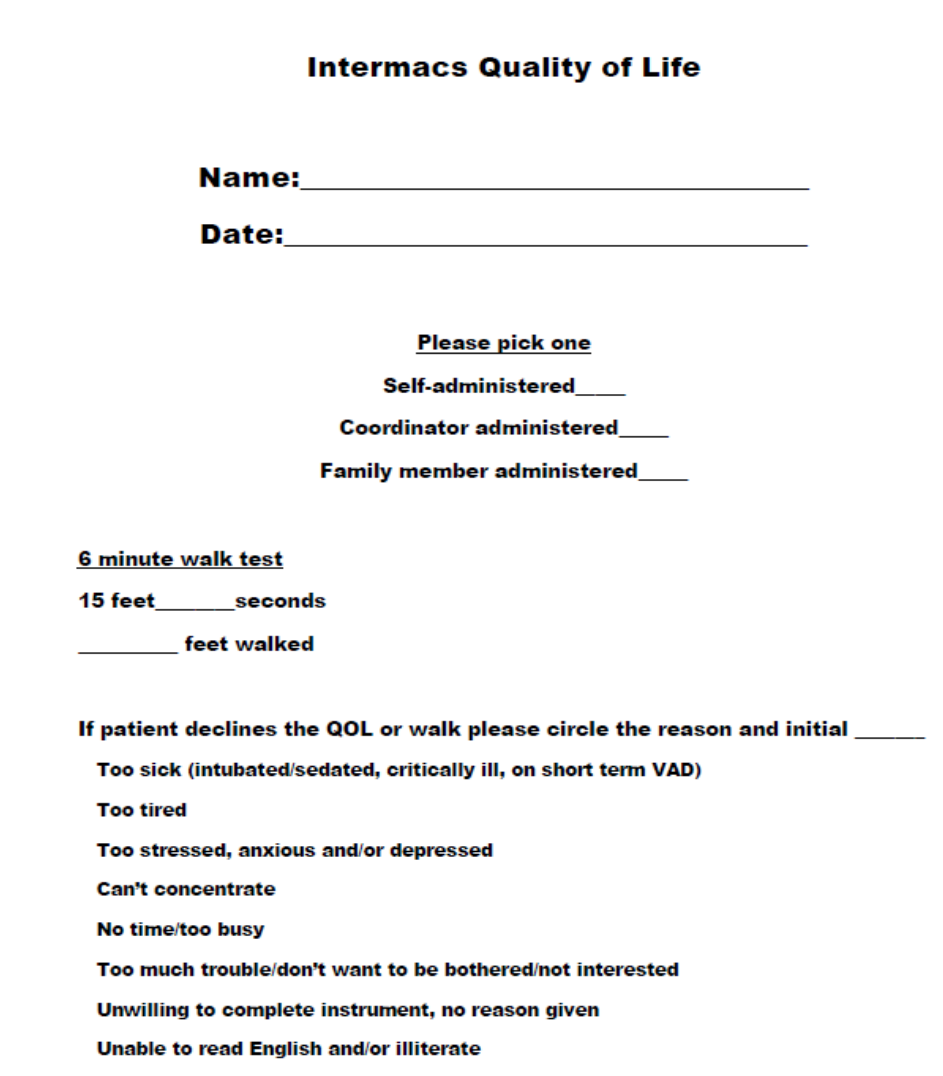
**No (not being used)** - If there is no reason to believe that they have taken those agents, and reasonable certainty that information is accurate, check No.

**Unknown** - If it is not known whether the patient has taken those 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)** | ○ Yes ○ No ○ Unknown |
| **Nitric oxide**<br>Document Flolan here | ○ Yes ○ No ○ Unknown |
| **Loop diuretics** | ○ Yes ○ No ○ Unknown |
| **Outpatient (prior to admission) inotrope infusion:** | ○ Yes ○ No ○ Unknown |
| **Is patient on Metalozone/Thiazide?**<br>within 60 days of the implant date | ○ Yes ○ No ○ Unknown |
| **Is patient on Phosphodiesterase inhibitors?**<br>Please enter only for the indication of Pulmonary Hypertension or Right Heart Failure | ○ Yes ○ No ○ Unknown |
| **Is patient on direct oral anticoagulants (DOACs) or novel oral anticoagulants (NOACs)?**<br>Such as: dabigatran (Pradaxa), rivaroxaban (Xarelto), apixaban (Eliquis), edoxaban (Savaysa), and betrixaban (Bevyxxa) | ○ Yes ○ No ○ Unknown |

# Pre-implant Form-Quality of Life (QOL)



**Intermacs Quality of Life**

**Name:**_____

**Date:**_____

**Please pick one**

**Self-administered____**

**Coordinator administered____**

**Family member administered____**

**6 minute walk test**

**15 feet_____seconds**

**_____ feet walked**

**If patient declines the QOL or walk please circle the reason and initial _____**

**Too sick (intubated/sedated, critically ill, on short term VAD)**

**Too tired**

**Too stressed, anxious and/or depressed**

**Can't concentrate**

**No time/too busy**

**Too much trouble/don't want to be bothered/not interested**

**Unwilling to complete instrument, no reason given**

**Unable to read English and/or illiterate**

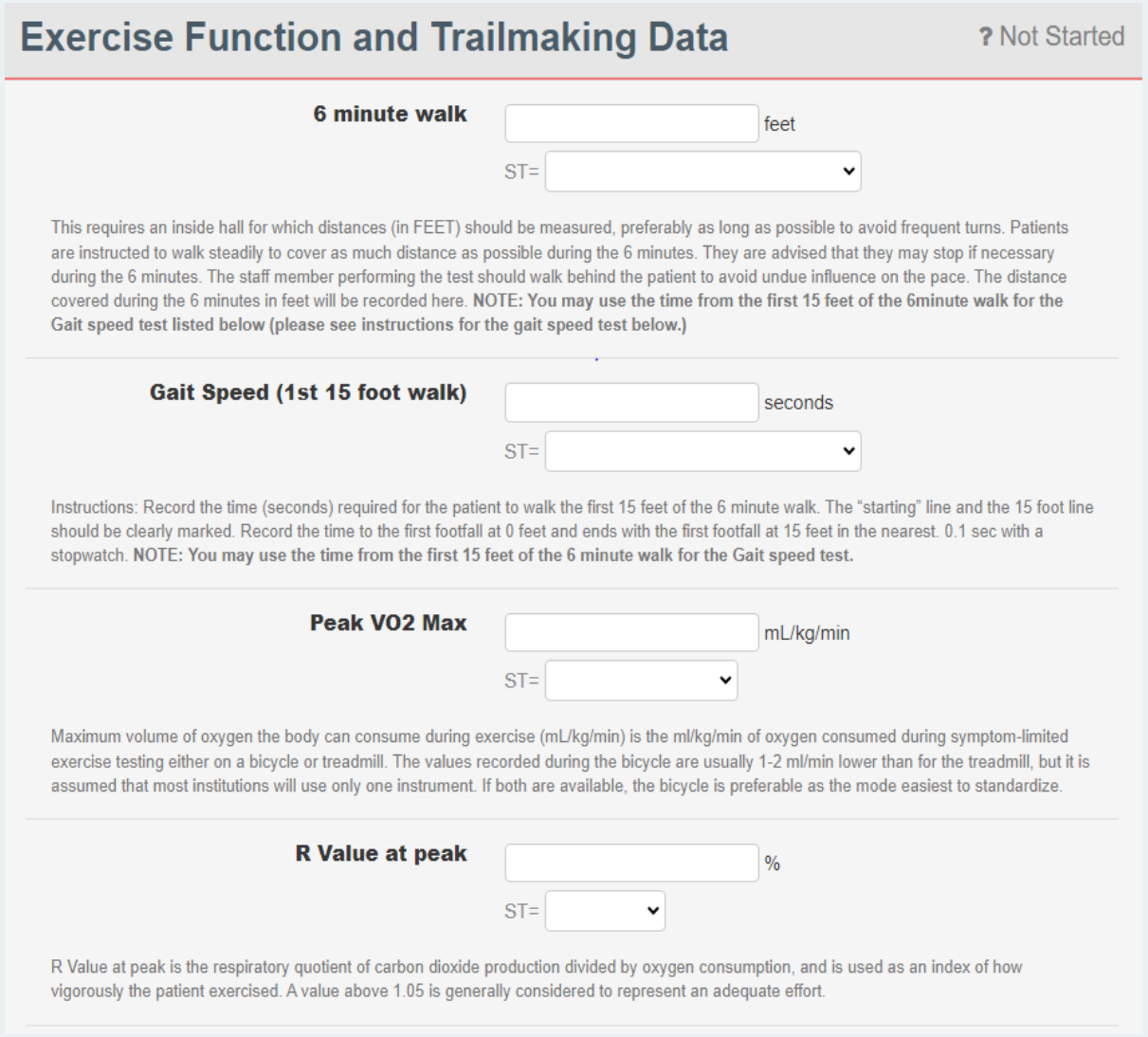
- QOL forms can be found on https://intermacs.kirso.net/intermacs-documents/
  - Appendix F – Quality of Life Questionnaires

    EQ-5D: Please contact the **DCC** for a copy of the EQ-5D survey

    **English Adult Quality of Life Questionnaire**
    - **Pre-Implant QoL Questionnaire**
    - **Post Implant QoL Questionnaire**

    **Spanish Adult Quality of Life Questionnaire**
    - **Pre-Implant QoL Questionnaire**
    - **Post Implant QoL Questionnaire**
- Make sure you are
  - Keeping hard copies of QOL forms
  - Scanning them into the medical record

# Pre-implant Form-Exercise Function



## Exercise Function and Trailmaking Data

? Not Started

**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 6minute 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

- ○ Yes
- ○ No
- ○ 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

**Prior Sternotomy**

- ◉ Yes
- ○ No
- ○ Unknown

**If yes, how many**

ST:

**Psychosocial Issues**
NOTE: Smoking History has been moved to this section.

This section includes, substance abuse disorders along with a detailed smoking history. Please read this section thoroughly and check the boxes accordingly.

- ◉ 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 pO2 < 60 or pCO2 > 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**

- ○ Yes
- ○ No
- ○ Unknown

**If yes, check all that apply**

- ☐ Depression
- ☐ History of Severe Depression
- ☑ Alcohol Abuse
- ☐ Limited Cognition
- ☐ Limited Family Support
- ☐ Noncompliance
- ☐ History of Narcotic Dependence
- ☐ Active Illicit Drug Use
- ☑ History of Smoking
- ☐ Other Specify

**Smoking**

- ○ Remote use (more than 3 months ago)
- ○ Recent use (within 3 months)
- ○ Unknown

**Alcohol Abuse**

- ○ 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**

**Induction: 0723**

**Incision: 0842**

**Extubation:**

**Inotropes off:**

**Tx to stepdown:**

**ICU:**

**Surgery time:**

**Stepdown:**

**Dates of AEs/notes:**

**a fib 3/3/24**

**Re-intubated 3/2/24**

# Implant Form

## Durable Implantable VAD Support

**Device type**
LVAD

**Approach to insertion**

**LVAD device brand**
HeartMate III

**LVAD: Serial Number**
ST:

**LVAD: cannulae location-inflow**

**LVAD: cannulae location-outflow**

**Associated findings**
Surgical observations or Intraoperative TEE
- ☐ PFO / ASD
- ☐ Aortic Insufficiency
- ☐ Mitral insufficiency
- ☐ Tricuspid Insufficiency
- ☐ None

**Is the VAD implant occurring in the setting of a failed cardiac operation (same operation or hospitalization)?**
- ○ Yes
- ○ No

**Concomitant surgery**
Planned or accompanying LVAD procedure
- ☐ None
- ☐ ASD closure
- ☐ PFO closure
- ☐ CABG
- ☐ VSD closure
- ☐ Congenital cardiac surgery, other
- ☐ Aortic Valve Procedure
- ☐ Aortic Valve Surgery - Replacement - Biological
- ☐ Aortic Valve Surgery - Replacement - Mechanical
- ☐ Mitral Valve Surgery - Repair
- ☐ Mitral Valve Surgery - Replacement - Biological
- ☐ Mitral Valve Surgery - Replacement - Mechanical
- ☐ Tricuspid Valve Surgery - Repair - DeVega
- ☐ Tricuspid Valve Surgery - Repair - Ring
- ☐ Tricuspid Valve Surgery - Repair - Other
- ☐ Tricuspid Valve Surgery - Replacement - Biological
- ☐ Tricuspid Valve Surgery - Replacement - Mechanical
- ☐ Tricuspid Valve Surgery - Excision
- ☐ Pulmonary Valve Surgery - Repair
- ☐ Pulmonary Valve Surgery - Replacement - Biological
- ☐ Pulmonary Valve Surgery - Replacement - Mechanical
- ☐ Left ventricular aneurysmectomy
- ☐ Other, specify
- ☐ Arrhythmia surgery (ablation)
- ☐ Ligation of left atrial appendage
- ☐ Temporary MCS Removal (ECMO, IABP removal documented here)
- ☐ Extracorporeal Membrane Oxygenation (ECMO Insertion)

**Was the patient put on Cardiopulmonary Bypass Pump?**
- ○ Yes
- ○ No

**Surgery Time**
Enter total surgery time from primary incision to closure
minutes
ST:

**Status of incision at end of procedure**
Select one
- ○ Open (i.e., delayed sternal closure)
- ○ Closed
- ○ Unknown

# Implant Form

## Additional Operative Details

**Was left ventricular thrombus present at operation?**
If you select Yes, you are confirming that the left ventricular thrombus was removed.
- ○ Yes
- ○ No
- ○ Unknown

**Was left atrial appendage clot present at operation?**
- ○ Yes
- ○ No
- ○ Unknown

**Was palpable atherosclerotic plaque or calcified plaque present in the ascending aorta or aortic arch at operation?**
- ○ Yes
- ○ No
- ○ Unknown
- ○ Did not evaluate

**Was a patent foramen ovale present at operation?**
- ○ Yes
- ○ No
- ○ Unknown

**Were traction/stabilization sutures utilized to optimize (inlet cannula) LVAD pump position?**
- ○ Yes
- ○ No
- ○ Unknown

**Which deairing techniques were utilized at device implantation?**
Select all that apply
- ☐ 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

**Was the LVAD procedure complicated by vasoplegia (MAP <60 mmHg requiring> 1 vasopressor to treat or unexpected ECMO) during or following cardiopulmonary bypass in the operating room?**
- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Applicable

*Use the surgeon op-note for this data

## Implant Hemodynamics

(At the start of procedure following induction of anesthesia but prior to skin incision):

**Heart rate** _____ beats per min
ST: ▾

**Systolic blood pressure**
(millimeters of mercury) should be determined from auscultation or arterial line if necessary.
_____ mmHg
ST: ▾

**Diastolic blood pressure**
(millimeters of mercury) should be determined from auscultation or arterial line if necessary
_____ mmHg
ST: ▾

## Intraoperative Transfusions

Intraoperative transfusions are not counted as a major bleeding event

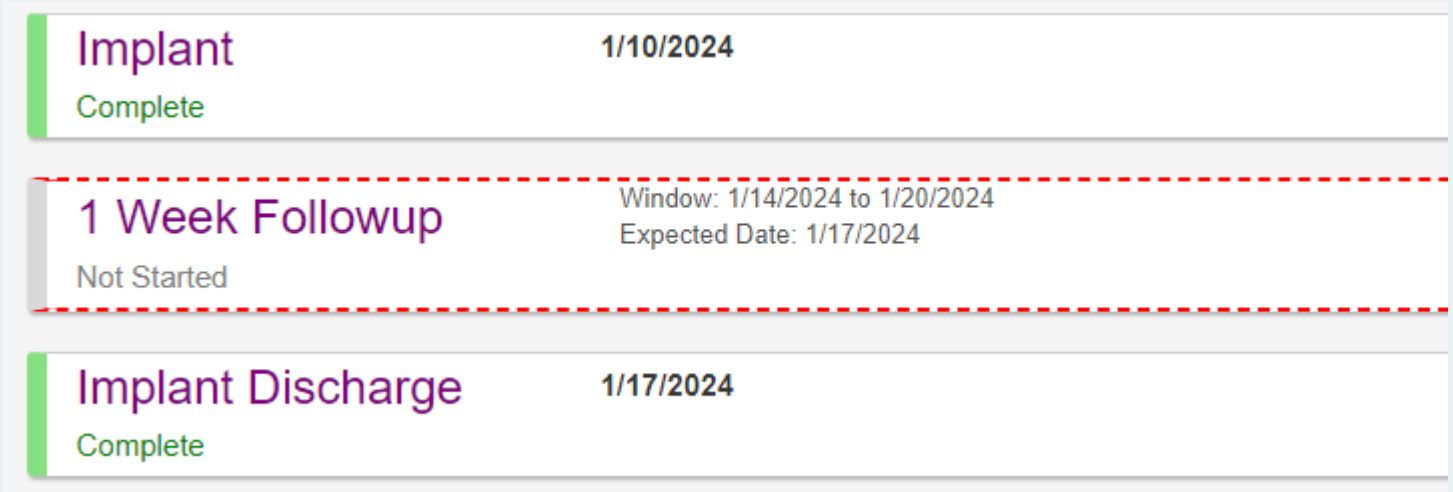
**Were intraoperative blood products or clotting factors given to treat bleeding/coagulopathy?**
- ◉ Yes
- ○ No
- ○ Unknown

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

* Use the anesthesia note for this data

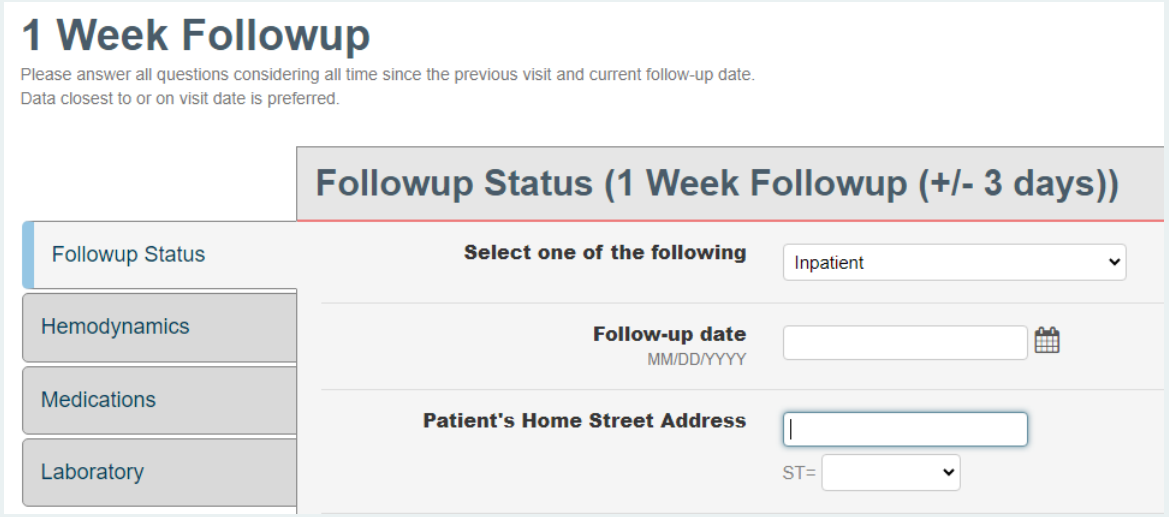
# Follow-up Forms

- 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

## Implant Discharge

**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**
MM/DD/YYYY
Date of transplant, death or explant for recovery during implant hospitalization will be considered date of discharge. (If LVAD Exchange, please fill out Explant Form)
03/22/2024
ST=

**Acute care (ICU / CCU) duration of post-implant stay**
Type the number of days patient in Acute care (i.e. ICU/CCU). Days should not exceed number of days from implant date to implant discharge date.
5 days
ST=

**Intermediate / step-down care - duration of post-implant stay**
Type the number of days patient in Intermediate care (i.e. Step Down care). Days should not exceed number of days from implant date to implant discharge date.
12 days
ST=

**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**
Since VAD implant date
Check all that apply

- ☐ Transplant
- ☐ Invasive Cardiac Procedures (Other than Heart Cath)
- ☐ Unknown
- ☑ None

**Surgical Procedures:**
- ☐ Device Related Operation
- ☐ Surgical Procedure - Non Cardiac Surgical Procedure
- ☐ Surgical Procedure - Other Procedure
- ☐ Surgical Procedure - Unknown

**Cardiac Surgical Procedures:**
- ☐ Reoperation for Bleeding within 48 hours of implant
- ☐ Reoperation for Bleeding and/or tamponade > 48 hours
- ☐ Surgical Drainage of pericardial effusion
- ☐ Aortic Valve Surgery - Replacement - Biological
- ☐ Aortic Valve Surgery - Replacement - Mechanical
- ☐ Aortic Valve Procedure
- ☐ Mitral Valve Surgery - Repair
- ☐ Mitral Valve Surgery - Replacement - Biological
- ☐ Mitral Valve Surgery - Replacement - Mechanical
- ☐ Tricuspid Valve Surgery - Repair - DeVega
- ☐ Tricuspid Valve Surgery - Repair - Ring
- ☐ Tricuspid Valve Surgery - Repair - Other
- ☐ Tricuspid Valve Surgery – Excision
- ☐ 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
- ☐ Aneursyomectomy
- ☐ Mitraclip
- ☐ TAVR
- ☐ Other Cardiac Surgical Procedure
- ☐ Cardiac Surgical Procedure - Unknown

**Other Procedures:**
- ☐ Intubation/Ventilator
- ☐ Dialysis
- ☐ Bronchoscopy
- ☐ Ultrafiltration
- ☐ Other, specify

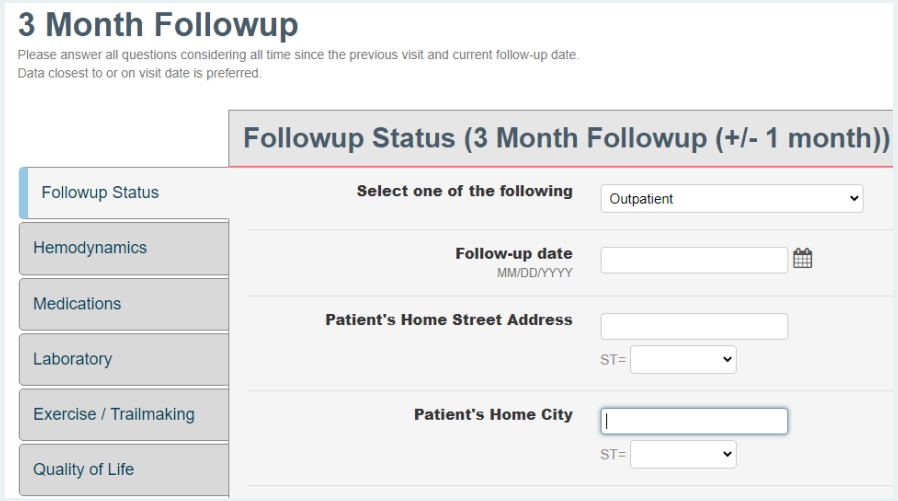
**Was ECMO initiated at any time after VAD implant?**
- ○ Yes
- ◉ No
- ○ Unknown

### Console Change

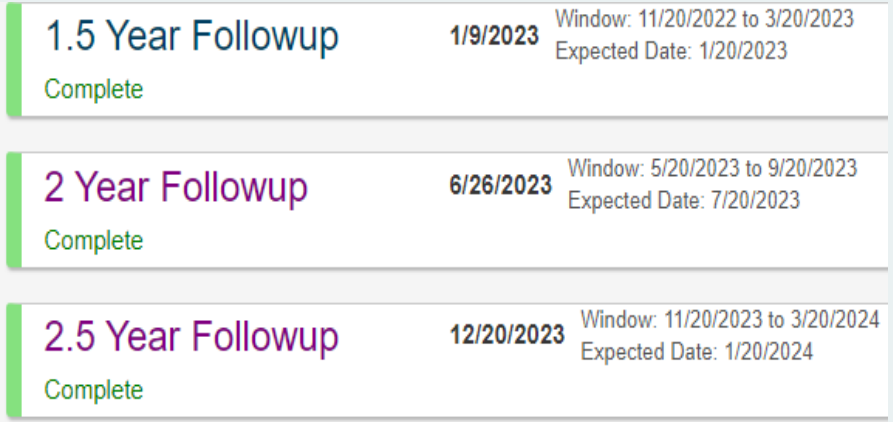
**Was there a Console Change? (For TAH or Berlin Heart Consoles)**
- ○ Yes
- ◉ No
- ○ Unknown

# 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

| | |
|---|---|
| **Was there a hemolysis event since the last followup?** | ○ Yes ○ No ○ Unknown |
| **Was there a right heart failure event since the last followup?** | ○ Yes ○ No ○ Unknown |
| **Has the patient experienced a Neurological Event since time of implant?** Note: This applies only to patients who have had a CVA, TIA or Anoxic Brain Injury. | ○ Yes ○ No ○ Unknown |

- 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)

| | LDH |
|---|---|
| 12/6/2023 | 184 |
| 11/7/2023 | 172 |
| 10/12/2023 | 183 |
| 9/14/2023 | 165 |
| 8/16/2023 | 170 |
| 7/22/2023 | 150 |

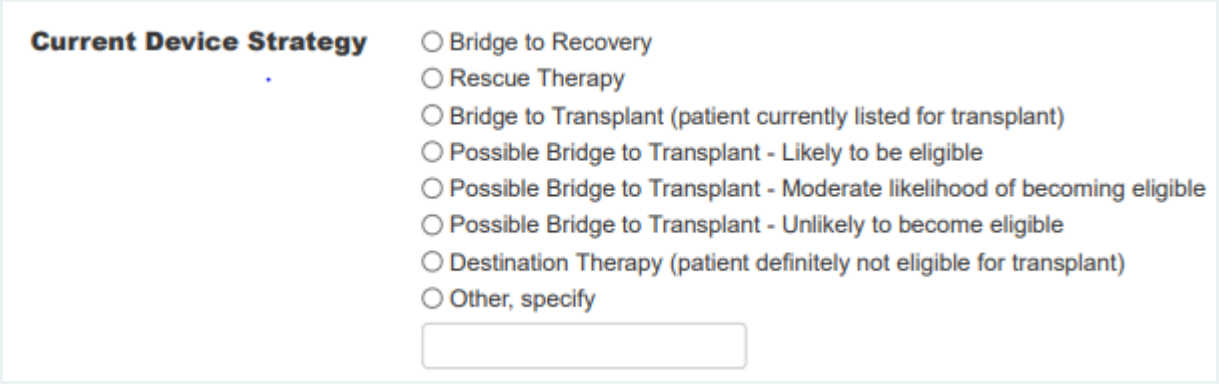
  - Was the patient admitted during this window?
    - If so, look for IV diuretic/IV inotropes ≥ 72hrs or ECMO to assess for RHF

| | |
|---|---|
| **If late RHF, select category** | ○ Need for implantation of an RVAD (including ECMO) greater than 30 days after an LVAD implantation show more<br>○ Hospitalization that occurs greater than 30 days post-implant and which requires intravenous diuretics or inotropic support for at least 72 hours |

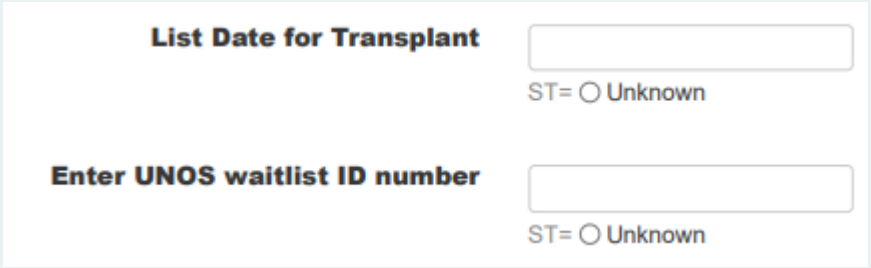
  - Has the patient experienced a neurological AE post VAD?
    - If so, look for a documented MRS
    - Determine a MRS based off of clinical judgement from the available documentation

# 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



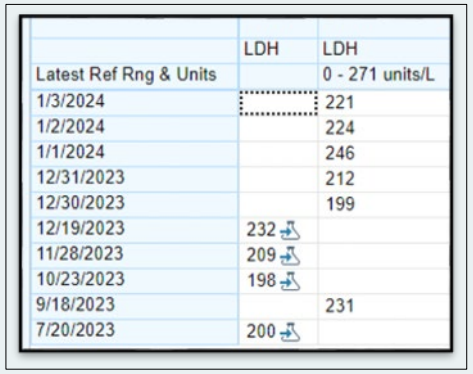

- When you abstract Bridge to Transplant the following will open




- 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



| | LDH | LDH |
|---|---|---|
| Latest Ref Rng & Units | | 0 - 271 units/L |
| 1/3/2024 | | 221 |
| 1/2/2024 | | 224 |
| 1/1/2024 | | 246 |
| 12/31/2023 | | 212 |
| 12/30/2023 | | 199 |
| 12/19/2023 | 232 | |
| 11/28/2023 | 209 | |
| 10/23/2023 | 198 | |
| 9/18/2023 | | 231 |
| 7/20/2023 | 200 | |

  - 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 them 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 you 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 great than 72hrs? 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 inotropic 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 (>16 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
- SVO2 < 50%
- Cardiac index < 2.2 liter/min/m2
- Elevated lactate >3.0 mmol/liter

# Adverse Events-Hepatic Function

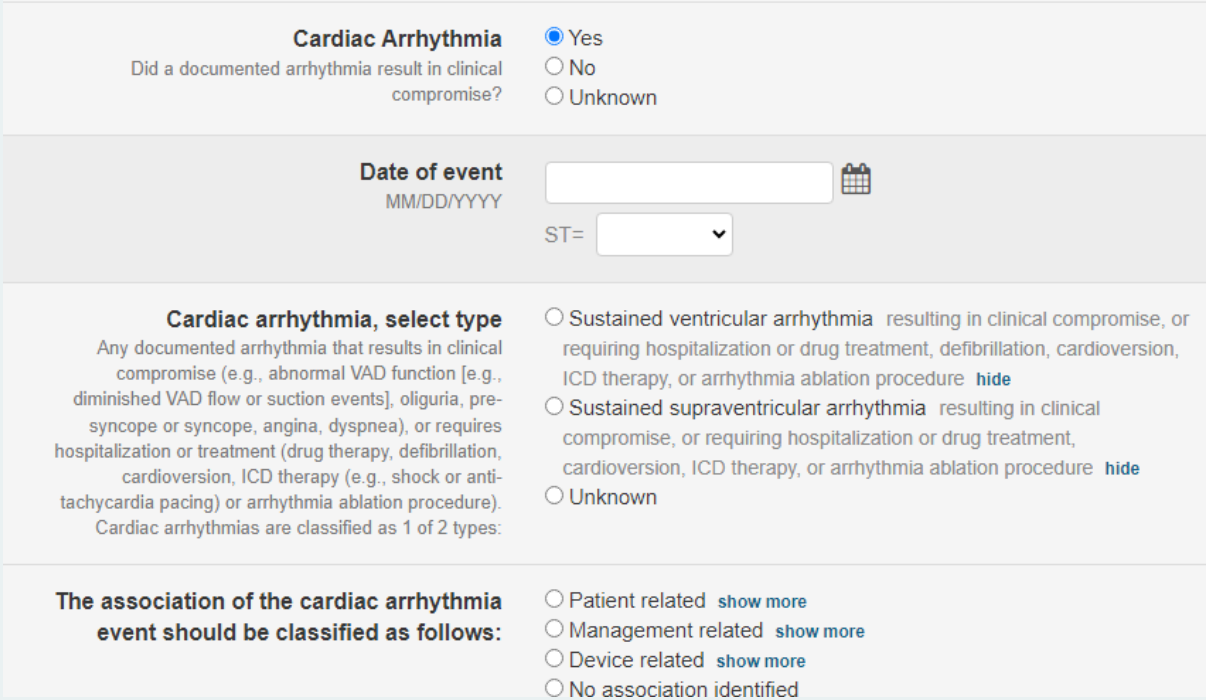
- Any time after POD 14 a patient can meet definition for a hepatic AE
- Using the search function in the EMR look at all ALT, AST, and Total Bilirubin results during the window
  - Look for levels 3x the upper limit of normal for your hospital

| | | | | | |
|---|---|---|---|---|---|
| ALT (SGPT) | 0 - 52 units/L | 74 ^ | 25 | 22<br>12 | 12 |
| Alkaline Phosphatase | 34 - 104 units/L | 59 | 32 v | 30 v<br>28 v | 30 v |
| AST (SGOT) | 0 - 39 units/L | 151 ^ | 94 ^ | 91 ^<br>64 ^ | 53 ^ |
| Bilirubin Total | 0.0 - 1.0 mg/dL | 0.7 | 0.8 | 0.7<br>0.7 | 0.7 |

- 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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