ADVANCES IN QUALITY & OUTCOMES:
A Data Managers Meeting
October 23-25, 2019 • New Orleans Marriott

sts.org/AQO
Objectives

Upon completion of the STS Intermacs Database sessions, participants will be able to:

- Describe the Audit process
- Discuss the Quality Assurance Report and how to use it
- Explain the version upgrade
- Summarize how to capture and code chronic GI bleeding
- Identify different Intermacs patient profiles
- Summarize how to capture and code chronic driveline infections
- Identify temporary devices on the preimplant form
Oh the Places You Will Go: Brief Summary Highlighting Major Events and Changes during the Transition from NHLBI to STS

Francis D. Pagani MD PhD
Otto Gago MD Endowed Professor of Cardiac Surgery
University of Michigan
INTERMACS REGISTRY JOINS THE STS NATIONAL DATABASE

STS News, Winter 2018 -- The STS National Database now has a fourth component. The Interagency Registry for Mechanically Assisted Circulatory Support, or Intermacs, became part of the STS National Database on January 1, 2018, joining the Adult Cardiac Surgery Database, the Congenital Heart Surgery Database, and the General Thoracic Surgery Database.

STS National Database
Using data to drive quality
“By including Intermacs as a component of the STS National Database, the Society will expand the scope of its registry activity, while providing Intermacs with a foundation for its future.”

*Richard L. Prager, MD*
INTERMACS

- Established at the UAB in 2005 as a joint effort of the NHLBI, FDA, CMS and clinical centers
- North American registry for patients who receive an FDA-approved durable implantable, mechanical circulatory support (MCS) device to treat advanced heart failure
- Participation in a national registry is required by the Joint Commission for all US centers implanting MCS devices for destination therapy
Performance Measurement (DSPM)

Standard DSPM.1
The program has an organized, comprehensive approach to performance improvement.

Element of Performance for DSPM.1
A 5. The program collects data related to its target population to identify opportunities for performance improvement.
Eligibility for Advanced Certification in Ventricular Assist Device
April 24, 2014

- Be an active continuous member of a national, audited registry for mechanically assisted circulatory support devices that requires submission of health data on ventricular assist device destination therapy patients* from the date of implantation throughout the remainder of their lives.
Longitudinal Follow-up

• Inclusion of INTERMACS represents a new chapter in the history of the STS National Database in light of the registry’s collection of longitudinal data
• INTERMACS collects longitudinal data throughout the life of a patient with an MCS device
• This brings an entirely new perspective to the STS National Database
### INTERMACS Clinical Site Enrollment: as of September 2019

<table>
<thead>
<tr>
<th>STS Intermacs:</th>
<th>STS Pedimacs:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Active (Prior UAB participants): 159</td>
<td>• Active (Prior UAB participants): 41</td>
</tr>
<tr>
<td>• Active (New): 15</td>
<td>• Active (New): 6</td>
</tr>
<tr>
<td>• Pending: 3</td>
<td>• Pending: 2</td>
</tr>
<tr>
<td>• Percent (prior UAB): 98%</td>
<td>• Percent (prior UAB): 95%</td>
</tr>
<tr>
<td>• Expected (prior UAB): 162</td>
<td>• Expected (prior UAB): 43</td>
</tr>
<tr>
<td>• Total number of active Intermacs sites: 174</td>
<td>• Total Number of active Pedimacs sites: 47</td>
</tr>
</tbody>
</table>
Multidisciplinary Task Force Composition

• INTERMACS Task Force brought into the STS current structure of its national databases

• Task Force is unique in that it is comprised of surgeons and cardiologists

• This unique collaboration is essential to the field and insures engagement and leadership from all stakeholders
STS INTERMACS Leadership

Frank Pagani, Chair
David Morales
Chris Salerno
Robert Higgins
James Young
Lynne Warner
Stevenson
Danial Goldstein
David Rosenthal
Betsy Blume
Iki Adachi
Jeff Jacobs
Jeff Tueteburg

Jennifer Cowger
Joe Cleveland
Joe Rossano
Jonathan Haft
Josef Stehlik
Ezequiel Molina
Pavan Alturi
Simon Maltais
Tom McGillivray
Scott Silvestry
Nir Uriel
Kristen Nelson
David Peng

William Seward,
STS Associate Executive Director
Donna McDonald
Kathryn Hollifield
Elaine Weiss,
STS Executive Director
Data and Clinical Coordinating Center

The Data and Clinical Coordinating center for the STS Intermacs database is housed at the University of Alabama at Birmingham under the direction of Dr. James Kirklin.
Important Priorities

• Emphasis of the registry on Quality Initiatives / Quality Assurance
  - Development of NQF-endorsed measures
• Ensuring the registry is relevant to Stakeholders
• Quarterly Site Reports
  - Data quality reports
  - Quality assurance reports
Quarterly Site Reports

Each quarter, Intermacs provides site specific information to Site Administrators at active sites. This includes the Quarterly Assurance Report and Data Quality Report. These reports are distributed through the web based data entry file delivery system.

Data Quality Report

- Provides each hospital with a snapshot of key data they have entered into Intermacs
- Provides a list of inconsistent and improbable data values
- Provides a useful tool for auditing
Quarterly Site Reports

Each quarter, Intermacs provides site specific information to Site Administrators at active sites. This includes the Quarterly Assurance Report and Data Quality Report. These reports are distributed through the web based data entry file delivery system.

**Quality Assurance Report**

- Contains information from your site compared to the overall Intermacs experience
- Primary prospective patients are analyzed to facilitate the comparison
- Facilitates the refinement of patient selection to maximize outcomes with current and new device options
# Report Distribution Schedule

<table>
<thead>
<tr>
<th>Calendar Quarter</th>
<th>Coverage Stop Date</th>
<th>Distribution Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>March 31st</td>
<td>June 30th</td>
</tr>
<tr>
<td>Q2</td>
<td>June 30th</td>
<td>September 30th</td>
</tr>
<tr>
<td>Q3</td>
<td>September 30th</td>
<td>December 31st</td>
</tr>
<tr>
<td>Q4</td>
<td>December 31st</td>
<td>March 31st</td>
</tr>
</tbody>
</table>
Intermacs
Interagency Registry for Mechanically Assisted Circulatory Support

INTERMACS Quality Assurance Quarterly Report (2016 Q4) - Cumulative
Hospital X - (Random 100 Patients)
Implant and event dates: June 23, 2006 to December 31, 2016

03/27/2017
Prepared by:
The Data and Clinical Coordinating Center
University of Alabama at Birmingham

James K. Kirklin, MD
Ryan S. Cantor, MSPH
Susan L. Myers
Mary Lynne Clark
Craig Collum, MPH
Kathryn Hollifield, RN
Maceo Cleggett

CONFIDENTIAL: This information is only intended for:
Hospital X - (Random 100 Patients)
## Current State of Intermacs

**INTERMACS Quality Assurance Quarterly Report (2016 Q4) - Cumulative**
**COVERAGE: June 23, 2006 - December 31, 2016**
**SITE: Hospital X - (Random 100 Patients)**

### II.A. Pre-Implant Summaries - Demographics

#### Exhibit 2: Age Group

The following tables summarize age groups at your site and Intermacs over time.

<table>
<thead>
<tr>
<th>AGE GROUP (yr)</th>
<th>HOSPX-9999</th>
<th>Intermacs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 2010</td>
<td>2010-2011</td>
</tr>
<tr>
<td>18-39</td>
<td>2 15.3%</td>
<td>2 11.1%</td>
</tr>
<tr>
<td>40-69</td>
<td>9 69.2%</td>
<td>11 61.1%</td>
</tr>
<tr>
<td>60-79</td>
<td>2 15.3%</td>
<td>5 27.7%</td>
</tr>
<tr>
<td>80+</td>
<td>. .</td>
<td>. .</td>
</tr>
<tr>
<td>TOTAL</td>
<td>13 100.0%</td>
<td>18 100.0%</td>
</tr>
</tbody>
</table>
Current State of Intermacs

Exhibit 24a. Time to First Device Malfunction and/or Thrombus

Freedom From Device Malfunction and/or Thrombus
Primary Prospective implants: June 23, 2006 to December 31, 2016

Shaded areas indicate 90% confidence limits
p (log rank) = 0.009
Event: First DM/Throm (censored at death on device, transplant, or recovery)

Percent Free From Device Malfunction and/or Thrombus

<table>
<thead>
<tr>
<th>Months after Device Implant</th>
<th>Intermacs</th>
<th>ICYMOYI.1P.000B</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>95.6%</td>
<td>91.1%</td>
</tr>
<tr>
<td>3</td>
<td>93.4%</td>
<td>91.6%</td>
</tr>
<tr>
<td>6</td>
<td>97.5%</td>
<td>97.5%</td>
</tr>
<tr>
<td>12</td>
<td>98.5%</td>
<td>98.5%</td>
</tr>
<tr>
<td>24</td>
<td>99.3%</td>
<td>99.3%</td>
</tr>
<tr>
<td>36</td>
<td>99.3%</td>
<td>99.3%</td>
</tr>
<tr>
<td>60</td>
<td>99.3%</td>
<td>99.3%</td>
</tr>
</tbody>
</table>
Current State of Intermacs

STS Intermacs Follow-up Compliance Percentages (2019-09)
All Patients and Devices: June 23, 2006 to August 31, 2019
-0007 Follow-up Form Completion: 100.0%

Note: Compliance score calculation includes ALL patients and ALL devices
This figure is limited to sites that have at least 10 follow-up forms expected
# Future State of Intermacs

**STS Public Reporting Online**

<table>
<thead>
<tr>
<th>Adult Cardiac</th>
<th>Congenital Heart</th>
<th>General Thoracic</th>
<th>Resources</th>
<th>Contact</th>
</tr>
</thead>
</table>

## CABG Results

<table>
<thead>
<tr>
<th>Year</th>
<th>Overall Composite Score*</th>
<th>Absence of Operative Mortality</th>
<th>Absence of Major Morbidity</th>
<th>Use of Internal Mammary Artery</th>
<th>Receipt of Required Perioperative Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2017 -</td>
<td>96.8</td>
<td>97.8</td>
<td>88.0</td>
<td>98.9</td>
<td>96.7</td>
</tr>
<tr>
<td>December 2017</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>January 2018 -</td>
<td>96.8</td>
<td>97.6</td>
<td>87.5</td>
<td>99.7</td>
<td>97.3</td>
</tr>
<tr>
<td>December 2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
STS continues to develop and maintain quality performance measures in the areas of adult cardiac, general thoracic, and congenital heart surgery. STS measures have either been endorsed or are being considered for endorsement by the National Quality Forum. In addition, many of these measures are included in CMS’s Merit-Based Incentive Payment System.
# Developing Quality Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>NQF #</th>
<th>Procedure(s)</th>
<th>Measure Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>CABG Composite Score</td>
<td>0696</td>
<td>Isolated CABG</td>
<td>Outcome, Process, Composite</td>
</tr>
<tr>
<td>Postoperative Renal Failure</td>
<td>0114</td>
<td>Isolated CABG</td>
<td>Outcome</td>
</tr>
<tr>
<td>Surgical Re-exploration</td>
<td>0115</td>
<td>Isolated CABG</td>
<td>Outcome</td>
</tr>
<tr>
<td>Operative Mortality for CABG</td>
<td>0119</td>
<td>Isolated CABG</td>
<td>Outcome</td>
</tr>
<tr>
<td>Postoperative Prolonged Intubation</td>
<td>0129</td>
<td>Isolated CABG</td>
<td>Outcome</td>
</tr>
<tr>
<td>(Ventilation)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deep Sternal Wound Infection</td>
<td>0130</td>
<td>Isolated CABG</td>
<td>Outcome</td>
</tr>
<tr>
<td>Stroke/Cerebrovascular Accident</td>
<td>0131</td>
<td>Isolated CABG</td>
<td>Outcome</td>
</tr>
<tr>
<td>CABG Readmission Rate</td>
<td>2514</td>
<td>Isolated CABG</td>
<td>Outcome</td>
</tr>
</tbody>
</table>
The Society of Thoracic Surgeons
Intermacs Database Annual Report:
Evolving Indications, Outcomes, and Scientific Partnerships

Robert L. Kormos, MD, Jennifer Cowger, MD, MS, Francis D. Pagani, MD, PhD,
Jeffrey J. Teuteberg, MD, Daniel J. Goldstein, MD, Jeffrey P. Jacobs, MD,
Robert S. Higgins, MD, Lynne W. Stevenson, MD, Josef Stehlik, MD, Pavan Atluri, MD,
Kathleen L. Grady, PhD, RN, and James K. Kirklin, MD

Department of Cardiothoracic Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania; Division of Cardiovascular Medicine, Henry Ford Hospitals, Detroit, Michigan; Department of Cardiac Surgery, University of Michigan Health System, Ann Arbor, Michigan; Department of Medicine, Division of Cardiovascular Medicine, Stanford University, Stanford, California; Department of Cardiothoracic Surgery, Montefiore Medical Center, New York, New York; Division of Cardiovascular Surgery, Department of Surgery, Johns Hopkins All Children’s Heart Institute, Saint Petersburg, Florida; Division of Cardiovascular Surgery, Department of Surgery, Johns Hopkins All Children’s Hospital, Tampa, Florida; Division of Cardiovascular Surgery, Department of Surgery, Florida Hospital for Children, Orlando, Florida; Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland; Department of Medicine, Division of Cardiovascular Medicine, Vanderbilt University, Nashville, Tennessee; Division of Cardiovascular Medicine, University of Utah, Salt Lake City, Utah; Division of Cardiovascular Surgery, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania; Division of Cardiac Surgery, Northwestern University Feinberg School of Medicine, Chicago, Illinois; and Department of Surgery, University of Alabama at Birmingham, Birmingham, Alabama

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**CF Isolated LVAD Implants: April 2008 – December 2017, n=18539**

- **Continuous Flow Intracorporeal Isolated LVAD Pump - Axial**
- **Continuous Flow Intracorporeal Isolated LVAD Pump - Centrifugal**

**Graph 1:**
- Implants per year
- Y-axis represents implants per year
- X-axis represents years from 2008 to 2017
- Data points for each year from 2008 to 2017 are shown

**Graph 2:**
- % Survival over time post implant
- Y-axis represents % Survival
- X-axis represents Time post implant in months
- Data points for various time periods and survival rates

**Table:**
- n=18539, Deaths= 5241
- Event: Death (censored at transplant, death, recovery, device exchange)
- Months post implant
- n at risk: 18539 14105 10379 5938 3351 1805 987 471

**Conclusion:**
- The graph and table provide comprehensive data on CF isolated LVAD implants from April 2008 to December 2017, highlighting implant trends and survival rates over time.
INTERMACS Task Force

• Annual Writing Group Report
• Quality Initiative Sub-committee
• Patient Reported Outcomes Sub-committee
• Stakeholders group
Questions?
FAQ’S

• Do I put my patient in both Intermacs and the STS Adult Cardiac Surgery Database?

• My patient is receiving a non-approved FDA implantable LVAD. Do I put my patient into Intermacs?

• My patient is receiving a temporary mechanical circulatory support device (i.e., Impella or TandemHeart pump). Do I put my patient into Intermacs?