Greetings from Intermacs,

Again the registry finds itself in the middle of a very busy period. On March 11th and 12th Intermacs held its 10th Annual Meeting & Scientific Sessions in Atlanta, GA. Entitled, “Celebrating a Decade of Progress,” the meeting included a moderated poster session, followed by a selection of talks from registry personnel who highlighted several reporting products that are currently available (Data Quality and Quality Assurance Reports, Live Data Download, Site Datasets) and some on the near horizon (Customized Cohort Reports, Outcome Analytics). Our scientific sessions included presentations from invited speakers who covered many topics including new devices, pediatric challenges, Right Heart Failure, and the need for a better understanding of the quality of life for VAD patients. Visit our website to see slide sets from these presentations.

This intense period continues as our focus now turns to the ISHLT 2016 Annual Meeting & Scientific Sessions, April 27th – 30th in Washington, DC. We are excited as Intermacs registry data is being utilized for 13 presentations at the sessions. Please see the Research section of this newsletter for a schedule of those presentations, all of which will be available as slide sets on our website after the meeting’s conclusion. Our busy itinerary is a byproduct of the extraordinary amount of detail that our participating physicians, coordinators and data mangers put into supporting registry needs. This high level of detail is the reason we all celebrate a decade of progress and will push toward another.

Kind regards,
James K. Kirklin

10th Annual Meeting and Scientific Sessions

The two day Intermacs 10th Annual Meeting and Scientific Sessions, Celebrating a Decade of Progress, was held at the beautiful Centennial Olympic Park and CNN Omni Center in Atlanta, Georgia, March 11th and 12th. Approximately 170 attendees and 41 Speakers or Session Moderators participated in this year’s event. Below is a brief summary of the sessions.

Friday evening began with a moderated poster session presented by Coordinators and VAD or Heart Failure Physician Trainees. Our goal was to provide a format for coordinators and trainees to relay how Intermacs influences practices at their centers. Based on positive feedback from attendees, Intermacs plans to provide and expand poster presentation opportunities at future meetings.
This year’s posters included a variety subjects:

- Cardiac Remodeling after Heartware HVAD Left Ventricle Device in a 2 year old with Chemotherapy – Induced Dilated Cardiomyopathy (Cheryl Cammock)
- Utilization of the Intermacs Database to Evaluate Hospital Performance Standards for VAD JACHO Accreditation (Rachel Munoz and Marci Holladay)
- Changing to VAD Dressing Kits Yields Positive Results and Reduces Out of Pocket Expense (Linda Suplicki)
- UPMC Quality Assurance Project on Driveline Infections Driven by Intermacs Data (Nicole Kunz)
- A Review of Unplanned Readmissions Within Six-Months from the Primary Implant Hospitalization for Mechanical Circulatory Support Device with a Low Socioeconomic Patient Population (Sylvia Laudun)
- Using the Intermacs Registry to Evaluate the Left Ventricular Assist Device Programs in Quebec, Canada: Can Small Still be Beautiful? (Nicolas Thibodeau-Jarry)
- Using Intermacs Data for JC Disease-Specific Performance Review (David Baldwin)
- When is Hemolysis not an Indication for LVAD Exchange? A Case Report (Sarah Shettle)
- The Use of Intermacs Score and Discharge Disposition to Target Quality Improvement Effort (Meghan E. Muldoon)

Intermacs would like to thank each of these presenters and their co-contributors for an outstanding session.

Saturday’s sessions opened with Session II, The Vision of Intermacs, by Dr. John Watson who provided his vision from many years ago for a national collaboration and how the registry came to fruition. The discussion continued with an update of how the organization has evolved since its roll-out in 2006 and plans for continued growth. Dr. Adam Beck, representing the Surgical Vascular Society (SVS) provided how to use a Patient Safety Organization (PSO) to improve patient care.
Pedimacs representative, Drs. Angela Lorts, William Mahle and Jake Jaquiss, participated in presentations and a panel discussion in Session V, Small Size, Big Challenges: All Things Pediatric. Topics included the issue of overcoming trial design in pediatric mechanical support by Dr. Mahle, VADs designed for temporary support being used as durable devices in children by Dr. Lorts, and a case presentation by Dr. Jacquiss on selecting an appropriate device for the right ventricle.

In Session VI, Intermacs Right Heart Failure Task Force, Dr. Robert Kormos (moderator), Drs. Eduardo Rame, James Antaki, Michael Kiernan and Pavan Atluri provided understanding to new Right Heart Failure (RHF) definitions, Bayesian models and risk of RHF, and a case presentation of RV failure after LVAD.

Linking Intermacs to the World: The Power of Collaboration during Session III and New Devices and New Trials: New Outcomes?, in Session IV, updated attendees of Intermacs and Pedimacs collaborations with the Scientific Registry of Transplant Recipients, Pediatric Heart Transplant Study and the Centers for Medicare and Medicaid and also reviewed new devices and trials. Experts in the field discussed HeartMate II, MVAD, RoadMap, C-Pulse Extra-Aortic counterpulsation system, Prevent, SynCardia TAH-t PAS while Dr. John Sapirstein provided the FDA's perspective of new device trials.
In depth discussions of the decision making process, quality of life and futility issues by experts, such as Drs. John Spertus, Kathleen Grady, Suzanne Arnold, and Joseph Rogers were given in Session VII, *More than Survival*.

Andrew Althouse, PhD, Suzanne Arnold, MD, Kathleen Grady, PhD, RN, MS, FAAN, Colleen McIlvennan, DNP, ANP, John Spertus, MD, MPH, Amrut Ambardekar, MD

The day culminated with closing remarks in Session VIII, *Celebrating a Decade of Progress*, by Dr. Marissa Miller (NHLBI) and Dr. James Young (Intermacs Chair).

Marissa Miller, DVM, MPH, DACVPM, James B. Young, MD

The 10th Annual Meeting Program Chair, Dr. Frank Pagani, and the Intermacs leadership wish to thank all the speakers and moderators for their contributions in making this year’s annual meeting a huge success! Please take an opportunity to view the Intermacs website for slide presentations and reporting product instructions and tutorials.

Presentations: [http://www.uab.edu/medicine/intermacs/past-intermacs-meetings/2016-annual-meeting](http://www.uab.edu/medicine/intermacs/past-intermacs-meetings/2016-annual-meeting)

Product tutorials: [http://www.uab.edu/medicine/intermacs/reports](http://www.uab.edu/medicine/intermacs/reports)
Statistical Reports Update

We are happy to announce several new features to the Intermacs Statistical Reports. Below are examples of the new features which are currently available in the reports being distributed in April:

New Example Reports

Example Quarterly Data Quality and Quality Assurance Site Reports are available on the statistical reports website (www.intermacs.org/reports/statistical-reports). These examples should be especially helpful to new sites who want to get an idea of the materials that are provided in the reports.

Confidence Intervals added to all Survival Tables

Confidence intervals have been added to the survival tables presented with every Kaplan-Meier. These confidence intervals depict the uncertainty in the specific estimates at various time points and will facilitate comparing information.

New Exhibit Comparing Outcomes after Device Exchange

We have included a new exhibit in the Intermacs Federal Partners Report to compare patient outcomes based on the number of device exchanges. This report is available for download at www.intermacs.org/reports/statistical-reports.

Below is an example of Kaplan-Meier Survival for Intermacs Overall Implants: June 23, 2006 to December 31, 2015

<table>
<thead>
<tr>
<th>Months after Device Implant</th>
<th>Intermacs Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>94.1% (93.9% - 94.3%)</td>
</tr>
<tr>
<td>3</td>
<td>89.2% (89.0% - 89.5%)</td>
</tr>
<tr>
<td>6</td>
<td>85.2% (84.9% - 85.5%)</td>
</tr>
<tr>
<td>12</td>
<td>78.9% (78.5% - 79.2%)</td>
</tr>
<tr>
<td>24</td>
<td>67.9% (67.4% - 68.3%)</td>
</tr>
<tr>
<td>36</td>
<td>57.8% (57.2% - 58.4%)</td>
</tr>
<tr>
<td>48</td>
<td>48.2% (47.4% - 48.9%)</td>
</tr>
</tbody>
</table>

Pedimacs

Pedimacs is pleased to announce 2 abstracts will be presented at ISHLT (see Research, page 6), and 3 manuscripts have been accepted for publication in the Journal of Heart and Lung Transplantation.

Outcomes of children implanted with ventricular assist devices in the United States: First analysis of the Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs)
ED Blume, DN Rosenthal, JW Rossano, JT Baldwin, P Eghtesady, D Morales, RS Cantor, J Conway, CS Almond, DC Naftel, JK Kirklin for the Pedimacs Investigators
The Journal of Heart and Lung Transplantation, Published online: February 10, 2016
Research

Research efforts this spring have focused on abstract presentations, and manuscript submissions, for the International Society of Heart and Lung Transplantation (ISHLT) 36th Annual Meeting and Scientific Sessions in Washington, DC, April 27-30, 2016. Intermacs and Pedimacs will be represented well during the sessions and hope everyone will take an opportunity to attend these presentations. A list of the Intermacs and Pedimacs presentations is provided below. Please refer to the ISHLT Program, (http://ishlt.org/meetings/annualMeeting.asp), for additional information.

**Wednesday, April 27, 2016**

**New Definition, Same Old Problem: Characterizing the Condition of Right Heart Failure in Intermacs**
Teuteberg, Kormos, Pagani, Kiernan, Naftel, Myers, Pamboukian, Kirklin

**Thursday, April 28, 2016**

**LVAD Explantation for Cardiac Recovery: Insights from the Interagency Registry for Mechanically Assisted Circulatory Support**
Wever-Pinzon, Drakos, McKellar, Koliopouloum Stehlik, Selzman

**Utilization and Outcomes of Temporary Ventricular Assist Devices in Children: A Report from the Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs)**
Lorts, Davies, Alejos, Kanter, Gossett, Cantor, Adachi

**Infectious Complications of Ventricular Assist Device Use in Children in the US: Data from the Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs)**
Auerbach, Richmond, Schumacher, Lopez-Colon, Mitchell, Turrentine, Cantor, Niebler, Eghtesady

**Stroke with Continuous-Flow LVADS**
Acharya, Morgan, Pamboukian, Loyaga-Rendon, Kirklin, Holman, Tallaj
Implant Strategy is Related to Health-Related Quality of Life at 2 Years After LVAD Implantation: An Intermacs Analysis
Grady, Fazeli, White-Williams, Myers, Pamboukian, Naftel, Kirklin

Insights from Intermacs into Patient Characteristics Leading to Futility in LVAD Therapy
Kormos, Pagani, Althouse, Stevenson, Teuteberg, Young, Kirklin

HRQOL Improves from Before to 2 years After MCS. Regardless of Implant Strategy: Analyses from Intermacs
White-Williams, Fazeli-Wheeler, Myers, Kirklin, Pamboukian, Naftel, Grady

Friday, April 29, 2016

Risk Factors Associated with Right Ventricular Assist Device Implantation: Insights from Intermacs
Kiernan, DeNofrio, Pham, Kapur, Ruthazer, Rame, Alturi, Birati, Myers, Oliveira, Kirklin, Kormos, Pagani, Teuteberg

Early Results of Biventricular Support with Durable, Intracorporeal Continuous Flow Centrifugal Ventricular Assist Devices: Analysis from Intermacs
Arabia, Milano, Mahr, McGee, Maltais, Boyce, Pretorius, Civitello, Mallidi, Mokadam, Rame, Naftel, Myers, Kirklin

Total Artificial Heart (TAH): Survival Outcomes, Risk Factors, Adverse events in Intermacs
Arabia, Gregoric, Kasirajan, Moriguchi, Naftel, Myers, Kirklin

Evidence of Mild Hepatic Dysfunction Identifies Patients Most Likely to Experience Improvement in Renal Function Following Mechanical Circulatory Support
Brisco, Zile, Tang, Testani

Saturday, April 30, 2016

Utilization and Outcomes of Ventricular Assist Device Support in Adult Congenital Heart Disease: An Analysis of the Interagency Registry form Mechanically Assisted Circulatory Support (Intermacs)
VanderPluym, Eghtesady, Maxwell, Gelow, Burchill, Maltais, Cantor, Blume

Clinical Affairs FAQ

What Do I Do?

“How do I enter the new combination medication Entresto (sacubitril/valsartan) in Intermacs?”
Select both Ace Inhibitor and Angiotensin receptor blocker in the medication section.

The Explant Form can now more accurately capture the reason for explantation and apply the endpoints as they relate to the Intermacs protocol. Please see the following description of the explant reasons:
1. End Point Reasons

- **Transplant**

- **Death**: Complete the Death Form. (Complete the explant form first if the device was explanted prior to death.)

- **Explant**: No Re-Implant (This option is chosen when a device is explanted and there is not another device re-implanted. For Example, Ventricular Recovery.) 1 year follow-up for death or transplant is required

- **Turned Off**: No Re-Implant (This option would be chosen if the device is not removed but turned off and another device was not implanted) 1 year follow-up for death or transplant is required

- **Device Removed** (or turned off) for reasons other than recovery, transplant or death—specify other reason. (This option would be chosen if an FDA approved device is exchanged for FDA Clinical Trial Device.) Please answer ‘Yes’ to the Exchanged device in an FDA IDE trial independent question on the explant form. 1 year follow-up for death or transplant is NOT required

2. RE-IMPLANT: Non-Endpoint Reasons (a subsequent device should theoretically occur)

Re-Implant: (The device was explanted and another device was re-implanted). Please choose from the following explant reasons:

- **Device Malfunction** (Elective or Emergent)

- **Device Thrombosis** (Elective or Emergent) If Pump Thrombosis is chosen, then answer ‘Yes’ if the pump had evidence of a pump thrombosis’ independent question on the explant form.

- **Infection** (Elective or Emergent)