

**OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee
Meeting Summary
May 11, 2023
Conference Call**

James Trotter, MD, Chair

Introduction

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via Citrix GoToMeeting teleconference on 05/11/2023 to discuss the following agenda items:

1. New Project Background
2. National Liver Review Board (NLRB) Transplant Oncology

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

1. New Project Background

The Subcommittee reviewed discussions from the April 13, 2023 Subcommittee and considered whether the solution to the new project idea required guidance or policy modifications.

Summary of discussion:

The Chair stated that creating guidance for the previously discussed diagnoses seems to be an appropriate solution due to the small population sizes. The Chair stated that developing policy requires more rigor and that more data may be necessary to support a policy solution.

A member noted support for developing policy because it would enforce requirements rather than provide recommendations. The member stated that the policy could require transplant programs to create protocols similar to requirements for cholangiocarcinoma MELD or PELD score exceptions in OPTN Policy 9.5.A. The member stated that the number of transplants for colorectal liver metastases may be small now, but it could rise in the coming years which may overburden reviewers on the NLRB. The member supported developing policy due to the more rigorous and standardized nature.

Another member agreed that developing policy may be the correct approach due to monitoring and for consistency considerations.

A member suggested that guidance could be created as a first step, then policy could be developed at a later time.

The Chair stated that the advantage of creating guidance is that it is a faster process to develop and implement than policy for new standardized exceptions.

Another member asked if the population size impacts the decision to choose policy or guidance. Staff stated that the OPTN Policy Oversight Committee considers impact to population sizes when reviewing new projects and the Subcommittee should have a robust argument for why the policy or guidance is necessary. The member stated that policy should be the solution because there may be a lot of declines and appeals which may be onerous to NLRB reviewers.

2. NLRB Transplant Oncology

The Subcommittee continued discussing three potential diagnoses to add to NLRB guidance or OPTN policy.

Summary of discussion:

Unresectable Colorectal Liver Metastases

The Chair stated that more data may be necessary. The Chair suggested that it may be important to engage the community to understand the current number of transplants occurring for individuals with colorectal liver metastases as well as the treatment and screening details. A member stated that finding out the specific transplant programs that are performing these transplants would be helpful to acquire this information.

A member suggested that if a protocol was developed, it should specify the type of surveillance. The member added that it will be important to define the timing of diagnosis. The member stated that time of diagnosis could be considered when the individual is diagnosed or when the resection was performed. Another member stated that the literature suggests the importance of one-year biomarkers. The member stated that some protocols require a positron emission tomography (PET) scan as part of the evaluation.

A member asked if the literature indicates a specific number of lesions. Another member responded that there is no limit.

A HRSA representative asked whether this should be studied under a formal clinical research protocol. A member responded that these transplants are occurring without Institutional Review Board (IRB) approval.

Another member stated that determining the score recommendation and the justification will be difficult due to the small amount of data. The member added that some feedback from the community suggested median MELD at transplant (MMaT) minus ten. The member noted that the community may have a difficult time agreeing that livers could be allocated to individuals that have an estimated 50 percent survival. The member explained there are organ utility considerations for this new project. The Chair agreed.

Unresectable Intrahepatic Cholangiocarcinoma < 2 cm

A member asked why the population is limited to less than 2 centimeters rather than less than 3 centimeters. Another member responded there is more data to support less than 2 centimeters. The member noted that this is a smaller population but an exception would still impact individuals who did not previously have access to transplant due to low MELD scores.

A member suggested to incorporate protocols for this diagnosis into the current policy for cholangiocarcinoma (OPTN Policy 9.5.A). Another member responded that this is a different disease than hilar cholangiocarcinoma and requires different considerations.

A member stated that MMaT minus three is a lot for a disease that does not have the same survival prospects as other exceptions like hepatocellular carcinoma (HCC). Another member agreed and noted that there is a small amount of heterogeneous data in the U.S.

Unresectable downstaged intrahepatic cholangiocarcinoma

The Chair stated that this diagnoses should not be added to guidance or policy at this time. The Chair explained that there are very few patients, a high amount of attrition, and marginal outcomes.

Another member stated that this diagnosis does not have an adequate large number of data and some literature indicates a fair number of recurrences. The member stated that it is too soon for MELD exceptions and not yet appropriate to place into policy.

The Chair asked if there are ways to determine the difference between cholangiocarcinoma from random adenomas. A member responded that pathologists are able to indicate through markers from biopsy tests.

Another member stated that due to the small number of cases, it still feels experimental. The member added that there is more value in guidance rather than policy.

A member supported including this diagnosis into the new project as guidance. The member explained that the increased usage of machine perfusion has increased the amount of offers for livers that were typically not utilized. The member stated that these marginal livers would be ideal for patients in this specific diagnosis.

Next steps:

The Subcommittee will continue to discuss the project idea and refine the project scope.

Upcoming Meeting

- June 8, 2023 @ 2:30 PM ET (teleconference)

Attendance

- **Subcommittee Members**
 - Alan Gunderson
 - Allison Kwong
 - Erin Maynard
 - Jim Trotter
 - Kym Wyatt
 - Neil Shah
 - Shimul Shah
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Representatives**
 - Katie Audette
- **UNOS Staff**
 - Erin Schnellinger
 - Laura Schmitt
 - Matt Cafarella
 - Meghan McDermott
 - Niyati Upadhyay