OPTN Liver and Intestinal Organ Transplantation Committee
Meeting Summary
June 24, 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 06/24/2022 to discuss the following agenda items:

1. Multi-Organ Allocation Discussion
2. Continuous Distribution Attribute: Post-transplant Survival
3. Member Recognition

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

1. Multi-Organ Allocation Discussion

The Committee discussed simultaneous liver-kidney allocation and liver-intestine allocation.

Summary of discussion:

Simultaneous liver-kidney (SLK) allocation

The Committee has received feedback that SLK policy should align with other multi-organ policy which utilizes a 500 NM distance for allocation. Currently, OPTN Policy requires SLK sharing to candidates who are within 150 nautical miles (NM) of the donor hospital and have a MELD or PELD of 15 or higher; or are within 250 NM of the donor hospital and have a MELD or PELD of 29 or higher or Status 1A or 1B.

Several members confirmed that they have had SLK candidates who were unable to access a kidney offer because they were outside 250 NM. Members also agreed that SLK policy should align with the 500 NM distance for allocation of simultaneous heart-kidney (SHK).

A member of the community suggested increasing the MELD threshold to 32 or higher beyond 250 NM for SLK. The Chair responded that MELD of 29 was chosen because it was determined to be an inflection point where waitlist mortality increases. The Chair added that changes to MELD threshold may require modeling, so it may be beneficial to keep this project limited in scope in order to have a faster implementation. Another member added that a liver-kidney is likely to be allocated to a very sick candidate, so it may not be necessary to impose more restrictive MELD thresholds.

The Chair cited that it may be difficult to have data confirm this problem due to patients becoming too sick to utilize the safety net.

Liver-intestine allocation

The Committee has received feedback that the points given to liver-intestine candidates are not sufficient for accessing transplant post-implementation of the acuity circles (AC) policy. The Committee recognized that this concern can be addressed as part of continuous distribution of liver and intestinal

organs. The Committee will discuss whether they should create National Liver Review Board (NLRB) guidance for liver-intestine candidates as a short-term solution.

Next steps:

The Committee will continue discussing multi-organ policy concerns.

2. Continuous Distribution Attribute: Post-transplant Survival

The Committee discussed post-transplant survival as a potential attribute to incorporate into continuous distribution of livers and intestines.

Summary of discussion:

Research and input compiled from Committee members prior to this meeting included:

- Review of the following post-transplant survival models
  - LiTES Model (Goldberg, et al, 2021)[1]
  - Post liver transplant outcome (SRTR)[2]
  - Futility model (Asrani, et al, 2018)[3]
  - Acceptance Benefit (Volk, et al, 2015)[4]
  - Balance of Risk score (Dutkowski, et al, 2011)[5]
  - Mathematic Optimization (Kling, et al, 2022)[6]
- Patient characteristics identified in post-transplant survival: ventilator dependence, older age, comorbidities, prior liver transplant, high MELD
  - Literature identified a patient with these characteristics in combination with a suboptimal deceased donor liver may equal poor post-liver transplant survival
- Performance is about the same for each model; Most models are c-statistic of 0.6 and may not predict well
- Post-transplant survival is not currently in liver allocation; however it is included in kidney and lung allocation
- The utility of liver transplant is heavily weighted in medical urgency; Higher MELD tend to gain most life years from transplant so survival benefit is driven by waitlist mortality
- There are uncaptured variables in the post-transplant survival models
- Incorporating post-transplant survival may disadvantage certain groups (older patients, etiology, chronic conditions, races and ethnicities)
- Patient population is evolving
- Consider that selecting patients with increased post-transplant survival will increase waitlist mortality for other patients.

[1] Goldberg D, Mantero A, Newcomb C, Delgado C, Forde KA, Kaplan DE, John B, Nuchovich N, Dominguez B, Emanuel E, Reese PP. Predicting survival after liver transplantation in patients with hepatocellular carcinoma using the LiTES-HCC score. J Hepatol. 2021 Jun;74(6):1398-1406. doi: 10.1016/j.jhep.2020.12.021.

[2] Scientific Registry of Transplant Recipients, SRTR Risk Adjustment Model Documentation: Posttransplant Outcomes. Available at https://www.srtr.org/tools/posttransplant-outcomes/.

[3] Asrani SK, Saracino G, O'Leary JG, Gonzalez S, Kim PT, McKenna GJ, Klintmalm G, Trotter J. Recipient characteristics and morbidity and mortality after liver transplantation. J Hepatol. 2018 Jul;69(1):43-50. doi: 10.1016/j.jhep.2018.02.004.

[4] Volk ML, Goodrich N, Lai JC, Sonnenday C, Shedden K. Decision support for organ offers in liver transplantation. Liver Transpl. 2015 Jun;21(6):784-91. doi: 10.1002/lt.24113.

[5] Dutkowski P, Schlegel A, Slankamenac K, Oberkofler CE, Adam R, Burroughs AK, Schadde E, Müllhaupt B, Clavien PA. The use of fatty liver grafts in modern allocation systems: risk assessment by the balance of risk (BAR) score. Ann Surg. 2012 Nov;256(5):861-8; discussion 868-9. doi: 10.1097/SLA.0b013e318272dea2.

[6] Kling CE, Perkins JD, Biggins SW, Wall AE, Reyes JD. Building a Utility-based Liver Allocation Model in Preparation for Continuous Distribution. Transplant Direct. 2022 Jan 13;8(2):e1282. doi: 10.1097/TXD.0000000000001282.

- Reconsider post-transplant futility; Several models available which utilize variables that are collected so it is feasible
- Questions the Committee sought to answer:
  - Do we consider utility/futility in addition to urgency?
  - Should the Committee identify the population with the lowest post-transplant survival? Noted that would be easier than trying to stratify every transplant candidate
  - Have there been consequences to date because post-transplant survival is currently not liver allocation?
  - Timeframe to consider for post-transplant survival? Noted that the separation in outcomes appears early on

A member stated that transplant programs already consider post-liver transplant survival but incorporating it into continuous distribution as an attribute would be a more formal mechanism. The member explained that currently transplant programs will inactivate a candidate if the individual is too sick and the post-transplant outcomes are determined to be poor. Another member questioned whether post-transplant survival needs to be included in liver allocation if transplant programs are currently considering post-transplant survival from a regulatory standpoint. The member questioned whether it should be the Committee's role to redirect livers based on outcomes.

A member stated that the models show the importance of donor factors. The member suggested that the Committee consider donor factors in lieu of post-transplant survival. A member agreed and suggested a survival-benefit based system would be a better approach.

Another member stated that there are many perioperative factors that are included in post-transplant survival, such as prolonged hospitalization or infection. The member stated that the models do not account for these perioperative factors. The member suggested the Committee consider all components rather than focusing on trends for post-transplant survival.

The Chair stated that liver allocation may benefit from the development of an estimated post-transplant survival (EPTS) calculation. A member suggested considering years saved due to liver transplant. The member stated this takes into consideration age, pre-transplant mortality, and post-transplant survival. Another member summarized an article which concluded that MELD scores address the utility of liver transplantation.[7]

The Vice Chair suggested that identifying a threshold for post-transplant survival may be the best approach. The Vice Chair explained that identifying a model that would accurately stratify the population based on post-transplant survival would be a challenge. A member agreed and stated that during the next iteration of continuous distribution, there may be more research available to allow the Committee to appropriately incorporate post-transplant survival.

Another member suggested the Committee consider re-transplantation. The member explained that outcomes might be dependent on the timing of a re-transplant (e.g. shorter time between initial transplant and re-transplant). The member stated that re-transplantation is due to graft loss, so minimizing early re-transplantation will keep livers available. A member responded that some post-transplant survival models did incorporate graft loss as a variable.

The Committee discussed the timeframe in which to consider poor outcomes. Models show that the biggest separation in post-transplant survival appears within 1 to 3 years post-transplant. A member

[7] Luo X, Leanza J, Massie AB, Garonzik-Wang JM, Haugen CE, Gentry SE, Ottmann SE, Segev DL. MELD as a metric for survival benefit of liver transplantation. Am J Transplant. 2018 May;18(5):1231-1237. doi: 10.1111/ajt.14660.

stated that the models might be better at predicting post-transplant survival 1 to 3 years than 3 to 5 years. Another member responded that the allocation system would benefit from longer-term predictions. The Chair added that longer-term post-transplant survival becomes more difficult when considering older patients due to the increase in dying from other causes not related to transplant. A member responded that competing mortality risks are an important factor to consider because a liver transplant may not be beneficial in the long-term.

The Vice Chair of the OPTN Pediatrics Transplantation Committee emphasized that the models do not take into consideration children. The Vice Chair of the OPTN Pediatrics Transplantation Committee offered to collaborate in order to identify how pediatric patients should be incorporated in post-transplant survival. The Vice Chair responded that the pediatric population will be addressed in patient access, but the Committee will work to consider how pediatrics may also be impacted in other identified attributes.

Next steps:

The Committee will continue discussing the potential of adding post-transplant survival as an attribute into the framework of continuous distribution of liver and intestinal organs.

3. **Member Recognition**

The Committee recognized the members who are rolling off the Committee.

Upcoming Meeting

- July 8, 2022 @ 12:00 PM ET (teleconference)
- July 22, 2022 @ 12:00 PM ET (teleconference)
- August 5, 2022 @ 12:00 PM ET (teleconference)

Attendance

- **Committee Members**
  - Alan Gunderson
  - Allison Kwong
  - Bailey Heiting
  - Greg McKenna
  - James Markmann
  - James Pomposelli
  - James Trotter
  - Jennifer Kerney
  - Mark Orloff
  - Pete Abt
  - Peter Matthews
  - Ray Lynch
  - Scott Biggins
  - Sumeet Asrani
  - Sophoclis Alexopoulos
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Raelene Skerda
- **SRTR Staff**
  - Katie Audette
  - John Lake
  - Ray Kim
- **UNOS Staff**
  - Alison Wilhelm
  - Betsy Gans
  - Darby Harris
  - Darren Stewart
  - James Alcorn
  - Julia Foutz
  - Liz Robbins
  - Matt Cafarella
  - Meghan McDermott
  - Niyati Upadhyay
  - Rob McTier
  - Sarah Scott
  - Susan Tlusty
- **Other Attendees**
  - Christopher Sonnenday
  - Colleen Reed
  - Dave Weimer
  - Emily Perito
  - Neil Shah
  - Michael Volk
  - Pratima Sharma

- Vanessa Pucciarelli
- Erin Maynard