OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
January 17, 2019
Conference Call

Julie Heimbach, MD, Chair
James Trotter, MD, Vice Chair

Introduction

The Liver and Intestinal Organ Transplantation Committee (the Committee) met via teleconference on 01/16/2019 to discuss the following agenda items:

1. Implementation Update
2. Board Update: monitoring and potential revision

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

1. Implementation Update

Prior to implementation of the National Liver Review Board (NLRB), the Committee discovered some concerns regarding the transitional period between the implementation of the NLRB (January 31, 2019) and the new liver distribution system (April 30, 2019).

Summary of discussion:

Prior to NLRB implementation, the Committee received the median model for end-stage liver disease (MELD) at transplant (MMaT) scores for each transplant program based on a calculation using a 250 nautical mile (NM) circle (MMaT/250) around each transplant program. The identified, program-level data revealed four donation service areas (DSAs) where there were differences in MMaT/250 within the DSA. For the three-month interval between the implementation of the NLRB and the new Acuity Circle (AC) distribution policy, exception patients listed at some programs in these DSAs will be at a fixed score lower than other patients in the DSA. Additionally, during this transition period, DSA will still be used as a geographic unit of allocation so the candidates listed at the affected programs would be disadvantaged. This issue exists only during the transition period between implementation of NLRB and the new AC distribution system.

The chair proposed four solutions to this problem.

- **Option One**: Use DSA (instead of 250 NM circle around the transplant program) for calculation of MMaT until the AC distribution system starts. This solution would align calculation of MMaT with the local unit of distribution which is consistent with the intent of NLRB policy, is predictable, and is easy to explain. MMaT would then be calculated based on the 250 NM circle once the AC distribution system is implemented.
- **Option Two:** Manually adjust the affected programs to match the remaining programs within the DSA. This solution would allow for MMaT/250 to start as planned. It would get complicated, however, because a decision to adjust MMaT/250 scores either up or down would need to be made.
- **Option Three:** Delay NLRB implementation until the new distribution system is implemented. This solution is the easiest to explain but there would be two major changes going live at the same time which the Committee has tried to avoid.

- **Option Four:** No action and allow specific cohort of patients to have a fixed score below others in the same DSA during the transition period. The justification for this solution would be that only a small proportion of the waitlist is impacted.

Once the Committee agrees on a solution, it will go to the OPTN/UNOS Executive Committee for consideration. The chair indicated a preference for option one and asked members to provide their input.

A Committee member raised the concern that a similar issue will still be present once the new distribution policy is implemented. At that time, distribution will go out to 500 NM and there will be programs with different MMaT/250 close to each other. It will take a while for the MELD scores to adjust across the nation. The chair agreed that this is a valid concern but allocation will not be based on a fixed geographic unit so there will still be access for candidates listed at a program with a lower MMaT/250.

A Committee member agreed with the chair that option one is the best solution. Another Committee member asked if option one would have legal standing because it is reintroducing DSA into allocation policy. The chair stated that it would be allowed because it would only be in place for the transition period and DSA will still be a geographic unit of allocation during this time. A Committee member asked if option one was possible from an IT perspective. The chair stated that it is possible.

Staff shared that UNOS General Counsel has discussed the issue of reintroducing DSA. While there is some argument for using DSA, it does raise concerns to introduce DSA into a policy that did not previously include DSA. The chair stated that the justification for using DSA would be ensuring equitable access to transplant for the affected candidates. The chair also noted that trying to use a DSA-based distribution system with a circle-based calculation at the same time is problematic and the Committee did not plan on using both of these systems concurrently.

UNOS staff clarified that even under the new AC distribution system, there will be candidates with similar clinical characteristics in the same geographic unit with different exception scores. During the transition, the geographic unit will be the DSA, but under AC allocation it will be a circle. Although the geographic unit will be different, the situation will be similar. The chair stated that the key difference is that under the new distribution policy the area of distribution is not fixed because the circle is based on the location of the donor. Under the current system, the DSA is a fixed geographic unit.

A Committee member expressed that option one was not reintroducing DSA because it was present in the original NLRB policy. In reference to option one, another Committee member noted that some community members may question why the Committee originally delayed NLRB in order to remove DSA when the MMaT calculation may be based on DSA anyway.

A Committee member put forth a motion to vote on option one. The motion was seconded. A Committee member asked if they could have more time to think about this issue. The chair stated that they do not have time to delay this decision. UNOS staff agreed that the timeline necessitated a vote at this meeting. A Committee member proposed having a national MMaT, which could be simpler. The current national MMaT is 29. The chair was concerned that this would be too large of a change for a problem that will only last for a few months. A Committee member asked if a national MMaT could be an interim solution. UNOS staff stated that any solution voted on at this meeting would be an interim solution because otherwise public comment would be needed. A Committee member felt that option one was not a significant change because the MMaT scoring within the NLRB policy was always meant to be based on the first unit of allocation. When this unit is DSA, the scoring should be based on the DSA. When it is a 250 NM circle, it should be a 250 NM circle. Another Committee member supported

option one for the transitional period but stated that a national MMaT should be something that the Committee considers for the future. The chair agreed that a national MMaT should be something that the Committee considers as a policy proposal in the future.

The Committee voted on the following questions:

1) Do you support option one? (13 Yes; 0 No; 1 Abstain)

UNOS staff then presented the updated policy language reflective of option one.

2) Do you support sending the language as presented? (15 Yes; 0 No; 0 Abstain)

UNOS staff asked if the Committee wanted to exclude nationally shared livers from the MMaT calculation for the DSA. UNOS staff suggested excluding donors from outside the region for the national median pediatric end-stage liver disease at transplant (MPaT) calculation instead of outside 500 NM. This would be more consistent with the MMaT calculation. The Committee agreed with both ideas.

3) Do you support sending the additional language as presented? (12 Yes; 0 No; 0 Abstain)

Next steps:

The Liver and Intestines Committee will send the proposed changes to the OPTN/UNOS Executive Committee for consideration.

2. Board Update: Monitoring and Potential Revision

NLRB Monitoring:

The chair presented a number of metrics that could be used to monitor the NLRB. These metrics included:

- Time from application to granting score
- Number of candidates with exception scores and diagnosis
- Number of standard versus non-standard diagnoses
- Auditing for consistency with policy
- Appeals and Appeals Review Team (ART) use
- Rate of reviewers not submitting votes and/or reviewers with two missed votes
- Member satisfaction survey at six months

The chair asked Committee members to think of anything else that should be monitored. The Chair reviewed the exception request and appeal process.

Acuity Circles Implementation:

AC is slated to be implemented on April 30 and education is expected to begin in late February.

AC Status 1 Challenge for Hawaii and Puerto Rico:

During the previous special public comment cycle, it was brought to the attention of the chair that in any of the proposed circle models, Status 1 candidates in Puerto Rico and Hawaii would lose access to regionally-shared livers. Currently, candidates listed as Status 1 or higher than MELD 35 in Puerto Rico and Hawaii can access offers from Regions 3 and 6, respectively. This is not possible under the AC policy because the largest distribution circle is 500 NM and this distance does not reach the contiguous United States. In 2017-2018, there were three Status 1 candidates in Puerto Rico and one Status 1 candidate in Hawaii that were transplanted with a regional share.

The chair proposed creating larger circles for Status 1 candidates listed in these two areas. To give candidates listed in Puerto Rico access to all of Florida, the circle would need to be approximately 1,400 NM. This circle would also include most of the east coast. For Hawaii to get access to all of California, the circle would need to be roughly 2,425 NM. To reach Seattle from Hawaii, it would take a 2,350 NM circle. A Committee member suggested implementing these large circles because it is a small number of candidates. A Committee member asked if it would be possible to draw a circle originating in the contiguous United States for these patients. UNOS staff clarified that the circles described above originate at the donor hospital location. The Committee agreed that this is an issue that needs to be addressed and to discuss it more during their next meeting.

AC Logistical Challenge: Time to Place Organs

During the Board discussion about AC, there was concern that the amount of time to place marginal livers could increase drastically due to broader sharing. The concern was that there is the potential for acceptance and subsequent decline of offers as better organs become available. This could cause the same liver to be accepted and declined for hours as candidates receive better offers. This happens under the current distribution system, but high-urgency candidates will receive more offers under AC so it may become a larger problem.

Current policy allows for acceptance of two offers. The chair proposed a solution where once a final acceptance has been entered, a program cannot decline that offer for any reason until they are in the operating room (OR) with visualization, except for an 801 turndown code (candidate is ill or donor is significantly changed). If an 801 code is entered, another offer cannot be accepted for 24 hours. If the program has already accepted another offer for the candidate, then this will not be impacted. The chair asked for feedback on this idea.

A Committee member stated that this solution is not favorable because it puts patients at risk due to their surgeon's behavior and it is an attempt to solve a problem that does not exist yet. The Committee felt that this solution would be a logistical challenge and could hurt patients. A Committee member suggested that if this situation occurs it should be reviewed but a candidate should not be prohibited from receiving another offer. The Committee agreed that they should monitor and collect data on this issue and then make a decision on whether or not they should come up with a solution.

The chair then presented another potential logistical issue with AC. Current policy allows acceptance of two livers but it does not determine when the second liver must be declined. This is happening under the current allocation system. The chair recommended that the second offer must be declined once the surgeon is in the OR with visualization of the first offer (or visualization plus biopsy if needed.) A Committee member noted that this does not apply to expedited livers or if the liver is on waivers, but only if the candidate has a primary acceptance on two offers. The Chair asked the Committee to continue to think about this topic. A Committee member expressed concern that the OR for the second liver is often delayed because of this issue.

Next Steps:

The Committee will continue to discuss the potential issues described above.

Upcoming Meeting

- February 21, 2019 - Teleconference

Attendance

- **Committee Members**
  - Andy Bonham
  - Terry Box
  - Sandy Florman
  - Eddie Island
  - George Loss
  - Willscott Naugler
  - Kevin O'Connor
  - Ruben Quiros
  - Joseph Roth
  - Patricia Sheiner
  - Shimul Shah
  - Jennifer Watkins
  - Scott Biggins
  - Julie Heimbach
  - James Trotter
- **HRSA Representatives**
  - Jim Bowman
  - Chris McLaughlin
- **SRTR Staff**
  - John Lake
  - Bryn Thompson
- **OPTN/UNOS Staff**
  - Roger Brown
  - Matt Cafarella
  - Shannon Edwards
  - Mary Ellison
  - Betsy Gans
  - Chelsea Haynes
  - David Klassen
  - Aaron McKoy
  - Tina Rhoades
  - Leah Slife
  - Tynisha Smith
  - Charleen Walters
  - Nicole Benjamin
  - Elizabeth Miller
  - James Alcorn
- **Other Attendees**
  - Ryutaro Hirose
  - Bert Kasiske
  - Alyson Lewis
  - Mike Hall