OPTN Liver & Intestinal Organ Transplantation Committee
Meeting Summary
October 22, 2020
Conference Call

James Trotter, MD, Chair
James Pomposelli, MD, PhD, Vice Chair

Introduction

The Liver & Intestinal Organ Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/22/2020 to discuss the following agenda items:

1. Further Enhancements to the NLRB: Post-Public Comment Review and Vote
2. Acuity Circles 6-month Monitoring Report
3. MMaT Calculation Project
4. Updating NLRB Guidance and Policy
5. MELD Project

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

1. Further Enhancements to the NLRB: Post-Public Comment Review and Vote

The Chair gave an overview of public comment feedback on the *Further Enhancements to the NLRB* proposal.

Summary of Data:

The Committee reviewed a summary of public comment feedback. All aspects of the proposal were generally supported. There was a patient-driven campaign to update guidance for candidates with primary sclerosing cholangitis (PSC). Additionally, the proposal received feedback that the criteria for moderate to severe protein calorie malnutrition should be more objectively defined in polycystic liver disease (PLD) guidance and the Pediatric Appeals Review Team (ART) leader should be a member of the Pediatric Specialty Board. The proposal was supported by American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO), North American Transplant Coordinators Organization (NATCO), and Society of Pediatric Liver Transplantation (SPLIT). The ASTS also provided specific feedback on portopulmonary hypertension (POPH) criteria.

The Committee then reviewed post-public comment changes and recommendations by the NLRB Subcommittee. The Subcommittee considered all public comment feedback, and recommended adding an ART leader to the Pediatric ART and more specificity to responsibilities of the ART leader. The Subcommittee recommended continuing discussion on PSC criteria. The Committee also reviewed post-public comment changes to clarify the policy language for reviewing *Post-Transplant Explant Pathology* forms and ASTS feedback on POPH criteria.

The Committee reviewed proposed transition measures to address candidates upon implementation of the proposal. The Committee agreed for changes to POPH, to educate and communicate that if there is a candidate with non-standardized POPH exception who meets new standardized criteria, then the program should submit a new standardized exception and allow the non-standardized exception to

expire. Additionally, candidates with a standardized POPH exception at the time of implementation will keep their exception but need to meet updated extension criteria upon their next extension. The Committee did not see a need for any additional transition plans to address other aspects of the proposal.

The Committee also reviewed a recommendation to make new fields on the initial POPH exception form required fields to align with other fields on the exception form.

The Committee reviewed the proposed policy language to be included in the briefing paper to go to the Board of Directors for consideration.

Summary of Discussion

The Committee had no questions or comments.

Vote

The Committee unanimously approved sending the *Further Enhancements to the NLRB* proposal as presented to the OPTN Board of Directors for consideration.

2. Acuity Circles 6-month Monitoring Report

The Committee reviewed the Acuity Circles 6-month monitoring report.

Summary of Data:

Staff presented the Acuity Circles 6-month monitoring report. The report evaluated pre- and post-Acuity Circles policy implementation including the number and percent of Waitlist registrations, the distribution of MELD/PELD score at listing, Waitlist removals due to death or too sick to transplant, Waitlist transplant rates, the volume of deceased donor liver transplants (DDLT), the median DDLT Allocation MELD/PELD score at transplant, the distribution of distance from donor hospital to transplant program for DDLT recipients, the distribution of cold ischemic time for DDLT recipients, DDLT by multi-organ type, OPO deceased liver donor volume, and deceased liver donor age by DDLT recipient age.

Additionally, the report evaluated National Live Review Board (NLRB) data pre- and post- Acuity Circles NLRB implementation including exception request forms (initial and extension) submitted, total process time of exception forms, volume of liver candidates removed due to death or too sick to transplant by exception status, Waitlist deaths or removals by exception type, transplants by exception type and MELD/PELD score, and DDLT by exception status, age at transplant, classification distance, donor type, and donor age group.

The report concluded:

- Liver Waitlist addition volumes were impacted by COVID-19, though proportionally characteristics remained constant
- Waitlist removal rates (death/too sick to transplant) increased for MELD/PELD 29-32, 33-36 score groups
- Waitlist transplant rates increased for MELD/PELD 29-32, 33-36, and 37+/Status 1s score groups
- Decreased variation in median allocation score at transplant when examined by different geographies
- Increased distance (nautical miles) from donor hospital to transplant program of recipients, particularly for high MELD/PELD score/status recipients
- The decreased approval rates from Regional Review Board (RRB) to RRB plus pre-acuity circles (AC) NLRB period are increasing post-AC NLRB
- Increased percentage of exception request forms automatically approved

- Decreased time to adjudication for initial and extension exception request forms
- No changes in waiting list removal for death/too sick to transplant rates by candidate exception status
- Increased waiting list transplant rates for non-exception status candidates
- Increased percentage of non-exception liver transplant recipients

Summary of Discussion:

Committee members questioned why the Waitlist removal rates due to death or too sick to transplant increased for the MELD/PELD 29-32, 33-36 score groups. Staff informed the Committee that there were not as many candidates in those score groups, therefore the data shows a higher percentage rate of removal. Some members commented the COVID-19 pandemic may be affecting the number of candidates in the score groups.

A member commented there seems to be a disconnect between higher transplant rate and higher mortality rate. The member also commented the data presented shows small programs are being impacted greatest by broader allocation.

A member commented that the data showing transplants occurring faster could be due to those transplant hospitals having broader access and being able to accept offers from farther away. A member questioned if the number of transplants in higher MELD scores should be increasing. Another member commented that candidates aren't reaching the higher MELD scores because they're receiving transplants earlier. A member requested to evaluate DDLT by allocation MELD or PELD score between exception and lab MELD patients. Another member requested to see DDLT transplant center volume by region. Some members commented the mortality and transplant rates need to be evaluated with a competing risk analysis.

A member commented there seemed to be a noticeable change for non-HCC exception candidates being removed from the Waitlist due to death or too sick to transplant. The Committee was informed there are fewer non-exception candidates on the Waitlist.

The Chair commented distributing this data to the broader community would be helpful. Another member commented reconciling exceptions and lab MELD patients may be an issue, but it's still early in the post-implementation era and the COVID-19 pandemic occurred simultaneously.

SRTR representatives commented the data presented is a transition period and over time, the effects of the new policy will become more evident. Committee members were invited to review tools available on the SRTR website related to Acuity Circles allocation. An SRTR representative further commented it's hard to sort out effects of Acuity Circles and COVID-19 as they overlap in periods. The SRTR representative advised the Committee to be cautious in evaluating what is causing these effects.

Next Steps

The Committee will continue to monitor data.

3. MMaT Calculation Project

The Committee was updated on the *Updating the MMaT Calculation* project.

Summary of Data:

The project intends to address the concern that exception candidates with similar clinical condition can be listed with two different exception scores due to being registered at transplant programs with different MMaT scores within close proximity.

The Committee reviewed updated post-implementation data, understanding the COVID-19 pandemic complicates any data analysis on the post-implementation period.

Summary of Discussion:

Previously, the Committee has communicated that the issue does not need to be captured by available data and decided not to pursue modeling. The Committee was informed as the project moves beyond the Committee, the lack of a quantifiable problem may raise concerns with the proposal. The Committee was also reminded that Acuity Circles allocation policy was implemented eight months ago and the effects of the policy are still being determined. Additionally, the current system was intentionally designed to assign higher scores to candidates in higher MELD areas.

A member commented data on donor quality and use of DCDs would be beneficial to review. Another member requested to review programs doing more transplants post-policy and where those organs are originating from. Another member commented surgeon acceptance behavior is also a factor that could affect data.

A member stated the solution is being proposed to address an equity issue and has broad support across the community. Another member commented there are members of the community with different perspectives and it's important to evaluate the solution from every perspective.

A member commented the proposed change would be consistent with the Committee's mandate and philosophy of equalizing access to transplant for patients with similar risk of mortality. The Chair commented the proposed solution is not changing allocation, but would be making an adjustment for an anticipated problem.

The Committee reviewed recommendations from the Acuity Circles Subcommittee. The Committee agreed with the following Subcommittee recommendations:

- Use 150 NM as the initial circle size in calculating MMaT/donor hospital
- MMaT around the donor hospitals should be calculated based on transplants
- 10 qualifying transplants and two transplant programs is the appropriate size cohort to calculate MMaT around the donor hospital
- The transplant programs included in the cohort must have performed a qualifying transplant
- MMaT around the donor hospital should have the same exclusions as MMaT around the transplant program
- If there is not a sufficiently large cohort within 150 NM circle around the donor hospital, increase the circle size in 50 NM increments until cohort threshold is met
- MMaT program scores should be updated twice a year based on a cohort from a previous 365 day period
- For Hawaii and Puerto Rico, require them to meet the minimum number of transplants threshold but not the two program requirement and if the cohort does not meet the minimum number of transplants, expand the cohort time period from 365 days to 730 days
- No action necessary for donor hospital in Alaska
- There should be a minimum exception score for standardized and non-standardized exceptions of 15

The Committee discussed whether the proposal should include changes to Median PELD at Transplant (MPaT). A member commented this should be a different project as it is a separate issue.

Next Steps

The Committee will vote on the proposed solution in November.

4. Updating NLRB Guidance and Policy

The NLRB Subcommittee Chair presented proposed NLRB updates and policy clarifications to the Committee.

Summary of Data:

The Committee is slated to sponsor another public comment proposal in January 2021 to update NLRB guidance and make a policy clarification.

The upcoming public comment proposal is slated to include:

- Updates to Pediatric Guidance, including:
    - Complications of portal hypertension, including ascites and gastrointestinal bleeding
    - Growth failure/nutritional insufficiency
    - Metabolic liver disease
    - Conclusion to account for situations not discussed elsewhere in the guidance document
- Updates to PSC guidance based on public comment feedback
- Clarification of diagnostic criteria for standardized cholangiocarcinoma (CCA) exceptions in policy
- Improvements to NET guidance by removing age over 60 threshold

The Committee then reviewed available data on PSC including:

- Number and percentage of PSC patients on the Waitlist
- Liver Waitlist drop-out rates
- Number and percent of deceased donor, liver-alone transplant recipients with PSC
- Liver transplant rates with PSC diagnosis

A Committee member presented data on age of patients with on neuroendocrine tumors (NET) in relation to CCA.

Summary of Discussion:

The NLRB Subcommittee Chair presented proposed changes to Pediatric Guidance and the Committee did not have any questions or comments.

The NLRB Subcommittee Chair then presented proposed changes to PSC criteria in NLRB Guidance. A member commented there should be more consultation with experts. The Subcommittee Chair commented the existing guidance is not optimal and should be modified. Another member commented that data shows higher mortality for PSC patients goes back several years and PSC policy has been implemented only recently.

A member suggested that when PSC patients receive a high MELD score, allowing them to qualify for that score for a longer amount of time. The Subcommittee Chair responded that could be an option, but there is no precedence in policy for this.

A member commented any changes to PSC guidance should be minimal. Other members suggested comparing PSC data to HCC patients. Members also suggested evaluating PSC data by age and gender as well as MELD score prior to removal from the Waitlist for PSC. The Subcommittee will evaluate additional data points and bring recommendations back to the Committee at a later date.

The Committee then reviewed a proposed change to remove the age restriction from diagnostic criteria for neuroendocrine tumors (NET) in guidance for CCA. The Committee agreed with the removal of the age restriction.

Next Steps

The Committee will vote on proposed changes in November.

5. MELD Project

A Committee member presented a project idea to improve the MELD calculation to better predict mortality in women. The Committee member presented an upcoming publication that outlines a potential pathway to improve the MELD score for the Committee's consideration. The Committee discussed additional ways that the MELD score could be improved and decided to continue conversations on a potential project to update MELD at a future meeting,

Next Steps

The Committee will continue to discuss this project idea at a future meeting.

Upcoming Meetings

- November 6, 2020

Attendance

- **Committee Members**
  - Peter Abt
  - Diane Alonso
  - Sumeet Asrani
  - Kimberly Brown
  - Derek DuBay
  - James Eason
  - Alan Gunderson
  - Julie Heimbach
  - Bailey Heiting
  - Jennifer Kerney
  - Shekhar Kubal
  - Ray Lynch
  - Greg McKenna
  - Mark Orloff
  - James Pomposelli
  - Jorge Reyes
  - James Trotter
- **HRSA Representatives**
  - Jim Bowman
  - Arjun Naik
  - Robert Walsh
- **SRTR Staff**
  - Michael Conboy
  - John Lake
  - Ryutaro Hirose
  - Ray Kim
- **UNOS Staff**
  - Nicole Benjamin
  - Matt Cafarella
  - Craig Connors
  - Shannon Edwards
  - Betsy Gans
  - Lindsay Larkin
  - Jason Livingston
  - Victor Melendez
  - Jennifer Musick
  - Joel Newman
  - Samantha Noreen
  - Matt Prentice
  - Liz Robbins Callahan
  - Leah Slife
  - Karen Williams
  - Amber Wilk
- **Other Attendees**
  - Emily Perito
  - James Sharrock