OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Meeting Summary

OPTN Liver and Intestinal Organ Transplantation Committee
Meeting Summary
May 17th, 2024
Conference Call

Scott Biggins, MD, Chair
Shimul Shah, MD, MHCM, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via WebEx teleconference on 05/17/2024 to discuss the following agenda items:

1. Machine Perfusion Project Plan + Feedback
2. Continuous Distribution: Medical Urgency Attribute

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

1. Machine Perfusion Project Plan + Feedback

The Committee received a presentation from the OPTN Organ Procurement Organization (OPO) Committee regarding their project on machine perfusion. The Committee provided feedback surrounding machine perfusion.

Summary of discussion:

There were no decisions regarding this agenda item.

The Chair suggested that the OPO Committee connect with the OPTN Data Advisory Committee on this project, as they are an important stakeholder. They added that the American Society of Transplant Surgeons (ASTS) is looking to create a registry for machine perfusion data collection. An SRTR representative pronounced that this effort by the OPO Committee is long overdue and that the most important part of this project is implementing it, and the details can be figured out later. A member who works for an OPO agreed that it will not be easy to collect some of this data. Still, their organization has already begun collecting high-level pieces within their electronic record. They added that they would be willing to share this information with the OPO Committee and offered their support in any development that will be needed. The Vice Chair noted that several transplant programs with perfusion are extending beyond thirty minutes. Hence, metrics surrounding machine perfusion need to be urgently collected and it must come from both transplant programs, as well as OPOs. They added that for it to be a seamless collection of data, this information must be collected by a national organization.

One member questioned if it was better to collect minimal data, but have it collected immediately, or if it would be better to refine what data should be collected, but not have it available until a later time point. They voiced their preference for using a two-step approach of immediately pushing out data collection and refining the details later. They noted the importance of having the perfusion companies involved in this effort, as they will have a lot of the data that is currently being collected.

A member voiced their opinion that the bare minimum for collecting machine perfusion data would be to include it on the deceased donor registration (DDR) form. The Chair of the OPO Committee informed the member that this is awaiting approval from the Office of Management and Budget (OMB). An SRTR representative stated that the data fields containing "pump on" and "pump off" time would be the minimum they would expect to be included. One member suggested adding who is performing the machine perfusion, as results may differ, depending on if it is cardiothoracic versus abdominal only, and if it is OPO versus transplant program driven. Recording and tracking who the perfusing surgeon is can help inform the data that will be collected through this project.

Next steps:

The OPTN OPO Committee is continuing to solicit input from all of the OPTN organ-specific committees and is in the process of forming a multi-disciplinary workgroup group. The OPO Committee will reach out to the Committee if they need additional information.

2. Reintroduce HCC Stratification Attribute & Discuss

The Committee continued to discuss the Hepatocellular Carcinoma (HCC) Stratification Attribute within the first version of liver continuous distribution. The reviewed information previously presented regarding a potential HCC Stratification attribute

Summary of discussion:

The Committee has decided to explore stratifying HCC candidates within liver continuous distribution.

A member advocated for the use of the Optimized Prediction of Mortality (OPOM) model as it is a model that interdigitates HCC candidates. The Chair reminded the Committee that previously a majority of the Committee agreed that the continued use of MELD and PELD was the most appropriate decision for the first version of liver continuous distribution and as such are now exploring exceptions with the continuous distribution framework.

A member suggested that if the Committee incorporates HCC stratification into the continuous distribution model, the results should be compared to the optimized predictor of mortality (OPOM) model to ensure that whatever solution is decided upon performs as well, if not better than other models. Another member agreed and noted that there are several models that stratify HCC candidates in addition to OPOM.

Another member asked why the Committee would work to stratify HCC candidates if other models such as OPOM already exist. The member expressed interest in the more dynamic models. A member noted that interdigitation and stratification are different. The member explained that interdigitating HCC candidates within a medical urgency model is very different than stratification of HCC candidates under the goal of patient access. The member noted that HCC does not behave like end-stage liver disease which is what MELD accounts for so there are some considerations to be made whether that is the appropriate solution for interdigitating the HCC population. Another member added that their understanding of OPOM is that there are some low MELD HCC candidates with more aggressive tumor biology that could then be interdigitated at a higher MELD that have similar risks to a non-HCC candidate. The Chair explained that the continuous distribution framework allows for additional points to be awarded to HCC candidates that does not require adjustment to a medical urgency score.

A member noted that there is a benefit to having an independent HCC stratification attribute because it would offer a model for the other exceptions. The member explained that if OPOM is chosen, the Committee would still have to address the other standard exceptions. Another member suggested the

Committee consider how to address candidates with ACLF since that is not accounted for in the current system.

The Chair summarized what they interpreted from the Committee, which was that while they are working on continuous distribution, they also want to try to stratify the HCC candidates within a composite allocation score. Members agreed, and one member suggested the Committee should develop a stratification solution and compare it to other models to see how it compares. The Chair agreed and reminded the Committee that they can explore categorical and continuous stratifications and several tools can be used to investigate how HCC candidates will be stratified.

Next steps:

The Committee will continue this discussion at their June 7th meeting.

Upcoming Meetings

- June 7, 2024, at 2 pm ET (teleconference)
- June 21, 2024, at 2 pm ET (teleconference)

Attendance

- **Committee Members**
  - Scott Biggins
  - Shimul Shah
  - Aaron Ahearn
  - Allison Kwong
  - Christine Radolovic
  - James Pomposelli
  - Joseph DiNorcia
  - Kathy Campbell
  - Kym Watt
  - Neil Shah
  - Shunji Nagai
  - Sophoclis Alexopoulos
  - Vanessa Cowan
  - Vanessa Pucciarelli
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jack Lake
  - Katie Audette
  - Nick Wood
  - Ryo Hirose
- **UNOS Staff**
  - Benjamin Schumacher
  - Betsy Gans
  - Cole Fox
  - Erin Schnellinger
  - Laura Schmitt
  - Meghan McDermott
  - Niyati Upadhyay
  - Robert Hunter
  - Susan Tlusty
- **Other**
  - Jen Lau (visiting board member)
  - Joshua Norman
  - PJ Geraghty (Chair of the OPTN OPO Committee)