OPTN Heart Transplantation Committee
Primary Graft Dysfunction Subcommittee
Meeting Summary
October 19, 2020
Conference Call

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

Introduction

The Primary Graft Dysfunction Subcommittee met via Citrix GoToMeeting teleconference on 10/19/2020 to discuss the following agenda items:

1. Review Project Form Revisions
2. Next Steps

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

1. Review Project Form Revisions

Summary of discussion:

The Chair reviewed the project's background, problem statement, and proposed solution included on the project form. Edits submitted by the members prior to the meeting were included in the version reviewed.

The Chair asked if any members had concerns about sending the project form as it is to the Policy Oversight Committee (POC) for review and approval. UNOS staff asked if there is enough information and adequate descriptions provided for the heart transplant community to agree with the proposed solutions and provide meaningful feedback.

A member suggested adding more mortality and morbidity data. UNOS staff said these references could be added to the project form and/or public comment document. The member suggested the single center study that used the International Society for Heart and Lung Transplantation (ISHLT) definition included in the Sabatino article. This article has already been cited but this additional data will be included.

A member commented that they were unsure of the level of detail required for the project form. The Chair commented that it looked pretty full and that more data will be included in the public comment document. UNOS staff commented that some of the proposed data elements are included in the document and will add the other data elements outlined in the slides that are included in the meeting materials.

The members discussed if procurement data should be added to the scope of the project. As currently planned, data elements would only be added to the Transplant Recipient Registration (TRR) form. Including procurement data would mean adding fields to a separate donor form.

The Vice Chair commented that POC will want to know the data elements in order to assess level of data burden. He suggested providing a general outline of data elements to the POC. The Chair asked how POC will respond to the first phase in which initial feedback is being requested of the transplant

community through public comment. UNOS staff agreed to include a general description of the overall data collection effort in the documents going to POC.

UNOS staff commented that adding data elements is always controversial but may be supported by those with a research interest. The members need to consider how the data will be used to develop policy. The least amount of data that has the most amount of impact needs to be collected.

A member asked about the data included on the procurement form. Another member responded that the type of perfusion solution but not the amount of solution is included in the database for heart and heart-lung procurement. The volume of solution is recorded but only as a written note on scanned documents submitted by the organ procurement organization (OPO), rather than entered into a data field. The form that is scanned is not an OPTN form. The member commented that this information is important, especially if lungs are being procured using 4-6 liters of solution and the heart is not adequately decompressed, as it may cause right ventricular distention or PGD. They also commented that Perfadex lung preservation solution may be toxic to the heart, although this information is only anecdotal.

The Chair suggested including language in the project form that states that procurement data elements relating to perfusion solution volume and donor after cardiac death (DCD) data are being considered as part of the PGD project.

A member commented that every data field added will need to be filled in by someone. They raised a concern that this will cause push back, however, the document provides a good reason why the data is important. They suggested strengthening the case by including the goal of the data, whether it be to inform a heart allocation score or other purpose.

The Chair asked if a comment about potentially collecting procurement data elements should be added to the project form going to POC. UNOS staff raised a concern about including data elements that are related to PGD rather than those that can be used to identify PGD because this project should be framed as a data collection project for defining PGD and not a research project. They recommended only included PGD identifying data elements rather than potential risk factors. The Chair asked if this project should take a stepwise approach with first identifying PGD and then adding risk factors at another point. UNOS staff agreed and recommended only including data elements to define PGD in this first step.

A member disagreed with this approach. They commented that it is up to the Committee to settle on the definition and stratification of PGD. They stated that there is enough information and opinion in the literature to decide on a definition of PGD, stratify PGD, and write a definition in short-form to determine whether or not PGD is occurring. They suggested including the other data elements relating to procurement and implant information to allow for an evaluation of risk factors and potential treatments.

The Chair commented that the member is right in the scientific sense but this project needs to inform process and policy. The first step needs to be collecting data on PGD in the OPTN dataset.

The member suggested writing two or three questions that lead to a definition (yes or no) of PGD and whether it is moderate or severe. They commented that this would accomplish the goal without needing a long additional data element query. They also noted that there could be a couple of other elements relating to procurement, implant, or warm ischemia time as well as warm ischemia techniques. They posed the question of whether the objective is to investigate defining PGD or to define PGD for the users of the database. They see it as the latter and that the Committee will define PGD for the database.

The Chair defined phase one as including the submission of a public comment document to solicit feedback on potential data elements that should be considered, including procurement, implant, and

post-transplant. UNOS staff expressed a concern about the scope of the project may be perceived as answering research questions rather than defining data elements.

A member suggested adding language to the project form that states "added data elements will be kept to a minimum to achieve the goal of identifying and stratifying PGD, and determining treatment and factors."

A member suggested including language describing that since the consensus document was put out by ISHLT in 2014, there have been significant changes to the procurement process and therefore there may be a need for data elements relating to these changes. UNOS staff asked if the ISHLT PGD definition is no longer enough to cover what PGD is. The member agreed that these procurement changes may impact the definition but this is unknown.

A member questioned that the ISHLT definition has not changed but rather the risk factors have, which includes procurement practices.

The Chair commented that the OPTN is not responsible for changing the science but collecting data that is most helpful for the transplant community. She reiterated that this cannot be a research project and that it needs to be simple so the problem can be analyzed.

A member commented that transplant begins at procurement and there is potential that procurement factors define PGD. They recommended adding two data elements relating to the volume of perfusion solution used during procurement and warm ischemic time to the scope of the project.

A member commented that if questions are nested, only 5-10% of cases will need additional data entry related to PGD. The Chair commented that the Subcommittee will discuss whether the data is collected for all recipients or just those who have PGD identified.

The Chair asked the Subcommittee if they want to add the sentence "other data elements under consideration include volume of solution and warm ischemic time" to the project form. UNOS staff said this sentence can be added for review by the POC.

A member questioned how PGD can be assessed post-transplant when it can happen intraoperatively. The Chair commented that considering PGD as being post-transplant is mostly due to how the forms are organized.

For the *Target Audience* section of the project form, the Chair asked the Subcommittee to comment on whether the proposed data elements should be collected on all patients or if the questions should be nested and only requested for those that have PGD identified. UNOS staff raised a concern about programs not being able to identify PGD as this could limit who enters the data if PGD is not identified consistently. The members and UNOS Research staff agreed that the data elements will be collected on all heart recipients.

For the *Vulnerable Populations* section of the project form, the Subcommittee chose to include DCD. No other populations were suggested.

For the *Potential Controversy or Barriers* section of the project form, the Subcommittee discussed including the additional collection of data elements, the fluidity of patient population, and the definition of data collection time frames. The fluidity of the patient refers to, as an example, the variations in the use of inotropes and when clinical data is collected on the patient. There can be flux in the patients' various levels. There need to be concrete moments when the measures are taken. The Subcommittee chose to replace the "fluidity of the patient population" with "how to define data collection timeframes" as a barrier. A member commented that the definition of PGD may be a controversy. UNOS staff

commented that since the data is collected on all patients, there is always an opportunity to redefine PGD based on the data.

The Vice Chair commented that the definitions and risk factors identified will be important to Continuous Distribution.

A member asked if the Subcommittee will set the definition for PGD. They requested clarity on whether this project's objective is to collect data and do retrospective review or to define a stratify PGD. UNOS staff commented that the first step is to determine the data the needs to be collected, after this is addressed, the project scope can be widened.

Next steps:

UNOS staff will meet to update the project form based on discussion. The updated version will be sent to the Subcommittee for final edits.

2. Next Steps

The Subcommittee reviewed the deadlines for the project.

Summary of discussion:

The Chair commented that the project form will go to POC on October 21st. This will be reviewed at the November 5th POC meeting. The next deadline is submitting a draft of the public comment document on November 10th.

The public comment document will go out for public comment between January 25th and March 26th and then the feedback received will be used to develop a proposal which will be voted on by the Committee in May and then will go out for public comment in August 2021. Feedback from this public comment cycle will be used to finalize a proposal which will be voted on by the Committee in October and sent to the Board of Directors for approval in December 2021.

The Subcommittee was asked to consider what data, information, or analysis would be beneficial to the development of this project.

As a recap, the Subcommittee reviewed the Lung PGD data element on the Lung TRR, the Heart TRR, and the proposed data elements the Subcommittee discussed previously.

During the Heart Committee in-person meeting on October 29th, the full Committee will review the public comment document draft, discuss the scope of the data collection effort, draft a list of data elements to include in the public comment document, and review the Data Advisory Committee's checklist and update as necessary.

The next Subcommittee meeting will be used to review and finalize the public comment document, discuss feedback received from the full Committee during the in-person meeting, and finalize the list of data elements to be included in the public comment document.

Next steps:

UNOS staff will send the draft public comment document and project form. The Subcommittee was asked to review the slides and consider which data elements should be included in the public comment document.

Upcoming Meeting

- TBD

Attendance

- **Subcommittee Members**
  - David Baran
  - Donna Mancini
  - Hannah Copeland
  - Jondavid Menteer
  - Kelly Newlin
  - 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
  - Nicole Benjamin
  - Sara Rose Wells
  - Sarah Konigsburg