

Meeting Summary

OPTN Liver and Intestinal Organ Transplantation Committee Meeting Summary September 9, 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 09/09/2022 to discuss the following agenda items:

- Public Comment Presentation: Enhancements to OPTN Donor Data and Matching System Clinical Data Collection
- 2. Continuous Distribution Attribute Recap: Social Determinants of Health
- 3. Continuous Distribution Attribute: Willingness to Accept a Split Liver
- 4. Public Comment Update

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

1. Public Comment Presentation: Enhancements to OPTN Donor Data and Matching System Clinical Data Collection

The Committee received a presentation on the OPTN Organ Procurement Organizations Committee's public comment proposal, *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection*.

Summary of discussion:

The Vice Chair suggested that data regarding warm perfusion support be included. A member suggested that data elements that are redundant or out dated may be replaced with more relevant data elements. The member stated that a rigorous evaluation of current data fields is beneficial.

Another member supported the notion of creating a new, separate page within the donor summary in the OPTN Donor Data and Matching System. The member suggested that pre-withdrawal information, such as vital sign prior to withdrawal and at the time of withdrawal, may be beneficial. The member explained that this information will be more important with greater use of warm perfusion due to a greater separation between procurement and transplant.

2. Continuous Distribution Attribute Recap: Social Determinants of Health

The Committee reviewed their discussions from the August 19, 2022 Committee meeting, and continued discussing social determinants of health as a potential attribute to incorporate into continuous distribution of livers and intestines.

Summary of discussion:

A member of the community noted that efforts to measure social determinants of health at the individual level and understand the strength of area measures may be important in order to specify patients that would benefit from priority in allocation. SRTR staff stated that the OPTN currently collects zip code, but it is an assumption that individuals in the same zip code are impacted by social

determinants of health in the same way. SRTR staff added that transplant programs' waitlists also might not be reflective of the surrounding general populations. The member of the community noted that the Committee may suggest an action item related to understanding how well area level measures pertain to individuals.

Another member stated that there has been a focus on access to transplant from a patient's perspective. The member suggesting shifting the focus on access to transplant from a transplant program's perspective. The member explained that there are initiatives that transplant programs could undertake in order to increase access to transplantation. A member of the community agreed with this suggestion but noted that it would be difficult to address that in allocation policy.

Another member stated they do not support incorporating social determinants of health into allocation policy at this point in time. The member stated that access to transplant is dependent on state policies which vary widely across the U.S. The member stated that more affluent patients may be listed in southern states due to poor Medicaid funding for transplant. The member stated that due to this consideration, incorporating social determinants of health may worsen the problem because of the fundamental restrictions that lower socioeconomic individuals face. The member added that allocation policy is not the main driver of disparities in social determinants of health, it is poor state funding and poor insurance coverage. A member agreed and stated that this occurs in the Northeast as well as the South. The member explained that in the Northeast, a transplant candidate who has Medicaid can not receive care outside of their state, even though they may live near a transplant program in a neighboring state.

Another member asked whether individual level data would help differentiate the problem stated above. A member of the community responded that individual level may not fully address the problem, but it may add informative analyses.

A pediatric representative stated that children have broader medical coverage. The pediatric representative stated that incorporating social determinants of health may benefit the pediatric population. The member explained that due to this, they would be supportive of incorporating some aspect of social determinants of health for children as the impact may be different compared to the adult population.

A member stated that livers are allocated based on location of the transplant program, not location of the transplant candidate. The member suggested to review data regarding location of transplant candidates and area of allocation. A member of the community responded that there is literature which shows there may be an impact of distance to transplant program and whether the individual has to cross state lines. The member of the community added that the interplay of distance and socioeconomic status is an important consideration.

SRTR staff stated that the Committee could recommend reviewing risk adjustments to the SRTR review group. A member stated that transplant programs should not be penalized for what Medicaid does and does not cover. SRTR staff responded that allocation can only effect individuals who are on the list.

The Vice Chair stated the Committee should consider where social determinants of health would be incorporated in the system (e.g. pre-transplant, post-transplant, or access).

A member of the community noted that more empirical data is needed at an individual level. The member of the community stated that risk adjusting for social determinants of health would address a confounding factor that disproportionally affects transplant programs. The member of the community asked whether the Committee wants to request a model to analyze the association of deprivation index and distance. The member of the community asked whether the Committee would consider prioritizing

transplant candidates with low social determinants of health based on the ethical argument that is a just approach because social determinants of health affect quality of care and access to care. Another member of the community stated that the least controversial option to consider is providing risk adjustment for deprived individuals who receive transplant. The member of the community supported a modeling effort to understand the effect. SRTR staff added that the Committee could request transplant programs to submit physical address to the OPTN in addition to the zip code.

Next steps:

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

3. Continuous Distribution Attribute: Willingness to Accept a Split Liver

The Committee discussed willingness to accept a split liver 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:

- Split liver transplantation has theoretical potential for significant impact in liver transplantation
- In practice, concerns have existed about risk of split liver transplant, especially in adults
- Split liver transplant remains underutilized in U.S. despite initiatives to incentive utilization
- Missed opportunities in split liver transplantation are associated with risk of waitlist death in small children
- In practice, left lateral segment/right trisection split for pediatric/adult recipients are vast majority of split opportunities
- Older series describe increased risk of graft loss in split liver transplantation but outcomes have improved over time^{1,2}
- Split liver transplantation confers survival advantage to small children and adults³
- In small children, split liver transplantation and living donor liver transplantation offer equivalent outcomes⁴
- In adults, extended right lobe grafts provide similar outcomes to whole grafts⁵
- Split liver transplantation remains uncommon (3-4% of liver transplantation); Segment discard (right lobe or right trisection) unfortunately common⁶
- Split liver transplantation is underutilized relative to opportunity, contributing to pediatric waitlist death⁷
- Split liver transplantation performed by a minority of centers⁸

¹ Feng S et al, AJT 2006; 6: 783-790

² Sasaki K et al, Liver Transplantation 2019;25:741-751.

³ Bowring MG et al. Liver Transplant. 2022;28:969-982.

⁴ Dalzell C et al, Transpl Int 2022 Mar 22;36:10437.

⁵ Lozanovski VJ et al. Liver Transplant 2022;28:807-818.

⁶ Montgomery JR et al, Liver Transpl 2022;28(2):247-256.

⁷ Perito ER et al. Transplantation 2019;103:552-557.

⁸ Ge J et al, Am J Transplant 2020;20:1116-1124.

- Risk of graft loss has improved significantly over time; but risk of early graft loss remains significant versus whole graft⁹
- Adult outcomes better in low-risk recipients¹⁰
- Higher risk of graft loss when split between two adult¹¹

A member stated that split liver utilization is a lot lower in the U.S. compared to other countries. The member suggested that the Committee review best practices in other countries in order to understand how to increase split liver utilization. Another member responded that in the United Kingdom, split liver allocation is transplant program based, which means that the transplant program controls the outcome of the second segment. The member stated this has been found to be associated with greater utilization. The member stated that Italy created an algorithm for livers that met split-able criteria which enables whole graft transplant candidates to be bypassed. The member explained that if there was not a high status liver transplant candidate, then a separate allocation was run to prioritize transplant candidates who had previously been identified as split liver candidates. The member added that this approach increased split liver utilization in Italy but it was not a significant increase in absolute numbers.

A member of the community stated that the current split liver variances in OPTN policy have not increased utilization of split livers. The member of the community suggested that the definition of split liver needs to be more stringent. The member of the community stated that pediatric liver transplant candidates aged 0 – 2 have the highest mortality in the pediatric community. The member of the community explained that split liver grafts should be made available to that pediatric transplant candidate population, perhaps prioritizing them above status 1A. The member of the community suggested prioritizing transplant programs who have a history of accepting tri-segmental livers. The member summarized their suggestion that increasing utilization of split livers will require allocating split livers on a separate allocation sequence and prioritizing pediatric liver transplant candidates, especially small pediatric candidates.

The Chair of the OPTN Pediatric Committee stated that increasing utilization of split livers is a need that the pediatric transplant community have recognized for a long time. The Chair of the OPTN Pediatric Committee emphasized that a system needs to be developed to ensure transplant programs are willing to accept a partial liver graft and ensure placement of the remaining liver segment. The Chair of the OPTN Pediatric Committee urged the Committee to review the discard rates for split livers.

A member agreed and stated that accountability needs to be implemented alongside any changes to split liver allocation policy.

Next steps:

The Committee will continue to discuss willingness to accept a split liver as a potential attribute in the continuous distribution of livers and intestines.

Upcoming Meeting

• September 16, 2022 @ 3:00 PM ET (teleconference)

⁹ Sasaki K et al, Liver Transplantation 2019;25:741-751.

¹⁰ Ibid.

¹¹ Ibid.

Attendance

Committee Members

- o Alan Gunderson
- o Allison Kwong
- Bailey Heiting
- o Christopher Sonnenday
- o Derek Dubay
- o James Trotter
- o Neil Shah
- o Peter Abt
- o Scott Biggins
- o Sophoclis Alexopoulos
- o Vanessa Pucciarelli

• HRSA Representatives

- o Jim Bowman
- Marilyn Levi

SRTR Staff

- o John Lake
- o Katie Audette
- o Nick Wood
- o Ryo Hirose
- o Tim Weaver

UNOS Staff

- o Erin Schnellinger
- o James Alcorn
- Jason Livingston
- o Joel Newman
- o Julia Foutz
- Krissy Laurie
- o Liz Robbins Callahan
- o Matt Cafarella
- o Meghan McDermott
- Niyati Upadhyay
- o Rob McTeir
- o Robert Hunter
- Sarah Scott
- o Susan Tlusty
- o Thomas Dolan

Other Attendees

- o Catherine Kling
- o Ellie Karls
- o Emily Perito
- o Evelyn Hsu
- o Jesse Schold
- Kurt Shutterfly
- o Pratima Sharma
- o Samantha DeLair

- o Sanjay Mehrotra
- o S Taylor