

OPTN Liver and Intestinal Organ Transplantation Committee

Meeting Summary

October 28, 2022

Conference Call

James Pomposelli, MD, PhD, Chair

Scott Biggins, MD, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/28/2022 to discuss the following agenda items:

1. OPTN Committee Vice Chair Application and Nomination Process
2. In-person Meeting Recap and Project Updates
3. Continuous Distribution Project Plan
4. Continuous Distribution Attribute: Post-transplant survival/futility
5. Continuous Distribution Attributes

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

1. OPTN Committee Vice Chair Application and Nomination Process

The Committee reviewed the vice chair application and nomination process for OPTN committees.

Summary of discussion:

There were no comments or questions.

Next steps:

The Committee will begin the vice chair application and nomination process.

2. In-person Meeting Recap and Project Updates

The Committee debriefed on the October 11, 2022 in-person meeting, and received project updates.

Summary of discussion:

Project updates presented:

- OPTN Board of Directors will vote on the *Continued Review of National Liver Review Board (NLRB) Guidance* proposal during their December 5, 2022 meeting
- OPTN Executive Committee approved *Review of Liver and Intestine Variance in OPTN Policy* on October 26, 2022
- National Liver Review Board Subcommittee is drafting guidance for multivisceral candidates, and is expected to go to public comment in January 2023
- OPTN Multi-organ Transplantation Committee is continuing work on the simultaneous liver-kidney (SLK) project, and has submitted a data request

There were no comments or questions.

3. Continuous Distribution Project Plan

The Committee discussed the project plan for developing the continuous distribution of livers and intestines.

Summary of discussion:

The Committee reviewed a list of attribute for continuous distribution based on their discussions from the October 11, 2022 meeting.

The Chair reminded that Committee that in addition to the new attributes, there are several other attributes in current policy that will also need to be incorporated into continuous distribution.

4. Continuous Distribution Attribute: Post-transplant survival/futility

The Committee continued discussing post-transplant survival as a potential attribute to incorporate into continuous distribution

Summary of discussion:

Recap of previous discussions:

- Suggestion to address post-transplant survival by incorporating two attributes, futility and utility
 - Futility (shorter term): Could set threshold to give small increase in priority for transplant unlikely to be futile
 - Utility (longer term): Could give priority to candidates likely to see longer term benefit from transplant
- Futility
 - Benefits
 - Could stratify between otherwise similar candidates
 - Easier to incorporate than utility as this would be a threshold
 - Considerations
 - What is the benefit of including? It is accounted for in SRTR outcomes monitoring and bedside decision making
 - Are the models accurate?
 - Perception of including a “futility threshold” – reduce access to liver transplant for candidates who derive some benefit
 - Would it be consistent across transplant programs?
 - SRTR/Program-specific reports (PSRs) already account for futility
- Utility
 - Benefits
 - Included in other organs
 - Models exist to incorporate
 - Perceived as important aspect of allocation for patients
 - Considerations
 - Most models around c-statistic of 0.6 and may not predict well
 - Pre-transplant variables may not predict post-transplant outcomes well
 - May disadvantage certain groups (age)
 - Prediction based on historical data
 - Categorical threshold versus continuous score
 - Can be accomplished in other ways

A member of the community recognized the difficulty of including post-transplant survival in allocation policy. The member of the community noted that the c-statistics of models may be low because they do not account for all the factors that are predictive of post-transplant survival. The member of the community stated that futile patients are usually not waitlisted, and clinical decision-making is very good for the futile patients that are waitlisted. The member of the community added that if futility is incorporated into allocation policy then new models based on 90-day survival are needed due to 90-day survival being incorporated into PSRs. The member of the community stated that due diligence is needed in developing an appropriate post-transplant survival in order to ensure that candidates are not disadvantaged.

Another member stated that utility is best monitored by the transplant programs. The member stated that an appropriate metric should be developed before incorporating utility into continuous distribution.

The Chair stated that PSRs currently monitor futility, and it is not necessary to change an urgency score to address it further.

A member asked how post-transplant survival would be applied to multivisceral candidates. The member stated that the multivisceral population likely has different considerations than the liver-alone transplant population.

Additional members of the Committee agreed that post-transplant survival, nor futility or utility, is not ready to be incorporated into the first version of continuous distribution.

Next steps:

The Committee will continue to finalize a list of attributes to be incorporated into continuous distribution.

5. Continuous Distribution Attributes

The Committee reviewed the current list of attributes to incorporate in the first version of continuous distribution

Summary of discussion:

The Committee discussed prior living donor priority attribute.

The Chair suggested the Committee consider determining a threshold for priority to give to prior living donors.

A member asked if the prior living donor priority should be limited to the organ donated. Staff responded that the OPTN Living Donor and Ethics Committees developed recommendations for the organ-specific committees to incorporate prior living donor priority into continuous distribution. Staff explained that these recommendations suggested that priority should be given to all prior living donors, regardless of the organ donated.

The Chair stated that the long-term risk of donating a kidney is different than donating a liver.

A member stated that the priority given to prior living donors should be graded. The Chair agreed that guardrails will be needed to ensure that medical urgent candidates are not losing access to livers due to prior living donors receiving priority. Another member noted that prior living donor priority is five percent in lung continuous distribution.

A member suggested the Committee could consider providing an expedited pathway for previous living liver donors who have subsequent liver complications. The Chair stated that National Liver Review Board guidance may be a pathway to consider.

A HRSA representative informed the Committee that the OPTN Living Donor and Ethics Committees discussed prior living donor priority based on organ donated. The HRSA representative stated the OPTN Living Donor and Ethics Committees concluded that it is difficult to place value on the different organs donated.

Another member was concerned with giving priority to all prior living donors. The member stated that the risk of donating a uterus may not be the same risk as donating a liver. The Chair stated it is difficult to place value judgements on an individual's altruism.

Upcoming Meeting

- November 10, 2022 @ 3:00 PM ET (teleconference)
- November 18, 2022 @ 3:00 PM ET (teleconference)
- December 2, 2022 @ 3:00 PM ET (teleconference)

Attendance

- **Committee Members**
 - Alan Gunderson
 - Allison Kwong
 - Christopher Sonnenday
 - Colleen Reed
 - Greg McKenna
 - James Eason
 - James Pomposelli
 - James Trotter
 - Kym Watt
 - Neil Shah
 - Peter Abt
 - Peter Matthews
 - Shunji Nagai
 - Sophoclis Alexopoulos
 - Sumeet Asrani
 - Vanessa Pucciarelli
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - John Lake
 - Katie Audette
 - Ryo Hirose
- **UNOS Staff**
 - Betsy Gans
 - James Alcorn
 - Joel Newman
 - Julia Foutz
 - Katrina Gauntt
 - Matt Cafarella
 - Meghan McDermott
 - Niyati Upadhyay
 - Rob McTier
 - Susan Tlusty
- **Other Attendees**
 - Catherine Kling
 - Dave Weimer
 - Pratima Sharma
 - Simon Horslen