

**OPTN Heart Transplantation Committee
Primary Graft Dysfunction Subcommittee
Meeting Summary
November 6th, 2020
Conference Call**

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

Introduction

The Primary Graft Dysfunction Subcommittee met via Citrix GoToMeeting teleconference on 11/6/2020 to discuss the following agenda items:

1. Review “Request for Input” document

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

1. Review “Request for Input” document

Summary of discussion:

UNOS staff shared that the Policy Oversight Committee (POC) provided their endorsement at the November 5th meeting. The next steps include submitting the Request for Input document to Policy and Community Relations (PCR) management by November 10th and then having the Heart Committee vote to approve the document for public comment during the December 15th meeting. This document will go to public comment in January 2021.

UNOS staff reminded the Subcommittee about the proposed solution to add data elements to the Heart Transplant Recipient Registration (TRR) to identify and stratify, and monitor the incidence of as well as measure the effects of Primary Graft Dysfunction (PGD).

A member suggested adding “identify causes” as part of the solution since this may be a secondary outcome or endpoint of the data collected. UNOS staff asked if this outcome should be considered as a component of the project’s second phase. The Chair commented that the first phase should only include soliciting input on PGD data elements from the community and the data that is ultimately collected after implementation can be used when conducting research. Members agreed.

The edits to the list of data elements presented were from the suggested revisions discussed at the October 29th Heart Committee meeting.

Transplant programs will need to consider the burden associated with data collection. This consideration is included in the Request for Input document. The Chair supported including that TRR data elements are being considered for removal which may lessen the burden.

A member questioned the usefulness of the “functioning or failed” data element currently on the TRR. There is not clarity on whether needing support would be categorized as a failed graft. Some individuals entering the data would only consider it “failed” if the outcome is death. Also, this death may not be associated with the functioning of the graft. Members supported removing this data element as well as the “date of graft failure” data element. The Chair suggested including the picture of current form in the Request for Input document so the reader knows what is being considered for removal or replacement.

Members suggested changing the question to be more specific by asking if the graft requires higher than normal inotropic or mechanical support not attributable to transplant surgery three days after transplant. The Chair commented that this can be determined during the second phase.

A member commented that the data elements such as stroke, dialysis, etc. should not have “unknown” options. They commented that the PGD questions should only have “yes” or “no” answers and not allow for unknown or missing variables. A member raised a concern about situations such as if the patient is not on a Swan-Ganz catheterization and therefore certain measures may not be collected. The member suggested including an option such as “N/A” or “not measured” but noted that most patients will have hemodynamic data in the first couple of days and this data could be mandatory. The members decided that if data is unavailable, the individual entering the data should provide a reason for why the data was not collected on the patient.

UNOS staff will draft a paragraph asking the community for their feedback on whether the data elements should be mandatory. UNOS staff raised a concern that form submission should not be blocked if the data elements are not available.

The Subcommittee discussed the data elements included in the Request for Input document draft. The members discussed collecting cardiac output rather than cardiac index since cardiac index can be calculated using height and weight which is already collected. A member asked if body surface area (BSA) could be automatically calculated. UNOS Research staff commented that this is possible but noted that if any variables needed to complete the formula are not entered, then the calculation will not work. A member commented that the measure for BSA needs to be changed to meter squared. The Subcommittee will use the DuBois formula to auto calculate BSA.

A member asked if the cardiac output value reported should be the best or worst or typical. Members discussed if values should be collected at time points or if the highest or lowest values over a period of time should be reported. The Chair said these decisions will continue to be discussed by the Subcommittee as the project evolves. The members agreed to the list of data elements included in the Request for Input document.

The members discussed if ranges (low, high) of dosages or specific dosage information should be collected on inotropic support. This will be further discussed by the Subcommittee. A member commented that the ISHLT definition requires specific dosing information rather than a range.

The members decided that intra-aortic balloon pump (IABP) will be listed as a left ventricular support device and venoarterial extracorporeal membrane oxygenation (VA-ECMO) will be listed as a left, right, and bi-ventricular support device. The members decided to list all known percutaneous devices and CentriMag but include an “other” option to allow other, newer devices be entered. The members discussed requesting the type or category of support device rather than the specific type of device. Another member commented that it is easier for those entering the data to list the device. The Request for Input can reference the existing list of devices to allow readers to review.

The members discussed if there needs to be more explicit language that allows the person entering the data on the TRR form to know the data is being collected for left-ventricular failure due to PGD rather than infarcts or acute rejection. The Subcommittee discussed how “failure” is defined differently and decided to edit the two data elements to “PGD Left Ventricular Dysfunction/Failure” and “PGD Right Ventricular Dysfunction/Failure.” A member offered to send language to further define the PGD Left Ventricular Dysfunction/Failure data element through an asterisk note in the Request for Input document. They will add this language to the draft.

The Chair agreed that including risk factors as part of the project is out of scope but if the community has an overwhelming response that they want to include risk factors, these factors could be included in the formal data collection proposal as part of phase two. The members decided to keep the inclusion of risk factor data elements as a consideration for community feedback in the Request for Input document.

A member suggested adding a feedback question about if the maximum or minimum values should be collected. Members discussed if average, concrete, or representative values should be collected. A member suggested collecting data before the patient receives support. The Chair said that support is given in the operating room on occasion. The members could not determine which values would provide the most value and how this could be phrased to solicit feedback without causing confusion.

Members discussed how support may affect the data values. A member commented that some supports are used prophylactically. The Chair commented that some patients receive transplant surgery with an IABP and continue to be supported with an IABP after surgery to prevent failure. Another member commented that the hemodynamic data prior to transplant may be difficult to collect.

Members will provide suggested language for feedback questions in a draft that will be sent by UNOS staff.

Next steps:

UNOS staff will send the members a revised version of the Request for Input document. Members will provide comments prior to November 10th.

Upcoming Meetings

- November 30, 2020
- December 17, 2020

Attendance

- **Subcommittee Members**
 - David Baran
 - Donna Mancini
 - Hannah Copeland
 - J.D. Menteer
 - Rocky Daly
 - Shelley Hall
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Monica Colvin
 - Yoon Son Ahn
- **UNOS Staff**
 - Eric Messick
 - Janis Rosenberg
 - Keighly Bradbrook
 - Sarah Konigsburg
 - Susan Tlusty