

**OPTN Heart Transplantation Committee  
Primary Graft Dysfunction Subcommittee  
Meeting Summary  
January 28, 2021  
Conference Call**

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

## **Introduction**

The Primary Graft Dysfunction Subcommittee met via Citrix GoToMeeting teleconference on 01/28/2021 to discuss the following agenda items:

1. Regional meetings and public comment
2. Review proposed new data elements against Data Element Standard of Review Checklist

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

### **1. Regional meetings and public comment**

UNOS staff reminded the Subcommittee of the upcoming regional meeting dates and showed them where to find the Primary Graft Dysfunction (PGD) request for feedback proposal and other proposals out for public comment on the OPTN website.

#### Summary of discussion:

UNOS staff shared that a Heart Committee member did a great job presenting the PGD request for feedback project at the Region 4 meeting. The Region 4 meeting attendees were responsive and provided good feedback.

The PGD request for feedback document is posted on the OPTN website. Members were invited to visit the website to review the public comments received.

### **2. Review proposed new data elements against Data Element Standard of Review Checklist**

UNOS staff shared that all data elements included in data collection proposals need to be evaluated against the Data Element Standard of Review checklist. The justification and rationale for proposing changes to data collection tools must be documented and shared with the Data Advisory Committee (DAC).

#### Summary of discussion:

The Subcommittee evaluated the proposed data element "Primary Graft Dysfunction (Yes/No)" using the Standards of Review checklist.

#### *Purpose, Relevancy, and Face Validity*

The members considered the intent or purpose of collecting this specific data element and whether the data element will measure what it intends to measure.

This data element is being proposed due to PGD's negative impact to mortality following heart transplant, the lack of a standardized definition of PGD which has limited diagnosis and treatment, and that data collection may help identify and understand PGD's impact on morbidity and mortality.

The Chair commented that the determination of whether a patient has PGD is dependent on the transplant program and may vary between programs. A member commented that this data element improves on the previous data element of "graft failure" by updating to current terminology and is more helpful as it includes a definition on the form. This definition will provide guidance to the user entering data.

A member commented that the incidence of PGD varies so widely in the literature and needs to be tracked to better understand it. The Chair also commented that collecting this data may also help identify risk factors of PGD. A member raised a concern that including the identification of risk factors as part of the rationale may create a perception that this is a research project. The Vice Chair commented that the intention is to avoid graft waste by learning more about recipient and donor combinations.

A member commented that the definition provided on the form will help with decision making but the program will provide the final determination of whether PGD is present. The members chose to refer to this PGD definition as "descriptive language."

A HRSA member suggested adding that the data will support future policy development and allocation as well as an intent to improve consistency in reporting among transplant programs as part of the rationale.

### *Reliability*

Members were asked to consider if the element is designed to consistently reproduce the same results and if there are objective measures, rather than calculations which may produce varied results depending on methods used.

UNOS staff shared that since programs will self-report, there is potential for inconsistency in identifying the presence of PGD. The descriptive language included on the form will help increase consistency. The Chair commented that in addition to collecting this data element, the other data elements being considered will support whether or not PGD occurred.

### *Alternative data sources*

Members agreed that there is no alternative for collecting this data element.

### *Availability, burden, and interoperability*

Members agreed that this data element does not require additional testing and is widely available. A member questioned if assessing the presence of PGD requires echocardiograms. The members decided that performing echocardiograms is not required to answer the question, although echocardiograms are commonly performed if PGD is suspected as part of clinical care.

The members considered whether this data could be easily and readily discovered by a clinical or non-clinical coordinator in an Electronic Health Record (EHR). The Chair commented that this is dependent on the program's chart practices which may need to be changed so the coordinators have access to this information. A member commented this information would usually be included in the narrative of the day. The Chair commented that documenting PGD would need to be included in their workflow, either in their charts or EHR if their system permits.

A member asked if there is a diagnostic or International Classification of Diseases (ICD) code associated with PGD. A member commented that they do have options to enter left ventricle PGD, right ventricle

PGD, biventricular PGD options in their EHR. The members determined there are no ICD codes specific to PGD so it would not be possible to query their EHR for this data element. The Chair confirmed there is only one comprehensive ICD code that covers all post-transplant heart complications.

### *Usability and conformity*

UNOS staff suggested returning to this topic after there is a mock up created for the Transplant Recipient Registration (TRR) form to allow for the members to respond to the design and placement decisions.

UNOS staff asked for comments about the descriptive language used to describe the data element:

*PGD refers to graft dysfunction occurring immediately after transplant, requiring greater than typical medical support, or mechanical support. PGD is graft dysfunction not attributable to hyperacute rejection, acute rejection, antibody mediated rejection, surgical implant issues, or acute infarction.*

The Chair raised a concern about “surgical implant issues” being misinterpreted and applied to situations where ischemic time may have been longer than planned. This prolonged ischemic time could be a factor contributing to PGD. The intention of including “surgical implant issues” in the descriptive language is to describe a catastrophe. A member commented that technical issues are typically underreported. The Vice Chair commented that surgical implant issues could refer to bleeding and transfusions.

The Vice Chair referenced the International Society for Heart and Lung Transplantation (ISHLT) consensus definition for PGD which includes that there is no discernable cause for graft dysfunction such as hyperacute rejection, pulmonary hypertension, and known surgical complications. He suggested changing “surgical implant issues” to “known surgical complications.” This terminology may help differentiate from issues relating to bleeding from adhesions and coagulopathy. The descriptive language was updated to use the phrase “known surgical complications.” The members will readdress additional edits at a later date.

A member mentioned that pulmonary hypertension can lead to right-sided graft failure which is classified as right-sided PGD. The Chair agreed and suggested not including pulmonary hypertension in the descriptive language.

### *Definition*

UNOS staff commented that there is no current definition of PGD in OPTN data but that the descriptive language discussed will support PGD’s identification.

UNOS staff asked how programs should respond if the presence of PGD is not available or unknown. The Chair commented that since PGD is a clinical determination, it should be provided by the transplant program. A member agreed that this should not be unknown.

Members discussed if data will be collected on all patients or just those who are indicated to have PGD. The Chair commented that ideally the data will be collected on all patients but this is dependent on the feedback received from the community.

### Next steps:

UNOS staff will divide the remaining data elements that need to be evaluated and assign to subgroups of the Subcommittee. Their responses will be shared with the full Subcommittee at a future meeting.

### **Upcoming Meeting**

- February 22, 2021

## Attendance

- **Subcommittee Members**
  - David Baran
  - Donna Mancini
  - Hannah Copeland
  - J.D. Menteer
  - Monica Colvin
  - Rocky Daly
  - Shelley Hall
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Yoon Son Ahn
- **UNOS Staff**
  - Eric Messick
  - Janis Rosenberg
  - Julia Chipko
  - Keighly Bradbrook
  - Leah Slife
  - Sara Rose Wells
  - Sarah Konigsburg
  - Susan Tlusty