

**OPTN Heart Transplantation Committee
Primary Graft Dysfunction Subcommittee
Meeting Summary
June 9, 2021
Conference Call**

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

Introduction

The Primary Graft Dysfunction (PGD) Subcommittee met via Citrix GoToMeeting teleconference on 06/09/2021 to discuss the following agenda items:

1. Final review and acceptance of new data elements for inclusion on TRR
2. Final review and acceptance of data collection timeframes for new data elements on TRR
3. Discussion of other potential data elements related to donors, procurement and operational practices

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

1. Final review and acceptance of new data elements for inclusion on TRR

The members reviewed the proposed data elements and provided final revisions prior to being reviewed by the full Heart Committee on June 15, 2021.

Summary of discussion:

Right Ventricular Dysfunction (RVD)

The Chair asked if the criteria included in this data element's description and definition should include the language "based on" or "suggested by." The Chair also questioned whether rationale should be included in the descriptions going out for public comment. UNOS staff commented that the rationale should be included.

The members ultimately decided to modify the RVD data element description to "RVD is determined using imaging and/or hemodynamics (e.g., dilated hypokinetic RV on echo, low EF, CVP>15, CVP/PCW>0.63, PAPI<1.85, CI under 2.2.) RVD is considered important for identifying whether PGD involves the left, right, or both ventricles." The members agreed to be general about the mechanisms used to collect the clinical data, using the terms "imaging" rather than "echocardiogram" and "hemodynamics" rather than specifying hemodynamics collected through a Swan Ganz catheter.

Left Ventricular Dysfunction (LVD)

The members considered how much detail should be included in this data element's description. A member asked if specific criteria needs to be included since the description already references that LVD is defined in standard society standards. A member questioned if Swan Ganz needs to be referenced specifically or made more general as "invasive hemodynamics." Members agreed to replace any reference to "Swan Ganz" with "hemodynamics" throughout to be more general and widely applicable.

The members agreed that the LVD description needs to be more specific to help users identify and accurately report LVD. The member ultimately decided to edit this data element's proposal to "LVD is defined by common society standards, and the presence of LVD can be determined using imaging and/or hemodynamics (e.g., low EF, cardiac index < 2.2). LVD is considered the most important aspect of graft performance following transplant (other than gross graft failure)."

The members agreed with the other data elements and descriptions as proposed.

Inotrope data collection

The Chair shared that collecting inotrope ranges rather than discrete values was determined to be easier to report and will reduce typing. UNOS staff commented that collecting ranges will not allow for inotrope scores to be calculated. UNOS staff also commented that the ranges need to be continuous. A member commented that coordinators will rely on primary documentation which will include discrete values. The Chair reminded the members that the community expressed a preference for ranges during the request for feedback.

The Chair presented proposed inotrope dosing ranges for the inotrope and vasopressors listed below. Each range is organized into three options representing high, medium, and low doses. UNOS Research staff agreed to draft proposed ranges to ensure there are no gaps in the values provided.

Epinephrine

The Chair commented that Epinephrine is a standard post-transplant drug but is not a pre-transplant heart failure drug so the high dose definition provided in OPTN policy may not be applicable.

The members agreed to provide the following ranges:

- None
- Up to or equal to 0.05 mcg/kg/min
- Greater than 0.05 to less than or equal to 1
- Greater than 1

Milrinone

A member recommended having the maximum value for the low dose option be 0.25 microgram per kilogram per minute (mcg/kg/min). Another member suggested .03 mcg/kg/min as the maximum value in the low dose range. UNOS staff asked if there is any literature that could be referenced. A member commented that single high dose inotropes are defined in OPTN policy.

The members agreed to the following ranges:

- None
- Up to or equal to 0.3 mcg/kg/min
- Greater than 0.3 mcg/kg/min to less than or equal to 0.5 mcg/kg/min
- Greater than 0.5 mcg/kg/min

The high dose range was selected to be consistent with existing policy.

Dobutamine

The members agreed to the following ranges:

- None

- Up to or equal to 3 mcg/kg/min
- Greater than 3 mcg/kg/min to up to or equal to 7.5 mcg/kg/min
- Greater than 7.5 mcg/kg/min

The high dose range was selected to be consistent with existing policy.

Dopamine

A member commented that Dopamine is used similarly to Dobutamine and recommended using the same ranges.

The members agreed to the following ranges:

- None
- Up to or equal to 3 mcg/kg/min
- Greater than 3 mcg/kg/min to up to or equal to 7.5 mcg/kg/min
- Greater than 7.5 mcg/kg/min

Levophed

A member commented that this vasopressor is only used for adult patients. UNOS Research staff asked if any of the dose ranges need to be reconsidered for pediatric patients. The member responded that although the doses are typically lower, what has been proposed will be adequate for pediatric patients. The members considered the unit of measure for Levophed noting that some hospitals use mcg/kg/min while others may still use mcg/min. The Chair commented that her hospital uses the same unit of measure to reduce nursing errors. The Chair commented that a question could be included in the public comment proposal to determine a preferred unit of measure for vasopressors. A member commented that dosing may be relative to the patient's size. Another member commented that anesthesia received in the OR may also impact the level of dosing administered.

A member referenced the dosing ranges established in the Lexicomp library. Based on this standard, the members agreed to the following ranges:

- None
- Up to 0.05 mcg/kg/min or <5 mcg/min
- 0.05 up to or equal to 0.1 mcg/kg/min or 5-12 mcg/min
- Greater than 0.1 mcg/kg/min or >12 mcg/min

Vasopressin (Vaso)

Members commented that Vaso is usually administered in units per minute. The members agreed to use this unit of measure. UNOS Research staff commented that there is potential to program the various units and allow the user to select the unit they prefer and then select the corresponding range.

The members agreed to the following ranges:

- None
- Up to 0.05 mcg/min
- 0.05 up to 0.08 mcg/min
- Greater than 0.08 mcg/min

Neo-Syneprine (Neo)

The members discussed whether or not Neo should be included as an option for vasopressors. A member commented that it should be an option to support completeness of data collection, although it is not commonly used. The member discussed including an “other” option but ultimately decided to include Neo. The Chair referenced the dosing ranges included in Epocrates.

The members agreed to the following ranges:

- None
- >0 - < 100 mcg/min
- 100-200 mcg/min
- >200 mcg/min

Nitric Oxide and Flolan

The Chair asked the members if information should be collected on Nitric Oxide and Flolan and whether the user should report “yes/no” or select a range of dosing. The members agreed that this information should be collected as “yes/no.” The Chair noted that these medications are not always administered to treat PGD, but to treat a patient’s pulmonary hypertension to prevent PGD or graft dysfunction.

Next steps:

UNOS Research staff agreed to draft the ranges for the members to review and approve.

2. Final review and acceptance of data collection timeframes for new data elements on TRR

Summary of discussion:

Members agreed to the proposed time frames of 24 and 72 hours +/- 4 hours from arrival to the intensive care unit (ICU).

3. Discussion of other potential data elements related to donors, procurement and operational practices

Summary of discussion:

The members reviewed comments received during the request for feedback relating to data on donors and procurement. The Chair commented that donor after cardiac death (DCD) data is already being collected.

During the request for feedback, the community recommended collecting preservation device information. Currently, there is data collection for whether or not a heart was perfused but there are no other details collected. The members agreed that perfusion related data elements will not be included in the proposal.

The Chair shared that the community also recommended collected predictive heart mass. The Chair commented that including this calculation would involve additional programming. The members decided not to include this data element in the proposal.

The members discussed whether or not to collect data on troponin. UNOS staff informed the members that this information may already be collected for donors and will follow up via email to confirm.

Another recommendation from the community was to include the recipient risk factor of sensitization. The members decided to not include this or any additional data elements not already proposed.

Next steps:

The Heart Committee will review and vote on the proposed data elements at the upcoming Heart Committee meeting on June 15, 2021.

Upcoming Meeting

- TBD

Attendance

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