

OPTN Data Advisory Committee

Meeting Summary

June, 15, 2020

Conference Call

Rachel Patzer, Ph.D., M.P.H., Chair
Sumit Mohan, M.D., M.P.H., Vice Chair

Introduction

The Data Advisory Committee (DAC) met via Citrix GoToTraining teleconference on 06/15/2020 to discuss the following agenda items:

1. Committee Service Recognition
2. Refusal Codes Project
3. Enhancements to the National Liver Review Board (NLRB), Part Two
4. Guidance and Policy Modifications Addressing Adult Heart Allocation Policy
5. Q3 Data Definition Review

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

1. Committee Service Recognition

Outgoing DAC members were recognized for their service to the OPTN.

2. Refusal Codes Project

The DAC was updated on their upcoming sponsorship of the refusal codes project.

Summary of discussion:

UNOS staff explained that the refusal codes project is transitioning from an operational project to an OPTN committee-sponsored project led by DAC. This transition is in the early stages and formation of a workgroup is anticipated. There were no questions or comments from DAC members.

3. Enhancement to the National Liver Review Board (NLRB), Part Two

The DAC was updated on the OPTN Liver and Intestines Transplantation Committee's (Liver Committee) proposal for the upcoming Summer public comment.

Summary of discussion:

UNOS staff supporting the Liver Committee explained that the Liver Committee is updating the standard criteria for candidates receiving a MELD or PELD exception for portal pulmonary hypertension (POPH) by adding two new data fields in the initial exception form. The intention is to ensure that it is only candidates who need additional MELD or PELD points are receiving those. Within the initial exception form, "heart catheterization date" is being proposed to replace "test date" in order to match new policy language and with the extension form. Additionally, new data collection fields are proposed to be added and removed on the POPH exception extension form so that it has the same data collection as the initial exception form, for consistency. The proposed added data collection fields are "mean pulmonary arterial pressure (MPAP)", "pulmonary artery wedge pressure", and "cardiac output". The Liver Committee proposed to remove the peak mean arterial pressure level in the past 90 days data field.

A member asked for clarification on required fields and optional fields. UNOS staff responded that none of the fields are required, but if a program does not answer the fields then they will not get the exception and will be reviewed by the NLRB.

4. Guidance and Policy Modifications Addressing Adult Heart Allocation Policy

The OPTN Thoracic Organ Transplantation Committee (Thoracic Committee) presented Project Check in #1.

Summary of discussion:

UNOS staff supporting the Thoracic Committee explained that the proposal aims to change the triggering event associated with reporting of cardiac index value in *OPTN Policy 6.1.D.ii: Inotropes without hemodynamic monitoring*. The proposed change is from “7 days prior to submission of Heart Status 4 Justification form” to “7 days prior to inotrope administration or inotropic initiation”. The proposed updates include adding four data field capturing the date (mm/dd/yyyy) when inotropes administration started and revised instructions related to cardiac index on the initial heart justification form. Collection of the data of inotrope initiation is consistent with how these data are collected in *OPTN Policy 6.1.C.v: Mechanical Circulatory Support Device (MCSD) With Right Heart Failure*. UNOS staff explained that this data, specific to the inotrope without hemodynamic monitoring, is not available via another source.

A member asked when this form is completed and who is responsible for completing the form. UNOS staff responded transplant or data coordinators are completing forms, and it would be filled out once a candidate is first waitlisted and then also filled out to extend this status but would not need to fill in the date of initiation part as an extension request. A member asked why this is not part of the transplant candidate registration (TCR) form. UNOS staff explained that this data collection is on the heart justification form, however, it could pull the information to the TCR form, if that is recommended by the committee. A member asked who has been consulted outside of the Thoracic Committee about this project. UNOS staff responded that this came up late in the project so there has been no additional consultation, but there will be presentations to relevant committees during public comment.

Does the OPTN Data Advisory Committee endorse this proposed data collection effort?

Yes: 100% (10) No: 0%

5. Q3 Data Definition Review

The DAC reviewed and discussed data definitions shown in the following table. Members were asked for their feedback and whether or not they endorse the proposed changed. The table includes the members’ endorsement decision, as well as any proposed changes.

Data Element	Endorsed by DAC	Member Question	Proposed Additional Language	Changes Proposed after Discussion
Method of Dialysis	Yes	Is CVVH considered dialysis for this field on the Kidney TRR?	Adds “Continuous forms of dialysis such as Continuous Venovenous Hemofiltration (CVVH) are considered dialysis for the field. Other examples include Continuous Venovenous Hemodialysis (CVVHD)	“All forms of continuous renal replacement therapy”

Data Element	Endorsed by DAC	Member Question	Proposed Additional Language	Changes Proposed after Discussion
			and Continuous Arteriovenous Hemodialysis (CAVHD).	
Extracorporeal Support	Yes	Should I answer “yes” if the donor was already deceased when the patient went on ECMO?	Adds “Note: If ECMO is used to reanimate the heart and not sustain the donor, select NO ”	None
Thoracic Hospitalization	Yes	How do I report hospitalization and/or rejection during thoracic 6 month post transplant?	Adds “This includes: <ul style="list-style-type: none"> • Has the patient been hospitalized since the last patient status data • Functional status • Graft Function • Post Transplant Events • Post Transplant Malignancy • Immunosuppressive Information • Drugs used for induction, acute rejection, or maintenance • Drug used for induction or acute rejection • Drugs primarily used for maintenance • Other drugs 	None

Summary of discussion:

For “method of dialysis” definition, a member asked what percent of the population use this type of dialysis and are there other types of dialysis that should be clarified for future reference. UNOS staff responded that the original member question only addressed CVVH, so CVVHD and CAVHD were added in order to be more inclusive. The Committee Vice Chair responded that CVVH is used for anyone in the intensive care unit (ICU) with hypotension, it is not uncommon. The Committee Vice Chair also added that peritoneal dialysis (PD) could be included but it is almost never used. Another member agreed that it was not necessary to add PD. The Chair suggested the note could be shortened to “all forms of continuous renal replacement therapy (CRRT)” count. Another member asked if there needs to be clarification on the exclusion of ultrafiltration. The Chair agreed that this is an important question but believed it is beyond the scope of this data definition review. UNOS staff explained that the DAC could

either proceed approving the simplified definition, add one sentence to explain intent, or recommend more extensive data collection changes to the Kidney Committee during their data collection review. Members agree they would like to proceed with the simplified note and give recommendations to the Kidney Committee.

Members agreed that the notes added to extracorporeal support and thoracic hospitalization were clear and had no questions or comments.

Does the DAC endorse today's clarified definitions, and recommend including in the annual report to the OPTN Board of Directors?

Yes: 100% (7) No: 0%

Upcoming Meetings

- July 12, 2020 (teleconference)
- September 14, 2020 (teleconference)