OPTN Board of Directors
Meeting Minutes
March 10, 2020
Conference Call

Maryl Johnson, MD, Chair
David Mulligan, MD, Vice Chair

Introduction

The Board of Directors met via teleconference on 03/10/2020 to discuss the following agenda items:

1. OPTN Meetings & COVID-19
2. Creation of Heart and Lung Committees Bylaws Change Proposal
3. Mid-Public Comment Proposal Updates

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

1. OPTN Meetings & COVID-19

UNOS staff presented regarding the impact of COVID-19. CDC advice, public health advice, and concerns of the community are being monitored. Planning decisions will be made on an ongoing basis no more than a few weeks in advance.

Three regions (Regions 10, 11, and 9) with the most immediate upcoming in-person meetings will hold virtual meetings, where full discussions and votes will still take place. Remaining committee in-person meetings from mid-April and beyond may also be held virtually as necessary.

Regarding advice to the community, UNOS is working with AST. In addition, DTAC will meet next week. The groups will work together to determine what information is available and what advice will be given to the community. Specific donor/recipient advice will not be given.

UNOS site surveys for March and April will be done virtually. There is currently no general ban on travel for UNOS staff and they will continue to provide necessary services.

Summary of discussion:

One Committee Member asked about guidance to OPOs about COVID-19 testing. There is no generally-available test at this time for donors across the board. Another member added an OPO perspective, stating the issue is complicated due to supply chain disruption and concern about access to hospitals and necessary materials.

Next steps:

Emergency planning is currently underway.

2. Creation of Heart and Lung Committees Bylaws Change Proposal

The Thoracic Committee Chair presented the proposal to dissolve the current Thoracic Organ Transplantation Committee, which includes heart and lung transplants and create two separate OPTN committees. The purpose is to have a more complete and balanced representation of the thoracic community.

Currently, most Thoracic Committee members are only heart or lung experts, and perhaps only one member does both. This causes inefficient work split between heart and lung projects and insufficient representation for development of heart and lung policies. Heart and lung transplantations are independently complex and have significant enough volume to necessitate separate committees.

Changes in member responsibilities would be around submitting biography forms and proposing representatives for each committee. The financial impact will be addition of IT costs.

Summary of discussion:

UNOS staff stated all committees require different IT and programming requirements in any given year, so the projected IT costs are based on an average based on the other organ-specific committees. Policy changes will not happen immediately, so a budget amendment for this fiscal year should not be necessary. Then resources will be added as policy changes increase in the future.

One Committee Member was concerned about whether there is sufficient expertise amongst volunteers to populate the Lung Committee. The Thoracic Committee Chair felt there plenty of volunteers with expertise to do the work and willing to participate. Traditionally in the past, the Chair and Vice Chair alternated in heart and lung expertise, with the majority of committee members having heart expertise. The BOD Chair has also seen community enthusiasm for the change.

Counsel for OPTN/UNOS confirmed that the change will not need to undergo public comment. Bylaws that affect membership qualifications, for instance, would need to go out for public comment. This type of bylaw change is administrative in nature and therefore public comment is not necessary.

Other Committee Members expressed support for the proposal.

The Board of Directors took a roll call vote to approve the Creation of Heart and Lung Committees (Bylaws Change).

Results were as follows: 29 yes; 0 no; 1 abstained.

3. Mid-Public Comment Proposal Updates

A snapshot of the current status of the sentiment vote for the proposals out for public comment ending 3/24/2020 was presented. Feedback and potential changes for proposals will be discussed.

- **Liver & Intestine Committee: Enhancements to the National Liver Review Board**

  The Vice Chair of the Liver Committee presented on the proposal. The purpose is to incorporate improvements into the NLRB proposed after 6 months of experience. The goal of the proposal is to increase efficiency and reduce administration burden. Since 85% of HCCs that were reviewed were approved, some of those requests will be automated. The top 10 reviewers who failed to review their cases will be contacted to figure out why they did not fulfill their responsibility. Clarifications to certain definitions in reviewer guidelines will be made, including addition of guidance for secondary sclerosing cholangitis, metabolic disease, and portopulmonary hypertension, and candidates with prior history of HCC.

  Rationale for changes is based on feedback from committee members and the transplant community after 6 months' experience of the NLRB. Authority for the proposal is under OPTN Final Rule. There will be no changes in member responsibilities.

  Relatively favorable feedback to date reveals support for the changes with some specific feedback that could be incorporated, but no identifiable themes. No changes to the proposal will be made.

Summary of discussion:

One committee member brought up the issue of people with the same diagnosis in an acuity circle having two different MELD scores, and that in Ohio and Michigan, for example, there is about a 3-point difference, which has caused acceptance of more marginal organs. The difference needs to be eliminated and the data needs to be analyzed in a timely manner. The Liver Committee Vice Chair stated analysis will be done to see how much of a problem it really is. A one-point difference between Philadelphia and New York has also been an issue. The Acuity Circle Subcommittee will be discussing five potential remedies, including every patient with HCC or other exceptions within an assigned circle being assigned the same exception score. Reinstalling an escalator is another possibility, but the question would then be where the escalator stops. The number of HCC liver transplants in the last month seems to be significantly down and there does seem to be a disparity between programs in the same circle, which is a potential problem.

- **Thoracic Committee: National Heart Review Board for Pediatrics**

  The Thoracic Committee Chair presented the proposal. The purpose is designed to address two issues made clear since the 2016 criteria update. One is increase in the pediatric heart status 1A exceptions, in which exceptions are approved, but the outcomes appear to be better than patients under traditional criteria, likely due to limited pediatric expertise on regional review boards. The second is geographic variation and use of the exception pathway to provide higher-urgency listing to patients who may not merit it based on waitlist mortality.

  The proposal is to create a national review board for pediatric heart status 1A and 1B exceptions. The authority for the proposal is in the OPTN Final Rule.

  The rationale includes requests for exceptions for pediatric status for heart transplant has varied significantly across regions with significant increase in status 1A exceptions after criteria became more stringent. After reviewing waitlist mortality associated with the criteria and exceptions, approaches to equalize opportunity for exceptions and make exceptions more appropriate were discussed. Changes in member responsibilities will be that pediatric programs may appoint a representative and an alternate to the National Heart Review Board for pediatric heart exceptions, as well as may need to be educated further on the use of exception requests.

  Overall, the feedback has been relatively positive with recognition that lack of pediatric-specific expertise leads to most exceptions getting approved. There have been some comments regarding the method of representation, which is currently random selection pediatric program representatives, and the possibility for quotas or distribution requirements for volume or region to guarantee more diversity on individual reviews of exceptions. In addition, a more interactive feedback process was recommended. Based on feedback, changes to consider include incorporating guideline language into policy and revising proposed board representation to ensure equity and fairness.

Summary of discussion:

One Committee Member noted discussion at a regional meeting of lessons learned from the NLRB project and asked if those are applied to this proposal. The NLRB was somewhat used as a template for this proposal, but there are differences in terms of the way the communities work and the way the exception process works for different organs. Differences found between heart and liver included rapid premium timeline for exceptions, as well as the thought amongst pediatric heart practitioners is that the default should be to approve the exception request if the vote is a tie or if there is insufficient number of

voters. Since PELD/MELD is not used, just the three statuses, the exception really comes down to 1A or 1B or nothing.

- **Kidney Committee: Addressing Medically Urgent Candidates in New Kidney Allocation Policy**

  The Kidney Committee Vice Chair presented the proposal. The purpose was to address medically-urgent kidney candidates because the prior policies were DSA-based. The proposal would create a new definition for medical urgency, a new classification with high priorities for each of the four KDPI sequences, and create a process for documentation and retrospective review by Kidney Committee. Authority is listed in the Final Rule.

  The rationale is the proposal aligns with the new kidney allocation policy that eliminates DSAs, definition of medical urgency needs to include complete loss of dialysis access and imminent loss of dialysis access; and allocation priority for medically-urgent candidates will vary by donor KDPI and limited to inside the 250 NM circle. Changes to member responsibilities include transplant programs will have to document candidate's medical urgency in the waitlist.

  There has been limited feedback on the OPTN website. There was general support for classification for medically-urgent candidate across all regions, but two regions in support voted on alternative proposals. In addition, there were several suggestions for consideration.

  Based on feedback, suggested changes include a prospective review to avoid programs receiving kidneys that do not meet criteria, which was previously considered by the Kidney Committee; limiting medical urgency definition to candidates who had complete exhaustion of dialysis access; prioritizing medically-urgent candidates within their classification when those classifications have a higher-priority medical urgency; changing "medical urgency" to "elevated medical urgency"; further evaluation of where medically urgent classification falls within kidney allocation table; and suggestions for transition procedures for kidney candidates currently classified as medically urgent.

Summary of discussion:

The proposal does include a retrospective review subcommittee that is part of the Kidney Transplantation Committee verifying that the programs provided adequate documentation supporting the medical urgency status. Timing for a prospective review seemed unworkable. One Committee Member comment was that there is more time available for medically urgent kidneys relative to heart or liver.

- **Distribution of Kidneys and Pancreata from Alaska**

  The Kidney Committee Chair presented the proposal. The purpose of the proposal is to address potential inefficiencies that could impact organ utilization since there are no transplant programs within 250 NM of donor hospitals in Alaska. The proposal is that the Seattle-Tacoma International Airport would be the donor hospital substitute for Alaska donors as the center around which the 250 NM circle would be drawn for kidney and pancreas allocation

  The rationale is reduce inefficiencies and potential underutilization of kidneys flown in from Alaska, ischemic time and organ efficiency placement would be negatively affected by keeping the system the way it was with the 250 NM circle, and it is consistent with Board-approved changes to the kidney and pancreas allocation involving removing DSA and region.

  The proposal was widely supported at regional reviews and unanimously supported in Region 6, which is the affected region. There was limited feedback via the OTPN website. No changes to policy language are being considered.

Summary of discussion:

This proposal does not include Puerto Rico. UNOS policy analyst clarified that the Puerto Rico currently has a transplant program, whereas Alaska has no transplant programs, only donor hospitals. Without this proposal, organs from Alaska would be firstly national allocation, which was not felt to be the most efficient use of the system.

- **Minority Affairs Committee: Data Collection to Assess Socioeconomic Status and Access to Transplant**

  A member of the Minority Affairs Committee presented the proposal. The purpose is to collect additional patient-level socioeconomic status data (SES) to help further assess variance and access to transplant in outcomes by SES. The proposal is to add two fields to the Transplant Candidate Registration, including annual household income and household size. Authority for proposal is listed under the Final Rule.

  The rationale was that the current data like zip code or census tract being collected is not sufficient to understand SES of waitlist candidates or specific enough to yield desire benefit. The proposal will move towards an epidemiologically validated collection of data similar to the poverty index. Household size and income should be known and not cause patient burden.

  Changes in member responsibilities will include impacts to all transplant programs who register candidates and the transplant program staff will be required to submit two additional fields on the TCR moving forward only.

  Feedback to date has been mixed due to added burden with the new fields and a general feeling that the data collection may be too intrusive, leading dishonesty from the patient and limit data usefulness. There are concerns the data will be incorporated into listing status and used as a punitive for the patient.

  Next steps being considered include modifying data fields to assess SES; development of a revised proposal; and possible re-issue for public comment; and repurposing of the proposal into a white paper or guidance document instead data collection.

Summary of discussion:

One Committee Member commented on the Ethics Committee discussion and concern regarding the data being collected only at time of listing and not at time of transplant, so will not capture changes over time. The Minority Affairs Committee has discussed these concerns and their statistician felt this gives at least one data point. By the time of listing, the patient is probably accepted as financially stable to some extent. Collection at time of transplant being considered intrusive will be taken back for committee consideration. Another Committee Member stated her region had similar feedback.

One point brought up that other members had not been aware of is the concern that people with high economic status might actually hit up for donations or contributions. Another comment from the Region 6 meeting was that income of American Indian/Alaska Natives is a sensitive issue and the need to avoid making people uncomfortable.

- **OPO Committee: Modifications to Released Kidney and Pancreas Allocation**

  The OPO Committee Chair presented the proposal. The purpose is to look at opportunities to reallocate the kidney or pancreas, as the policies are not consistent with the recently Board-approved allocation policy changes. The proposal is to use the same distribution unit size and same number of proximity points as the original match run held, recognizing that the new

distribution unit will be based on the originally-accepting transplant hospital, particularly if the kidney is transported across the country. If utilized, the host OPO would remain responsible for the reallocation of the delegation to the Organ Center for continued placement. The authority for the proposal in relation to the OPTN Final Rule is cited.

The rationale includes reallocation is an important process when organs cannot be transplanted into originally-intended candidate; according to 2018 data, 10% of kidney acceptances came from reallocation or import match run and 34% of pancreases fell into same category with 3% of pancreas acceptances from reallocation or import match run; the host OPO would be responsible for reallocation; and the host OPO has a vested interest in assuring the organ is placed for transplant.

Feedback received to data included the host OPO could be considered an option, but could choose to delegate authority to the importing OPO. There was concern about pancreas reallocation due to cold ischemic time considerations and Pancreas Center unique logistical challenges. There were comments about proposed size of reallocation circle at 250 NM and availability of cross matching materials.

The OPO Committee is considering changes in pancreas allocation being specifically dealt with and the possibility of the host OPO to solely retain that responsibility, possibility delegated to the OPO in the new DSA or as originally proposed to the Organ Center.

Summary of discussion:

For clarification, the original OPO would retain allocation because of the vested interest and complete donor picture. The comments were that the host OPO could choose to delegate responsibilities to the OPO that serves the transplant center that accepted the organ. One Committee Member noted backup cross matches removed from the original OPO, the centers that have looked at the organ and considered backups could potentially be excluded, requiring additional cross matches for additional centers that weren't part of the original allocation. This indeed is a possibility, and leads to the previously-mentioned feedback of having enough cross matching material that will be a challenge in the future.

The five non-discussion items out for public comment were presented as a reminder. All are getting good feedback via the OPTN website.

Next steps:

Committee members should encourage their colleagues to comment on the OPTN website and any questions or comments will be helpful to the committees preparing final proposals for Board consideration.

The Committee should also prepare for the upcoming June Board meeting and ask questions about proposals ahead of time.

Upcoming Meetings

- March 30, 2020 11am ET (Teleconference)
- June 7-8, 2020 (Richmond, VA)

Executive Director thanked committee members for convening on short notice, as well as staff working extra hours to ensure timely implementation.