

OPTN Heart Transplantation Committee

Meeting Summary

May 3, 2023

Conference Call

Rocky Daly, MD, Chair

JD Menteer, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee, the Committee, met via Citrix GoTo teleconference on May 3, 2023, to discuss the following agenda items:

1. Regional Meeting Schedule
2. Continuous Distribution Rating Scale for Pediatric Candidates
3. Continuous Distribution Rating Scale for Prior Living Donors
4. Proximity Efficiency Introduction

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

1. Regional Meeting Schedule

Contractor staff shared the upcoming OPTN Regional meeting schedule and reminded the Committee there will be multiple presentations for Regional Representatives to make at these meetings.

Summary of discussion:

There was no discussion on this item.

2. Continuous Distribution Rating Scale for Pediatric Candidates

Staff led the Committee in a discussion regarding a pediatric candidate rating scale for continuous distribution for hearts.

Summary of Presentation:

Staff began by reminding the Committee that the proposed pediatric rating scale is binary, either a candidate is or is not a pediatric candidate. The goal is to reach a consensus on the proposed rating scale. For this meeting the Committee is not trying to figure out the relative weights of the attributes, other rating scales, optimization of rating scale or weight, or donor factors. These are factors that will repeat for each attribute. The Committee is still in the portion of continuous distribution framework development that requires building rating scales to assign points to attributes, which will be released for public comment as a concept paper. The final policy proposal is still on track for the December 2025 board meeting.

Building the rating scale is just one part of work being performed as part of the first version of continuous distribution. Staff briefly reviewed the difference between rating scales and weights. Rating scales calculate how much priority a candidate receives based on one attribute. Weights are the percentage each attribute gets within the total composite allocation score. Pediatric priority is a component within the patient access goal of continuous distribution for hearts. Staff also reviewed the rating scale graphs that are used within continuous distribution, highlighting the binary scale that will be used for the attribute.

Members were reminded that not all attributes are aligned or related to medical urgency. The purpose of the patient access goal is to promote access to transplant for specific candidates or populations who need additional priority or special considerations in the allocation system.

For pediatric priority, the binary scale captures whether a candidate is either registered prior to turning 18 years old and receives all the possible points, or was registered when turning 18 years old or after and; therefore, does not receive any of the possible points. NOTA requires the OPTN to recognize “the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children.” Additionally, there are ethical principles to consider for pediatric candidates such as the negative impact on childhood development that organ failure can have, the fact that children have yet to experience a full life, and the value placed on children’s life by society.

Pediatric candidates in current policy are prioritized, or receive special recognition, throughout heart allocation policy. This includes prioritization for pediatric and adult donors under certain circumstances and access to intended incompatible blood type donor hearts. Lung, kidney, pancreas, and liver have all chosen to use a binary rating scale for the pediatric candidates. Additionally, for modeling optimization purposes these rating scales need to be defined.

Summary of discussion:

A member asked if all the rating scale graphs have been used by other the organ groups that have developed, or are in the process of developing, continuous distribution. Staff responded that all graphs have been explored by the various organ groups but might not be in used.

A member asked if there was any data regarding clustering of registrants between 17 and 18 years old, in order to get a candidate pediatric priority? Staff responded they are not aware of any data that would suggest this is happening. A member asked if it would be possible to taper down points received by pediatric candidates after they turn 18. Staff responded that in order to do this there has to be compelling evidence that this is necessary and medically sound.

A member pointed out that pediatric congenital heart disease (CHD) matters as much as chronological age. The Chair pointed out that within the medical urgency attribute such a candidate could receive additional points for CHD and receive points for being registered as a pediatric candidate. The Chair reminded the Committee that the other organ groups had all picked the binary rating scale for pediatric candidates with registration prior to 18 being the only requirement.

A member stated they are supportive of the pediatric rating scale being binary because of both the ethical components and to align with the other organs. The member did say they would be open to considering other options but the binary scale made the most sense. Several members agreed. One member asked if there is anyone on the committee who disagreed with the binary scale. The Vice Chair stated their support for the binary scale because it is consistent with current policy and is consistent with the other organ groups.

A member asked why 18 was the cutoff rather than some other age. Another member responded that 18 is the legal definition for an adult. Staff responded that the age is set by NOTA.

Staff asked if anyone was opposed to the binary scale for pediatric candidates, no member responded as opposed.

3. Continuous Distribution Rating Scale for Prior Living Donors

The Committee discussed the binary rating scale option for prior living donor priority within the patient access attribute.

Summary of presentation:

Staff pointed out the discussion for prior living donors (PLD) is similar to pediatrics in that a binary rating scale seems the most obvious option because a candidate either is or is not a PLD. In current heart policy, PLDs do not receive any priority meaning this will be a change in policy for continuous distribution. Previously, the OPTN Living Donor Committee offered four recommendations to help guide committee discussions of PLD priority. The recommendations are: PLDs should receive priority if they are listed for transplant, all PLDs should receive priority for any organ needed, PLD priority should not have a time restriction, and PLD should not be valued differently based on organ type. Between April 1994 and July 2019, a total of 13 PLDs have been on the waitlist for a heart transplant. PLDs should not be divided based on which organ they donated, PLDs undergo extensive psychosocial and medical evaluation to determine health and motivation for donation. Finally, whether to provide PLDs with priority should be a community decision because sometimes PLDs do not advocate for themselves.

Heart policy would have to be modified to prioritize candidates who are PLDs. Heart allocation policy does not currently prioritize candidates who are prior living donors. Patients, living donors, and stakeholder organizations are very aware of how proposed continuous distribution allocation frameworks address living donors. During the January to March 2023 public comment cycle, the OPTN Kidney Transplantation Committee reassured living donor advocates that their continuous distribution allocation framework would not remove priority for PLDs. The Committee's decision regard PLDs will be used for modeling optimization exercise.

For continuous distribution of lungs, a binary rating scale was chosen and PLDs receive five percentage points towards their composite allocation score within the patient access attribute. There is no time limit on PLD status and there is no delineation between the types of organs donated. The definition of a PLD within OPTN policy requires the candidate to have donated at least one organ within the United States or its territories, along with some reporting requirements.

Summary of discussion:

The Vice Chair stated that it makes sense to give priority to PLDs and also to make it binary regardless of what organ was donated. Another member mentioned that this topic was brought up at a recent conference that an unintended consequence of this attribute could be that it gives some additional points to certain socioeconomic groups that may already have certain advantages; this member pointed out they do not believe that is necessary and PLDs do deserve priority. The Chair pointed out that this attribute must be considered in continuous distribution.

A member asked if someone who has donated more than one organ should be given additional priority above other PLDs. Some members expressed some general support for this idea, but preferred a binary scale regardless of the number of organs donate. A second member asked if the binary scale could be weighted in a way that would allow for other points to become available for other attributes. Staff responded that could be a possibility and can be discussed during a conversation about weights, but the goal for today is to discuss the rating scale.

The Committee reached a consensus that a binary rating scale for prior living donor priority in the most appropriate.

4. Proximity Efficiency Introduction

The Committee began their discussion on the proximity efficiency in preparation for more detailed conversations at a future meeting.

Summary of presentation:

Proximity efficiency can be described as measuring the efficiency of transporting hearts shorter distances. The Committee will be considering factors such as the distance from transplant hospital to donor hospital, and the efficiencies or inefficiencies associated with driving versus flying to recover a donor heart. The Committee will also discuss the major inflection points associated with traveling for an organ, this includes how far a program is willing to drive or fly and the threshold distance for each, and how much efficiency is lost when switching from driving to flying.

Summary of discussion:

The Chair pointed out that part of the intent of this attribute is to give more points to candidates who are closer to the donor hospital, and, for example, this could be done with a linear graph that decreases points based on distance. In Lung Continuous Distribution, proximity efficiency is only 10% of the composite allocation score which allows medical urgency and post-transplant survival to be the main drivers of lung allocation. The OPTN Lung Committee spent a lot of time discussing proximity efficiency to ensure areas with low population density were not disadvantaged. It will also be important to keep in mind that technological advances have been made to allow for the organs to be transported further which reduces concerns regarding cold ischemic time.

Upcoming Meeting

- March 16, 2023; 5:00 pm – 6:00 pm (ET); virtual conference call

Attendance

- **Committee Members**
 - Rocky Daly
 - JD Menteer
 - Dmitry Yaranov
 - Earl Lovell
 - Glen Kelley
 - Jennifer Carapellucci
 - Jennifer Cowger
 - Jonah Odum
 - Martha Tankersley
 - Nader Moazami
 - Timothy Gong
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Katherine Audette
 - Monica Colvin
 - Yoon Son Ahn
- **UNOS Staff**
 - Eric Messick
 - Alex Carmack
 - Alina Martinez
 - Holly Sobczak
 - James Alcorn
 - Kelsi Lindblad
 - Kimberly Uccellini
 - Laura Schmitt
 - Sara Rose Wells
- **Other Attendees**
 - Cindy Martin
 - Daniel Yip