

OPTN Kidney Transplantation Committee

Meeting Summary

September 20, 2021

Conference Call

Martha Pavlakis, MD, Chair

Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 09/20/2021 to discuss the following agenda items:

1. Question from the Ad Hoc Multi-Organ Committee
2. Continuous Distribution of Lungs and Multi-Organ Allocation
3. Ethical Considerations of Continuous Distribution in Organ Allocation

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

1. Question from the Ad Hoc Multi-Organ Committee

The Committee provided feedback on metabolic disease diagnosis for heart-kidney and lung-kidney, as requested by the Ad Hoc Multi-Organ Committee.

Data Summary:

The Ad Hoc Multi-Organ Committee supports using the existing liver-kidney eligibility criteria for heart-kidney and lung-kidney allocation, and is seeking feedback on the potential omission of metabolic disease for heart-kidney and lung-kidney allocation.

The OPTN Lung Transplantation Committee was not aware of any cases of lung-kidney transplant due to metabolic disease, and recommended omitting metabolic disease from lung-kidney allocation. The OPTN Heart Committee will provide feedback at their September meeting.

Summary of discussion:

The Chair shared that upon most recent discussion, the Committee was not aware of any metabolic disease diagnoses for heart-kidney and lung-kidney, and that omission of metabolic disease should not be an issue.

The Committee had no additional comments or questions.

2. Continuous Distribution of Lungs and Multi-Organ Allocation

The Vice Chair of the OPTN Lung Transplantation Committee presented the *Establish Continuous Distribution of Lungs* proposal, and the Committee provided feedback.

Data summary:

The purpose of the Establish Continuous Distribution of Lungs proposal is to move lung allocation from classification groups with hard boundaries to a points-based allocation system that considers individual candidates holistically. This will align lung allocation community, ethical, and regulatory goals, and medical advancements.

The Continuous Distribution proposal will also update multi-organ allocation for lung multi-organ combinations:

- For lung-kidney and lung-liver, organ procurement organizations (OPOs) will be required to offer the multi-organ combination to lung candidates with a composite allocation score (CAS) of 28 or higher on the lung match run. Once those candidates have been exhausted, then the kidney and liver may be offered from their respective match runs.
- For heart-lung, OPOs will be required to offer the heart-lung on the heart match run to candidates status 1 and 2 within 500 nautical miles (NM), and then on the lung match run to candidates with a CAS of 28 or higher. Once these candidates have been exhausted, the OPO may offer the heart alone on the heart match run to candidates further than 500NM or listed at a status 3 or lower.

Summary of discussion:

A representative from the Scientific Registry of Transplant Recipients (SRTR) asked if the Lung Committee has reviewed or has data on the impact of the proposed allocation system on highly sensitized patients, adding that the weighting for high calculated panel reactive antibody (cPRA) candidates is relatively low. The Lung Committee Vice Chair explained that Lung wait listing and allocation historically did not readily collect cPRA data. As a result, high sensitization was not able to be readily incorporated into modeling, and so the Lung Committee did not feel comfortable further increasing the weighting.

A member asked how the high cPRA attribute was scaled, noting that sensitization can impact access to transplant significantly for kidney candidates. The member expressed concern about the weight allocated to height compatibility, particularly as height affects female candidates and can reduce access to transplant. The member suggested increasing emphasis on sensitization and size with small for small matching. The Lung Committee Vice Chair shared that the Lung Committee deliberated on these points, including discussion on disparity in access for women with shorter stature. Ultimately, the Lung Committee decided to equally distribute weighting between attributes within candidate biology. Staff clarified that research support for the Lung Committee utilized the same methods used to create the cPRA scale, which calculates access based on sensitization, and applied it to height and blood type. Sensitization, blood type, and height are equally weighted because they are all on the same scale. Staff explained that, in theory, a candidate could receive the full five points for height, because height can have the same impact as having 100 percent cPRA. However, a candidate can never receive five points for blood type, because no matter the level of disadvantage with blood type, the disadvantage in access is never as extreme in blood type as it would be with a 99 percent cPRA or very short height. The member expressed support for increased weighting for highly sensitized patients and size matching. Staff explained that clinical data is used to drive how blood type, height, and sensitization interact with each other, and that values – expressed in weighting – drive interactions between the goals (such as candidate biology).

The Chair remarked that the weighting for prior living donor priority seems relatively small, adding that the rarity of prior living donors needing a lung transplant shouldn't dictate or determine the level of priority they receive. The Vice Chair of the Lung Committee shared that the Lung Committee wanted to recognize prior living donors and allocate points to those candidates, but felt that ultimately it very rarely occurred and that 5 percent was an appropriate weighting. A member pointed out the kidney allocation scheme currently honors living donors of any organ and they are ranked highly in kidney allocation classifications. Staff shared that this was a values-based decision that the Lung Committee felt was appropriate, and noted that there has not been an agreement or requirement for the weights of

certain attributes to be equal across the committees. Staff also noted that prior living donor priority is new to lung allocation. One member recommended utilizing modelling to better understand how a living donor, who now needs a lung, falls into the allocation scheme. The Vice Chair of the Lung Committee noted that there was negligible data on prior living donors in lung allocation, due to the infrequency of prior living donors among lung candidates.

The Committee expressed support for the multi-organ allocation scheme for lung multi-organ allocation candidates.

3. Ethical Considerations of Continuous Distribution in Organ Allocation

The Chair of the OPTN Ethics Committee presented the Ethical Considerations of Continuous Distribution in Organ Allocation currently released for public comment.

Data summary:

The *Ethical Considerations of Continuous Distribution in Organ Allocation* white paper considers whether the continuous distribution framework is supported by ethical principles guiding organ allocation, and identifies key questions, metrics, and opportunities for organ committees to consider when developing and implementing the new allocation framework. The paper performs ethical analysis of classification-based and continuous distribution systems of organ allocation, reinforces the idea that allocation changes should not negatively impact vulnerable groups, and advises the OPTN organ-specific committees about ethical benefits and challenges associated with moving to the continuous distribution framework. This paper specifically considers advantages and challenges in utility, equity, transparency, and autonomy.

Summary of discussion:

One member pointed out the ethical challenges of allocating priority to pediatric patients on a binary, under 18 or over 18-years old basis. The Chair of the Ethics Committee agreed, remarking that continuous distribution allows many of the previously binary characteristics to take on more depth and nuance in allocation.

The Chair expressed support for these ethical considerations in context with community input in weighting attributes and goals. The Chair emphasized that ethical principles will be foundationally important when developing the Continuous Distribution framework. The Chair of the Ethics Committee agreed, and shared that the Ethics Committee is interested in ensuring there is widespread and well-rounded engagement in values-based community exercises. The Chair of the Ethics Committee continued that values-based prioritization should be developed via a deliberative, democratic approach where a well conducted and representative analytic hierarchy process (AHP) exercise is one important input in a broader discussion about balancing ethical principles. Staff shared that there are populations of the general public that could be considered in the demographics of participants for an AHP, especially given that organ transplant and donated is rooted in public trust. Staff also pointed out that there are a number of laws, including the Final Rule, that apply to organ transplantation and allocation that will play a part in that balancing of ethical principles.

The Committee expressed support for these considerations posed by the OPTN Ethics Committee.

Upcoming Meetings

- October 8 – Virtual “In-Person” Meeting
- October 18 – Teleconference

Attendance

- **Committee Members**
 - Martha Pavlakis
 - Jim Kim
 - Vincent Casingal
 - Amy Evenson
 - Arpita Basu
 - Asif Sharfuddin
 - Bea Concepcion
 - Caroline Jadlowiec
 - Deirdre Sawinski
 - Elliot Grodstein
 - Precious McCowan
 - Sanjeev Akkina
 - Stephen Almond
 - Peter Kennealey
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Ajay Israni
 - Bryn Thompson
 - Jonathan Miller
 - Peter Stock
- **UNOS Staff**
 - Lindsay Larkin
 - Ross Walton
 - Kayla Temple
 - Amanda Robinson
 - Ben Wolford
 - Elizabeth Miller
 - James Alcorn
 - Jennifer Musick
 - Joel Newman
 - Kaitlin Swanner
 - Krissy Laurie
 - Laura Schmitt
 - Leah Slife
 - Matthew Prentice
 - Melissa Lane
 - Nicole Benjamin
 - Sara Moriarty
 - Sara Rose Wells
- **Additional Attendees**
 - Dave Weimer
 - Keren Ladin
 - Marie Budev