

**OPTN Heart Transplantation Committee  
Primary Graft Dysfunction Subcommittee  
Meeting Summary  
October 14, 2020  
Conference Call**

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

## **Introduction**

The Primary Graft Dysfunction Subcommittee met via Citrix GoToMeeting teleconference on 10/14/2020 to discuss the following agenda items:

1. Organizing the Subcommittee's work
2. Project Discussion

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

### **1. Organizing the Subcommittee's work**

The Chair and UNOS staff shared the objective, composition, and timeline of deliverable for the PGD Subcommittee.

#### Summary of discussion:

The Chair shared that the Subcommittee was created to efficiently develop the draft project proposal which will be reviewed by the full Heart Committee. Members were chosen in order to have representation of both professions and regions.

The Chair noted that the Subcommittee is not developing a research trial or scientific document. The work produced is only to facilitate policy development or grow knowledge through policy. Deadlines will need to be met in order to have a proposal go out to public comment. The Chair proposed requesting initial feedback from the community at the upcoming January-March public comment and then submitting a final proposal for public comment during the next cycle in August-October.

### **2. Project Discussion**

The Subcommittee reviewed the project's background, problem statement, and other topics for consideration during the planning stage.

#### Summary of discussion:

UNOS staff reviewed the project's background and problem statement. PGD remains a leading cause of early mortality post-heart transplantation and there are concerns from as far back as 2014 that the prevalence of PGD may be increasing. In 2014, the Thoracic Committee wanted to address this topic and questioned if the lack of data presented a patient safety issue. Collecting PGD data will permit outcome monitoring and future policy development.

The Chair commented that this issue has been raised several times before but has not been addressed. However, it remains a persistent concern of the community.

UNOS staff reviewed the proposed solution which includes adding data elements to Heart Transplant Recipient Registration (TRR) form, potentially eliminating the collection of some data elements, and collecting sufficient amounts of data for analysis. In the future, this data can support the monitoring and reporting of outcome information, and potential policy development.

Since this is a data collection project, the Data Advisory Committee (DAC) will be involved. DAC provides oversight for data collection across the OPTN to ensure consistency and that members are not overburdened. DAC will provide tools and checklists to guide the project development process.

A member asked who is on DAC. UNOS staff shared that DAC members are individuals with data experience and shared the roster which is available on the OPTN website.

The first step in developing data collection projects is presenting an overview of the project to DAC. UNOS staff gave this presentation on 9/29/20. DAC endorsed the project at this preliminary stage especially in light of the mortality rate of PGD and did not have concerns. There will be at least two other touchpoints with DAC, one prior to public comment and then one prior to sending to the Board for approval.

DAC requires that data collection projects be aligned with the OPTN data collection principles. The PGD project aligns with the principle of developing of transplant, donation, and allocation policies.

UNOS staff posed the following questions for the Subcommittee to consider:

- What problem is the Committee trying to solve?
- Should data collection effort should be narrow or broad?
- Should pediatrics be included?
- Which data elements should be included?
- When should data be collected post-transplant?
- Are the data as discrete and objective as possible to ensure high confidence data will be reported consistently by all programs?
- Target population / Impacted and vulnerable populations? Who may be advantaged or disadvantaged?
- Future monitoring activities?

UNOS staff shared that there are standard monitoring activities completed by Research but asked if there should be additional considerations such as including donation after circulatory death (DCD) donors in the data collection.

A member asked if the data collected will be incorporated in expected survival information. The Chair responded that the Subcommittee is not designing a trial or writing a scientific paper. The goal is to identify PGD in patients through data collection by determining the fewest number of data elements that provide useful information about PGD. The data collected may be used for a variety of purposes. The Chair noted that this data may help inform a heart allocation score (HAS).

UNOS staff described that the spring public comment cycle would be used to collect community feedback about what they see as important as well as what data elements they consider to be most critical to collect in identifying PGD. The paper submitted for the January-March public comment cycle would not include guidance or a policy recommendation. The Chair noted that due to the timeline, it is not feasible to prepare a full proposal so instead, the community can be asked to provide input up front to incorporate into the proposal for the next cycle.

A member commented on the importance of DCD on PGD. They shared that the DCD component of the Organ Care System (OCS) Heart Clinical Trial is done for now but may reopen in January. There is a defined risk of PGD associated with DCD donors so DCD information should be tracked.

When reviewing the list of questions for the Subcommittee to consider, the Chair said pediatrics should be included in this project and that the rest of the questions will be answered as the proposal is developed.

UNOS staff asked if there need to be any additional considerations included in the project's problem statement.

A member responded that the Subcommittee, by way of defining the data elements that identify PGD, will be defining PGD. They commented that the variation of PGD definitions used across transplant programs is due to the variation of data elements and treatments being used. In addition to defining PGD, the data will also allow to grade the severity of PGD. Ultimately, the goal is to isolate the risk factors and the treatments. In summary, this member sees this project as having four buckets: definition, stratification of severe and moderate, risk factors, and treatments. They commented that some risk factors are already in the database so they may not need to be addressed. The Chair agreed that this is a good way to organize the Subcommittee's thoughts.

A member questioned whether data collection would need to take three or four years in order to have enough data to have meaningful insights. The Chair responded that it depends on how many post-transplant data elements they will want to look at, as well as if they want to look at 6 month or 1 year outcomes. A member commented that PGD typically has an impact on 30 day outcomes.

UNOS staff asked about best next step in determining elements. The Chair defined the focus to first completing the project form and problem statement so it can be released for public comment as well as a list of preliminary data elements that the community can respond to. The project form needs to be completed by October 21<sup>st</sup>.

The Subcommittee reviewed the project form. UNOS staff will send the project form to the Subcommittee to have them review and provide comments and edits by the October 21<sup>st</sup> deadline.

A member asked about what data was requested by the Committee in 2014. UNOS staff commented that the request was related to graft failure mortality. At the time, the Thoracic Committee never reviewed the data. Current data can be pulled if helpful to the Subcommittee.

The initial public comment document draft is due November 10<sup>th</sup>. UNOS staff has started drafting this document using an Operations and Safety Committee document that had a similar purpose of requesting public comment feedback as a template.

Upcoming meetings include one Subcommittee meeting during the week of October 19<sup>th</sup>, one hour with the full Heart Committee during the October 29<sup>th</sup> in-person meeting, and one Subcommittee meeting during the week of November 2<sup>nd</sup>.

UNOS staff will send Doodle Polls to the Subcommittee members to schedule the next meetings.

UNOS staff asked what data or analyses would support the Subcommittee's work. The Chair asked that the slides be sent to the Subcommittee and that the members come to the next meeting with some ideas about what data would be most useful in guiding the development of the project proposal.

UNOS staff commented that the members need to focus on the feedback questions posed to the community as part of the public comment document.

The Chair encouraged the Subcommittee to share ideas via email in between meetings.

A member asked about the specificity of ventricular assist device (VAD) data included in the OPTN dataset. Specifically, if it includes implant/ explant dates and whether the type of VAD is investigational. They commented that patients who are on long term VAD support or have 2<sup>nd</sup> or 3<sup>rd</sup> pumps have much more PGD. The Chair commented that this could be additional data the Subcommittee needs to know to develop this project.

Next steps:

UNOS staff will send the Subcommittee a summary of next steps and timeline, the draft project form, and Doodle Polls to schedule next meetings.

**Upcoming Meeting**

- October 19, 2020

## Attendance

- **Subcommittee Members**
  - David Baran
  - Donna Mancini
  - Hannah Copeland
  - Jondavid Menteer
  - Kelly Newlin
  - Rocky Daly
  - Shelley Hall
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Yoon Son Ahn
- **UNOS Staff**
  - Eric Messick
  - Janis Rosenberg
  - Keighly Bradbrook
  - Sara Rose Wells
  - Sarah Konigsburg