

**OPTN Heart Transplantation Committee  
Primary Graft Dysfunction Subcommittee  
Meeting Summary  
November 30<sup>th</sup>, 2020  
Conference Call**

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

## **Introduction**

The Primary Graft Dysfunction Subcommittee met via Citrix GoToMeeting teleconference on 11/30/2020 to discuss the following agenda items:

1. Data Element Standard of Review Checklist
2. Project planning

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

### **1. Data Element Standard of Review Checklist**

The Subcommittee members discussed proposed data elements and reviewed the *Data Element Standard of Review Checklist*.

#### Summary of discussion:

UNOS staff shared that this project was retitled to *Develop Measures for Primary Graft Dysfunction (PGD)*.

The project will be reviewed by the Data Advisory Committee (DAC) at various touchpoints. The first touchpoint has been completed and the second is scheduled to occur in February while the *Request for Input* document is out for public comment. The third touchpoint will follow public comment but occur before the formal proposal goes out for public comment in August 2021.

The objective for meeting with the DAC is to provide the members with an overview of the proposed data solution and the anticipated associated impact to data collection and data collection instruments. The proposed data elements need to be aligned with the *Data Element Standard of Review Checklist*. The DAC members will provide feedback and insights to help develop the project. The Chair commented that the DAC helps to refine the proposed data elements to ensure that what is included in the proposal can be feasibly implemented.

This project aligns with the Data Collection Principle "Develop transplant, donation, and allocation policies." Collecting the proposed PGD data elements will help determine the impact of PGD on patient outcomes and provide information for future policy development. The Chair agreed that the project aligns with this Data Collection Principle.

UNOS staff presented a list of PGD data elements identified by the Subcommittee. A member requested correcting the list to read that cardiac output data needs to be collected and cardiac index will be calculated in UNet.

The Chair expressed wanting to update the heart device brands by category list. UNOS staff will follow up to see if the list can be updated as part of the PGD proposal. A member suggested reordering the

more commonly used options to appear at the top of the picklist if programming prohibits removing obsolete devices from the list. UNOS staff commented that they will follow up on the device lists included on the justification forms.

The members discussed the proposed data elements “PGD-Left Ventricular Dysfunction/Failure (yes/no)” and “PGD-Right Ventricular Dysfunction/Failure (yes/no).” Including “Left/Right Ventricular Dysfunction/Failure” as part of the title was intended to make it easier for the person entering data (user) to understand. A member commented that dysfunction and failure are different. The members agreed that including a description of PGD on the form will help the user.

UNOS staff commented that the “PGD (yes/no)” element not be needed since the following questions may be enough to indicate whether or not PGD is present and raised a concern that there may be inconsistencies in how the user defines PGD. Using the other data elements may help reduce discrepancies and errors in identifying PGD. The Chair raised a concern that this would rely too heavily on the data entered which may vary based on when it was collected. The members agreed that there should be a “PGD (yes/no)” question to alleviate the concern that PGD may not be identified otherwise.

Members discussed if this data element is a parent question to the rest of the data elements. It was previously determined that data elements will be collected for all patients.

The Chair suggested adding a data element that identifies whether the surgeon’s team or local recovery team performed the procurement. Members questioned whether data elements describing a “technical issue,” damage to the organ caused by surgery, should be included.

To address concerns that surgeons may not want to commit to “PGD (yes),” a member suggested only adding data elements labeled “Left Ventricular Dysfunction (yes/no)” and “Right Ventricular Dysfunction (yes/no).” Ultimately, the members chose to include the following data elements:

- PGD (yes or no)
- Left Ventricular Dysfunction (yes/no)
- Right Ventricular Dysfunction (yes/no)

A member suggested adding definitions to help coordinators understand the intention of the data elements. The Chair commented that directors will help guide and train staff. Members agreed to include definitions on the form.

A member commented that PGD is usually identified at a later date and recommended waiting up to two weeks post-surgery for form submission in order to have better data that allows for a more accurate identification of PGD. The Chair noted that forms are not due at the time the clinical values are collected and can be completed later using retrospective data.

Member commented that the definition of PGD provided on the form should consistently use the term “dysfunction” rather than “failure.” UNOS staff will confirm that this PGD definition can appear on the form next to the question. A member recommended including the PGD definition before the “PGD (yes/no)” question. The Chair noted that educational components will be developed as part of implementation to assist members with these changes.

The members agreed that data elements relating to inotrope dosing will be determined based on public comment feedback.

UNOS staff commented that “Graft Status” and “Date of Graft Failure” data elements previously considered for removal by the Subcommittee will not be removed since these elements are used in data reporting.

UNOS staff shared a spreadsheet that reviews the proposed data elements and assesses them based on criteria provided by the *Data Element Standard of Review Checklist*. The Chair suggested sharing this spreadsheet with the members so the members can circulate emails and complete work between meetings. UNOS staff will draft some initial content for the members to consider and respond to.

Next steps:

UNOS staff will add content to the *Data Element Standard of Review Checklist* spreadsheet and send to the members.

**2. Project planning**

UNOS staff reviewed the project milestones.

Summary of discussion:

The plan is that the *Request for Input* document goes out for public comment January-March 2021. Following the incorporation of community feedback received, the Heart Committee will vote on a formal data collection proposal in May 2021. The data collection proposal will go out to public comment in August 2021, the Heart Committee will vote to approve in October 2021, and the Board of Directors will vote to approve in December 2021.

**Upcoming Meetings**

- December 17, 2020

## Attendance

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