OPTN Liver and Intestinal Organ Transplantation Committee
Meeting Summary
August 5, 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 08/05/2022 to discuss the following agenda items:

1. Continuous Distribution Attribute: Prior Living Donor
2. Continuous Distribution Attribute: Surgical Complexity and Re-transplant
3. Continuous Distribution Attribute: Frailty
4. Acuity Circles: 2 Year Monitoring Report

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

1. Continuous Distribution Attribute: Prior Living Donor

The Committee reviewed their discussions from the June 15, 2022 Committee meeting, and continued discussing prior living donor as a potential attribute to incorporate into continuous distribution of livers and intestines.

Summary of discussion:

The Committee agreed that prior living donor priority should be incorporated as an attribute.

A member was in favor of prior living donors having high priority. The member added that a prior living donor needing a transplant is a rare event; therefore giving them high priority would not affect access for other populations.

Members agreed that a prior living liver donor should receive more priority if waitlisted for a liver than a prior living uterus donor.

Next steps:

The Committee will finalize attribute discussions during the October 11, 2022 Committee meeting. The Committee will determine weight and rating during the next phase of the project.

2. Continuous Distribution Attribute: Surgical Complexity and Re-transplant

The Committee reviewed their discussions from the June 22, 2022 Committee meeting, and continued discussing surgical complexity and re-transplant as a potential attribute to incorporate into continuous distribution of livers and intestines.

Summary of discussion:

The Committee noted there is consensus that surgical complexity may lead to worse outcomes, but there is a lack of data. The Vice Chair stated that indications are important when considering re-transplant. The Vice Chair explained that an individual who received a transplant when they were a child

and is now in need of a re-transplant in their 30s, may be a different consideration than an adult who had their initial transplant in their 50s.

The Vice Chair noted that some re-transplant patients have expedited access through Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD Score Exceptions.

The Vice Chair stated that portal vein thrombosis requires different considerations such as the need to find a quality graph, and whether the patient needs a mutli-visceral transplant. The Vice Chair stated that the conclusion was that those with portal vein thrombosis do not require prioritization in the context of re-transplant.

A member noted that previous discussions considered the possibility of extending the 14 day priority for HAT to 30 days.

The Committee requested the following data to inform their discussions:

- Liver waitlist registrations added between January 1, 2017 and December 31, 2021 stratified between registrations with a previous liver transplant and registrations without a previous liver transplant
    - Distribution of time since first liver transplant
    - Distribution of most recent allocation MELD or PELD score
    - Distribution of most recent lab MELD or PELD score
    - Reason for removal (transplant, removal for death/too sick, other removal reason, still waiting)
    - Number and proportion by age group (0-11, 12-17, 18-39, 40-64, 65+)
- Liver waitlist registrations ever waiting between January 1, 2017 and December 31, 2021
    - Waitlist mortality rates stratified by registrations with a previous liver transplant and registrations without a previous liver transplant (overall and by MELD/PELD score and status)
    - Transplant rates stratified by registrations with a previous liver transplant registrations without a previous liver transplant (overall and by MELD/PELD score and status)
- Liver transplant recipients transplanted between January 1, 2017 and December 31, 2021 stratified between recipients with a previous liver transplant and recipients without a previous liver transplant
    - Distribution of time since first liver transplant
    - Distribution of most recent allocation MELD or PELD score
    - Distribution of most recent lab MELD or PELD score
    - Number and proportion by DCD/DBD
    - Number and proportion by age group (0-11, 12-17, 18-39, 40-64, 65+)
- Liver transplant recipients transplanted between January 1, 2017 and December 31, 2021 stratified between recipients with a previous liver transplant and recipients without a previous liver transplant
    - One year patient survival
        - Overall
        - By DCD/DBD (as sample size allows)
        - By MELD/PELD (as sample size allows)

3. Continuous Distribution Attribute: Frailty

The Committee discussed frailty 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:

- Frailty in one metric of physical fitness
- Increased mortality in waitlisted candidates with poor physical fitness
- Post-transplant mortality is acceptable among frail and sarcopenic recipients but increases the cost of care after transplant
- Available metrics for physical fitness and implementation challenges
- Fitness can improve with physical training; Policy should be careful not to disincentive physical training
- Metrics currently available to assess physical fitness in liver transplant candidates
    - Frailty (physical)
        - Liver frailty index (best validated)
        - Gait Speed Test
        - Short physical performance battery
    - Cardiorespiratory fitness
        - 6-minute walk test (best validated)
        - Cardiopulmonary exercise test
        - Daily step count
    - Sarcopenia (less validated)
        - Computed Tomography (CT) scan
        - Ultrasound (US)/Magnetic Resonance Imaging (MRI)
        - Dual X-ray absorptiometry (DXA)/Phase angle
    - Malnutrition (subjective or biased)
        - Royal Free Hospital-Nutritional Prioritizing Tool
        - Subjective global assessment
        - Prealbumin
- Data shows that about a quarter of the liver waitlist population may be classified as frail[1]
- Research shows that the cardiorespiratory fitness level of liver candidates on the waitlist compared to a healthy population have about a third of the degree of pulmonary fitness, which is comparable to the heart candidates on the waitlist[2]
- Research on liver frailty index and 6-minute walk testing have found that frailty has an impact on waitlist mortality[3, 4]

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[1] Lin FP, Visina JM, Bloomer PM, Dunn MA, Josbeno DA, Zhang X, Clemente-Sanchez A, Tevar AD, Hughes CB, Jakicic JM, Duarte-Rojo A. Prehabilitation-Driven Changes in Frailty Metrics Predict Mortality in Patients With Advanced Liver Disease. Am J Gastroenterol. 2021 Oct 1;116(10):2105-2117. doi: 10.14309/ajg.0000000000001376.

[2] Lizaola-Mayo. AASLD. The Liver Meeting 2021

[3] Kardashian A, Ge J, McCulloch CE, Kappus MR, Dunn MA, Duarte-Rojo A, Volk ML, Rahimi RS, Verna EC, Ganger DR, Ladner D, Dodge JL, Boyarsky B, McAdams-DeMarco M, Segev DL, Lai JC. Identifying an Optimal Liver Frailty Index Cutoff to Predict Waitlist Mortality in Liver Transplant Candidates. Hepatology. 2021 Mar;73(3):1132-1139. doi: 10.1002/hep.31406.

[4] Dang TT, Ebadi M, Abraldes JG, Holman J, Ashmead J, Montano-Loza AJ, Tandon P. The 6-Minute Walk Test Distance Predicts Mortality in Cirrhosis: A Cohort of 694 Patients Awaiting Liver Transplantation. Liver Transpl. 2021 Oct;27(10):1490-1492. doi: 10.1002/lt.26087.

- Research has shown decreased waitlist mortality in liver transplant candidates and sarcopenia[5]
- More research is needed on whether frailty impacts post-transplant mortality
- Different metrics will impact different genders[6]
- Different metrics will impact different ethnicities and races[7]
- Prehabilitation will impact waitlist survival[8]
    - Frailty metrics should not be a contraindication for liver transplant; Improving physical fitness should not make it less likely that a transplant candidates get better access to transplant
- Concerns regarding manipulative capabilities
    - Inability to complete any component of liver frailty index results in a score of infinity; Would need a threshold similar to international normalized ratio (INR) or creatinine cutoffs in Model for End Stage Liver Disease (MELD) score
    - It is not applicable to use liver frailty index for in-patients; What can be used as an equivalent?
    - Inexperience in training and resources across liver transplant centers which may lead to higher liver frailty index scores
    - Disparities and co-dependent variables (gender, age, ethnicity)

A member asked whether frailty would be incorporated as an attribute to address post-transplant outcomes or pre-transplant mortality. The Vice Chair answered that the OPTN Lung Transplantation Committee incorporated the 6-minute walk test into both sides of the lung allocation score. The Vice Chair explained that a reduced 6-minute walk score will have increase priority on the pre-transplant component of the lung allocation score while reducing some priority in the post-transplant component due to decreased outcomes.

The Vice Chair stated that adding frailty into liver allocation policy would add extra complexity, introduce potential game-ability, and further disparities with gender or ethnicity/race.

Another member emphasized that frailty should not be used as a reason to not transplant a candidate. The member explained that frailty should be used to identify candidates that should have prehabilitation. The member added that frailty may be added into future iterations of continuous distribution once more data is available.

Committee members agreed that more research is needed before incorporating frailty into liver allocation policy.

<u>Next steps:</u>

The Committee will continue discussions on this attribute.

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[5] Carey EJ, Lai JC, Wang CW, Dasarathy S, Lobach I, Montano-Loza AJ, Dunn MA; Fitness, Life Enhancement, and Exercise in Liver Transplantation Consortium. A multicenter study to define sarcopenia in patients with end-stage liver disease. Liver Transpl. 2017 May;23(5):625-633. doi: 10.1002/lt.24750.

[6] Ibid.

[7] G B, As R. Implications of Race and Ethnicity in Sarcopenia US National Prevalence of Sarcopenia by Muscle Mass, Strength, and Function Indices. Gerontol Geriatr Res. 2021;4(1):126.

[8] Lin FP, Visina JM, Bloomer PM, Dunn MA, Josbeno DA, Zhang X, Clemente-Sanchez A, Tevar AD, Hughes CB, Jakicic JM, Duarte-Rojo A. Prehabilitation-Driven Changes in Frailty Metrics Predict Mortality in Patients With Advanced Liver Disease. Am J Gastroenterol. 2021 Oct 1;116(10):2105-2117. doi: 10.14309/ajg.0000000000001376.

4. Acuity Circles: 2 Year Monitoring Report

The Committee reviewed the 2-year post-implementation monitoring report for the *Removal of Donation Service Area (DSA) and Region from Liver and Intestine Allocation* proposal.

Data summary:

Summary findings:

- Removals for death/too sick went down; transplant counts went up
- Distribution of transplant by MELD or Pediatric End-stage Liver Disease (PELD) score or status remained similar; variance in median MELD at transplant (MMaT) decreased by OPTN Region, DSA, and State
- Median distance from donor hospital to transplant program increased
- Cold ischemic time (CIT) went up slightly
- No statistically significant change in patient survival
- Slight increase in discard rate; decrease in utilization rate

Summary of discussion:

A member stated that some of the data might be affected by COVID-19 pandemic as opposed to a change in allocation.

Another member noted that transplant rates dropped in areas where candidates with low MELD scores were being transplanted, but the mortality rates did not drop. The member explained that this finding seems to indicate a possible improvement from the implementation of the proposal. The member added that the number of candidates that were transplanted with an exception, especially non-hepatocellular carcinoma (HCC) exceptions decreased, which increased the number of livers in the deceased donor pool. The member stated this decrease is attributable to the national liver review board (NLRB).

The Chair noted that the removals for death/too sick decreased, which is a positive trend. The Chair added this trend, as well as others, may have been mitigated by COVID-19 pandemic. Another member asked if the trends changed from 1-year data report compared to 2-year data report. Staff responded that the 18-moth data report is very similar to the 2-year data report.

A member noted that the transplant rates by MELD decreased for intestine candidates. The member also noted that while not statistically significant, the waitlist mortality for intestine candidates increased.

Upcoming Meeting

- August 19, 2022 @ 12:00 PM ET (teleconference)
- September 9, 2022 @ 12:00 PM ET (teleconference)

Attendance

- **Committee Members**
  - Alan Gunderson
  - Allison Kwong
  - Bailey Heiting
  - Christopher Sonnenday
  - Colleen Reed
  - Erin Maynard
  - Greg McKenna
  - James Markmann
  - James Pomposelli
  - James Trotter
  - Joseph Dinorcia
  - Kym Watt
  - Neil Shah
  - Scott Biggins
  - Sumeet Asrani
  - Vanessa Pucciarelli
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - John Lake
  - Katie Audette
  - Nick Wood
- **UNOS Staff**
  - Betsy Gans
  - Chelsea Haynes
  - Erin Schnellinger
  - James Alcorn
  - Joel Newman
  - Julia Foutz
  - Kaitlin Swanner
  - Lauren Mauk
  - Lindsay Larkin
  - Liz Robbins Callahan
  - Matt Cafarella
  - Meghan McDermott
  - Niyati Upadhyay
  - Samantha Weiss
  - Sarah Scott
  - Thomas Dolan
- **Other Attendees**
  - Catherine Kling
  - Ellie Karls
  - Emily Perito
  - Jesse Schold

- Samantha DeLair