PediMACS Tutorial: September 20, 2012

Washington University
St. Louis, Missouri
Welcome

Elizabeth Blume, MD
Chair of the INTERMACS Pediatric Committee

Tim Baldwin, PhD
NHLBI Representative to INTERMACS and PediMACS
Purpose of Today’s Tutorial

• Provide Information on PediMACS
  --AND--

• Provide Instruction on entering patient data into the web based data entry system for pediatric patients who receive MCSDs
<table>
<thead>
<tr>
<th>Section</th>
<th>Presenter</th>
</tr>
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<tr>
<td>I. Welcome</td>
<td>Drs. Blume &amp; Baldwin</td>
</tr>
<tr>
<td>II. PediMACS</td>
<td>Dr. Kirklin</td>
</tr>
<tr>
<td>III. PediMACS Structure</td>
<td>Dr. Blume</td>
</tr>
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<td>IV. Hospital Enrollment</td>
<td>Dr. Naftel &amp; ML Clark</td>
</tr>
<tr>
<td>V. Patient Enrollment</td>
<td>Susan Myers</td>
</tr>
<tr>
<td>VI. Data Elements and Definitions</td>
<td>Dr. Rosenthal</td>
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<tr>
<td>VII. Adverse Events Definitions</td>
<td>Dr. Morales</td>
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<tr>
<td>VIII. Training and Hands-on Data Entry</td>
<td>Kathryn Hollifield, RN</td>
</tr>
<tr>
<td>IX. Data Quality and Hospital Evaluation</td>
<td>Dr. Naftel</td>
</tr>
<tr>
<td>X. Wrap Up</td>
<td>Dr. Blume</td>
</tr>
</tbody>
</table>
PediMACS

• Overview of INTERMACS
• Genesis of PediMACS
• Goals & Expected Analyses

James K. Kirklin, MD
What is INTERMACS?

INTERMACS is the United States national (North American) registry for patients who are receiving durable, FDA approved mechanical circulatory support device therapy to treat advanced heart failure. This registry was devised as a joint effort of the National Heart, Lung and Blood Institute (NHLBI), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), clinicians, scientists and industry representatives.
Goals of the Registry

- Facilitate the refinement of patient selection to maximize outcomes with current and new device options.
- Identify predictors of good outcomes as well as risk factors for adverse events after device implantation.
- Develop consensus “best practice” guidelines to improve clinical management by reducing short and long term complications of MCSD therapy.
- Utilize Registry information to guide improvements in technology, particularly as next generation devices evolve.
Between June 23, 2006, and June 30, 2012, 145 hospitals participated in INTERMACS and, of these, 131 hospitals actively contributed information on a total of 6633 patients. Cumulative patient accrual and the number of participating hospitals over this time period are displayed above.
### Age Category

<table>
<thead>
<tr>
<th>AGE GROUP (yr)</th>
<th>Pre 2011</th>
<th>2011</th>
<th>2012 (Jan-Jun)</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>0-18</td>
<td>52</td>
<td>1.3%</td>
<td>17</td>
<td>0.9%</td>
</tr>
<tr>
<td>19-39</td>
<td>546</td>
<td>14.0%</td>
<td>222</td>
<td>11.9%</td>
</tr>
<tr>
<td>40-59</td>
<td>1859</td>
<td>47.9%</td>
<td>704</td>
<td>37.8%</td>
</tr>
<tr>
<td>60-79</td>
<td>1412</td>
<td>36.4%</td>
<td>903</td>
<td>48.5%</td>
</tr>
<tr>
<td>80+</td>
<td>7</td>
<td>0.1%</td>
<td>15</td>
<td>0.8%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>3876</td>
<td>100.0%</td>
<td>1861</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
The Pediatric Component of INTERMACS Prior to PediMACS Launch

- Limited pediatric adverse event definitions
- Limited tailoring for pediatric patients
- Little proactive recruitment of pediatric hospitals
- Essentially no FDA approved durable devices for small children (prior to December 2011)
- No temporary devices as primary device
- Limited pediatric involvement in the INTERMACS committee structure
- Few pediatric patients (n=72) enrolled into INTERMACS (essentially teenagers with adult devices)
What have we learned about pediatric patients from INTERMACS?
Outcomes of Children Implanted with Ventricular Assist Devices in the United States: Analysis of the Interagency Registry for Mechanical Circulatory Support (INTERMACS)

D Morales, A Lowry, D Epstein, D Rosenthal, J Chen, C Almond, P Wearden, D Naftel, J Kirklin, E Blume
n=84 patients (age at implant 0-21 years)
June 2006 – March 2011: Outcomes of Children with VADs

Adverse Event Rates after Device Implantation (Events/100 Patient Months) in the First 3 Months post implant and 3 months or more post implant for Pediatric Patients

<table>
<thead>
<tr>
<th>Event</th>
<th>Entire Time Period</th>
<th>Adverse Event Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># of events</td>
<td># of patients*</td>
</tr>
<tr>
<td>Infection</td>
<td>81</td>
<td>31</td>
</tr>
<tr>
<td>Bleeding</td>
<td>74</td>
<td>28</td>
</tr>
<tr>
<td>Cardiac Arrhythmia</td>
<td>23</td>
<td>16</td>
</tr>
<tr>
<td>Device Malfunction</td>
<td>21</td>
<td>12</td>
</tr>
<tr>
<td>Neurological Dysfunction</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Renal Dysfunction</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Right Heart Failure</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Hepatic Dysfunction</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Hypertension</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Pericardial Drainage</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Psychiatric Episode</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Venous Thromboembolism</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Other*</td>
<td>30</td>
<td>17</td>
</tr>
</tbody>
</table>

* # of patients with one or more events
Planning PediMACS:

- Pediatric adverse event definitions
- Data element tailoring for pediatric patients
- Proactive recruitment of pediatric hospitals
- Berlin Heart EXCOR approved December 2011
- Includes temporary devices
- Pediatric involvement in the INTERMACS committee structure
- Expect to enroll the majority of pediatric patients in North America
PediMACS

- Planned, created and implemented: August 2011 – August 2012

- Launched: September 19, 2012
What devices will be part of PediMACS?

Retrospective information exists in the Pediatric Heart Transplant Study (PHTS)
Outcome of Children Bridged to Transplant with Ventricular Assist Devices: A Multi-Institutional Study

for the PHTS Investigators

Children’s Hospital Boston, University of Alabama, Cleveland Clinic Foundation, Children’s Hospital of Pittsburgh
### Patient Characteristics: VAD Type

**January 1993-December 2003**

**PHTS**

<table>
<thead>
<tr>
<th>VAD Device</th>
<th>Total</th>
<th>LVAD</th>
<th>L+R VAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulsatile, chronic</td>
<td>70</td>
<td>29</td>
<td>24</td>
</tr>
<tr>
<td>Thoratec</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heartmate</td>
<td>12</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Novacor</td>
<td>3</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Berlin</td>
<td>1</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Pulsatile, temporary</td>
<td>10</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Abiomed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuous flow</td>
<td>16</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>Biomedicus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biomedicus, Thoratec</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>59</td>
<td>37</td>
<td></td>
</tr>
</tbody>
</table>
Ventricular assist device support as a bridge to pediatric heart transplantation: a practice in evolution.

To be presented at AHA 2012

Anne Dipchand¹, David Naftel², Betsy Blume³, Richard Kirk⁴, Bob Morrow⁵, David Rosenthal⁶, Marc Richmond⁷, James Kirklin²

¹ Hospital for Sick Children, Toronto; ² University of Alabama at Birmingham; ³ Children’s Hospital, Boston; ⁴ Freeman Hospital, Newcastle Upon
⁵ Arkansas Children’s Hospital, Little Rock; ⁶ Stanford University Medical Center, Stanford ⁷ Columbia University – Babies Hospital, New York
### PHTS: 1993–2010, Ventricular Assist Devices

#### All Listing VADs (n=126)

<table>
<thead>
<tr>
<th>Type VAD</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berlin Heart EXCOR</td>
<td>34</td>
<td>27%</td>
</tr>
<tr>
<td>Thoratec (primarily HMII)</td>
<td>57</td>
<td>45%</td>
</tr>
<tr>
<td>All others</td>
<td>35</td>
<td>28%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>126</td>
<td>100%</td>
</tr>
</tbody>
</table>
1. **Approved Durable Devices** (potential for patient discharge): These devices **SHOULD BE ENTERED** into PediMACS except in rare circumstances where a patient with an approved device is in the control arm of an FDA approval study.

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
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<tbody>
<tr>
<td>Abiomed, Inc.</td>
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<td>HeartMate II LVAS</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>HeartMate IP</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>HeartMate VE</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>HeartMate XVE</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>Thoratec IVAD</td>
<td>L/R</td>
</tr>
<tr>
<td></td>
<td>Thoratec PVAD</td>
<td>L/R</td>
</tr>
<tr>
<td>WorldHeart, Inc.</td>
<td>NovaCor PC</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>NovaCor PCq</td>
<td>L</td>
</tr>
<tr>
<td>Berlin Heart</td>
<td>Berlin Heart EXCOR</td>
<td>L/R</td>
</tr>
</tbody>
</table>
### 2. Approved Temporary Devices:

These devices SHOULD be entered into PediMACS.

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abiomed, Inc.</td>
<td>Abiomed AB5000</td>
<td>L/R</td>
</tr>
<tr>
<td></td>
<td>Abiomed BVS 5000</td>
<td>L/R</td>
</tr>
<tr>
<td></td>
<td>Impella</td>
<td>L</td>
</tr>
<tr>
<td>CardiacAssist, Inc.</td>
<td>Tandem Heart</td>
<td>L/R</td>
</tr>
<tr>
<td>Levitronix Medical Division</td>
<td>Levitronix Centrimag</td>
<td>L/R</td>
</tr>
<tr>
<td></td>
<td>Levitronix Pedimag</td>
<td>L/R</td>
</tr>
<tr>
<td>Medtronic Biomedicus, Inc.</td>
<td>Biomedicus</td>
<td>R</td>
</tr>
<tr>
<td>Maquet Cardiovascular</td>
<td>Jostra Rotaflow</td>
<td></td>
</tr>
</tbody>
</table>
Goals & Expected Analyses from PediMACS

- The goals of PediMACS are the same as the goals of INTERMACS – but, with a focus on pediatric patients and an expansion to temporary devices.
Goals of the Registry

• Facilitate the refinement of patient selection to maximize outcomes with current and new device options.
• Identify predictors of good outcomes as well as risk factors for adverse events after device implantation.
• Develop consensus “best practice” guidelines to improve clinical management by reducing short and long term complications of MCSD therapy.
• Guide clinical application and evolution of next generation devices.
• Utilize Registry information to guide improvements in technology, particularly as next generation devices evolve.
PediMACS Structure

- Committees
- Benefits to hospitals
- Quality Assurance reports

Elizabeth Blume, MD
pediMACS Launch Status

- pediMACS will follow the structure of INTERMACS

- A few important changes from INTERMACS:
  - Pediatric patients (< 19 yrs. at time of implant)
  - Includes both durable and temporary support MCSDs
  - Modifications of AE definitions
  - Possible expansion of quality of life instruments
PediMACS Committees
PediMACS Committees
• Coordinators Council
• Industry
• Operations Committee
• Hospital Standards
• Medical Event Review
• Data Access, Analysis & Publications
Benefits to Hospitals
Hospitals

• What services do the hospitals receive for their participation fee?
  • Services
    • Meets CMS/Joint Commission requirement for Destination Therapy Certification
    • Meets FDA required submission of Medical Device Reports (MDRs) by hospitals
    • Provides clinical summaries of patients
    • Provides quality assurance reports
    • Provides electronic data transfer
    • Provides standardized datasets
    • Provides benchmarking
    • Provides training and continuing education units
What benefits do the hospitals receive for their participation fee?

Benefits

- Fulfills CMS DT Certification requirement
- Become part of the national dialogue on the evaluation and evolution of MCSDs
- Invited to participate in the INTERMACS Annual Meeting
- Invited to join the INTERMACS Committees
  - Coordinators Council and other committees
- Select Hospital Administrators will have the opportunity to serve on the Business Advisory Committee
Quality Assurance Reports
INTERMACS Quality Assurance Quarterly Report
Hospital: [Redacted]
Implant and event dates: June 23, 2006 – March 31, 2012

Implantation of FDA Approved Mechanical Circulatory Support Devices:

Results at your hospital and across the country
- Statistical summaries
- National benchmarks
- Registry Compliance

June 22, 2012

Prepared by:
The Data Collection and Analysis Center of INTERMACS
University of Alabama at Birmingham
David C. Matel, Ph.D, Director of DCC
Susan L. Myers, Database Administrator
Sijian Zhang, Database Administrator
# Table 1: Age Group

<table>
<thead>
<tr>
<th>Age Groups</th>
<th>#</th>
<th>Pct %</th>
<th>INTERMACS #</th>
<th>Pct %</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: 0-18</td>
<td>3</td>
<td>4.0%</td>
<td>69</td>
<td>1.1%</td>
</tr>
<tr>
<td>B: 19-39</td>
<td>13</td>
<td>17.3%</td>
<td>815</td>
<td>13.3%</td>
</tr>
<tr>
<td>C: 40-59</td>
<td>34</td>
<td>45.3%</td>
<td>2703</td>
<td>44.3%</td>
</tr>
<tr>
<td>D: 60-79</td>
<td>25</td>
<td>33.3%</td>
<td>2492</td>
<td>40.7%</td>
</tr>
<tr>
<td>E: 80+</td>
<td>-</td>
<td>-</td>
<td>25</td>
<td>0.4%</td>
</tr>
<tr>
<td><strong>Total Patients</strong></td>
<td>75</td>
<td>100.0%</td>
<td><strong>6694</strong></td>
<td>100.0%</td>
</tr>
</tbody>
</table>

# Table 2: Gender

<table>
<thead>
<tr>
<th>Gender</th>
<th>#</th>
<th>Pct %</th>
<th>INTERMACS #</th>
<th>Pct %</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>16</td>
<td>21.3%</td>
<td>1285</td>
<td>21.9%</td>
</tr>
<tr>
<td>M</td>
<td>59</td>
<td>78.6%</td>
<td>4808</td>
<td>78.8%</td>
</tr>
<tr>
<td>U</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>0.0%</td>
</tr>
<tr>
<td><strong>Total Patients</strong></td>
<td>75</td>
<td>100.0%</td>
<td><strong>6694</strong></td>
<td>100.0%</td>
</tr>
</tbody>
</table>
INTERMACS Quarterly Quality Assurance Report
Implants: June 2006 - March 2012

Figure 1: Post Implant Survival: Primary Implants
Hospital Enrollment

David C. Naftel, PhD
You too can participate in PediMACS!
### Currently Enrolled in INTERMACS

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently Enrolled</td>
<td>139</td>
</tr>
<tr>
<td>Approved for PediMACS Enrollment</td>
<td>56</td>
</tr>
<tr>
<td>Stand-alone Pediatric Hospitals</td>
<td>11</td>
</tr>
</tbody>
</table>
Currently enrolled in INTERMACS:

• Current approval to include pediatrics

OR

• Add pediatric patients
New Sites:

Enroll through the INTERMACS website

www.intermacs.org
Welcome to INTERMACS™!

The Interagency Registry for Mechanically Assisted Circulatory Support is a North American registry established in 2005 for patients who are receiving mechanical circulatory support device therapy to treat advanced heart failure. INTERMACS™ was established as a joint effort of the National Heart, Lung and Blood Institute (NHLBI), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), clinicians, scientists and industry representatives in conjunction with Dr. James K. Kirklin and the University of Alabama at Birmingham.

INTERMACS™ is a prospective registry that collects clinical data, including follow up, essentially as it happens. Post implant follow up data is collected at 1 week, 1 month, 3 months, 6 months and every 6 months thereafter. Major outcomes after implant, e.g. death, explant, rehospitalization and adverse events, are entered as they occur and also as part of the defined follow-up scheduled intervals.

INTERMACS™ provides contemporary data to demonstrate the continued progress of outcomes, with additional insight into appropriate risk stratification and patient selection.
To begin the Site Enrollment process complete the online application form. You will then be contacted by the INTERMACS Data Collection Repository to assist you through the remainder of the process.

For assistance with Site Enrollment contact Ruth Henson at ruth.henson@unos.org or (304) 782-4858.
Welcome to INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) enrollment application. Your participation in the registry will enable research to determine "best medical practices" with respect to the use of MCSs for the treatment of heart failure.

1. Enter Hospital Information

- Hospital Name
- Address
- Address (cont.)
- City
- State/Province
- Zip/Postal Code

Institutional Review Board Information
- Does your facility require IRB approval?  
  - YES  
  - NO  
  - UNK

continue
Regulatory Requirements

- Participation Agreement
- Federal Wide Assurance Number
- IRB / Ethics Board Approval
- Approved Consent/Authorization Forms
- Clinical Laboratory Improvement Amendments (CLIA)
- Financial Disclosure / Conflict of Interest
- Human Subjects Training
The final step for activation is

Training

Please make sure you signed the registration sheet. This is our documentation that you received training.
Mary Lynne Clark
Regulatory Director

mlclark@uab.edu
intermacs@uab.edu
205-934-2555
Patient Enrollment

- Inclusion / Exclusion
- Structure of database

Susan Myers
Database Administrator
pediMACS Launch Status

- Live test site: August 29, 2012
  - Testing by INTERMACS Nurse Monitors
  - Testing by the DCC Data Managers
  - Testing by the INTERMACS Co-PIs
  - Testing by 3 Hospitals (Beta Sites)
  - Testing by Pediatric Committee

- Launch Date: September 19, 2012
  - Online training will be available
  - Training Session in September 2012
Overview of Data Entry

This is to:

Current members AND
New members

- Inclusion/exclusion criteria
- Devices
- Patient flow
Inclusion / Exclusion

**Inclusions**

- Patient less than 19 years of age at time of implant
- Patient receives a mechanical circulatory support device (MCSD) which is FDA approved
- Implant on or after September 19, 2012 (The device does not need to be the first implant for a patient)
- Patient/Parent signed informed consent

**Exclusions:**

- Patient 19 years or older at time of implant (patient should be enrolled into INTERMACS)
- Patient receives a mechanical circulatory support device (MCSD) which is not FDA approved
- Patient is incarcerated (prisoner)
- Patient (legal guardian) did not sign informed consent
  - Too sick pre-implant and died early post implant
  - Missed opportunity to consent
  - Patient or legal guardian refused
  - Patient and/or legal guardian is unable to communicate in English
Device Brand List
Pediatrics (< 19 Years of Age)

1. **Approved Durable Devices** (potential for patient discharge): These devices **SHOULD BE ENTERED** into PediMACS except in rare circumstances where a patient with an approved device is in the control arm of an FDA approval study.

<table>
<thead>
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<td>Micromed Technology, Inc.</td>
<td>MicroMed DeBakey VAD – Child</td>
<td>L</td>
</tr>
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<td>SynCardia CardioWest</td>
<td>TAH</td>
</tr>
<tr>
<td>Thoratec Corporation</td>
<td>HeartMate II LVAS</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>HeartMate IP</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>HeartMate VE</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>HeartMate XVE</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>Thoratec IVAD</td>
<td>L/R</td>
</tr>
<tr>
<td></td>
<td>Thoratec PVAD</td>
<td>L/R</td>
</tr>
<tr>
<td>WorldHeart, Inc.</td>
<td>NovaCor PC</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>NovaCor PCq</td>
<td>L</td>
</tr>
<tr>
<td>Berlin Heart</td>
<td>Berlin Heart EXCOR</td>
<td>L/R</td>
</tr>
</tbody>
</table>
## 2. Approved Temporary Devices:

These devices **SHOULD** be entered into PediMACS.

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
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</tr>
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<tbody>
<tr>
<td>Abiomed, Inc.</td>
<td>Abiomed AB5000</td>
<td>L/R</td>
</tr>
<tr>
<td></td>
<td>Abiomed BVS 5000</td>
<td>L/R</td>
</tr>
<tr>
<td></td>
<td>Impella</td>
<td>L</td>
</tr>
<tr>
<td>CardiacAssist, Inc.</td>
<td>Tandem Heart</td>
<td>L/R</td>
</tr>
<tr>
<td>Levitronix Medical Division</td>
<td>Levitronix Centrimag</td>
<td>L/R</td>
</tr>
<tr>
<td></td>
<td>Levitronix Pedimag</td>
<td>L/R</td>
</tr>
<tr>
<td>Medtronic Biomedicus, Inc.</td>
<td>Biomedicus</td>
<td>R</td>
</tr>
<tr>
<td>Maquet Cardiovascular</td>
<td>Jostra Rotaflow</td>
<td></td>
</tr>
</tbody>
</table>
INTERMACS Printable Forms

- Screening Log
- Patient Demographics Form
- Pre-Implant Form
- Implant Form
- 1 Week/1month Follow-up Form
- 3 month/6month Follow-up Form
- Implant Discharge Form
- Rehospitalization Form
- AE Infection Form
- AE Neurological Dysfunction Form
- AE Device Malfunction Form
- AE Bleeding Form
- Other Adverse Events
- Explant/Transplant Form
- Death Form
- Patient Transfer/Withdrawal Form
<table>
<thead>
<tr>
<th>Screening Log</th>
<th>AE Infection Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Demographics Form</td>
<td>AE Neurological Dysfunction Form</td>
</tr>
<tr>
<td>Pre-Implant Form</td>
<td>AE Device Malfunction Form</td>
</tr>
<tr>
<td>Implant Form</td>
<td>AE Bleeding Form</td>
</tr>
<tr>
<td>1 Week/1month Follow-up Form</td>
<td>Other Adverse Events</td>
</tr>
<tr>
<td>3 month/6month Follow-up Form</td>
<td>Explant/Transplant Form</td>
</tr>
<tr>
<td>Implant Discharge Form</td>
<td>Death Form</td>
</tr>
<tr>
<td>Rehospitalization Form</td>
<td>Patient Transfer/Withdrawal Form</td>
</tr>
</tbody>
</table>
Data Structure Follow-up

- Follow-up schedule
- Adverse Events
- Adding a device
- Ending patient participation
<table>
<thead>
<tr>
<th>Expected Clinic Visit</th>
<th>Acceptable Time Window for Clinic Visit</th>
<th>Example: Apr 1\textsuperscript{st} implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 week</td>
<td>4–10 days post implant (+/- 3 days)</td>
<td>Apr 7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Apr 4 - Apr 10</td>
</tr>
<tr>
<td>1 month</td>
<td>23–37 days post implant (+/- 7 days)</td>
<td>May 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Apr 24 - May 8</td>
</tr>
<tr>
<td>3 month</td>
<td>60–120 days post implant (+/- 30 days)</td>
<td>Jul 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Jun 1 - Aug 1</td>
</tr>
<tr>
<td>6 months</td>
<td>120-240 days post implant (+/- 60 days)</td>
<td>Oct 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aug 1 - Dec 1</td>
</tr>
<tr>
<td>12 months</td>
<td>300–420 days post implant (+/- 60 days)</td>
<td>Apr 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feb 1 – Jun 1</td>
</tr>
<tr>
<td>18 months</td>
<td>480–600 days post implant (+/- 60 days)</td>
<td>Oct 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aug 1 - Dec 1</td>
</tr>
<tr>
<td>24 months</td>
<td>660-780 days post implant (+/- 60 days)</td>
<td>Apr 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feb 1 - Jun 1</td>
</tr>
</tbody>
</table>
Adding an Adverse Event

• During implant hospitalization
• Outside of hospital
• During re-hospitalization
• Adverse Event “Triggers”
Adding a Device

INTERMACS® allows for entry of multiple implants for an individual patient. The LVAD implantation date will be the “driving force” of the follow up clock. If an LVAD is removed and then replaced with a new LVAD then the follow up clock restarts with the new LVAD. If the initial device implanted is an RVAD alone then the RVAD will ‘drive’ the follow-up clock and if an LVAD is subsequently implanted then the LVAD will ‘restart’ the follow-up ‘clock’.

There are two possible scenarios.
Adding a Device

• **Replacement of an existing device**
  If a patient has a device replaced (e.g., a patient with an LVAD receives a replacement LVAD) then the previous implant for the patient must be explanted and all forms related to this implant must be completed and validated. Once the forms for the previous implant have been submitted then the “Add Device” icon is available for the entry of a new implant for the patient.

• **Additional device**
  If an additional device is implanted (e.g., a patient with an LVAD subsequently receives an RVAD) then select the “Add Device” icon for the entry of a new implant for the patient.
1.4 Ending Patient Participation

A patient’s participation in INTERMACS® may end for clinical or administrative reasons:

**Clinical**
(1) **Death:**
(2) **Transplant:** Patient will be followed through the OPTN database.
(3) **1 year after removal of a device due to recovery:** Regular follow-up form completion ceases, but the coordinator reports to the registry whether the patient died or was transplanted for a period of 1 year post-explant.

**Administrative**
(1) **Patient transfers** medical care to another hospital: This will end the patient participation at your hospital. The receiving hospital will then continue following this patient.
(2) **Patient revokes/withdraws his/her informed consent:**
Let’s take a look at a couple of sample patients
Test Patient: Anastasia Myers

- 12 year old white female
- Dilated Cardiomyopathy
- Advanced heart failure
- PediMACS Level 3 – Stable but inotrope dependent

09/19/2012: HeartMate II
09/26/2012: 1 week follow-up
10/19/2012: 1 month follow-up
10/31/2012: Patient discharged home
12/01/2012: Patient re-hospitalized for infection - sepsis
12/15/2012: Patient discharged home
12/19/2012: 3 month follow-up
12/30/2012: patient re-hospitalized – explant – device exchange
01/10/2013: patient transplanted - End of Follow-up
Test Patient: Anastasia Myers

Time zero starts

1 wk, 1mth, 3 mth, 6mth F/U

Automatically generated by WBDE

Patient transplanted 01/10/2013

End of Follow-up

Time zero restarts

Implant Discharge 10/31/2012
1 month follow-up 10/19/2012
1 week follow-up 9/6/2012
Implant 9/19/2012

Re-hospitalization (infection) 12/1/2012
Patient discharged 12/15/2012
3 month follow-up 12/19/2012
1 week follow-up 12/30/2012
Device exchange/Explant 9/26/2012

PediMACS Tutorial: September 20, 2012
Data Structure

Patient

Anastasia Myers

HeartMate II

Devices

HeartMate II

Events

Infection

Follow-up

Explant

Follow-up

Transplant

End of Follow-up
Test Patient: Princess Leia

- 9 year old Hawaiian female
- Dilated Cardiomyopathy: Viral
- Elective VAD placement
- PediMACS Level 2 – Progressive Decline

06/27/2012 HeartMate II
07/04/2012 1 week follow-up
07/04/2012 Hemolysis
07/05/2012 Patient discharged home
08/03/2012 1 month follow-up
08/27/2012 3 month follow-up (includes QOL)
09/01/2012 Patient re-hospitalized for infection: line sepsis
09/04/2012 Device Malfunction
09/10/2012 Infection: Fungal
09/10/2012 Patient explanted: Emergent: viral infection
09/18/2012 Patient dies
PediMACS Tutorial: September 20, 2012

Test Patient: Princess Leai

- Implant: 07/04/2012
- Discharged home: 07/05/2012
- 3 month follow-up: 08/27/2012
- Re-hospitalized: 09/01/2012
- Device malfunction: 09/04/2012
- Infection: 09/10/2012

- 1 week, 1 mth, 3 mth, 6 mth F/U
- Hemolysis: 07/04/2012
- Automaticall generated by WBDE

End of Follow-up: 09/18/2012

Patient dies: 09/18/2012
Data Elements and Definitions

- Disease Severity, Patient Selection and Potential Risk
- Quality of Life and Functional Capacity

David Rosenthal, MD
PediMACS Levels
PediMACS 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, with critical organ hypo perfusion often confirmed by worsening acidosis and lactate levels. This patient can have modifier A or TCS (see ‘Modifiers’ below).

PediMACS 2: Progressive decline describes a patient who has been demonstrated “dependent” on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, hepatic function, respiratory function, fluid retention, nutrition, tachyarrhythmia, or other major status indicator. Patient profile 2 can also describe a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions cannot be maintained due to tachyarrhythmia, clinical ischemia, or other intolerance. This patient can have modifiers A or TCS.
PediMACS 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 symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal). It is critical to monitor nutrition, renal function, fluid balance, and overall status carefully in order to distinguish between a patient who is truly stable at Patient Profile 3 and a patient who has unappreciated decline rendering them Patient Profile 2. This patient may be either at home or in the hospital. Patient Profile 2 can have modifier A, and if in the hospital with circulatory support can have modifier TCS. If patient is at home most of the time on outpatient inotropic infusion, this patient can have a modifier FF if he or she frequently returns to the hospital.

PediMACS 4: **Resting symptoms** describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with ADL. He or she may have orthopnea, shortness of breath during ADL such as dressing or bathing, gastrointestinal symptoms (abdominal discomfort, nausea, poor appetite), disabling ascites or severe peripheral edema (extremity or facial). This patient should be carefully considered for more intensive management and surveillance programs, by which some may be recognized to have poor compliance that would compromise outcomes with any therapy. This patient can have modifiers A and/or FF.
PediMACS 5: **Exertion Intolerant** describes a patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or housebound. This patient has no congestive symptoms, but may have chronically elevated volume status, frequently with renal dysfunction, and may be characterized as exercise intolerant. This patient can have modifiers A and/or FF.

PediMACS 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. Activities of daily living are comfortable and minor activities outside the home such as visiting friends or going to a restaurant can be performed, but fatigue results within a few minutes or any meaningful physical exertion. This patient has occasional episodes of worsening symptoms and is likely to have had a hospitalization for heart failure within the past year. This patient can have modifiers A and/or FF.

PediMACS 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. This patient is usually able to walk more than a block. Any decompensation requiring intravenous diuretics or hospitalization within the previous month should make this person a Patient Profile 6 or lower. This patient may have a modifier A only.
PediMACS
Quality of Life
2.14 Quality of Life

Introduction

The PediMACS quality of life section will be similar to the core INTERMACS quality of life as far as the time they are collected (pre-implant, 3 mth, 6mth and every 6mth thereafter) and some of the same basic structure of how we have set up quality of life instrument data entry (i.e., EQ-5D and KCCQ) for core INTERMACS. There are several PediMACS quality of life forms (child and parent reports).

- PEDSQL Toddler 2-4 yrs (Parent Report)
- PEDSQL Young Child 5-7 yrs (Child Report)
- PEDSQL Young Child 5-7 yrs (Parent Report)
- PEDSQL Child 8-12 yrs (Child Report)
- PEDSQL Child 8-12 yrs (Parent Report)
- PEDSQL Teen 13-18 yrs (Child Report)
- PEDSQL Teen 13-18 yrs (Parent Report)
- VAD QOL (> 8 yrs) Child Report
- VAD QOL (< 2 yrs) Parent Report
- VAD QOL (≥ 2 yrs) Parent Report
PEDSQL: Child
Did the child complete a form?  Yes/No/Unknown
If no, please enter the reason the PEDSQL form was not completed:
  Too Sick
  Administrative (check specific reason)
    Urgent implant, no time
    Coordinator too busy or forgot
  Unable to contact patient
  Other reason, specify

If yes, please select the ‘Child’ form:
  • PEDSQL Young Child (5-7yrs)
  • PEDSQL Child (8-12 yrs)
  • PEDSQL Teen (13-18 yrs)
The appropriate form ‘opens’ once the form (along with its instruction/direction page).
YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.

Show the child the template and point to the responses as you read.

If it is not at all a problem for you, point to the smiling face

If it is sometimes a problem for you, point to the middle face

If it is a problem for you a lot, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let’s try a practice one first.

<table>
<thead>
<tr>
<th>Is it hard for you to snap your fingers</th>
<th>Not at all</th>
<th>Sometimes</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>😊</td>
<td>😞</td>
<td>😞</td>
</tr>
</tbody>
</table>

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.
Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

**PHYSICAL FUNCTIONING (problems with...)**

<table>
<thead>
<tr>
<th>Item</th>
<th>Not at all</th>
<th>Sometimes</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is it hard for you to walk</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>2. Is it hard for you to run</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>3. Is it hard for you to play sports or exercise</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>4. Is it hard for you to pick up big things</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>5. Is it hard for you to take a bath or shower</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>6. Is it hard for you to do chores (like pick up your toys)</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>7. Do you have hurts or aches (Where?)</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>8. Do you ever feel too tired to play</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

Remember, tell me how much of a problem this has been for you for the last few weeks.

**EMOTIONAL FUNCTIONING (problems with...)**

<table>
<thead>
<tr>
<th>Item</th>
<th>Not at all</th>
<th>Sometimes</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you feel scared</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>2. Do you feel sad</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>3. Do you feel mad</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>4. Do you have trouble sleeping</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>5. Do you worry about what will happen to you</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

**SOCIAL FUNCTIONING (problems with...)**

<table>
<thead>
<tr>
<th>Item</th>
<th>Not at all</th>
<th>Sometimes</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is it hard for you to get along with other kids</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>2. Do other kids say they do not want to play with you</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>3. Do other kids tease you</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>4. Can other kids do things that you cannot do</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>5. Is it hard for you to keep up when you play with other kids</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

**SCHOOL FUNCTIONING (problems with...)**

<table>
<thead>
<tr>
<th>Item</th>
<th>Not at all</th>
<th>Sometimes</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is it hard for you to pay attention in school</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>2. Do you forget things</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>3. Is it hard to keep up with schoolwork</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>4. Do you miss school because of not feeling good</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>5. Do you miss school because you have to go to the doctor's or hospital</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>
PEDSQL: Parent
Did the parent complete a form? Yes/No/Unknown
If no, please enter the reason the PEDSQL form was not completed:
  Too Sick
  Administrative (check specific reason)
    Urgent implant, no time
    Coordinator too busy or forgot
    Unable to contact patient
  Other reason, specify _____________________________
If yes, please select the ‘Parent’ form:
  PEDSQL Toddler (2-4 yrs)
  PEDSQL Young Child (5-7yrs)
  PEDSQL Child (8-12 yrs)
PARENT REPORT for TODDLERS (ages 2-4)

DIRECTIONS

On the following page is a list of things that might be a problem for your child. Please tell us how much of a problem each one has been for your child during the past ONE month by circling:

0 if it is never a problem
1 if it is almost never a problem
2 if it is sometimes a problem
3 if it is often a problem
4 if it is almost always a problem

There are no right or wrong answers. If you do not understand a question, please ask for help.
**Parent Report for Toddlers (ages 2-4)**

**In the past ONE month, how much of a problem has your child had with ...**

<table>
<thead>
<tr>
<th>PHYSICAL FUNCTIONING (problems with...)</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Walking</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Running</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Participating in active play or exercise</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Lifting something heavy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Bathing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. Helping to pick up his or her toys</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. Having hurts or aches</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. Low energy level</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EMOTIONAL FUNCTIONING (problems with...)</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Feeling afraid or scared</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Feeling sad or blue</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Feeling angry</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Trouble sleeping</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Worrying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SOCIAL FUNCTIONING (problems with...)</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Playing with other children</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Other kids not wanting to play with him or her</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Getting teased by other children</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Not able to do things that other children his or her age can do</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Keeping up when playing with other children</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

*Please complete this section if your child attends school or daycare*

<table>
<thead>
<tr>
<th>SCHOOL FUNCTIONING (problems with...)</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Doing the same school activities as peers</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Missing school/daycare because of not feeling well</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Missing school/daycare to go to the doctor or hospital</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
VAD QOL: Child (for children > 8yrs of age)

Did the child complete a form? Yes/No/Unknown
If no, please enter the reason the PEDSQL form was not completed:
  Too Sick
  Administrative (check specific reason)
    Urgent implant, no time
    Coordinator too busy or forgot
    Unable to contact patient
  Other reason, specify _____________________________

If yes, the VAD QOL (Child form opens – see attached form)
# VAD QOL: Child (> 8 years)

**Directions**  
Children with heart conditions sometimes need a special device to help their heart function. Please fill in the circle which best describes your feelings about the ventricular assist device (VAD). Feel free to add any additional comments to the text lines.

1. The VAD noise bothers me when I am awake.  
   - [ ] Always  
   - [ ] Very Often  
   - [ ] Sometimes  
   - [ ] Rarely  
   - [ ] Never

2. The VAD noise bothers me when I am trying to sleep.  
   - [ ] Always  
   - [ ] Very Often  
   - [ ] Sometimes  
   - [ ] Rarely  
   - [ ] Never

3. I have pain or discomfort at the driveline or tubing pump exit site.  
   - [ ] Always  
   - [ ] Very Often  
   - [ ] Sometimes  
   - [ ] Rarely  
   - [ ] Never

4. I have difficulty sleeping due to the position of the driveline or tubing pump exit site.  
   - [ ] Always  
   - [ ] Very Often  
   - [ ] Sometimes  
   - [ ] Rarely  
   - [ ] Never

5. I am bothered by how I look with the VAD.  
   - [ ] Always  
   - [ ] Very Often  
   - [ ] Sometimes  
   - [ ] Rarely  
   - [ ] Never

6. I worry about the VAD breaking or malfunctioning.  
   - [ ] Always  
   - [ ] Very Often  
   - [ ] Sometimes  
   - [ ] Rarely  
   - [ ] Never

7. I am bothered that I cannot visit family or friends outside the home or hospital with the VAD.  
   - [ ] Always  
   - [ ] Very Often  
   - [ ] Sometimes  
   - [ ] Rarely  
   - [ ] Never

8. I am bothered that I cannot move easily from place to place with the VAD.  
   - [ ] Always  
   - [ ] Very Often  
   - [ ] Sometimes  
   - [ ] Rarely  
   - [ ] Never

9. I cannot participate in usual play activities with the VAD.  
   - [ ] Always  
   - [ ] Very Often  
   - [ ] Sometimes  
   - [ ] Rarely  
   - [ ] Never

10. I find it difficult to express feelings and talk to others about the VAD.  
    - [ ] Always  
    - [ ] Very Often  
    - [ ] Sometimes  
    - [ ] Rarely  
    - [ ] Never

11. Overall, I would describe my day-to-day level of worry with the VAD to be:  
    - [ ] High  
    - [ ] Medium  
    - [ ] Low

12. Overall, I would describe my day-to-day level of happiness with the VAD to be:  
    - [ ] High  
    - [ ] Medium  
    - [ ] Low
PediMACS
Functional Capacity
Captured at Follow-up

Functional Capacity for follow-up time period: Answer Yes or No

- Sedated
- Paralyzed
- Intubated
- Ambulating
- Primary Nutrition orally
- Primary Nutrition per feeding tube
- Primary Nutrition TPN

Has the patient had any non-medically required excursions off the unit?
If so, where (please select all that apply)

- Playroom
- Cafeteria
- Walk outside
- Sitting room
- General rehab
- None
- Other, specify ____________________
EXERCISE FUNCTION

All patients ≥ 10 yrs of age at time of implant should attempt to complete these functional capacity measurements especially for those patients classified as PediMACS patient profile levels 4-7.

6 minute walk: 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.

All efforts should be made to perform the 6 minute walk test for any patient able to walk more than a few steps. A distance as short as 3 feet may be recorded. If the test is not done, the reason must be indicated as “not done: too sick” or “not done: other”, for which an example might be a patient needing to remain supine after a groin puncture for routine catheterization. Any musculoskeletal limitation to walking should be recorded as “not done: too sick”.

Gait speed (1st 15 foot walk): _____ seconds

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.
Adverse Events

David Morales, MD
June 2006 – March 2011: Outcomes of Children with VADs

Adverse Event Rates after Device Implantation (Events/100 Patient Months) in the First 3 Months post implant and 3 months or more post implant for Pediatric Patients

<table>
<thead>
<tr>
<th>Event</th>
<th># of events</th>
<th># of patients*</th>
<th>% of patients</th>
<th>1st 3 months</th>
<th>≥ 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>81</td>
<td>31</td>
<td>37%</td>
<td>56</td>
<td>28.68</td>
</tr>
<tr>
<td>Bleeding</td>
<td>74</td>
<td>28</td>
<td>33%</td>
<td>61</td>
<td>31.24</td>
</tr>
<tr>
<td>Cardiac Arrhythmia</td>
<td>23</td>
<td>16</td>
<td>19%</td>
<td>18</td>
<td>9.22</td>
</tr>
<tr>
<td>Device Malfunction</td>
<td>21</td>
<td>12</td>
<td>14%</td>
<td>2</td>
<td>1.02</td>
</tr>
<tr>
<td>Neurological Dysfunction</td>
<td>12</td>
<td>10</td>
<td>12%</td>
<td>7</td>
<td>3.58</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>10</td>
<td>10</td>
<td>12%</td>
<td>9</td>
<td>4.61</td>
</tr>
<tr>
<td>Renal Dysfunction</td>
<td>8</td>
<td>8</td>
<td>10%</td>
<td>8</td>
<td>4.10</td>
</tr>
<tr>
<td>Right Heart Failure</td>
<td>8</td>
<td>7</td>
<td>8%</td>
<td>7</td>
<td>3.58</td>
</tr>
<tr>
<td>Hepatic Dysfunction</td>
<td>7</td>
<td>7</td>
<td>8%</td>
<td>7</td>
<td>3.58</td>
</tr>
<tr>
<td>Hypertension</td>
<td>7</td>
<td>7</td>
<td>8%</td>
<td>6</td>
<td>3.07</td>
</tr>
<tr>
<td>Pericardial Drainage</td>
<td>7</td>
<td>5</td>
<td>6%</td>
<td>7</td>
<td>3.58</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>6</td>
<td>3</td>
<td>4%</td>
<td>5</td>
<td>2.56</td>
</tr>
<tr>
<td>Psychiatric Episode</td>
<td>6</td>
<td>3</td>
<td>4%</td>
<td>3</td>
<td>1.54</td>
</tr>
<tr>
<td>Venous Thromboembolism</td>
<td>4</td>
<td>4</td>
<td>5%</td>
<td>4</td>
<td>2.05</td>
</tr>
<tr>
<td>Other*</td>
<td>30</td>
<td>17</td>
<td>20%</td>
<td>20</td>
<td>10.24</td>
</tr>
</tbody>
</table>

* # of patients with one or more events

Table 6: Version 1
### Adverse Event Rates after Device Implantation (Events/100 Patient Months) in the First 3 Months post implant and 3 months or more post implant for Pediatric Patients

<table>
<thead>
<tr>
<th>Event</th>
<th>1st 3 months</th>
<th>≥ 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>rate</td>
</tr>
<tr>
<td>Infection</td>
<td>56</td>
<td>28.68</td>
</tr>
<tr>
<td>Bleeding</td>
<td>61</td>
<td>31.24</td>
</tr>
<tr>
<td>Cardiac Arrhythmia</td>
<td>18</td>
<td>9.22</td>
</tr>
<tr>
<td>Device Malfunction</td>
<td>2</td>
<td>1.02</td>
</tr>
<tr>
<td>Neurological Dysfunction</td>
<td>7</td>
<td>3.58</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>9</td>
<td>4.61</td>
</tr>
<tr>
<td>Renal Dysfunction</td>
<td>8</td>
<td>4.10</td>
</tr>
<tr>
<td>Right Heart Failure</td>
<td>7</td>
<td>3.58</td>
</tr>
<tr>
<td>Hepatic Dysfunction</td>
<td>7</td>
<td>3.58</td>
</tr>
<tr>
<td>Hypertension</td>
<td>6</td>
<td>3.07</td>
</tr>
<tr>
<td>Pericardial Drainage</td>
<td>7</td>
<td>3.58</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>5</td>
<td>2.56</td>
</tr>
<tr>
<td>Psychiatric Episode</td>
<td>3</td>
<td>1.54</td>
</tr>
<tr>
<td>Venous Thromboembolism</td>
<td>4</td>
<td>2.05</td>
</tr>
<tr>
<td>Other*</td>
<td>20</td>
<td>10.24</td>
</tr>
</tbody>
</table>

*Table 6: Version 2*
### Adverse Event Definitions:

<table>
<thead>
<tr>
<th>Major Adverse Events</th>
<th>Triggered Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Device Malfunction</td>
<td>• Renal Dysfunction</td>
</tr>
<tr>
<td>• Bleeding</td>
<td>• Hemolysis</td>
</tr>
<tr>
<td>• Infection</td>
<td>• Hepatic Dysfunction</td>
</tr>
<tr>
<td>• Neurological Dysfunction</td>
<td></td>
</tr>
<tr>
<td>11 Adverse Events</td>
<td></td>
</tr>
<tr>
<td>• Cardiac Arrhythmia</td>
<td></td>
</tr>
<tr>
<td>• Right Heart Failure</td>
<td></td>
</tr>
<tr>
<td>• Arterial Non-CNS Thromboembolic Event</td>
<td></td>
</tr>
<tr>
<td>• Hypertension</td>
<td></td>
</tr>
<tr>
<td>• Other SAE</td>
<td></td>
</tr>
<tr>
<td>• Pericardial Fluid Collection</td>
<td></td>
</tr>
<tr>
<td>• Myocardial Infarction</td>
<td></td>
</tr>
<tr>
<td>• Venous Thromboembolism</td>
<td></td>
</tr>
<tr>
<td>• Psychiatric Episode</td>
<td></td>
</tr>
<tr>
<td>• Wound Dehiscence</td>
<td></td>
</tr>
<tr>
<td>• Respiratory Failure</td>
<td></td>
</tr>
</tbody>
</table>
Device Malfunction

Device malfunction denotes a failure of one or more of the components of the MCSD system which either directly causes or could potentially induce a state of inadequate circulatory support (low cardiac output state) or death. A failure that was iatrogenic or recipient-induced will be classified as an Iatrogenic/Recipient-Induced Failure.

Device failure should be classified according to which components fails as follows:

1) **Pump** failure (blood contacting components of pump and any motor or other pump actuating mechanism that is housed with the blood contacting components). In the special situation of **pump thrombosis**, thrombus is documented to be present within the device or its conduits that result in or could potentially induce circulatory failure.

2) **Non-pump** failure (e.g., external pneumatic drive unit, electric power supply unit, batteries, controller, interconnect cable, compliance chamber)
MAJOR BLEEDING
AN EPISODE OF SUSPECTED INTERNAL OR EXTERNAL BLEEDING THAT RESULTS IN ONE OR MORE OF THE FOLLOWING:

1. Death,
2. Re-intervention,
3. Hospitalization
Neurological Dysfunction

Any new, temporary or permanent, focal or global neurologic deficit ascertained by a standard neurological examination (administered by an neurologist or other qualified physician and documented with appropriate diagnostic tests and consultation note); or an abnormality identified by CNS imaging. The examining physician will distinguish between a transient ischemic attach (TIA), which reverses fully within 24 hours, and a stroke, which lasts longer than 24 hours (or less than 24 hours if there is evidence of infarction). Alternatively, a neurologic event may be recognized by seizure activity or as a clinically silent event detected by CNS imaging alone. Each neurologic event should be subcategorized as:

1. Transient Ischemic Attack (complete resolution of clinical findings within 24 hours, and no infarction seen by imaging if performed).
2. Ischemic or Hemorrhagic Cardiovascular Accident (clinical findings persist beyond 24 hours, or for less than 24 hours with infarction seen on imaging study).
3. Infarction seen by imaging, without clinical findings of TIA/Stroke at the time of event recognition.
4. Extra-axial bleeding seen by imaging study.
5. Clinical seizure activity or EEG demonstrating seizure activity.

For infants less than 6 months of age, head ultrasound is an acceptable imaging modality.
Major Infection

A clinical infection accompanied by pain, fever, drainage and/or leukocytosis that results in either initiation of a new anti-microbial agent, or a surgical exploration/debridement. This will include all presumptive use of antibiotics for periods exceeding 72 hours. The event will be considered resolved when all antibiotics are stopped for 72 hours, with the resolution date considered to be the last day of antibiotic administration. The general categories of infection are listed below:

Localized Non-Device Infection
Infection localized to any organ system or region (e.g. mediastinitis) without evidence of systemic involvement (See sepsis definition), ascertained by standard clinical methods and either associated with evidence of bacterial, viral, fungal or protozoal infection, and/or requiring empirical treatment.

Percutaneous Site and/or Pocket Infection
A positive culture from the skin and/or tissue surrounding the drive line or from the tissue surrounding the external housing of a pump implanted within the body, coupled with the need to treat with antimicrobial therapy when there is clinical evidence of infection such as pain, fever, drainage, or leukocytosis.

Internal Pump Component, Inflow or Outflow Tract Infection
Infection of blood-contacting surfaces of the LVAD documented by positive site culture. (There should be a separate data field for paracorporeal pump that describes infection at the percutaneous cannula site, e.g. Thoratec PVAD).

Bacteremia/Sepsis
Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension OR positive blood culture. There may be more than one site of infection in the event of a positive blood culture in conjunction with a specified site above.
Cardiac Arrhythmias

Any rhythm disturbance requiring initiation of a new anti-arrhythmic medication, electrical cardioversion, or defibrillation. Events shall be classified as ventricular or supraventricular. The treatment event shall be recorded (i.e. cardioversion, defibrillation, or medical therapy with name of medication). Event is resolved when all anti-arrhythmic medications have been discontinued for at least 72 hours. Time of resolution will be the time of discontinuation of the last anti-arrhythmic medication. Cardiac arrhythmias are classified as 1 of 2 types:

1) Sustained ventricular arrhythmia requiring defibrillation or cardioversion, or initiation of medication.
2) Sustained supraventricular arrhythmia requiring drug treatment or cardioversion
Right Heart Failure
Clinical evidence of right heart failure (e.g. elevated CVP, diminished cardiac output, reduced LVAD filling) requiring RVAD implantation, inotropic or inodilator therapy, or inhaled nitric oxide; in the absence of pericardial tamponade, pneumothorax, uncontrolled cardiac arrhythmia, or LVAD dysfunction. OR, persistent requirement for inhaled nitric oxide or inotropic therapy for a duration of more than 1 week, or reinitiation of such therapy at any time after LVAD implantation.

LEVEL OF RIGHT HEART FAILURE

Please select the level of right heart failure severity below:

**Severe RHF:** RVAD
**Moderate RHF:** Inotrope or intravenous/inhaled pulmonary vasodilator such as Nitric Oxide

**Select all that apply:**
- IV Inotrope therapy
- Inhaled pulmonary vasodilator
Arterial Non-CNS Thromboembolic Event
An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by one or more of the following:

1) standard clinical and laboratory testing
2) operative findings
3) autopsy findings

This definition excludes neurological events.

Hypertension
New onset blood pressure elevation greater than or equal to 140 mm Hg systolic or 90 mm Hg diastolic (pulsatile pump) or 110 mm Hg mean pressure (rotary pump).

Pediatric patients: for patients under 18 years of age weighing < 50 kg, hypertension is defined as systolic, diastolic, or mean blood pressure greater than the 95th percentile for age which requires the addition of a new iv or oral therapy for management. The event shall be considered resolved upon the discontinuation of the treatment.
Other SAE
An event that causes clinically relevant changes in the patient’s health (e.g. cancer). Enter other serious adverse event that occurred since last PediMACS report/last follow-up into the block provided.

Pericardial Fluid Collection
Accumulation of fluid or clot in the pericardial space that requires surgical intervention or percutaneous catheter drainage. This event will be subdivided into those with clinical signs of tamponade (e.g. increased central venous pressure and decreased cardiac/VAD output) and those without signs of tamponade.

Myocardial Infarction
Defined as the presence of troponin or CK > normal range w/ + MB fraction (≥ 3% total CK) & a new regional LV or RV wall motion abnormality by myocardial imaging & 1 of the following 2 criteria being present post-implantation:
  - Chest pain characteristic of myocardial ischemia
  - ECG pattern or changes consistent with an MI
Pre-implant MI: The clinical suspicion of MI together with CK-MB or Troponin > 10 x ULN, found w/in 7d following implant & acute MI ECG findings.

These events will not be captured in the database.
Venous Thromboembolism
Evidence of venous thromboembolic event (e.g. deep vein thrombosis, pulmonary embolism) by standard clinical and laboratory testing.

Check all that apply:
Deep Vein thrombosis – enter date in MMDDYYYY format
Pulmonary Embolism – enter date in MMDDYYYY format
Other – if selected, enter in block provided
Unknown

Psychiatric Episode
Initiation of a new psychotropic medication, or referral to a mental health professional. Usual causes will be disturbance in thinking, emotion or behavior that impairs functioning, but this definition should be understood to exclude use of medications that are being administered to control post-operative pain or to facilitate withdrawal from such agents.
Suicide is included in this definition.

Wound Dehiscence
Disruption of the apposed surfaces of a surgical incision, excluding infectious etiology, and requiring surgical repair.
Respiratory Failure
Impairment of respiratory function requiring reintubation, tracheostomy or (for patients older than age 5 years) the inability to discontinue ventilatory support within 7 days post-VAD implant, except if the patient had pre-operative tracheostomy. This excludes intubation for re-operation or temporary intubation for diagnostic or therapeutic procedures, provided the total length of such intubation is 48 hours or less. If the intubation is prolonged beyond 48 hours, the start date of the event shall be the time of intubation, not the 48 hour period.
Renal Dysfunction
Two categories of renal dysfunction will be identified:

Acute
Abnormal kidney function requiring renal replacement therapy in patients who did not require it prior to implant.
A serum creatinine increase > 3 x baseline creatinine or > 3 x ULN for age sustained > 48 hours.

Chronic
Requirement for renal replacement therapy for at least 90 days

Hemolysis
A plasma-free hemoglobin value that is greater than 40 mg/dl, in association with clinical signs associated with hemolysis (e.g., anemia, low hematocrit, hyperbilirubinemia) occurring after the first 72 hours post-implant. Hemolysis related to documented non-device-related causes (e.g. transfusion or drug) is excluded from this definition.

Hepatic Dysfunction
An increase in any two hepatic laboratory values (total bilirubin, aspartate aminotransferase/AST and alanine aminotransferase/ALT) to a level > 3x UNL >14 days post-implant. Any case where hepatic dysfunction is the primary cause of death as noted on medical chart and/or death certificate
Training and Hands-on Data Entry

Kathryn Hollifield, RN
Nurse Monitors

- Kathryn Hollifield, BSN, RN  
  Phone: 205-996-9290/kathryn@uab.edu

- Gail Mertz, BS, RN, CCRC  
  Phone: 205-996-9292/gmertz@uab.edu

- Janella Miller, BSN, RN  
  Phone: 205-996-9291/jmiller@uab.edu

- Tammy Davis, RN  
  Phone: TBD/trdavis@uab.edu
PediMACS WBDE Forms

- Screening Log
- Demographics
- Pre-Implant
- Implant
- 1 week/1 Month
- Implant Discharge
- 3 Month/6 Month and Thereafter Follow-Up Forms
- Events
- Death/Explant/Recovery/Transplant
- Rehospitalization
**FOLLOW UP VISITS AND DATA ENTRY GUIDELINES**

- The windows for visits are not the same as the guidelines for form completion.

- The web-based data entry (WBDE) system is prospective and the forms should be filled out as the implant, follow-up dates, and as events occur.

- Forms should generally be completed within seven (7) days of an event, but always within 30 days.

<table>
<thead>
<tr>
<th>Follow Up Visit</th>
<th>Acceptable Time Window for Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 week</td>
<td>± 3 Days (4 – 10 days post implant)</td>
</tr>
<tr>
<td>1 month</td>
<td>± 7 Days (23 – 37 days post implant)</td>
</tr>
<tr>
<td>3 month</td>
<td>± 30 Days (2 – 4 months post implant)</td>
</tr>
<tr>
<td>6 months and beyond</td>
<td>± 60 Days (4 – 8 months post implant, etc.)</td>
</tr>
</tbody>
</table>
• Patient Scenarios

• How Do I Enter Data?
Web Based Data Entry

http://test.intermacs.org/registry/login.aspx/

User Name: training1
Password: training1
Please Login

This section is password-protected for secure data entry by authorized centers only. Contact the INTERMACS Registry Manager by e-mail or at (804) 782-4869 or (804) 782-4859 for information on becoming an authorized center.

User name:*  training1
Password:*  *********

login
Click on PediMACS
Click on Edit an existing patient

PediMACS is the pediatric portion of INTERMACS. While INTERMACS has always included durable devices implanted in pediatric patients, PediMACS has been developed to focus on capturing data elements unique to pediatric patients. PediMACS evaluates special issues in the pediatric population receiving Mechanical Circulatory Support Device (MCSD) therapy, differences in devices available, and the particular pediatric population for whom this therapy may be most effective.
Select Patient # according to the number on your laptop

### Recent Patients at Training

<table>
<thead>
<tr>
<th>Pt#</th>
<th>Device#</th>
<th>Name</th>
<th>Hospital</th>
<th>Medical Record Number</th>
<th>SSN (last 5 digits)</th>
<th>Implant Date</th>
<th>Device Type</th>
<th>Brand Name</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>49</td>
<td>42</td>
<td>Patient 13</td>
<td>Training</td>
<td></td>
<td></td>
<td>02/09/2012</td>
<td>LVAD (Left Ventricular Assist Device)</td>
<td>HeartMate II LVAS</td>
<td>Alive</td>
</tr>
<tr>
<td>50</td>
<td>43</td>
<td>Patient 14</td>
<td>Training</td>
<td></td>
<td></td>
<td>02/09/2012</td>
<td>LVAD (Left Ventricular Assist Device)</td>
<td>HeartMate II LVAS</td>
<td>Alive</td>
</tr>
<tr>
<td>52</td>
<td>45</td>
<td>Patient 15</td>
<td>Training</td>
<td></td>
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<td>02/09/2012</td>
<td>LVAD (Left Ventricular Assist Device)</td>
<td>HeartMate II LVAS</td>
<td>Alive</td>
</tr>
<tr>
<td>34</td>
<td>27</td>
<td>Patient 2</td>
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<td></td>
<td>02/09/2012</td>
<td>LVAD (Left Ventricular Assist Device)</td>
<td>HeartMate II LVAS</td>
<td>Alive</td>
</tr>
<tr>
<td>36</td>
<td>29</td>
<td>Patient 3</td>
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<td>02/09/2012</td>
<td>LVAD (Left Ventricular Assist Device)</td>
<td>HeartMate II LVAS</td>
<td>Alive</td>
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<td>39</td>
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<td>02/09/2012</td>
<td>LVAD (Left Ventricular Assist Device)</td>
<td>HeartMate II LVAS</td>
<td>Alive</td>
</tr>
</tbody>
</table>
To be completed by the sending institution, after all the patients forms and visits have been completed. The Receiving hospital will have ‘read only’ access to the pre-transfer records.
### Patient Transfers

<table>
<thead>
<tr>
<th>Sending Institution</th>
<th>Receiving Institution</th>
</tr>
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<tbody>
<tr>
<td>▪ Ensure <strong>All Forms and Visits Have Been Completed</strong></td>
<td>▪ Patient must agree to continued participation in INTERMACS at the new institution</td>
</tr>
<tr>
<td>▪ Complete <strong>Patient Registry Status Form</strong></td>
<td>▪ Receiving institution must have IRB approval</td>
</tr>
<tr>
<td></td>
<td>▪ Obtain “Authorization to Release Information Consent” at the receiving institution.</td>
</tr>
<tr>
<td></td>
<td>▪ Obtain INTERMACS Registry Consent Form at receiving institution.</td>
</tr>
<tr>
<td></td>
<td>▪ Please forward copies of both consents to Mary Lynne Clark at the INTERMACS DCC</td>
</tr>
</tbody>
</table>
Questions?
Data Quality and Hospital Evaluation

David C. Naftel, PhD
• Audits
• Implant reconciliation
• Medical Event Review
• Hospital Compliance
REGISTRY MONITORING PROCESS

- Screening Log Reconciliation
  - Included patients
  - Excluded patients
  Goal: To capture all MCSD patients at each institution

- Data Resolution via phone
  - Quarterly
  - Pre on-site visit (approximately 14 days prior to on-site visit)
  Goal: To identify and correct data discrepancies efficiently

- Major Events Review
  - Via phone
  - On-site monitoring
  Goal: To discover unreported events and increase data accuracy and quality
• For Cause Audits
  – Hospital Compliance < 70%

• Scheduled Audits
  – Each hospital is scheduled to be audited ‘on site’ once during the 5 year contract period
Implant Reconciliation

- Thoratec implant counts
- Syncardia implant counts
Major Adverse Events Reviewed by MER Committee
April 2008 - March 2012

- Device Malf
- Neuro Dys
- Bleeding
- Infection
- Death
- Total Events

Bi-Annual Review

Number of Events

Q2-Q3 2008: 402
Q4 2008 - Q1 2009: 501
Q2-Q3 2009: 965
Q4 2009 - Q1 2010: 1733
Q2-Q3 2010: 2606
Q4 2010 - Q1 2011: 2315
Q2 2011 - Q3 2011: 2435
Q4 2011 - Q1 2012: 3816

Q2-Q3 2008 (n=184 pts)
Q4 2008 - Q1 2009 (n=272 pts)
Q2-Q3 2009 (n=369 pts)
Q4 2009 - Q1 2010 (n=698 pts)
Q2-Q3 2010 (n=952 pts)
Q4 2010 - Q1 2011 (n=975 pts)
Q2 2011 - Q3 2011 (n=1099 pts)
Q4 2011 - Q1 2012 (n=1560 pts)
Hospital Compliance
PediMACS Registry
brought to you by
-- UNOS --
“Robert Todd”

Fantastic Job!!
Wrap-up

Elizabeth Blume, MD
## PediMACS Tutorial:  September 20, 2012

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<td>Dr. Kirklin</td>
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<td>III. PediMACS Structure</td>
<td>Dr. Blume</td>
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<td>Kathryn Hollifield, RN</td>
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