

## **OPTN Executive Committee**

### **Meeting Summary**

**October 26, 2022**

**Webex**

**Jerry McCauley, MD, MPH, FACP, Chair**

### **Introduction**

The OPTN Executive Committee met via Cisco Webex Meetings teleconference on 10/26/2022 to discuss the following agenda items:

1. New Projects from the Policy Oversight Committee (POC)\*
2. Clarifications to the Continuous Distribution of Lungs\*
3. Transition Periods for Recertification of Liver Laboratory Values and other Technical Corrections\*
4. Review of Liver and Intestine Variances in OPTN Policy\*
5. OPTN Public Comment: Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) HOPE Act Recommendations

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

#### **1. New Projects from the Policy Oversight Committee (POC)**

Nicole Turgeon, Chair of the Policy Oversight Committee (POC), presented a new project proposal from the Multi-Organ Transplantation Committee (MOT). The committee plans to determine when kidneys should be offered to single organ candidates before multi-organ candidates, how to determine which kidney to offer to which candidate, while also promoting consistency in OPO practices to leave a certain level of flexibility.

The project addresses the strategic goal to provide equity in access to transplant and the strategic policy priority to improve the equity for multi-organ and single organ candidates.

The POC's had no concerns about the project during their evaluation. The project plans to go out for public comment during the Winter 2023 Public Comment Cycle.

#### Vote:

The Executive Committee unanimously approved the project proposal with a final vote of 9 approve, 0 decline and 0 abstentions.

#### **2. Clarifications to the Continuous Distribution of Lungs**

Marie Budev, Chair of the Lung Transplantation Committee, presented the clarifications on behalf of the committee. The committee is suggesting minor clarifications to the policy language for continuous distribution, including delay implementation of distance calculation until there is a consistent approach established across organs, to clarify requirements, and to update the probability table for post-transplant survival calculation. The clarifications also include placement efficiency equations, requirements to maintain assignment to pediatric priority 1, requirements for updating clinical values every 28 days for certain candidates, and how supplemental oxygen and functional status factor into the allocation score.

Summary of discussion:

President McCauley asked Dr. Budev if she thought these clarifications were going to substantially delay the implementation of the project overall or the predicted timeline. Dr. Budev responded that the committee's timeline right now is to implement towards the end of January and the only reason that a delay may occur is due to the educational opportunities that the committee would like to offer to the transplant community.

Vote:

The committee voted in unanimous approval of the clarifications with a final vote of 9 approve, 0 decline, and 0 abstentions.

**RESOLVED**, that the changes to *Policies 10.1: Lung Composite Allocation Scorem 10.1.A.2.a: Candidates Less than 12 years Old – Priority 1, 10.1.E: Promoting the Efficient Management of the Organ Placement System, 10.3.A: Lung Clinical Values That Must Be Updated Every Six Months, 21.1.D: Efficient Management Formulas, 21.2.A: Values Used in the Calculation of Lung Waiting List Survival, 21.2.B.1: Coefficients Used in Calculating Lung Post-Transplant Outcomes, and 21.2.B.2: Probabilities Used in Calculating Lung Post-Transplant Survival, as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.*

**3. Transition Periods for Recertification of Liver Laboratory Values and other Technical Corrections**

James Trotter, Former Chair of the Liver and Intestinal Organ Transplantation Committee, presented the proposed liver clarifications on behalf of the committee. Improving Liver Allocation: MELD, PELD, Status 1A, 1B was approved by the Board of Directors in June 2022 and is slated for implementation in 2023. These amendments propose the removal of two unnecessary data fields and the addition of one data field to address a patient's current sex. The committee is recommending the removal of "Bilirubin PSC/PBC/Other Cholestatic" field and the transition period for lab updates upon implementation which is the same procedure as the MELD Na implementation. The committee suggests an additional data field to simplify data collection for "current sex". This will be a new field required for new registrations after the implementation. Candidates who are already registered will default to their birth sex. If their birth sex is not representative of their current sex, then their doctors may manually change the field.

Summary of discussion:

President McCauley asked how the Bilirubin PSC/PBC/Other Cholestatic field will be populated. Dr. Trotter clarified that there are two bilirubin fields. There is a bilirubin field that doctors enter for patients and then there is another bilirubin field that a doctor would enter if their patient has PSC, PBC or Other Cholestatic. Dr. Trotter noted that this as a housekeeping clarification because this field is not relevant to their work and likely dates back two decades when doctors would use this field. Matt Cafarella, UNOS Policy Analyst, clarified that the two different fields are Bilirubin and Bilirubin PSC/PBC/Other Cholestatic fields. Transplant programs cannot provide a value for both of the fields, but the calculation of the scores is the same in determining a patient's MELD score.

A committee member is asked how current sex is identified by the programs. Dr. Trotter explained that patients are self-identifying for this field. Dr. Trotter explained that the committee did engage with transgender specialists to receive their advice on the best way to approach the field, and these specialists recommended that they allow patients to self identify.

Dr. McCauley asked if someone could gain an advantage by self identifying as a female because MELD 3.0 is designed to correct a historic under prioritization of females. Dr. Trotter said yes, someone could try and do this but that he does not foresee this being an issue.

A representative from HRSA commented that someone’s sex is based on legal documentation and asked if this is a change to self-identification. Dr. Trotter replied that centers do not look up self-identifying fields to verify, and that this would not be realistic or efficient for centers to do. Dr. Trotter commented that there is no formal way to collect this field. Mr. Cafarella clarified that this was an intermediary question the committee has proposed to include as a field, and this is really the formalization of the question in policy. The policy will still require the collection of birth sex but will also now require the collection of current sex.

Vote:

The committee unanimously approved the proposal with a vote of 9 approve, 0 decline and 0 abstentions.

RESOLVED, that liver transplant candidates whose recertification schedules change upon implementation of the *Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B* proposal, adopted by the OPTN Board of Directors on June 27, 2022, will be granted transition periods for transplant programs to report their labs values as follows:

Upon implementation, if a candidate’s MELD or PELD score increases such that their new laboratory recertification date is:	Then the following transition period will be provided for submitting updated laboratory values:
Prior to implementation	Seven days from the day of implementation
The day of implementation	Seven days from the day of implementation
One to six days after implementation	Seven days from the day of implementation
Seven days or more after implementation	None

The committee unanimously approved the proposal with a vote of 9 approve, 0 decline and 0 abstentions.

FURTHER RESOLVED, that the proposed modifications to data collected by the OPTN, as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

OPTN Waiting List System Field	Action
Is current sex same as birth sex?	Remove
Current Sex	Change from optional to required data field
Bilirubin (mg/dl) (PBC/PSC/Other Cholestatic)	Remove

**4. Review of Liver and Intestine Variances in OPTN Policy**

Dr. Trotter presented the policy for the Review of Liver and Intestine Variances in OPTN Policy. The purpose of the policy is to align expiration dates of four current OPTN liver allocation variances. The four variances are the Region 8 Split Liver Variance, Open Split Liver Variance, Access for Medically Urgent Candidates in Hawaii and Puerto Rico, and ABO Blood Type Variance for Hawaii and Puerto Rico. The committee is extending and aligning the end dates for the four variances to allow the committee to consider how to incorporate the variances into continuous distribution as they develop the points-based framework. The committee will continue to monitor variances at least annually and can sponsor projects to amend the variances as needed.

The proposal was on the non-discussion agenda at regional meetings and was supported by all regions, ASTS, AST and NATCO. After implementation, OPOs will need to be familiar with the variances and continue to work with transplant programs who are participating in the variances to allocate livers and intestines accordingly. As for participating transplant programs, they will continue to submit required data for duration of variances. The committee does not expect any fiscal impact on members and minimal OPTN resources needed to implement the policy.

Summary of discussion:

There were no questions from the committee.

The committee unanimously approved the Review of Liver and Intestine Variances in OPTN Policy with a vote of 9 approve, 0 decline and 0 abstentions.

**RESOLVED**, the following variances are hereby extended to expire upon the implementation of the continuous distribution of livers and intestines.

**5. OPTN Comment: Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) Hope Act Recommendations**

Lara Danziger-Isakov, Chair of the Disease Transmission and Advisory Committee (DTAC), presented the comment related to the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) HOPE Act recommendations. In October 2021, the OPTN Executive Committee sent a letter to the HHS Secretary recommending that the Secretary remove the statutory research requirement for organ transplants from HIV positive organ donors to HIV positive transplant recipients. In October of 2022, the committee published draft recommendations and this letter from DTAC is a response to those recommendations.

Summary of discussion:

A representative from HRSA asked to clarify the recommendation that the OPTN revise the research criteria and that they would not use the current NIH Research Criteria, to which Dr. Danziger-Isakov confirmed this was correct. HHS would be tasking the OPTN to create research requirements within the scope of the OPTN. This request would task the OPTN with something they have never done before and if the recommendation was confirmed, then the OPTN would need to confirm this work was within the purview of their work.

A committee member asked for a timeline on when the OPTN expects a response from the HHS Secretary. They worried that until the new process begins, then many patients will be affected by this. Dr. Danziger-Isakov informed the committee member that they have been corresponding with the ACBTSA and this committee has provided feedback to the HHS Secretary regarding these recommendations. A representative from HRSA explained that the ACBTSA will provide a recommendation to the HHS Secretary, the Secretary will then make a decision from these recommendations, and then the recommendation would come back to the OPTN, but they were not aware of a specific timeframe.

A committee member asked what the best-case scenario would be from the recommendations and how to best get these recommendations to the HHS Secretary. A representative from HRSA commented that the recommendation from the ACBTSA was tied to the availability of data. The ACBTSA thought there was plenty of data on kidney and liver but there was not sufficient data to make conclusions about non-kidney and non-liver organs. Dr. Danziger-Isakov furthered the conversation by explaining that one of the complications has been establishing a standard to engage with non-kidney, non-liver organs. She explained that this standard would be incredibly hard for many centers to meet. She noted that to date,

only two centers meet the current standards for thoracic and one program meets the requirements for heart.

Next steps:

The letter will be sent to the Committee for their review once the DTAC has approved. The committee should expect the vote to be conducted via email.

**Upcoming Meeting**

- December 4<sup>th</sup>, 2022

## Attendance

- **Committee Members**
  - Gail Stendahl
  - Irene Kim
  - Jeff Orlowksi
  - Jerry McCauley
  - Jim Sharrock
  - Linda Cendales
  - Lloyd Ratner
  - Matt Cooper
  - Valinda Jones
- **HRSA Representatives**
  - Chris McLaughlin
  - Frank Holloman
  - Shannon Taitt
- **SRTR Representative**
  - Ajay Israni
- **UNOS Staff**
  - Alex Tulchinsky
  - Anna Messmer
  - Cole Fox
  - David Klassen
  - Desiree Tenenbaum
  - Jason Livingston
  - Kaitlin Swanner
  - Mary Beth Murphy
  - Matt Cafarella
  - Maureen McBride
  - Morgan Jupe
  - Roger Brown
  - Sarah Payamps
  - Susan Tlusty
  - Susie Sprinson
  - Taylor Livelli
  - Tina Rhoades
  - Tony Ponsiglione
  - Tynisha Smith
- **Other Attendees**
  - James Trotter
  - Lara Danziger-Isakov
  - Marie Budev
  - Nicole Turgeon