

OPTN Ad Hoc Multi-Organ Transplantation Committee

Meeting Summary

May 24, 2021

Conference Call

Charles Alexander, RN,MSN,MBA,CPTC, Chair

Introduction

The Ad Hoc Multi-Organ Transplantation (MOT) Committee met via Citrix GoToMeeting teleconference on 05/24/2021 to discuss the following agenda items:

1. Scope of Committee Work
2. MOT in Continuous Distribution of Lungs
3. Eligibility Criteria & Safety Net

The following is a summary of the Ad Hoc Multi-Organ Transplantation Committee's discussions.

1. Scope of Committee Work

UNOS staff provided an overview of the charge for the Committee, as determined by the OPTN Board of Directors and consistent with the Final Rule and NOTA. The Committee Chair discussed the proposed principles for the Committee's work, including the goal to allocate organs to those most in need, at the highest priority, with an appropriate proximity to the donor in a way that maximizes the gift.

UNOS staff presented the proposed project map, which depicts the potential for the Committee's public comment time frame in line with the organ specific committees' work to shift organ allocation to a continuous distribution framework.

UNOS staff discussed the ethical allocation principles, equity and utility, and how these principles play a role in balancing patient access of multi-organ transplant and single-organ transplant.

Summary of discussion:

Members expressed support of the proposed project map. Members were appreciative to have touchpoints to share feedback with their committees and a plan that allowed flexibility but also kept them focused and on task.

In reference to ethical allocation principles, a member shared that the utility argument could be made for multi-organ transplant and candidate biology. The member representing the OPTN Ethics Committee agreed that multiple factors could fit into either the equity or utility categories depending on how they are being used. There was an inquiry about the goal of reducing waste and the potential loss of organs, and the OPTN Ethics Committee has traditionally categorized this allocation principle under utility. A member added to the equity discussion that patient access should be consistent across the country and emphasized the opportunity the Committee has to increase clarity and consistency.

The Chair posed whether or not it is within the scope of this Committee to address the reallocation of organs during a multi-organ transplantation, where the first organ is transplanted but a clinical decision is made to not transplant the second organ? UNOS staff responded that would be within the scope of this Committee to address, they would just need to decide on the best timeframe to do that. The Chair responded that the Committee could most likely address this at the end of the existing project plan and

was pleased to know that it was within the scope. A member included the possibility of developing a more robust policy that identifies the possibility for a backup recipient should reallocation during transplant be necessary. A member supported this idea in favor of reducing loss of high quality organs.

2. MOT in Continuous Distribution of Lungs

Marie Budev, the OPTN Lung Committee Vice Chair and member of the Ad Hoc Multi-Organ Transplantation Committee, updated the Committee on the Lung Committee's proposed approach for addressing multi-organ allocation involving lungs once lung allocation shifts to a continuous distribution framework.

Summary of discussion:

The Chair asked if members would be interested in receiving data on the frequency of lung multi-organ combinations and members responded favorably. UNOS staff shared this data with the Committee.

In terms of guidance for Organ Procurement Organizations (OPOs), members were in favor of developing policies that provide a sense of flexibility but are still clear in how to navigate the allocation process. Presently, there are not a large amount of multi-organ candidates on the waiting list but there is concern that number will continue to increase. A member inquired if, similar to Simultaneous Liver Kidney (SLK) allocation policy, there will be more prescriptive markers of which allocation is preferred versus permissible. UNOS staff informed the member that the current multi-organ allocation policy proposal by the OPTN Organ Procurement Organizations Committee, which is headed to the Board of Directors in June for approval, is anticipating providing a match run that is similar to the SLK match run. This will provide a visual cue for OPOs to know when to allocate to multi-organ candidates and provide functionality to drive the policy.

The Chair recognized the overwhelming challenges in developing an allocation policy that addressed every factor necessary while still maintaining the flexibility to be implemented realistically. The Chair identified the importance of using sound clinical judgement when determining what these policies should look like.

A member shared a concern held by the OPTN Kidney Transplantation Committee and pediatric kidney community that multi-organ donors tend to be the most ideal donors. There is precedent in how the allocation of donors are split for kidney recipients, in terms of Kidney Donor Profile Index (KDPI), and different allocation methods for safety net. Although there are very few candidates in need of a kidney-lung combination, the conversations occurring now will echo the ones to come for more common combination types such as heart-kidney. Furthermore, the member identified that balancing equity and utility concerns may differ between organ systems and will remain an important discussion through the development of multi-organ allocation policy.

A member inquired on how the OPTN Lung Transplantation Committee's upcoming policy will impact pediatric candidates and donors. Due to the small number of pediatric heart-lung donors and recipients, the Committee was unable to make an indication on how their policy would impact this population. The Chair requested to obtain the frequency data that has been referenced during the meeting thus far in order to gain further clarification on the size of this population.

A member called out the need to look at the data on kidney combinations by race as African Americans are disproportionately impacted in their need for kidney transplants. The member said that as there are 1,912 multi-organ combinations that require a kidney, making up 10.4% of the deceased donor kidney

allocations, the ‘small’ numbers quickly add up and should be kept in mind as the Committee proceeds.¹ Multiple members agreed with the importance of this comment. A member added that regard for organ specific vulnerable or highly sensitized populations needs to be constantly remembered, but that this Committee should first establish medical eligibility criteria and safety nets then develop a framework around high risk candidates. The member reiterated the need for equity and uniformity across organ systems and nationwide.

A member highlighted the work addressed in the OPTN Organ Procurement Organizations Committee’s current multi-organ allocation proposal as setting the groundwork for this Ad Hoc Multi-Organ Transplantation Committee to take it to the next level. Members agreed on the great timing for this Committee’s work and the support throughout the community for multi-organ allocation to be fully addressed.

A member noted that with a successful safety net it would be possible to provide guidance on when its best to do a sequential transplant versus a simultaneous one. This ideology may not work for every organ system, but with improvements in dialysis it may be possible to develop some clinical criteria for liver and kidney allocation.

3. Eligibility Criteria & Safety Net

Vincent Casingal, the OPTN Kidney Transplantation Committee Chair and Ad Hoc Multi-Organ Transplantation Committee member, provided background and initiated a conversation on SLK eligibility criteria and safety net.

Summary of discussion:

Eligibility Criteria

A member commented on the unusual prescriptiveness of the SLK policy in mandating which formulas must be used to determine eligibility and not allowing nephrologists to determine what’s best for the patient. The member recommended keeping in mind this stringency while developing additional kidney policy and suggested being prescriptive on where the cutoff is but not how a nephrologist must arrive there. The presenter recognized the unique nature of this policy language compared to others but informed the members that the OPTN Kidney Transplantation Committee’s goal was to be prescriptive in order to eliminate gaming and find the most in-need patients. However, as research has evolved in the field there are definitely things that need to be revisited especially in terms of race based formulas. Ultimately, the presenter encouraged making evidence-based and data-driven decisions that reflect the different ways various diseases impact different organs.

Safety Net

A member noted one of the main challenges that the OPTN Kidney Transplantation Committee faced when developing the safety net policy was limitations in the available data on kidney after liver transplantation. This challenge informed the decision to make the SLK as strict as it is to provide as much specific data as possible, which now allows for the policy to be changed or fine-tuned in any necessary manner.

A member inquired about the status of research on the possibility that a multi-organ recipient may gain additional protection from rejection due to the transplanting multiple organs and how that will influence this Committee’s work. A member informed the Committee that the survival rate for heart-lung transplants is higher than for lung alone but the research is limited and unlikely to be a major

¹ Analysis of OPTN database as of June 11, 2021.

contributor to this discussion. Another member noted that while today's discussion has been primarily focused in kidney combinations, it's important to keep all potential combinations in mind while discussing multi-organ transplantation as a whole.

A member praised the information presented today and the policy developed by the OPTN Organ Procurement Organizations Committee in informing and clarifying multi-organ transplantation. The presenter agreed that being prescriptive and using data to drive policy decisions will allow this group to make a positive impact on allocation policy.

Next steps:

UNOS staff informed the Committee that the next meeting will pick up the conversation on heart-kidney transplants, following the results of the 2019 consensus conference, and receive a presentation from Shelley Hall, the Chair of the OPTN Heart Transplantation Committee and member of the Ad Hoc Multi-Organ Transplantation Committee.

Upcoming Meetings

- June 21, 2021
- July 26, 2021

Attendance

- **Committee Members**
 - Alden Doyle
 - Alejandro Diez
 - Charles Alexander
 - Christopher Curran
 - Evelyn Hsu
 - Garrett Erdle
 - James Sharrock
 - Jennifer Prinz
 - Keren Ladin
 - Kurt Shutterly
 - Marie Budev
 - Nicole Turgeon
 - Oyedolamu K. Olaitan
 - Stacy McKean
 - Vincent Casingal
- **HRSA Representatives**
 - Marilyn Levi
- **UNOS Staff**
 - Abby Fox
 - Amber Wilk
 - Courtney Jett
 - Eric Messick
 - Elizabeth Miller
 - Kaitlin Swanner
 - Krissy Laurie
 - Laura Schmitt
 - Leah Slife
 - Matt Prentice
 - Nicole Benjamin
 - Robert Hunter
 - Ross Walton
 - Susan Tlusty
 - Tina Rhoades
- **Other Attendees**
 - Dave Weimer