OPTN Liver and Intestinal Organ Transplantation Committee
Hepatocellular Carcinoma (HCC) Stratification Subcommittee
Meeting Summary
November 21, 2024
Conference Call

Chris Sonnenday, MD, Chair

Introduction

The OPTN Hepatocellular Carcinoma Subcommittee (the Subcommittee) met via WebEx teleconference on 11/21/2024 to discuss the following agenda items:

1. Background
2. Finalize Hepatocellular Carcinoma (HCC) Stratification Model Recommendation/Continued Discussion

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

1. Background

Summary of Presentation

The Subcommittee has determined that there is sufficient data to support stratifying HCC priority scores based on biology, dropout risk, and post-transplant survival. They have discussed including a waiting time elevator in their stratification system that addresses access to transplant concerns for candidates that would receive lower priority under the purposed stratification system. The Subcommittee has determined that an HCC stratification score should include MELD 3.0, or otherwise have the ability to assess impact of native liver disease on dropout risk. They have also determined that the proposed stratification system should be consistent with Continuous Distribution 1.0 by not considered post-transplant survival directly. Finally, the Subcommittee has discussed including currently collected data elements in their stratification system to ensure a smooth acceptance by the transplant community.

Summary of discussion:

No decisions were made regarding this agenda item.

One member asked how strong the data was for the conclusion that 20% of patients within Milan criteria likely have lower urgency for transplant. Another member responded that the data came from multiple, reliable sources.

Next steps:

There are no next steps for the Subcommittee to take.

2. Finalize HHC Stratification Model Recommendation/Continued Discussion

Summary of Presentation

The Subcommittee reviewed the Multi-HCC stratification system. The Multi-HCC stratification system is based on MELD 3.0, Alpha-fetoprotein (AFP), and tumor burden. It is a simple system that performs as well or better than other HCC stratification systems and should not change post-transplant survival of

patients. The Multi-HCC system stratifies patients into quartiles for priority. These quartiles are recalculated every three months which allows patients to potentially move up in priority but not down. Finally, the system uses an elevator method that increases a patient's priority over the course of nine months.

Summary of discussion:

Decision #1: Change the last column of the Multi-HCC stratification system from nine months to twelve months.

Decision #2: Report out the Multi-HCC stratification system to the full Liver and Intestines Committee

The Subcommittee discussed the last column of the Multi-HCC stratification system. The purposed column increased quartile 1 HCC patient's priority from Median Meld at Transplant (MMaT)-5 to MMaT-3 at nine months from the patient being put on the transplant list. The Subcommittee discussed whether this should be twelve months instead of nine months. One member pointed out the patients in quartile 1 are the lowest priority quartile and probably do not need a transplant within a year. Another member pointed out many transplant centers have wait times over a year long anyways. The Subcommittee felt the data did not really indicate that either time frame was better than the other. They decided to change the timeframe to twelve months as the quartiles are recalculated every three months, so anyone who has a tumor progression that would push them into quartiles 2 or 3 would get MMaT-3 and those that stay in quartile one probably do not need MMaT-3 at nine months.

The Subcommittee discussed quartile 1 HCC patients' priority. They considered three options.

1. Removing additional priority for HCC patients in quartile 1
2. Leaving the model as is with HCC patients in quartile 1 receiving MMaT-5 at six months on the transplant list and MMaT-3 at twelve months on the transplant list.
3. Assigning MMaT-5 priority to HCC patients in quartile 1 at six months and having no increase at twelve months

The Subcommittee decided to leave the model as is with HCC patients in quartile 1 receiving MMaT-5 at six months on the transplant list and MMaT-3 at twelve months on the transplant list. They felt this system would help disincentivize transplant centers from letting patient's tumors grow to move them up to a higher quartile and thereby get transplanted. There was some talk of potential modifying this in the future as more data becomes available as many patients in quartile 1 do well with or without transplant.

The Subcommittee decided against removing additional priority entirely for quartile 1 patients because they felt the community liked the ability to transplant quartile 1 patients even if those patients do not benefit from transplant as much as the patients in the other quartiles. They also decided against only moving quartile 1 patients to MMaT-5 priority after six months with no increase at twelve months because they felt some cases justify giving quartile 1 patients increasing priority for transplant. One example given was a patient who has a low AFP and is compensated but keeps having reoccurring tumors. They felt a patient under those conditions would benefit from a pathway to transplant.

The Subcommittee discussed having a few scenarios that help showcase how patients move up in priority quartiles. They also expressed concern that transplant centers may count ablated tumors as tumors when listing patients for transplant. This led to a discussion of the differences between transplant centers and when they list patients for transplant. The consensus was that many transplant centers list patients for transplant as soon as possible and this was another reason to have a six month wait period to ensure that priority for transplant is going to those who need it most.

The Subcommittee voted unanimously to recommend the Multi-HCC stratification system with modifications to the full Liver and Intestine Committee.

Yes: 6

No: 0

Abstain: 0

The Subcommittee discussed potentially separating HCC stratification from continuous distribution and sending it to the Policy Oversight Committee (POC) on its own in an effort to get the HCC stratification system implemented faster and so that it would get its own consideration in public comment separate from continuous distribution.

Next steps:

- Report the Subcommittee's decision on the use of the Multi-HCC stratification system to the full Liver and Intestine Committee.

Upcoming Meetings

- No upcoming meetings

Attendance

- **Subcommittee Members**
  - Chris Sonnenday
  - Scott Biggins
  - Shimul Shah
  - Allison Kwong
  - Neil Shah
  - Joseph DiNorcia

- **SRTR Staff**
  - Katie Audette
  - Jake Lake
  - Nick Wood

- **UNOS Staff**
  - Emily Ward
  - Cole Fox
  - Ben Schumacher
  - Alina Martinez
  - Niyati Upadhyay

- **Other Attendees**
  - Neil Mehta
  - Parissa Tabrizian
  - Anjana Pillai