

**OPTN Heart Transplantation Committee
Primary Graft Dysfunction Subcommittee
Meeting Summary
February 22, 2021
Conference Call**

**Shelley Hall, MD, Chair
Richard Daly, MD, Vice Chair**

Introduction

The Primary Graft Dysfunction Subcommittee met via Citrix GoToMeeting teleconference on 02/22/2021 to discuss the following agenda items:

1. Review public comment and consider general themes to address in Data Collection proposal
2. Discuss timelines for both Request for Feedback and Data Collection proposal
3. Review responses associated with Data Element Standard of Review Checklist

The following is a summary of the Subcommittee's discussions.

1. Review public comment and consider general themes to address in Data Collection proposal

UNOS staff provided an overview of the request for feedback document currently out for public comment and gave a summary of the feedback received to date.

Summary of discussion:

The *Develop Measures for Primary Graft Dysfunction (PGD) in Hearts* request for feedback document has been presented during the region 3, 4, 5, 6, and 8 regional meetings as well as to the Transplant Coordinator, Transplant Administrator, and Data Advisory Committees. No comments have been received from any societies to date.

Comments received have been generally supportive of collecting PGD specific information although there is general concern about associated data burden. There have been no concerns raised about eliminating "Airway Dehiscence" from the Heart Transplant Recipient Registration (TRR) form.

There have been mixed responses for data collection at 24 hours post-transplant, with a preference for a timeframe longer than 24 hours.

Several additional data elements have been suggested:

- Re-listing for transplant
- Recipient on MCSD prior to transplant
- Predictive Heart Mass between recipient and donor
- Adding an "other" field to allow programs to report presence of non-HLA antibodies that may not be causative, but still associated with PGD
- Donor-related information
 - Time to stand still

- Donor down time
- Data on donor cause of death
- DCD-related data elements

The Chair commented that some of this information is already captured such as re-listing for transplant. She shared that most comments have been supportive and the concerns raised around burden and inotrope data are not surprising.

UNOS staff shared that the Data Advisory Committee (DAC) supports collecting data on the full population of recipients rather than a subset. Limiting the data to a self-identified group will produce diminished results. A member commented that collecting data on the full population will support identifying PGD.

Next steps:

UNOS staff will provide another public comment update at the next Heart Transplantation Committee meeting. Public comment closes on March 23.

2. Discuss timelines for both Request for Feedback and Data Collection proposal

UNOS staff provided upcoming project deadlines.

Summary of discussion:

Important upcoming dates include:

- 03/16 – Next public comment update to Committee
- 03/23 – Public comment closes
- 03/23 – PGD Subcommittee meeting
- 04/12 – Second DAC check-in
- 04/20 – Finalize summary of Request for Feedback for June Board of Directors (BOD) meeting
- 06/14 – OPTN BOD meeting
- 06/28 – Data collection proposal due to Policy and Community Relations (PCR) Director for public comment
- 07/14 – Proposal finalized and due to HRSA and Policy Oversight Committee (POC)
- 07/(TBD) – POC meeting
- 07/27 – Executive Committee meeting
- 08/03 – 09/30 – Public comment period
- 10/(TBD)– Finalize proposal language with Committee
- 10/22 – Data collection proposal due to PCR Director for BOD
- 12/06 – BOD meeting for approval of data collection proposal

The Chair commented that inotrope data collection and timing of data collection need further discussion in order to finalize the proposal.

3. Review responses associated with Data Element Standard of Review Checklist

Prior to the meeting, Subcommittee members were tasked with evaluating the proposed data elements using the Standard of Review Checklist. The Subcommittee reviewed their collaborative responses in a document included in the meeting materials. The data elements below were discussed.

Summary of discussion:

Left Ventricular (LV) Dysfunction (Yes or No) Data Element

A member commented that this LV dysfunction may need a definition such as 50% or more dysfunction. A member suggested refining this data element to read “clinically significant LV dysfunction.” The Chair commented that the PGD description on the form may help provide definition. A member suggested providing the International Society for Heart and Lung Transplantation (ISHLT) statement to help identify left heart and right heart dysfunction.

Members discussed whether objective measures should be collected that would identify LV dysfunction rather than collecting yes or no. The Chair commented that the purpose of this data element is to allow the program to self-identify whether their patient has LV dysfunction. Collecting multiple clinical data elements may be overwhelming. Descriptive information will be provided as guidance when completing the data collection.

The Chair clarified that the objective of completing the Data Element Standard of Review Checklist is to provide rationale and analysis to DAC for why the data should be collected and the final product will not be an externally facing document used by transplant coordinators. Educational material will be created at a later date.

The Chair referenced the evaluation of the data element “PGD (yes or no)” to provide an example and framework for the LV and Right Ventricular (RV) dysfunction data element evaluation.

A member commented that LV dysfunction is universally available. The Chair commented that this data would not be pulled directly from an electronic medical record when considering seamless data exchange.

Right Ventricular (RV) Dysfunction (Yes or No) Data Element

A member commented that the evaluation of the RV dysfunction data element will be largely similar to the LV dysfunction data element. He commented that determining reliability of the data is slightly more challenging since many transplants have a degree of RV dysfunction but do not rise to the level of needing additional support beyond inotropes. A member commented that this data element would be self-defined, there are no alternative data sources, and the data is very useable.

Left Ventricular Ejection Fraction (LVEF) (Percentage) Data Element

A member commented that LVEF is a determinant of LV failure, is relevant, and is intertwined with LV dysfunction. He reviewed the draft responses included in the evaluation document and noted that the OPTN definition will be used to define this element. The member commented that this data element is widely available and there are no other alternative data sources.

The Chair asked if using calculations from other existing data elements to create new data elements are considered new data collection and need to be justified. She gave the example of cardiac index which is

not being collected but will be calculated from the other proposed elements. UNOS staff will look into what is required in these cases.

A member emphasized the importance of referencing the ISHLT definitions when determining whether right and left ventricular dysfunction is present when reporting data on a recipient. This will increase the objectivity of the data.

Next steps:

The Chair requested the Subcommittee members review and update their responses as needed. The updated version will be circulated with the Subcommittee.

Upcoming Meeting

- March 23, 2021

Attendance

- **Subcommittee Members**
 - David Baran
 - Donna Mancini
 - Jondavid Menteer
 - Kelly Newlin
 - Shelley Hall
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
 - Monica Colvin
 - Yoon Son Ahn
- **UNOS Staff**
 - Eric Messick
 - Janis Rosenberg
 - Julia Chipko
 - Keighly Bradbrook
 - Leah Slife
 - Sara Rose Wells
 - Sarah Konigsburg
 - Susan Tlusty