

OPTN Liver and Intestinal Organ Transplantation Committee

Meeting Summary

August 15, 2025

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 08/15/2025 to discuss the following agenda items:

1. OPTN Operations & Safety Committee: *Re-evaluation of Deceased Donor Testing Requirements* Project Update
2. Hepatocellular Carcinoma (HCC) Project Scope Discussion

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

1. OPTN Operations & Safety Committee: *Re-evaluation of Deceased Donor Testing Requirements* Project Update

The Committee received an update on the progress of the OPTN Operations & Safety Committee's project, *Re-evaluation of Deceased Donor Testing Requirements*.

Summary of discussion:

The Committee reviewed the proposed updates to deceased donor testing requirements. The Committee discussed the proposed removal of direct bilirubin as a required test for deceased donor liver offers. A member explained that the Operations & Safety Committee's rationale for proposing removal was that direct bilirubin was not essential for initial donor evaluation.

Members agreed that direct bilirubin is not routinely used in decision-making for liver acceptance. While it can provide reassurance in specific scenarios—such as when total bilirubin is elevated and direct bilirubin is normal, it is not considered critical for every donor evaluation. A member noted that obtaining direct bilirubin results within the required timeframe can be challenging for organ procurement organizations (OPOs). Additionally, the member stated that the test is not always readily available, and delays in reporting can complicate the donor evaluation process.

The Committee emphasized that removing direct bilirubin from the list of required tests does not prohibit OPOs from obtaining or reporting the value. Transplant programs may still request direct bilirubin if clinically indicated, particularly in cases where total bilirubin is abnormal and further clarification is needed.

No members expressed opposition to the removal of direct bilirubin as a required test. The Committee agreed that the change would streamline donor evaluation and reduce unnecessary burden on OPOs, while still allowing for clinical discretion when additional information is needed.

Next steps:

The Committee's feedback will be forwarded to the Operations Safety Committee.

2. Hepatocellular Carcinoma (HCC) Project Scope Discussion

The Committee refined the scope and discussed potential data requests for a new project to update HCC policy and guidance. The summary of discussion identifies areas of HCC policy and guidance that the Committee seeks to update in addition to incorporating HCC stratification.

Summary of discussion:

The Committee discussed which HCC non-standard exception scenarios that could be placed into policy for automatic approval.

Members discussed the possibility of automating approval for HCC exception requests where the candidate has zero tumor burden following treatment. The Committee discussed data that will help them develop the necessary criteria for policy implementation. The Committee acknowledged that determining the timeframes for eligibility will be important. The Committee identified several data points for evidence gathering, including:

- Number of exception requests with 0 cm tumor burden, stratified by request outcomes
- Time between treatment date and exception request
- Time between index imaging and locoregional therapy
- Date of initial tumor diagnosis and treatment
- Number of exception requests that are categorized in the recurrent pathway
- Size of the original tumor
- Alpha-fetoprotein (AFP) levels
- Imaging results and biopsy findings

The Committee discussed whether missing extension deadlines should warrant automatic approval. Members agreed that if the data is easily obtainable, it would be valuable to analyze how often extension deadlines are missed to help decide whether these cases should be considered for automatic approval. Concerns were raised about potentially making deadlines less meaningful if grace periods are routinely granted. Additional data the Committee requested included:

- Timing and frequency of extension exceptions
- Center-level analysis (de-identified) to assess whether delays or missed deadlines are center-specific or systemic

The Committee discussed potential updates to HCC NLRB guidance. The Committee reviewed NLRB guidance for immunotherapy for HCC. The Chair stated that these scenarios should continue to be reviewed by the National Liver Review Board (NLRB). The Committee noted that there is currently no database field for immunotherapy as a treatment option. Members suggested adding immunotherapy to the OPTN computer system to better track its use and outcomes.

The Committee also reviewed the guidance related to recurrence. Members discussed the need to update guidance language to clarify scenarios such as recurrence after ablation versus resection, and to ensure that guidance reflects current clinical practice.

The Committee considered reevaluating the six-month wait period for HCC exception points, particularly in cases where candidates have already spent significant time with their cancer diagnosis prior to listing.

Members discussed whether the wait period should begin at diagnosis, treatment, or exception submission, and agreed that further data analysis is needed to inform any changes.

Next steps:

The Committee will continue to refine the scope of their project idea.

Upcoming Meetings

- September 5, 2025 at 2 pm ET (teleconference)

Attendance

- **Committee Members**
 - Allison Kwong
 - Chris Sonnenday
 - Christine Radolovic
 - Erin Maynard
 - Joseph DiNorcia
 - Kathy Campbell
 - Lloyd Brown
 - Michael Kriss
 - Neil Shah
 - Omer Junaidi
 - Scott Biggins
 - Shimul Shah
 - Shunji Nagai
 - Tovah Dorsey-Pollard
 - Vanessa Cowan
 - Vanessa Pucciarelli
- **SRTR Staff**
 - Katie Siegert
 - Nick Wood
 - Ray Kim
- **UNOS Staff**
 - Alina Martinez
 - Benjamin Schumacher
 - Joann White
 - Laura Schmitt
 - Matt Cafarella
 - Niyati Updahyay
 - Susan Tlusty
 - Tory Boffo