OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
May 17, 2018
Conference Call

Julie Heimbach, M.D., Chairman
James Trotter, M.D., Vice Chairman

Introduction

The Liver and Intestinal Organ Transplantation Committee met via teleconference on 05/17/2018 to discuss the following agenda items:

1. National Liver Review Board (NLRB) Scoring – Tiebreaker based on Initial Approved Exception Date
2. Transplants Included in Median Meld at Transplant (MMaT) Scoring Cohort
3. Region 8 Split Liver Variance
4. NLRB Operational Guideline Language Addition
5. Modification to Existing Boards

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

1. National Liver Review Board (NLRB) Scoring – Tiebreaker based on Initial Approved Exception Date

At the 180 days update meeting the committee identified a potential inequity that may happen when the median MELD score changes. The concern was that the tiebreaker of time on the waiting list doesn't as accurately capture the candidate's need for transplant as their time at the exception score does. The NLRB subcommittee recommended using the date initially approved for an exception as a tiebreaker. The committee was in agreement.

Discussion

The subcommittee considered the unintended consequence of placing a candidate who had been at an exception for longer behind a candidate who hadn't been at that exception score as long, but had previously had an exception and then a period at a lower score in the meantime. It considered an alternative tiebreaker of time since most recent exception approval, but concluded that it was more likely that time in between exceptions would be due to administrative reasons and not due to clinical reasons. Therefore, the recommendation was using the date of first approval for an exception.

Next Steps

A policy change is required. The committee will create official policy language and vote to approve. It will go to the Policy Oversight Committee, POC, the Executive Committee, and then to Public Comment for vote in August.

2. Transplants Included in Median Meld at Transplant (MMaT) Scoring Cohort

A question came up at the end of the last in-person committee meeting about what donors are included in the calculation of the MMaT score. Concern was raised about the effect including DCD and living donors would have on the calculation. The NLRB subcommittee reviewed data showing what the median MELD at transplant (MMaT) would be for each DSA, both including and excluding DCD, and both including and excluding living donor. In some DSAs, there was up to a 2 point difference in the resulting MMaT. The subcommittee recommended excluding both DCD and living donors from the cohort used to calculate MMaT.

Discussion

The committee considered whether there were other donor characteristics that should be used to rule out transplants from the cohort because they would represent outliers as well. Specifically, they considered donors over 70, since donors over 70 and DCD donors are allocated differently than other types of organs, using a separate allocation table. The consensus was that there were not many of those donors (although they may be on the rise), and the only clear, binary groups that should definitely be excluded from the calculation were DCD and living donors. They were willing to consider other groups if there was significant public comment concern about another specific group.

The committee supported the subcommittee recommendation to exclude DCD and living donors from the calculation of MMaT.

Next Steps

A policy change is required. The committee will create official policy language and vote to approve. It will go to the Policy Oversight Committee, POC, the Executive Committee, and then to Public Comment and the Board.

3. Region 8 Split Liver Variance

Region 8 is requesting a variance for split livers. Their proposed variance would allow a liver program in the region to keep the resulting lobe or segment for use in another of their patients on the wait list if they split a liver. There is currently an open variance that programs can elect to participate in that allows a center to use the remaining segment only if they use the right side in their initial candidate. This variance would not be limited to a side and allows use of the other side for a candidate of the hospital's choice only if there are no suitable 1A, 1B or high MELD candidates in the region.

Discussion

There was discussion about whether this might discourage cooperation with other liver programs that might occur when having to share the resulting segment, or whether this might allow for an increase in the number of transplants when a hospital is not inclined to work with another program.

The committee decided to proceed with the next steps to put forth this variance.

Next Steps

The next steps would be POC, Executive Committee, and then Public Comment. Approval will be for a specified period of time requested, three years, then the project would be followed for achievement of goals and if effective, the variance could be extended. This would only be for Region 8.

UNOS staff will write the proposal similar to the variance for Region 9 approved in December. It will be in policy language and would be with other variances as a closed variance unique to Region 8. Steps will be followed out through Public Comment set to begin on August 3rd and go to the Board of Directors in December of 2018. It would take effect immediately following Board approval. This variance will be sponsored by the Liver and Intestinal Committee.

4. NLRB Operational Guideline Language Addition

The NLRB operational guidelines direct that the pediatric specialty board will review exceptions for pediatric exceptions and also review exception applications for adults with certain pediatric diagnoses. The NLRB subcommittee discussed which diagnoses would be routed to the

pediatric specialty board. Programming will automatically send cases to a review board and can be based on diagnosis and/or age.

Discussion

The adult candidates asking for an exception based on metabolic diagnosis will be rare, and likely will be better understood by pediatric surgeons. Most comments were to remain with the age appropriate board. Cystic fibrosis was another concern but is considered rare.

There was a question about whether it was possible to treat urea cycle differently from other metabolic disease, but this was not recommended from a programming standpoint. The idea of allowing the applicant to select to be reviewed by the pediatric board, but there were concerns that that may result in inconsistent treatment for candidates depending on which board they were routed to.

Adults with metabolic disease will be routed to the pediatric specialty board.

Other conditions that the committee considered may be appropriate to be considered by the pediatric board may include cystic fibrosis, allogilles, cholangiocarcinoma, and NASH. Agreement that these diagnoses would still go to the age specified board. There will still be adequate expertise on both boards to make a decision on the cases.

There is staff that manages the review board process, and in rare circumstances where the adult review board members feel they don't have the expertise to address a case based on the diagnosis, then it could potentially be rerouted to the pediatric board manually.

5. Modification to Existing Boards

Current boards are Adult, Other, and Adult HCC. There was a suggestion to change reviews by the HCC board to include cancers that are not HCC and create a cancer review board instead.

Discussion

A member of the committee had concerns about malignant exceptions going to other committees where there might be less understanding of cancer. There may be many exception requests for that come in for resectable cholangiocarcinomas which will be routed to the "other" NLRB.

The HCC board is already going to have the largest case load, and was separated out because there are so many of that particular exception. There was a desire to keep the workload more balanced rather than add more to the HCC board.

Appointments on all of the specialty boards are voluntary and there may be some overlap in expertise. Trying to have all board members with more experience in cancer can be a future goal. There is also guidance for the other review board on how to handle certain cancers. The boards are spelled out in operational guidelines and changes have to be approved by the Board of Directors.

In order to make a change to create a cancer board to replace the HCC board, work would need to be done to identify specifically the diagnoses that would go to a cancer board instead of the adult other board. Ideally, the make-up of that cancer review board would be experts in cancers.

The recommendation is to monitor for now to see how diagnoses are being handled postimplementation, and then work to finalize what the tumor board should look like if needed.

Upcoming Meeting

- June 21, 2018