OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Meeting Minutes March 29, 2018 Chicago, IL

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Introduction

The OPTN/UNOS Liver and Intestinal Organ Transplantation met in Chicago, Illinois on 03/29/2018 to discuss the following agenda items:

- 1. Demonstration of National Liver Review Board (NLRB) Wizard and Implementation Discussion
- 2. Pediatric liver project
- 3. Sodium MELD post implementation data
- 4. Simultaneous Liver Kidney (SLK) post implementation data
- 5. Upcoming Work Subcommittees and update on Geography Committee

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

1. Demonstration of National Liver Review Board (NLRB) Wizard and Implementation Discussion

Summary of discussion:

UNOS staff walked the committee through the current NLRB wizard being developed to facilitate the changes to a NLRB. A committee member stated that it would be helpful for the NLRB to provide a history of offers that had been made to a candidate when the reviewer is presented a case. Committee members emphasized the value of this information but stated the complexity of having that kind of data in a blinded environment. Additionally, the extent of that data to be available in real-time when a case is being reviewed is not in the scope of the current implementation effort. The committee discussed that there is not a lot of guidance on the number of points that should be provided to candidates. It was emphasized that the current guidance and educational efforts emphasize the NLRB approving scores in line with what would be provided if the candidate met standardized criteria for a diagnosis. The Committee stated the scoring around Median MELD/PELD at Transplant (MMat) will be emphasized further in educational efforts, and the Committee will monitor scoring post-implementation.

The Committee reviewed a mock-up on how the exception submission process will work for programs to submit exception cases. The Committee agreed with the current direction of UNOS IT staff. The Committee stated that it is important to have granularity in the dropdowns available to indicate what diagnosis the candidate has. This is to avoid the amount of cases that are submitted as "other specify" and improve the quality of post-implementation data. The committee reviewed the concept that programs will be able to indicate that the MMaT score will be adjusted to be changed with each 180-day update to the MMaT scoring. It was emphasized by the Committee the programs will submit a score, based on their knowledge of the MMaT scoring. The NLRB reviewers will only see the score in relation to the MMaT. This is done to ensure blinding since the MMaT for a specific Donor Service Area (DSA) may be high/low enough to identify which DSA and/or region the candidate is in. The Committee discussed whether multiple email addresses should be available to receive the confirmation of the NLRB review. The Committee decided that one email address is required to receive the results, and

programs can create their own processes to ensure that the email address provided can reach multiple staff.

The Committee discussed being able to look back at prior cases as a review board member to see how they (a review board member) had voted previously. The idea being for a review board member to educate themselves and remain consistent. The Committee agreed that this would be helpful but may be out of scope for this initial implementation. They discussed that this could be important and the NRLB Subcommittee could continue to identify ways for the NRLB members to see how their voting compares with others.

The Committee discussed educating the community about the NLRB. It was reiterated that UNOS will be providing several educational offerings in 2018 leading up to the implementation of the NLRB. The Committee reiterated the difficulty in explaining the concept of scoring tied to the MMaT, but that programs should begin having those conversations now to prepare patients for the change. The Committee discussed the use of the guidance documents for the non-standard MELD/PELD exceptions. It was emphasized that meeting the criteria in the guidance documents does not automatically provide an approved exceptions, since those diagnoses are not standard diagnoses in policy. However, the guidance outlines the criteria that the NLRB members will use when making decisions on non-standard exception requests. Therefore programs should be aware and informed of the guidance to understand the criteria that their candidate will be compared to.

The Committee discussed the manner in which existing exception candidates will be treated at the implementation of the NLRB. The Committee emphasized the need for an implementation strategy that is equitable and also minimizes complexity for transplant programs and patients. The Committee discussed several options and decided to continue the discussion in the NLRB subcommittee and finalize at an upcoming conference call. The Committee discussed the current waiting time tiebreaker for exception candidates. With the implementation of the NLRB the Committee identified that there would be numerous exception candidates in a DSA at the same MMaT-3 score. The current tiebreaker is time at the MELD score, followed by total UNOS waiting time (based on registration date). The Committee identified a scenario where multiple candidates will have the same "time at MELD score" due to the 180 day update to exception scores, and total UNOS waiting time will be the tiebreaker. The Committee discussed that a candidate with more total UNOS waiting time could be prioritized over someone who has more time with an approved exception, since both candidates would have the same "time at MELD score". The Committee agreed to revisit this as a potential policy change in the future to prioritize the amount of time that a candidate has had an approved exception.

2. Pediatric Liver Project

Summary of discussion:

The Committee was presented with an update on the Pediatric Transplantation Committee's project to address pediatric waitlist mortality. Leadership of the Pediatric Committee presented the progress thus far and the plans to convene a workgroup that includes representation from the Liver Committee. Several committee members discussed that the cause of waitlist mortality for the lower age groups may have more to do with the characteristics of their disease, rather than their priority for organ allocation. Additionally, the Committee and Pediatric Committee leadership discussed the role of PELD, as a measure of medical urgency, in relation to the project. It was stated that the majority of pediatric candidates are transplanted with exception points which may highlight the shortcomings of PELD as a measure of medical urgency. Pediatric Committee leadership expressed their interest in discussing PELD, but emphasized the scope of the current project is currently limited to the allocation priority of pediatric candidates with respect to adult candidates.

3. Sodium MELD – Post Implementation Data

Summary of Discussion

The Committee was presented with the post-implementation analysis of the implementation of Sodium MELD policy. The Committee discussed the analysis and noted that there were no significant changes in demographics of candidates or recipients. Additionally there were no significant changes in post-transplant patient and graft survival pre- and post-policy. There was a decrease in MELD exception requests for ascites and hyponatremia post-implementation.

4. Simultaneous Liver Kidney (SLK) – Post Implementation Data

Summary of Discussion

The Committee was presented with the post-implementation analysis of the implementation of the changes to SLK policy. The Committee discussed the analysis and there was agreement that the post-implementation period was still early, but the changes were meeting the goals of the project. It was noted that the analysis does not show the increase in SLK transplants that were predicted by some members of the committee based on the new medical eligibility criteria.

5. Upcoming Work – Subcommittees and update on Geography Committee

Summary of Discussion

The Committee discussed the role of the NLRB Subcommittee moving forward. There was agreement that the subcommittee would continue to meet to coordinate the implementation of the NLRB with UNOS Staff. UNOS staff stated that the NLRB exception form interface would continue to be developed and the subcommittee would provide feedback, and answer any clarifications in the coming months.

Upcoming Meetings

- April 19, 2018 (Conference Call)
- May 17, 2018 (Conference Call)