OPTN Executive Committee
Meeting Minutes
March 6, 2019
Conference Call

Sue Dunn, Chair

Introduction

The Executive Committee met via teleconference on 03/06/2019 to discuss the following agenda items:

1. Welcome
2. Critical Comments to HHS Regarding Liver Policy
3. NLRB Implementation Transition Proposal Special Public Comment Period Update
4. Proposed OPTN Policy Corrections and Clarifications
5. New OPTN Policy Projects

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

1. Welcome

The Committee Chair welcomed everyone to the meeting.

2. Critical Comments to HHS Regarding Liver Policy

Data summary:

A copy of the letter submitted to the U.S. Secretary of Health & Human Services (HHS) on 2/13/2019 was distributed to committee members. It was submitted on behalf of 10 transplant hospitals and suggested that the liver policy that was just adopted in December 2018 is inconsistent with the Final Rule and requests the Secretary suspend the policy so a different policy can be developed. It does threaten a lawsuit if the Secretary doesn't do what they request.

The letter allegations include things that the Board considered in the process of developing the policy:

- New policy will reduce number of liver transplants. It will predict future behavior based on past behavior, rather than trying to estimate what the behavioral change will be, which means according to the model, organs shipped further will be declined more often.
- New policy disadvantages candidates with lower socioeconomic status. SRTR modeling showed the policy doesn't promote or harm lower socioeconomic status candidates. The letter alleges the modeling is not good enough and that OPTN is obligated to increase access to those of lower socioeconomic status.
- Allocation policy should be designed to increase access for unlisted patients based on wording in the Final Rule that refers to candidates and patients, as it is a general tenet of statutory construction that when different words are used, they are likely to mean different things. HRSA gave instruction at the Board meeting that it may not be possible for organs to be allocated to anyone other than those on the waitlist.
- MELD is flawed at predicting waitlist mortality and as metric of equity. Board discussions of models and options focused on Median MELD at Transplant (MMaT),

but that was not the only metric the Liver Committee considered or that is in the SRTR modeling.

The letter was addressed to the HRSA Secretary, so the Secretary will be the respondent. HRSA is anticipated to ask OPTN for formal input, which may include a request for SRTR input. Once that happens, the Executive Committee will convene to discuss that, put together a draft, and send that back to HRSA.

The new policy is different from the last, in that these things were intentionally addressed as the policy was being developed. Via letter to the Board, HRSA expressed belief that the new policy passed compliance and fulfilled their expectations. The plan remains for an April 30, 2019, rollout.

Summary of discussion:

The letter has come in since the first round of regional meetings, so it will be an update that will be included in the regional meetings that are still outstanding. These are arguments that have been made during development of the policy, and at and after the Board meeting, so it was not unexpected.

The matter is still under internal HRSA review. Likely in the near future OPTN feedback will be requested.

HRSA will likely formulate a response before the new policy implementation in April, so OPTN feedback will need to be made in a very short timeframe over the next few weeks. If Committee members receive drafts of the response letter, they should respond quickly by email with their comments.

Next steps:

This was an informational update and not an action item for today's meeting.

3. NLRB Implementation Transition Proposal Special Public Comment Period Update

Data summary:

Changes adopted in December included the 250 nm of the transplant hospital for mechanism of calculating MMaT. The unintended consequence of the change was due to a staged implementation of NLRB to acuity circle model, which created a conflict for similarly-situated candidates at different hospitals within the same DSA during the transition. The Liver Committee proposed that during the transition period, MMaT for DSA would continue to be used to calculate median MELD for NLRB. This proposal is currently out for public comment.

It has been presented in six regions thus far. For the most part, Region 2 is strongly against the proposal. The remaining regions are generally supportive or neutral. Region 2's objections are concerning the overall issue, rather than the transition. The important thing was to define the transition period and there have not been many comments on the transition, nor use of MMaT for DSA during the transition.

The questions relate more to the use of the MMaT and how it should be calculated. They include whether the calculation should be center-specific and whether exception scores be excluded from the calculation. One question was whether a 500 nm circle instead of 250 nm circle should be used during the implementation. The 250 nm circle was chosen because it best matched the policy that was being recommended, but the acuity-based uses the 500 nm circle more than the 250, so it might make sense to consider. There was patient feedback on particularly diagnoses that will be disadvantages, which will need to be discussed again.

A number of comments were regarding how the transition will go. Because the proposal went to public comment, it eliminated the desired 3-month timeframe. Therefore, when patients have an exception score, every 3 months the exception score has to be renewed. Scores that will need to be converted to MMaT will be standard (policy-based score that is automatically approved by Chair of regional review board), semi-standard (not automatically approved, but manually reviewed by RRB), and non-standard (classified as "other, specify," but actually in policy and approved by RRB).

The original plan was that patients with existing scores would keep their scores and would go to NLRB for renewal when the time came. Due to timeline with the public comment period, two-thirds of people with scores under regional review board will still have their scores when the NLRB takes effect. About 323 standard exceptions, 340 semi-standard exceptions, and 405 non-standard exceptions will exist after the April 30th policy implementation date. There is concern over excess workload with the NLRB having to review a large number of cases at the beginning, in addition to the continuous ones coming up every week.

The Liver Committee has not addressed these questions yet, but there is an NLRB Subcommittee that will meet on Friday to begin discussions. Decisions will have to be made about which scores to convert, how to convert them, and what the number should be. The timeline over the next month leading up to NLRB implementation was shown and is available to Committee members.

Summary of discussion:

Opposition to the Liver Committee proposal was expected. Region 2 (Chicago) and Region 10 (New York) were against the short transition time and not being able to cycle everybody through. Region 6 (San Francisco) is expected to say something similar. The Executive Committee considered putting out for public comment a conversion plan, but decided not to. UNOS staff questioned whether this was done because of a timing issue. But if the Liver Committee took 3 weeks to work on this and come back with a thoughtful recommendation, would that still be a possibility?

What needs to be considered is the group of patients that have a non-standard, diagnosis not based in policy. What happens is regions tend to award scores similar to the current exception scores set by policy, and then the scores creep up every 3 months. The Liver Committee Chair suspects that many of those will be granted MMaT -3 when they are reviewed. One option would be to let everyone have their high score and eventually they would get review when their score expires. Another option would be to automatically convert all RRB scores 22 and higher to an MMaT -3, and then 3 months later they would be reviewed by NLRB.

One Committee member applauded the conversion options proposed. There has been a lot of buy-in even during a time of disarray in the community.

Another Committee member commented that the Committee is the group of experts and so she agrees with what has been proposed. She does suggest a plain language rewrite that will make it easy for those who are involved in transplants, such as donors and families, but may not be liver experts to understand what is being done and why. The main thing is that people trust what the Committee is doing and that the process is transparent.

Many have found the whole process to be confusing because the changes are coming so quickly. It is important to keep lines of communication open.

UNOS staff replied that they are creating a briefing paper for the March 26th Executive Committee meeting to help explain the options in plain language terms, based on what the NLRB Subcommittee comes up with. In addition, following the March 26 meeting, UNOS staff

will create a public document that will go through HRSA and Executive Committee review that will be distributed when NLRB goes into effect. There will also be a request for public comment on the concept of conversion at the upcoming five regional meetings, in addition to the past regional meetings.

One comment was that besides doing studies that look at past behaviors and predicting future behaviors, it might be good to write up some type of live tracking of the patients that get transplanted and record how they get fairly assessed, something that says that OPTN is committed to providing a short-term live report on successes. Then that could demonstrate that most fears were unwarranted. UNOS staff agreed that something like this could be done. During the kidney policy change years ago, UNOS published monthly updates on data and results as they came in, and that slowed down after a while. Similar public updates on how the policy and NLRB is working could be done for liver as well.

4. Proposed OPTN Policy Corrections and Clarifications

There are three proposed clarifications to the liver policy as approved at the 12/18/2018 Board meeting. The intent is to make the acuity circle policy clearer and more complete.

- The definition of a circle was added into policy and approved in 2017. This definition is no longer necessary and is actually a little bit confusing. The proposal will remove the definition from policy.
- Column titles through some of the allocation tables in the acuity circle policy. Acuity circle policy was passed as an amendment at the Board Meeting. Prior to the acuity circle amendment the Board approved a technical clarification that updated the column titles and some of the allocation tables to the original policy proposed by the Liver Committee. Because that technical amendment was approved prior to the acuity circle policy, three tables introduced as a result of the amendment were not updated with those column titles that were part of the clarification. The proposal will update the column titles and clarify that the distance in policy is distance between transplant hospital and donor hospital.
- Classification in allocation tables for liver and intestine. The acuity circle system prioritizes blood type O and B candidates for type O donors. When the prioritization was written into the policy, additional information was added to the allocation tables and classification in the tables was split into two separate rows. Three rows were accidentally left out and the proposal adds the three rows back into the allocation tables.

Second, UNOS staff presented a policy change OPTN Policy 8.5.K, relating to the allocation of dual kidneys. In 2017, the Board approved the "Improving Dual Kidney Allocation" proposal sponsored by the Kidney Committee, which included splitting the combined local and regional list to accommodate for a single and dual allocation at the local and regional levels as shown on Page 4 for the briefing paper. A classification was inadvertently omitted within the allocation of kidneys from deceased donors with KDPI score of greater than 85% table, otherwise known as "Sequence C" in figure 2. The missing split was classification for candidates with blood type B matched with donors of type A2 or A2B within the candidate's DSA. The proposal will align classifications with the intent of the original proposal. The proposal is scheduled for implementation in 3rd quarter of 2019. Current allocation systems programming has not been impacted.

Summary of discussion:

A motion for the Executive Committee to approve the technical clarifications to the OPTN policies as drafted was made and seconded. Affected policies are: Policy 1.2; 9.8.E; 9.8.H; and 9.8.I.

A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

A motion for the Executive Committee to approve the technical clarifications to the OPTN policies as drafted was made and seconded. Affected policy is Policy 8.5.K.

A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

5. New OPTN Policy Projects

The Policy Oversight Committee (POC) met last week and recommended to the Executive Committee consideration to approve a new project from the VCA Committee to make updates to the VCA transplant outcomes data collection currently in place.

The problem is that transplant outcomes for VCA are currently not fully captured. Current data collection forms were modeled after the TIEDI solid organ transplant forms, but gaps were found in VCA transplant programs' reporting. The diversity of the waiting list is expanded significantly and does not include VCA transplants that were not done in 2014 when the forms were created, including penis, uterus, and larynx VCA transplants. Therefore, there is no VCA-specific functional outcome data on these types of transplants. The goal of the project is to improve VCA data collection. The data will be used to inform future policy decision making, identify patient safety concerns, and better understand overall of VCA transplant outcomes.

The POC felt this project best aligned with the "Improve waitlisted patient, living donor, and transplant recipient outcomes" OPTN/UNOS strategic goal. The target for public comment is January 2020, for Board consideration for adoption by June 2020, and depending on OMB approval and Board approval, implementation around December 2022. Current VCA data collection is not done in TIEDI, so the forms would require approval.

The POC recommends moving forward with the project.

A motion for the Executive Committee to approve new project proposal: update to VCA transplant outcomes data collection was made and seconded.

A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

The meeting was adjourned.

Upcoming Meetings

- March 26, 2019, at 10 a.m. ET
- April 12, 2019, at 12 pm to 4 pm CT, In-Person in Chicago