

iPHFR Steering Committee Minutes
Thursday April 6, 2017 @ 12:30-1:30 PM
Old Town B, Manchester Grand Hyatt

Present: AD, RK, WZ, WC, EP, EA, HN, CA, SA, jw
Regrets: RG, YL, AL, CV

Guests: Josef Stehlik (ISHLT R&D committee), Ryan Butts (PHFG Chair), many other non-steering committee attendees (interested centres)

1. Welcome

- a. AD welcomed Steering Committee members and the multiple other interested parties that attended the meeting and expressed interest in the registry (approx 20 non-committee members).

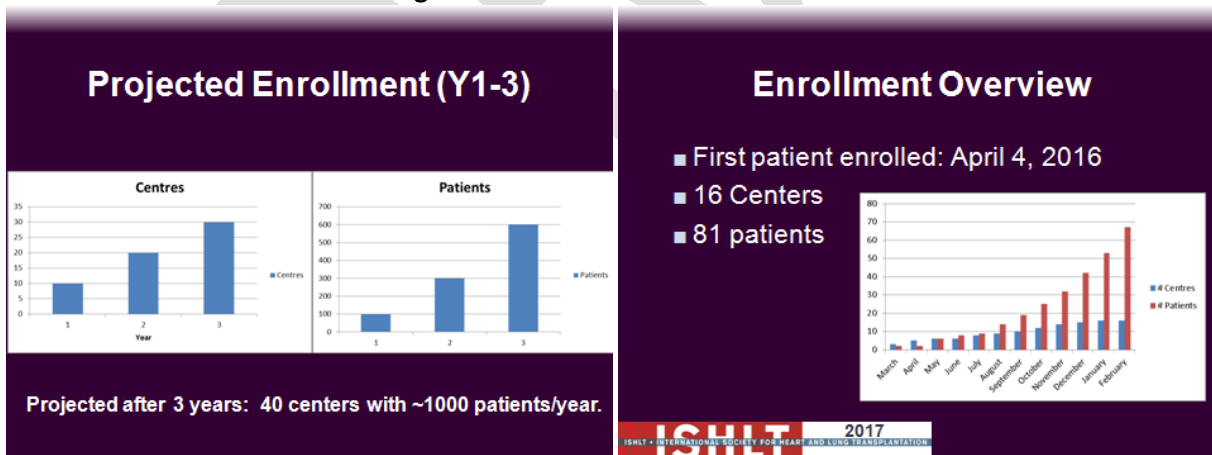
2. Review of Goals of the Registry & Directives from the Board

- a. **Reviewed Goals of the Registry:** To collect and analyze clinically relevant data on pediatric heart failure patients in order to better understand the natural history and response to current and future disease treatment regimes
- b. **Reviewed Directives from the Board:**
 - i. *The iPHFR Steering Committee will be required to provide annual reports to the Board. These should include updates on patient enrollment, on the iPHFR scientific productivity, the goals yet to be achieved, and any outstanding scientific questions that remain to be answered.*
 - ii. *The expectation is that, if this registry is to continue beyond 5 years, its functioning will become financially self-sustaining. At 3 years after registry initiation, the Board will ask that the iPHFR group start a transition to a participating center-funded registry. This point was discussed and emphasized. This needs to be discussed at a Steering Committee level over the next year.*

3. Review of Steering Committee Roles and Responsibilities (see below)

4. Center Enrollment

- a. **Reviewed enrollment goals and current status**



Enrollment is below target. Challenges were discussed – the biggest one being time and manpower for data entry. People present shared some of the strategies that their centres were using for data entry. Strategies to encourage enrollment discussed though it became apparent that there are a number of centres in the process of joining or who expressed interest in joining. AD to consolidate the existing “interest” lists and the list of centres that originally expressed interest for the Steering Committee members to divide up and approach individually.

5. Data and Analyses

- a. **ISHLT slide set review and discussion:** reviewed the first slide set produced by UNOS and feedback sought. Slide set will be finalized and posted on the ISHLT website.
- b. **Other**
 - i. Discussed IMPORT-EXPORT functionality of the database using Excel but not optimal as per UNOS. OPTN has worked with EPIC and individual centres in the past to customize reports directly from EPIC – Wida to inquire further with UNOS IT and feedback information to the Steering Committee although would likely require individual institutions working with EPIC to build a report with specifications from OPTN.
 - ii. Discussed the need for a regular and timely reminder to enter annual follow up forms like the Transplant Registry. Wida took note of this and will check to ensure that this feature has been enabled in the registry as previously discussed.

6. Standard Operating Procedures (SOPs)

- a. **First project / analysis plan:** Discussed timing as ideally would like some annual follow up forms and a great number of patients BUT need some productivity prior to the 3 year mark from a deliverable perspective. 2018 would be the earliest it will be feasible. Will be a Steering Committee project.
- b. **Data requests (*see form below*):** Reaffirmed that the registry will adhere to the ISHLT processes and procedures for data requests, data analysis, authorship, limited data sets, and young investigator award competitions. When the registry will be opened for data requests will be determined by the Steering Committee once we see how enrollment and patient entry proceeds.
- c. **Centre-specific reports:** Discussed the initial plan for centre-specific reports. Concept felt to be beneficial and desirable by the centres in attendance. Will need to discuss with UNOS the scope and time required to prepare and disseminate these. In the meantime, infrastructure exists within the Transplant registry database for centres to see their centre data and compare it with registry data – this is updated quarterly. Wida is going to explore the possibility of this extending to iPHFR and costs/time associated with this in the future.
- d. **Website content:** Group reminded that the website has been updated and has a wealth of helpful information about the registry. If anyone wants to see anything else on the website contact AD.

7. Steering Committee Member Terms: *Deferred to next Steering Committee TCON*

- a. *Selection of new SC members*
- b. *Succession planning moving forward*

8. Other Business

- a. **Education sessions for new centres:** Brought up as an idea to support new centres joining. AD to follow up.

9. Next Tcon

- a. **June 2017 – date and time TBD**

Steering Committee Roles and Responsibilities

PERSONAL QUALIFICATIONS

- Be an ISHLT member
- Be willing and able to make a time commitment for up to 3 years
- Have a background in pediatric cardiac care
- Enjoy and have skills in the administrative, as well as the academic aspects of the position
- Desire to be responsive to the ISHLT members
- Be thorough and have excellent follow-through on all pending matters
- Be committed to the establishment and growth of the iPHFR
- Be committed to maintaining full communications and a positive working relationship with the iPHFR Chair, the ISHLT staff, and the staff of the Registry database contractor (UNOS)
- **Be employed at an institution that is actively submitting, or in the process of securing approval to submit, data to the iPHFR**

JOB RESPONSIBILITIES

- The overall duties of the Steering Committee Chair include maintaining the scientific integrity of the Registry, working within the budget as set by the Board of Directors, and achieving the goals and objectives set for the Registry
- The Chair will lead the Steering Committee in:
 - **Overseeing the implementation of the registry and monitoring its ongoing progress, participation rates, and cost-benefit ratio**
 - Ensuring that the deliverables charged by the Board are met on a timely basis
 - Conducting regular evaluations regarding the need to continue to operate the registry
 - Identifying and revising, as needed, data collection fields and definitions that facilitate the collection of appropriate information
 - Interfacing with governmental agencies, international transplant networks, and individual centers to encourage their submission of data to the Registry and to enhance compliance with data submission
 - Reviewing abstracts and manuscripts generated with the use of Registry data prior to the submission for peer review/publication
 - Reviewing results of data collection and producing regular Annual Data Reports
 - Authorizing, reviewing, and approving the requests for access to the data for scientific studies
 - Overseeing compliance with data use agreements
 - Achieving the goals and objectives established annually by the Board for the Registry
 - Initiating and facilitating data analysis projects

ISHLT Data Analysis Request Form

All requests for data and/or analysis from the ISHLT heart and Lung Transplant Registry must be submitted using the **ISHLT Data/Analysis Request Form**. ISHLT staff evaluate the request and code it according to one of the below levels.

Level 1 requests are simple requests asking for explanation or additional detail about data in Registry reports or requests involving one hour of time. Individuals submitting Level 1 requests are NOT required to be ISHLT members. Priority of response is given first to Society members, second to non-members who need the information in the treatment of a patient, third to all others. Level 1 requests will be answered on an as received basis within 3 weeks.

Level 2 requests are those requests involving 1 - 5 hours of time. Level 2 requests will be fulfilled only for members of the Society who are working at a center which is actively reporting data to the Registry. Level 2 requests will be forwarded to the appropriate Registry Executive Committee member for approval. If approved, Level 2 requests will be answered within 4-6 weeks.

Level 3 are those requests involving 5 hours of time. Level 3 requests will be fulfilled only for members of the Society who are working at a center which is actively reporting data to the Registry. Level 3 requests will automatically be placed on the agenda for the next Registry Executive Committee Conference Call for approval. A Registry Executive Committee member will be assigned to consult on each such approved project. For extensive projects, the Registry Executive Committee may choose to recommend that the requestor complete a formal ISHLT Grant application and submit the proposal by the February 15 deadline. The deadlines for submitting Level 3 requests are as follows: January 31, May 31, Sept 30.

Individuals requesting any level of data must sign a statement that presentation or publication of this information will be accompanied by acknowledgment of the ISHLT/UNOS International Heart and Lung Transplant Registry as the source of the data.

Individuals receiving Level 2 and 3 data will be required to sign an agreement that any written or verbal presentations resulting from the data must be submitted to ISHLT for prior approval. Any publications or abstracts must list the ISHLT/UNOS International Heart and Lung Transplant Registry as a contributing institution and must list at least one Registry Executive Committee member and at least one UNOS staff member as co-authors. The ISHLT Annual Meeting Program Committee and the Journal of Heart and Lung Transplantation have the right of first refusal for abstracts and manuscripts, respectively, generated from Level 2 and 3 data requests.

Data/Analysis Request Form

To request only US data, please complete the form located at <http://www.optn.org> rather than this request form.

To request international data, please complete the following form. Most results can be provided within three weeks.

Your Information

First Name: *

Last Name: *

Institution Name: *

Address 1: *

Address 2:

City: *

State/Province: *

ZIP/Postal Code: *

Country: *

E-mail: *

Phone: *

Fax: *

Your Profession/Occupation: *

ISHLT Membership Status: *

Organ(s) for which data is requested: *

- Heart
- Lung
- Heart/Lung

Is data needed for the treatment of a specific individual? *

Please describe below that data/information you would like to receive and/or describe your project in detail: *

DRAFT