OPTN Lung Transplantation Committee
Meeting Summary
August 26, 2021
Conference Call

Erika Lease, MD, Chair
Marie Budev, DO, Vice Chair

Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 08/26/2021 to discuss the following agenda items:

1. Public Comment Item: Ethical Considerations of Continuous Distribution in Organ Allocation
2. Request for Feedback: Update on OPTN Regional Review Project
3. Multi-Organ Feedback

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

1. Public Comment Item: Ethical Considerations of Continuous Distribution in Organ Allocation

An OPTN Ethics Committee member presented the Ethics Committee's public comment proposal for the Ethical Considerations of Continuous Distribution in Organ Allocation. The purpose of this white paper is to serve as reference tool for organ specific committees to use as they develop ethically sound policies using the Continuous Distribution framework.

Summary of discussion:

A member asked for clarification on whether or not one of the goals of the white paper was to ensure that patients are treated fairly and the Ethics Committee member clarified that it is to ensure that patients are treated equitably. A member asked if there is a way to ensure that patients will not manipulate information and it was clarified that the Committee needs to make sure there are some guardrails in terms of objective criteria. Another member noted that the system has to be and will be adaptive since all systems that are created are not perfect, however with continuous distribution any identified issues will be able to be addressed more quickly.

2. Request for Feedback: Update on OPTN Regional Review Project

The purpose of the OPTN Regional Review project is to evaluate the structure, processes, performance, and effectiveness of the OPTN Regions. The review will consider current and future needs of the nation's donation and transplant community needs. The feedback provided as part of the request will be evaluated and will help inform any possible updates to the current regional structure.

Summary of discussion:

The Chair noted that the current regional structure and meetings are a good opportunity for relatively local people to network and talk. They also provide the opportunity for people to be peripherally involved with the OPTN and added that it should be considered how that would be a part of any new structure. The Chair also mentioned that currently each OPTN Committee has regional representatives which ensures that broad geographic representation. It was clarified that the same structure does not necessarily need to be applied to all facets of what the current regions encompass. For example, it may

make sense to keep a geographic map like today for electing representatives for committees, but have people organized differently for tasks such as policy proposals and implementations. Feedback on these possible structures and how they would be defined is what the OPTN Executive Committee is interested in. A member stated that one of the issues with the current regional structure is regional disparity where every region has one region with more patients with lower scores for getting transplants than the others, but some of this may already be addressed as all organ types move to continuous distribution. The member also asked for clarification on some of the benefits for reshaping regions. It was clarified that the feedback received so far is split with some thinking the current system is great and should not be altered with others feeling the current regions are arbitrary. Some of the concerns with the current regional system include the boundaries being outdated and certain populations are not adequately represented, but that is still all up for discussion and the possible changes could only include small changes that address the challenges we see with the current structure.

3. Multi-Organ Feedback

Committee feedback was requested for whether or not it is appropriate to omit the "metabolic disease" diagnosis category for lung-kidney allocation. The Vice Chair noted that they were unaware of any metabolic indications that have been identified with lung-kidney like they have with heart-kidney, so would suggest omitting it unless others felt differently. The Chair asked if there were any pediatric indications that need to be addressed and it was clarified that there has been only one pediatric lung-kidney transplant so far. A member asked for clarification outside of metabolic disease regarding patients that have a glomerular filtration rate (GFR) of less than 40 that would develop renal failure if they receive a lung transplant only and then advocate for those patients to be listed as lung-kidney, so there is some concern with the described eligibility criteria. It was clarified that the eligibility criteria would specify when the organ procurement organization (OPO) is required to allocate the kidney with the lung and a transplant hospital could register the candidate with the higher GFR for both lung and kidney, but the OPO would not be required to share the kidney with the lung. The member stated that would likely disadvantage the candidate because one of the criteria is that they cannot have organ failure. Another member asked if the safety net would address some of those concerns and it was clarified that those candidates would get priority over other general kidney candidates in the allocation sequences. The Committee supported removing the "metabolic disease" category, but would like to have more information on how it is currently used first and mentioned that it may be helpful to ask for a nephrologist perspective.

The Committee's feedback was also requested for whether or not the Committee supports a one-year window for safety net eligibility for kidney-after-lung candidates or would a longer time frame be preferred. A member asked what the expected wait time is for someone in the safety net and it was clarified that while they did not have the data the impression is that candidates do tend to get kidneys relatively quickly in the safety net. The Vice Chair commented that staging of lung and kidney transplants are happening more frequently at programs so the waiting time is reduced. The member agreed, but noted that it would be helpful to understand the expected waiting time in the safety net to ensure those candidates are not disadvantaged. It was clarified that the way it is currently set up for liver-kidney is that the eligibility for the safety net priority is between 60 days and 365 days following a single organ transplant and when this was previously discussed with the Committee there was some suggestion that the timeframe should be longer for lung-kidney. The Chair asked if there is data that shows the timing of lung recipients who develop end stage renal disease and the Vice Chair stated that those data were not available and there are a few different scenarios for why these candidates would need a safety net. A member mentioned that there are patients still needing dialysis 15 months out from their lung transplant and will be doing reasonably well from a lung transplant perspective but are

now stuck on dialysis, so would support a longer timeframe. Due to the nature of end stage renal disease in lung patients, the Committee supported a longer time frame and felt that 18-months would be reasonable.

Upcoming Meetings

- September 16, 2021 (Committee)
- September 23, 2021 (Subcommittee)

Attendance

- **Committee Members**
  - Erika Lease, Chair
  - Marie Budev, Vice Chair
  - Denny Lyu
  - John Reynolds
  - Julia Klesney-Tait
  - Whitney Brown
  - Errol Bush
  - Scott Scheinin
  - Pablo Sanchez
  - Cynthia Gries
  - Jasleen Kukreja
  - Kelly Willenberg
  - Nirmal Sharma
  - Staci Carter
  - Karen Lord
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Andrew Wey
- **UNOS Staff**
  - Elizabeth Miller
  - Janis Rosenberg
  - Susan Tlusty
  - Sara Rose Wells
  - Krissy Laurie
  - Tatenda Mupfudze
  - Kaitlin Swanner
  - Laura Schmitt
  - Darren Stewart
  - Eric Messick
  - Holly Sobczak
- **Other Attendees**
  - Laurel Avery
  - Roshan George