



SUPPORTING HEARTS THROUGH KNOWLEDGE

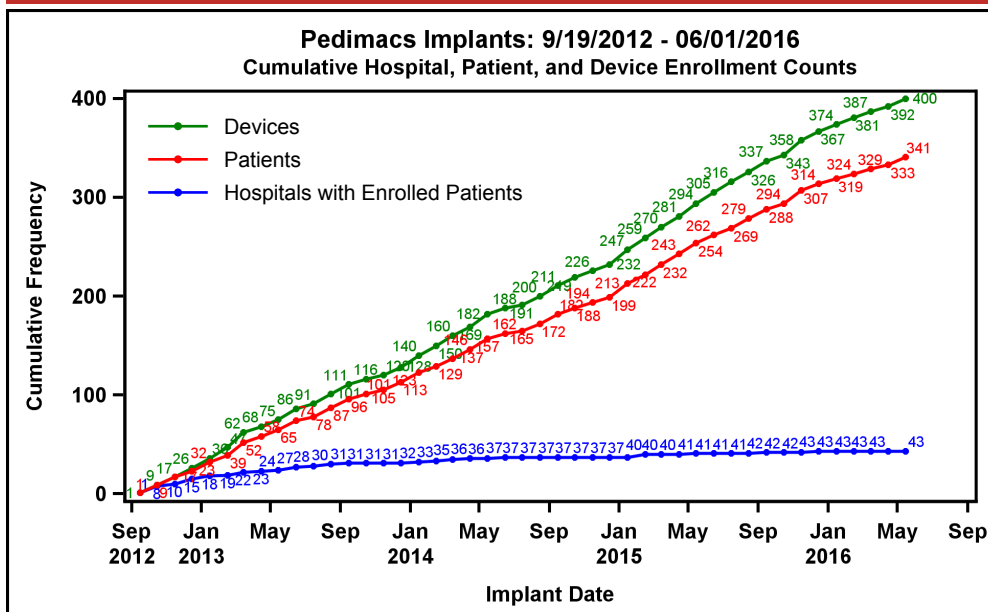
A message from Intermacs Principal Investigator

Greetings from Intermacs,

Of the many challenges faced in the field of mechanical circulatory support, one of the most pressing is the management of pediatric patients in need of temporary and/or durable device assistance. Seemingly, the most obvious obstacle to overcome is pediatric patient size. Engineers and clinicians have worked diligently over the past few years to develop smaller devices, reducing the amount of pericardial space needed for implantation. However, be reminded that the pediatric patient population includes not only neonates and infants, but teenagers too. These diverse physiologies require varied device and pharmacological management therapies when compared to each other, as well as adults. Needless to say, the complicated questions involved with pediatric VAD support are many. With these difficulties in mind I am pleased to report that the pediatric arm of Intermacs, the Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs), has recently published its first three manuscripts. A devoted group of investigators from several centers have analyzed Pedimacs registry data and focused their initial findings in the areas of outcomes and adverse events. Please find citations for these papers in the Pedimacs section of this newsletter. I would also like to encourage any investigator interested in pursuing research within the domain of pediatric MCS to visit the Research section of the Intermacs website for information on how to submit a study proposal. As of this writing 381 patients have been entered into the Pedimacs registry. This is truly an exciting time as we begin to query the many variables in Pedimacs to better understand this under-evaluated group of patients and to develop more useful management strategies.

Kind regards,
James K. Kirklin

Pedimacs Updates



- MILESTONE -

400 devices entered into Pedimacs!



With 341 patients less than 19 years old entered into Pedimacs from 43 hospitals as of June 2016, the Pedimacs registry has reached a milestone of 400 device implants. This represents a combined effort of many coordinators, Principal Investigators and research assistants at each hospital, physician leadership of Pedimacs and the extensive resources of the Data and Clinical Coordinating Center (DCC) at UAB. This large effort, supported by NHLBI represents a unique effort bridging heart failure cardiologists and pediatric VAD surgeons across the nation in a robust longitudinal database for mechanical support. Continued support at the individual institutions has been enormous.

Pedimacs Research Report:

With the publication of the first annual report as well as the first two manuscripts (adverse events and continuous flow pump outcomes), the Data Access, Analysis, and Publications Committee (DAAP) continues to evaluate new projects. Two Pedimacs abstracts were presented at 2016 ISHLT oral sessions, including Scott Auerbach (Denver) on the infectious complications following implant and Angie Lorts (Cincinnati) on the outcomes of the temporary device implants. Dr. Friedland-Little's (Seattle) project on changes in renal function following implantation was chosen for submission to the AHA 2016.

Linkage Studies:

The Executive committee and DAAP have been working with the [Pediatric Heart Transplant Study \(PHTS\)](#) to finalize the project that will begin with a single merger of PHTS and Pedimacs. This will allow for patients to be followed through transplant. There were three excellent proposals submitted to the PHTS call for applications. A joint process between PHTS and Pedimacs is reviewing applications.

Joe Rossano is leading an effort to merge a one-time Pedimacs dataset with the Public Health Information System (PHIS) in order to review the cost analysis of hospital charges for the VAD implant hospitalization.

We look forward to continuing to use Pedimacs in novel ways to gain more knowledge about this highly technologic procedure.

Upcoming Pedimacs Meetings

The Pedimacs DCC and Executive Committee will be available at booths and will be participating at sessions/gatherings at the following meetings. Keep an eye out for further details.

Everyone is welcome to attend!

International Pediatric VAD Summit 2016

Boston, Massachusetts
October 20 - 21, 2016

Pedimacs Meeting at AHA

New Orleans, Louisiana
November 13, 2016

Intermacs/Pedimacs Annual Meeting

Atlanta, Georgia
March 3 - 4, 2017



Protocol 5.0

Intermacs is excited to announce the release of the new Protocol, Version 5.0. Distribution of Protocol 5.0 and its associated documents began on August 5, 2016 and was sent to all participating and enrolling centers. The new documents can also be found on the opening page of the Intermacs website at www.intermacs.org.

Below are several important facts to keep in mind about the use of Protocol 5.0:

- Use of Protocol 5.0 will begin on Monday, October 17, 2016. Centers should continue to use Protocol 4.0 until October 17th.
- Centers requiring Institutional Review Board/Ethics Board (IRB/EB) review must provide documentation of Protocol 5.0 approval prior to October 17th in order to access the web based data entry system.
- Centers that are exempt from IRB/EB review must provide documentation/confirmation of exemption status prior to October 17th in order to access the web based data entry system.
- The Protocol has been streamlined with separate sections for Intermacs and Pedimacs.
- Revised Adverse Event definitions are included.
- A list of new elements is included.
- The Intermacs and Pedimacs User's Guides have added clarifications.
- Explanations for the use of Patient Information Sheets is provided.

The [Intermacs Regulatory Team](#) is available to assist with any questions regarding Protocol 5.0.

Annual Meeting

Intermacs 11th Annual Meeting
March 3 - 4, 2017

Westin Peachtree Plaza
210 Peachtree Street NW
Atlanta, GA 30303

Details and Registration to Follow





Reports

New Reports

The Intermacs and Pedimacs quarterly reports that were distributed this summer contain two new features which are mentioned below. Site Administrators at active centers are able to provide the reports to site personnel.

Intermacs

In addition to the standard quarterly quality assurance report, Intermacs has added a new report limited to patients implanted since the beginning of the last complete calendar year (January 1, 2015). The “recent year” version includes patients implanted in the most recent calendar year and any patients implanted in the current calendar year (2016). This comparison using a contemporary cohort will facilitate tracking changes in patient population and outcomes at your site.

Pedimacs

Pedimacs has posted the new Pedimacs Federal Partners Report on the Intermacs website (www.intermacs.org/reports/public-statistical-reports). This report contains an overview of Pedimacs patient characteristics and outcomes for the entire registry.

COMING SOON

Intermacs is happy to announce two additions coming soon to the Web Based Data Entry system. Site Administrators from active centers that have an executed [licensing agreement](#) will have access to:

- 1) the **Cohort Comparison Reports**
- 2) the **Outcome Analytics**

The **Cohort Comparison Reports** include selection of a single cohort from your center, comparison of subgroups (ex. male and female) at your center, or comparison of a cohort vs. an equivalent Intermacs cohort. Each Cohort Comparison Report will have bar charts and frequencies to allow centers to explore patient characteristics from several key items.

In an effort to provide centers with outcome analytic measures on a selected cohort, Intermacs has developed the **Outcome Analytic reports**. The structure is similar to the Cohort Comparison Report, yet the user will be able to generate Kaplan-Meier survival from their selected cohort.



Research

The last several months have been fruitful for InterMacS and PediMacS with several manuscripts reaching publication. Below is a list of manuscripts that have been published since the last newsletter (Spring 2016). Please take an opportunity to review the articles.

1) *Ventricular Assist Device in Acute Myocardial Infarction*

Acharya D, Loyaga-Rendon RY, Pamboukian SV, Tallaj JA, Holman WL, Cantor RS, Naftel DC, Kirklin JK.
J. Am. Coll. Cardiol. 2016 Apr 26;67(16):1871-80.

2) *Outcomes of pediatric patients supported with continuous-flow ventricular assist devices: A report from the Pediatric Interagency Registry for Mechanical Circulatory Support (PediMACS)*

Rossano JW, Lorts A, VanderPluym CJ, Jeewa A, Guleserian KJ, Bleiweis MS, Reinhartz O, Blume ED, Rosenthal DN, Naftel DC, Cantor RS, Kirklin JK.
J Heart Lung Transplant. May 2016 2016 May;35(5):585-90.

3) *A Bayesian Model to Predict Right Ventricular Failure Following Left Ventricular Assist Device Therapy*

Loghmanpour NA, Kormos RL, Kanwar MK, Teuteberg JJ, Murali S, Antaki JF.
JACC Heart Fail. 2016 May 26. [Epub ahead of print]

4) *Myocardial Recovery in Patients Receiving Contemporary Left Ventricular Assist Devices: Results from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)*

Topkara VK, Garan AR, Fine B, Godier-Furnémont AF, Breskin A, Cagliostro B, Yuzefpolskaya M, Takeda K, Takayama H, Mancini DM, Naka Y, Colombo PC
Circ Heart Fail. 2016 Jul;9(7).

5) *Myocardial Recovery in Patients Receiving Contemporary Left Ventricular Assist Devices: Results From the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)*

Topkara VK, Garan AR, Fine B, Godier-Furnémont AF, Breskin A, Cagliostro B, Yuzefpolskaya M, Takeda K, Takayama H, Mancini DM, Naka Y, Colombo PC.
Circ Heart Fail. 2016; Jul;9(7).

6) *Frequency of Poor Outcome (Death or Poor Quality of Life) After Left Ventricular Assist Device for Destination Therapy Results From the INTERMACS Registry*

Arnold SV, Jones PG, Allen LA, Cohen DJ, Fendler TJ, Holtz JE, Aggarwal S, Spertus
Circ Heart Fail. 2016; Aug;9(8).



Intermacs and Pedimacs data are available to researchers through a process overseen by the Data Access, Analysis and Publications Committees (DAAP). Request forms for the two available options, analysis by the DCC or request for de-identified datasets, can be found on the InterMac website.

[InterMac request](#)

[Pedimacs request](#)

In order to provide ample time for proposal review and/or analysis, we ask that proposals be submitted 4 or 5 months prior to scheduled deadlines. Please see the examples below from the Pedimacs DAAP Committee.

Spring Research Proposal Submission Deadline: May 31st

(Example: ISHLT abstracts)

Winter Research Proposal Submission Deadline: December 31st

(Example: AHA abstracts)

Clinical Affairs FAQ

What Do I Do?

“How do I enter an explant or death if it occurs during the implant hospitalization?”

If the patient is explanted for transplant, recovery, device exchange, or the device is turned off during the implant hospitalization, an explant form must be completed in addition to the implant discharge form. Please remember that the implant discharge and explant forms are not connected.

Likewise, if a patient dies during the implant hospitalization, a death form must be entered in addition to the implant discharge form. The death and implant discharge forms are not connected.

Data Integrity Checks

Clinical Affairs is performing data integrity checks. Your center may be contacted about missing, inconsistent, or improbable data identified throughout InterMac and Pedimacs. Your prompt attention in verifying or correction this data is crucial to ensuring high quality InterMac and Pedimacs data.