Greetings from Intermacs,

I am often asked to speak about Intermacs data analyses and research. Though research and data analyses are frequently the focus of Intermacs interest, I would like to take this opportunity to highlight one of the most useful tools within the Intermacs registry, the Intermacs Quarterly Site Report. This is a center specific report containing information based on data entered into the Intermacs web-based data entry application by center administrators. There are almost 50 exhibits within the report comparing your site’s performance with the performance of the entire Intermacs registry. Benchmarking and quality assurance have become key components to hospital procedure and the Intermacs Quarterly Site Report has been designed to provide an accurate and succinct presentation of your center’s MCS experience. Many of our member institutions have begun incorporating these reports into their protocols for dealing with Joint Commission and other regulatory organizations. We strongly encourage physicians, coordinators and investigators to examine and scrutinize these quarterly reports. Let us know what information is helpful and also what data you would like included. These reports have evolved over the life of the registry and will continue to do so with more feedback from you.

Kind regards,

James K. Kirklin

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10th Annual Meeting

Celebrating a Decade of Progress

Omni Atlanta Hotel at CNN Center
100 CNN Center, Atlanta, GA 30303

Friday, March 11, 2016

*Moderated Poster Session: 4:30 pm – 5:30 pm
Dinner 5:30 pm – 6:30 pm
Annual Meeting 6:30 pm – 8:30 pm

Saturday, March 12, 2016

Annual Meeting 7:30 am – 3:40 pm

Presenting authors will have meeting registration fee waived and receive $500 travel expense reimbursement (requires delivery of travel expense receipts)

*Moderated Poster Session: General Topic Categories

- Internal Quality Improvement
- Joint Commission / DNV
- Case Studies
- Clinical Influence (how does Intermacs/Pedimacs data influence a clinical visit)
- Scientifically Relevant Information

Coordinators and VAD/HF Physician Trainees are invited to submit a poster for presentation at the 10th Annual Meeting. Posters should summarize how sites utilize registry data. Submissions will be selected for presentation based on scoring by the Intermacs leadership and decisions will be returned to authors by February 1, 2016.
Regulatory Reminders

It is time for Intermacs to obtain annual Financial Disclosure and Conflict of Interest forms for all team members. Forms will be distributed to the Site Administrators in January and must be returned by February 29, 2016 in order remain active.

Transfer Process

Intermacs began tracking patients transferred from one Intermacs participating center to another in 2011. Since that time, the Intermacs Data Collection and Coordinating Center (DCC) has completed 248 transfers. Below is the process for managing transferred patients.

The transferring center must:
- Complete all outstanding data collection forms
- Complete the Add Patient Transfer form in the web based data entry system indicating the patient is no longer in their care

The receiving center must:
- Provide proper documentation to the Intermacs DCC

Due to the potential exchange of Protected Health Information (name, date of birth, etc.), all correspondence must be made using a secure method. Contact the DCC (intermacs@uab.edu, jeanne07@uab.edu), for access to the Intermacs secure e-mail (NeoCertified) and additional guidance.

The DCC staff will:
- Verify all data has been entered at the transferring center
- Verify the receiving center has completed the transfer documentation
- Program the switch from the transferring center to the receiving center
- Notify the receiving center that the transfer is complete

Quarterly Reports

Intermacs strives to continually update the site specific quarterly reports based on feedback received from participating centers. In the latest issue of the quarterly report, you will find several new exhibits for scored quality of life measure and bleeding adverse event rates by source. Below are examples of the new features provided in the site specific reports.

Scored Quality of Life Measurement Example (Intermacs Overall)

<table>
<thead>
<tr>
<th>Not Done: Other/Unk</th>
<th>Not Done: Too Sick</th>
<th>Complete</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>8823</td>
<td>57.6</td>
<td>1535</td>
<td>10.0</td>
</tr>
</tbody>
</table>

Bleeding by Source Example (Intermacs Overall)

<table>
<thead>
<tr>
<th></th>
<th>Early (During the First 3 Months)</th>
<th>Late (After the First 3 Months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Episodes</td>
<td>Rate (Per 100 pt. Months)</td>
</tr>
<tr>
<td>Device Anastomosis</td>
<td>31</td>
<td>0.08</td>
</tr>
<tr>
<td>ENT / Dental</td>
<td>212</td>
<td>0.56</td>
</tr>
<tr>
<td>Gl: Lower</td>
<td>983</td>
<td>2.59</td>
</tr>
<tr>
<td>Gl: Upper</td>
<td>1415</td>
<td>3.73</td>
</tr>
</tbody>
</table>

Quarterly Reports 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>
- New Feature -

Web Based Reporting

Intermacs is dedicated to providing participating centers the most benefit from their registry participation. Several mechanisms are available for centers to access their own “raw” data and periodic statistical reports. We are happy to announce that a new feature, Web Based Reporting, is now live! Participating centers can download all of the data they have entered into the system in a Microsoft Excel format directly from the Web Based Data Entry system. More details can be found at www.intermacs.org/reports.

This spring a second phase, incorporating instantaneous data quality reports and other patient and event listings, will also be available. We will be hosting a demonstration of the system options at the 10th Annual Meeting and Scientific Session in March 2016. Hope to see you there!

- New Feature -

Pedimacs Research Datasets

Pedimacs research datasets are now available to all active centers. Datasets from the previous quarter will be uploaded alongside the quarterly reports and will be available for download from the web based data entry system for a period of 90 days. Zip files containing these datasets are encrypted and can only be accessed by the site administrator. If problems occur downloading or extracting the files, contact either Jennifer Gunther (jgunther@uab.edu) or Maceo Cleggett (mclegg@uab.edu).

Pedimacs

The Pedimacs Data Access, Analysis and Publications Committee (DAAP) is responsible for issues of access to registry data for proposed research, review of publications and proposed analyses, and prioritization of such activities based upon available resources. To date, there have been 3 submitted manuscripts (36 authors from 14 institutions), as well as 2 submitted abstracts for the upcoming International Society of Heart and Lung Transplantation (ISHLT) Annual Meeting and Scientific Sessions.

Please note that you can either submit a request for data or a request for analysis.

The submission process is described in detail at the Pedimacs website: http://www.uab.edu/medicine/intermacs/research-proposals/pedimacs-research-proposals

Co-Chairs
Frank Pagani, MD David Rosenthal, MD

Members
James Kirklin, MD Christina VanderPluym, MD
Jeffrey Gossett, MD Sabrina Law, MD
David Morales, MD Aamir Jeewa, MD
Jake Jaquiss, MD

Continued
The DAAP committee conducts reviews of all proposals. Generally, a response to a proposal is provided within 4 weeks. Proposals for datasets are accepted on a rolling basis. If you wish to submit a data analysis request, there are 2 yearly cycles, timed to the abstract deadlines for the ISHLT and for the American Heart Association (AHA) Scientific Sessions.

**Deadline for proposals:**
- **AHA**: Submitted by 01/05/2016
- **ISHLT**: Submitted by 06/01 2016

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### Research

Twelve abstracts were accepted for presentation at the 2016 ISHLT Annual Meeting and Scientific Session. Half of the abstracts were performed by researchers using de-identified datasets while the remaining six were performed by the Intermacs Data Coordinating Center.

### Recent Publications

**Seventh INTERMACS Annual Report: 15,000 Patients and Counting**
Kirklin JK, Naftel DC, Pagani FD, Kormos RL, Stevenson LW, Blume ED, Myers SL, Miller MA, Baldwin JT, Young JB

**Variation of Quality of Life Data Collection Across INTERMACS Sites**
Gupta BP, Grady KL, Fendler T, Jones PG, Spertus JA.

**INTERMACS Profiles and Modifiers: Heterogeneity of Patient Classification and the Impact of Modifiers on Predicting Patient Outcome**

**Current Risks of Heartmate II Pump Thrombosis: Non-parametric Analysis of Interagency Registry for Mechanically Assisted Circulatory Support Data**
Smedira NG, Blackstone EH, Ehrlinger J, Thuita L, Pierce CD, Moazami N, Starling RC
J Heart Lung Transplant. 2015 Dec;34(12):1527-34.

**Pump Thrombosis in the Thoratec Heartmate II Device: An Update Analysis of the INTERMACS Registry**
Kirklin JK, Naftel DC, Pagani FD, Kormos RL, Myers S, Acker MA, Rogers J, Slaughter MS, Stevenson LW

**What is the Truth behind Pump Thrombosis in the Heartmate II Device? A National Heart, Lung, and Blood Institute Perspective Based on Data From the Interagency Registry for Mechanically Assisted Circulatory Support**
Jeffries N, Miller MA, Taddei-Peters WC, Burke C, Baldwin JT, Young JB.

[www.uab.edu/medicine/intermacs/existing-research/intermacs-existing-research/intermacs-publications](www.uab.edu/medicine/intermacs/existing-research/intermacs-existing-research/intermacs-publications)
Clinical Affairs FAQ

The Clinical Affairs team is available to assist with data collection and data entry questions.

What Do I Do?

We frequently receive questions about infections. The most frequently one asked is, how do I enter an ongoing infection? The Intermacs Nurse Monitors have provided tips regarding different infection scenarios.

Pre-implant infections:
If an infection was present pre-implant, it will not be counted as an infection adverse event unless the infection was treated and cleared and then recurs at a later time after implant.

Colonization:
If a patient is colonized as identified by screening cultures (ex. VRE, MRSA screenings, asymptomatic bacteruria), but is asymptomatic and is not being treated for the infection, do not count it as an infection adverse event.

Multiple organisms:
If multiple organisms are identified on cultures from different sources all within the same 1-2 days and is the same type of organism (ex. All are different types of bacteria), this may be counted as one bacterial infection. For the location of infection, select all the locations that apply.

However, if there are different types of infection identified (ex. One bacterial and one fungal), a separate infection for each type will need to be entered. You should select all locations that were positive for the fungal culture as one infection and all sites with a positive bacterial cultural as the other infection.

Ongoing infections:
If there is an ongoing infection in the same location with the same type of bacteria, enter the infection when it is first identified along with what type of treatment.

If the intervention documented when the first infection is entered changes (ex. Go from oral or topical to IV antibiotics or surgery is needed), then enter another infection adverse event to document the change in intervention.

Once the change in intervention is documented, there is no need to enter the infection again unless the infection is treated and cleared and then reoccurs.

If multiple debridements are needed and the infection has already been entered with surgery as an intervention, there is no need to enter a new adverse event for each debridement.

Can you have an infection adverse event without any positive cultures?
Yes, but only if the clinical evidence is strong enough. If the patient is having fevers, has a productive cough, chest consolidations on imaging, and is being treated for pneumonia (as noted in progress notes or I.D. consult notes) even if cultures have been unrevealing, then the clinical evidence would be strong enough for an infection: pulmonary adverse event.