OPTN Heart Transplantation Committee
Primary Graft Dysfunction Subcommittee
Meeting Summary
March 23, 2021
Conference Call

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

Introduction

The Primary Graft Dysfunction Subcommittee met via Citrix GoToMeeting teleconference on 03/23/2021 to discuss the following agenda items:

1. Review public comment and consider general themes to address in Data Collection proposal
2. Review Data Element Standard of Review Checklist
3. Pediatric considerations regarding primary graft dysfunction

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 a high level summary of the public comment feedback received on the *Develop Measures for Primary Graft Dysfunction (PGD) in Hearts* request for feedback document.

Summary of discussion:

UNOS staff shared that comments have been received from all 11 regional meetings and the Transplant Coordinator, Transplant Administrator, Data Advisory, and Organ Procurement Organization (OPO) Committees. Comments have also been received from two individuals, the International Society for Heart and Lung Transplantation (ISHLT), the Organization for Donation and Transplant Professionals (NATCO), the American Society of Transplantation (AST), and the American Society of Transplant Surgeons (ASTS).

UNOS staff shared that there has been general support for collecting PGD specific information. There has been no reported opposition. There has been a general sentiment that the required data collection should not overburden programs. It was noted that the level of burden has been considered by the Subcommittee when determining which data elements to include in the proposal.

UNOS staff shared that some of the feedback received suggested further consideration of what data points would need to be collected relating to warm ischemia time.

UNOS staff invited the Subcommittee members who presented at the regional meetings to share their experiences. The Chair commented that she attended the majority of the regional meetings and noted that the general sentiment is supportive and that data collection on PGD is long overdue. She noted that other comments were relating to the associated burden with collecting this data and the need to ensure that the data elements are clear cut, obvious, and easy to collect. She also shared that collecting data only at 24 hours by itself will be inadequate and that a second time point at 48 or 72 hours will be necessary. She also noted that when presenting to the OPO committee, the members did not express concern with proposed data elements presented.

A member commented that Region 9 was supportive and the attendees recommended data collection at 48 hours.

UNOS staff shared the comments from the Transplant Coordinator Committee (TCC). The members of TCC raised a concern about the level of work that will be required by transplant coordinators.

The Chair commented that the biggest challenge will be determining the time points for data collection and what inotrope information should be reported.

A member commented that severe PGD for pediatrics is typically identified by the need for mechanical support post-transplant. He commented that mild PGD is more difficult to identify and may be diagnosed a week or two post-transplant when biopsies and cardiac index information are collected at the catheterization laboratory. He commented that moderate PGD is usually indicated by the need for inotrope support in pediatric patients.

A member referenced the criteria included in the ISHLT PGD consensus definition that delineates severe and moderate PGD. The Chair asked if this definition can be applied to both adult and pediatric transplant recipients. The members discussed the timing of data collection and whether it would vary depending on if the patient is an adult or pediatric.

A member commented that on occasion transplant recipients may still require the support they were receiving pre-transplant. He commented that these patients, due to their need for support following transplant, may be identified as having PGD when in actuality they are just slower to wean off of the support. The Chair commented that whether the support is new or existing will need to be specified.

A member commented that Region 4 attendees asked if inotrope scores could be calculated by the data collection tool. UNOS staff commented that using an inotrope score rather than collecting dosages needs consideration. The Chair noted that the community will be unlikely to support requiring coordinators to calculate inotrope scores. A member commented that calculating inotrope scores is difficult and suggested collecting inotrope type and a dosing range (i.e. high, medium, low). The Chair supported this recommendation as it would limit the amount of typing required by the coordinator.

A member commented that collecting the number of inotropes and vasopressors a patient is on may be adequate and dosing information may not be necessary. Members commented that the number of inotropes and vasopressors may not be indicative of PGD since many clinical teams administer several inotropes as standard practice. A member commented that ISHLT post-operative guidelines recommend weaning transplant recipients off of vasopressors and inotropes starting at day 3 post-transplant. She suggested using day 3 as the time point for data collection since at this point the patient would show evidence that there is a failure to wean. A member agreed and suggested collecting data to compare day 3 post-transplant with day 7 post-transplant.

A member commented that there is variance in when clinical teams choose to taper support but agreed that an appropriate time point to determine if the patient is showing a failure to wean is later than 48 hours. Another member commented that the definition of PGD includes a timeframe of 24 hours post-transplant. She also commented that some patients with severe PGD can rapidly recover.

The Chair suggested creating a spreadsheet of the data elements and associated comments from public comment in order to assess the level of interest for each element. UNOS staff will provide this for the

Subcommittee to review and commented that the source of the comments should be considered as well when evaluating.

The members reviewed ISHLT's public comment response. ISHLT recommended collecting data on whether a patient returns to the operating room for mediastinal bleeding. A member commented that mediastinal bleeding can occur for other reasons beyond PGD. Another member commented that mediastinal bleeding is a risk factor for PGD. A member commented that the risk is not necessarily related to returning to the operating room but is due to the required blood transfusions and strain on the right ventricle associated with mediastinal bleeding.

A member asked how many time points for data collection are going to be requested. The Chair commented that 24 hours may be a necessary time point to align with the existing ISHLT PGD consensus definition. She suggested 24 hours, 48 hours, and a third later time point. Members agreed that there will need to be at least two time points collected. A member suggested 24 hours, 72 hours, and day 7 post-transplant.

A member asked how many time points are collected currently on the Transplant Recipient Registration (TRR) form. He asked if the coordinators' work will be tripled by requesting three time points and questioned if two time points would be more practical. UNOS staff shared that the TRR is currently due 60 days after the recipient is removed from the waiting list. A member commented more work will be required to enter the three data sets but the process of entering the data only once which may lend to more flexibility around what time points are selected.

A member asked if an additional time point should be added for patients who are still inotrope dependent by day 7. This additional time point would be when the patient is no longer on inotropes. A member commented that the duration of inotrope support is too subjective and that the duration of mechanical support may be more relevant.

A member asked if pediatrics receive more inotropic support, rather than mechanical support, than adults. Another member confirmed that pediatric recipients are more likely to be managed with inotropes, although programs are becoming more comfortable supporting pediatric patients with PGD using CentriMag and PediMag devices.

Next steps:

UNOS staff will organize the public comment feedback by data element and share with the Subcommittee. Members will review the feedback and either discuss via email or arrange a meeting prior to the April 20th Heart Committee meeting if deemed necessary.

2. Review Data Element Standard of Review Checklist

The members reviewed the work previously completed on the Data Element Standard of Review Checklist.

Summary of discussion:

Due to time constraints, the Chair will continue making edits to the draft document and share with the Subcommittee for final comments, revisions, and additions.

UNOS staff shared that the Scientific Registry of Transplant Recipients (SRTR) recommended ensuring that all data elements are reviewed for quality and accuracy. UNOS staff suggested adding columns to the list of data elements that describe the elements' existing locations and definitions.

UNOS staff asked if the members have any concerns about the proposed data elements not being well defined. Members commented that they do not have concerns but acknowledge that definitions will need to be very specific and include timing information.

Next steps:

The Chair will follow up with an updated version of the checklist for the members to review over email.

3. Pediatric considerations regarding primary graft dysfunction

UNOS staff shared a recent event in which two pediatric heart recipients experienced graft failure shortly after transplant. A question was raised about whether the patients could maintain their status or waiting time.

Summary of discussion:

The members discussed whether a proposed policy modification that would allow pediatric patients who require urgent relisting due to graft failure to maintain their status and waiting time should be included as part of this project. A member disagreed with including this policy modification with the current proposal and commented that smaller pediatric patients may not receive a second offer in time, even if their status is maintained. The member commented that this is an important discussion but does not recommend including this subject as part of the PGD project.

Upcoming Meeting

- TBD

Attendance

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