OPTN Executive Committee
Meeting Summary
December 2, 2019
Dallas, TX

Maryl Johnson, M.D., Chair
David Mulligan, M.D., FACS, Vice Chair

Introduction

The Executive Committee (EC) met in Dallas, TX on 12/2/2019 to discuss the following agenda items:

1. Action Items
    a. New OPTN projects
    b. Hawaii/Puerto Rico Liver Distribution Special Public Comment Period
    c. Proposed OPTN Committee Charges
2. Proposed Enhancement to Conflicts of Interests Policy and Process Discussion
3. OPTN Budget Development Process Enhancements
4. OPTN Kidney Accelerated Placement (KAP) Project Update

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

1. Action Items

a. <u>New OPTN Projects</u>

The Policy Oversight Committee (POC) Chair presented nine new projects recommended for EC approval. As a reminder, POC is in the process of changing how projects are reviewed, making sure the projects are in line with the three strategic policy priorities, as well as ensure there is enough bandwidth to get the work done. Three of the projects fall under the OPO Committee. Although the OPO is currently busy with efficient matching, they feel they can accomplish all projects in a timely manner.

The new projects are as follows:

- Review of the deceased cardiac donor (DCD) policy (OPO);
- Increasing access for high MELD status 1 candidates in Puerto Rico and Hawaii (Liver);
- Review deceased donor registration form (OPO); Adult heart exception review (Thoracic);
- Create medically urgent status in kidney allocation (Kidney);
- Import backup modifications for kidney and pancreas allocation (OPO);
- Distribution of kidneys and pancreata from Alaska (Kidney);
- Continuous distribution of kidneys (Kidney);
- Continuous distribution of pancreas (Pancreas)

The strategic plan alignment is greatest in increasing equity in access to transplants, but the POC will continue to move up the strategic policy priority of increasing number of transplants.

One Committee Member inquired as to the size of the DCD policy project and it was clarified the project will make changes to policy language to better align with current practices and allow OPOs to approach families at the appropriate time. It will not require extensive resources, data, or modeling.

Following discussion, the Executive Committee voted to approve the nine new OPTN projects as recommended by the POC.

Results were as follows: 100% yes; 0% no; 0% abstained

b) Hawaii/Puerto Rico Liver Distribution Special Public Comment Period

Under the acuity circles liver allocation policy, Hawaii and Puerto Rico candidates will not have any more access in larger circles than they already do in smaller circles, and thus will not receive offers outside the islands until they hit the national level of offer. The proposal will add a unit of distribution to include part of the mainland for candidate status 1A or 1B and MELD/PELD of 37 or higher for Hawaii and Puerto Rico, which will be 1,100 NM circle for Puerto Rico and 2,400 NM circle for Hawaii.

There were no questions from the Committee Members. The Executive Committee voted to approve sending the proposal for Access for Urgent Liver Candidates in Hawaii and Puerto Rico to a period of special public comment 12/5/19 to 1/9/20. The Executive Committee will then be asked to consider a recommendation from the Liver Committee based on the results of public comment.

Results were as follows: 100% yes; 0% no; 0% abstained

c. Proposed OPTN Committee Charges

The Director of the Policy & Community Relations for UNOS presented on proposed revisions to charter language to send through to the Board. A project review was presented as a refresher from 10/8/19 EC meeting.

Committee charges will be put on a regular review cycle by UNOS, but this can also be initiated by the EC at any time.

The Executive Committee voted to approve sending the revised OPTN committee charters as distributed to the Board on 11/20/19 to the full Board for consideration on 12/3/19.

Results were as follows: 100% yes; 0% no; 0% abstained

2. Proposed Enhancement to Conflicts of Interests Policy and Process Discussion

The staff attorney provided a background. The conflict of interests approach from the OPTN contract from April 2019 needs to be revisited and in doing so, bylaws and processes will be reviewed as well. The objectives are to remind EC of what approaches to conflict of interests (COI) are already in place, including processes that are undertaken, and highlight opportunities for improving upon them. The due process for handling COI could be made more public.

Conflicts of interests are defined as individuals with competing interests or loyalties that affect their free exercise of judgment for the best interests of the organization. The conflicts could be interests of a personal or financial nature. The purpose of the OPTN COI policy is to maintain credibility and integrity of the national transplant system, as well as facilitate participation from all perspectives while avoiding conflict and the appearance of conflict.

Existing measures are taken through OPTN contract requirements pertaining to avoiding conflict. One is to submit an annual conflict of interests plan, which includes looking at who serves on the Board and having Board members complete an attestation document, a COI disclosure, go through orientation, and reminders to focus on OPTN during Board meetings and planning. There is also a bylaw in place stating Board members will disclose and avoid conflicts of interest/appearance of conflicts of interest, and possibly abstain from voting or leaving discussions as necessary.

Feedback was then requested from the EC on whether conflict exists in certain scenarios as presented, as well as levels of handling the conflict ranging from no conflict, to able to vote on consent agenda, to excusal from discussion and vote, to removing the director from the Board. The objective of this exercise was to demonstrate who should have the discussion, where it happens, and how it happens when it comes up generally, because every conversation will be case-specific.

The issues will not always clearly be one or the other and will need to be discussed individually, including taking into account the timing of the issue giving rise to the question of whether a conflict exist. For example, did the issue occur five years ago, or is it something that a Director is currently experiencing?

HHS counsel stated that HRSA has provided guidance through a letter addressing many of the above issues due to concerns raised during liver litigation about whether directors with COI could be part of policy discussions. The letter should be distributed for EC members to review.

UNOS staff emphasized that rather than coming up with numerous scenarios to codify types of conflicts into the bylaws, it will be more important to codify a process into the bylaws. The current process relies on self-disclosure, but there are also opportunities for staff to identify conflicts.

- Conflicts could be publicized more openly. For example, at MPSC meetings, a slide is shown of who is excused from which conversations. Doing something similar would show OPTN members are governing themselves appropriately.
- The process for identifying conflicts could be publicized more openly.
- Self-disclosure could be disclosed with more frequency. Reminders to self-disclose could be made annually or even before every board meeting.
- A duty could be added to disclose if a director suspects another director has a conflict, which is always a good governance practice.
- Codify a process for handling someone who has a conflict that has not been self-disclosed or does not agree that there is a conflict. The process would hopefully take place separately from meetings. However, if a conflict is raised during a meeting, the President could adjust the agenda to convene a closed session of EC for detailed discussion including the director with the conflict. During closed session, the EC could vote to determine whether the director has a conflict, and if so, how that conflict should be remediated. If the EC were to determine that the conflict completely prevented the director's service on the Board, then the Bylaws already state that the entire Board would have to vote with a two-thirds majority to remove the director.

Next steps could include beginning to use this operationally. Broader publication of the rules and approaches to conflict could be considered. Changes to corresponding bylaws could be considered, but are not required. However, putting the process in the bylaws would provide notice to everyone what the steps are and that they will be done consistently.

Discussion began with what to do in the scenario if an Executive Committee member has a conflict. Indeed, the overall process would be similar. The conflict could be identified, the member could agree or disagree, and it would be handled on a case-by-case basis. The EC Chair stated she discloses any conflicts annually, rather than biannually or just when coming onto the Board, and feels an annual disclosure process could be put into place for all members. There was support for annual disclosure, as well as reminders before each in-person meeting, and spending more time giving new Board members illustrative examples of COI.

One Committee Member comment was that it makes sense for the EC to weigh out individual issues, as each will be unique and there will inherently be conflicts by nature. It needs to be taken into account that removing voting privileges from a member would take away certain representation on decision-making and policy, such as if the member comes from a certain patient sector, donor sector or healthcare provider sector. It's important to make sure policies being approved are actually supported by the representatives of all populations.

Additionally, the EC Chair commented if a conflict arises shortly after disclosure is signed, there should be a time limit as to when it should be reported, rather than waiting an additional year.

Next steps:

UNOS staff will start putting together bylaws regarding COI, taking into consideration feedback from the meeting today. Any questions that arise regarding language of the bylaws will be brought before the Executive Committee at a future meeting. The goal will be to have it ready for the Board of Directors to vote on at their June meeting.

3. OPTN Budget Development Process Enhancements

An overview of the current budget timetable was briefly presented. Currently, in October and November is when the CEO and department goal setting takes place. There have been no shifts in strategy requiring significant changes in goals or in the budget.

Right now, budgeting done in March/April is 18 months out from the end of the fiscal year that is being budgeted, so things could change during that timeframe. The fees and budget sent to HRSA must be approved at least three months before the beginning of the OPTN fiscal year, which the new budget year begins October 1st. Then department goals and individual goals are reviewed quarterly, along with progress on CEO goals.

The plan is that for the February to March timeframe, more formal workforce planning models will be completed, corporate goals for the current year will be reviewed, and then potential goals for the next year will be identified. There is a new HR department to help with this.

For the April to May timeframe, the Board President will review proposed CEO goals before the budgets get started. Then the budget cycle will begin internally, along with the director goal setting, developing budget internally, goal setting alignment, and then the CEO will review and approve the final proposal that will go to the Committee.

The budget draft will go to the Finance Committee in early June, who will review and approve the budget at their in-person meeting in June. The Board will review and approve the budget in late June on a separate budget phone call. Then HRSA will receive the fees and budget to review for approval and the corporate goals will be communicated with staff. The biggest changes to the process will be moving the Finance Committee timeframe and having a budget-only call for the Board.

The Treasurer commented that in discussions with UNOS staff and with the Finance Committee, the consensus was that it is in OPTN's best interest to have strategy drive the budget and align the budget with the goals. Although it will be more inconvenient, they should try to make the proposed changes to the budget timeline. The EC Chair agreed.

4. OPTN Kidney Accelerated Placement (KAP) Project Update

UNOS Research Scientist presented on the KAP concept, which focuses on increasing placement of hard-to-place kidneys in the Organ Center. Data was used to identify which donors and matches to accelerate, as well as the transplant centers that utilize the hard-to-place kidneys most often. This will

accelerate offers of hard-to-place kidneys to programs that are more likely to accept them, while continuing to offer to all programs if they're not accepted by the accelerated centers.

The project goals are to decrease placement time for kidneys and therefore lead to better organ quality and increased utilization.

The KAP donors and matches included are adults with KDPI of 80 or above. KAP is only applied once all offers have been made at the local and regional levels, and then being offered nationally by the Organ Center. Match characteristics in addition to KDPI also include age, peak serum creatinine, history of diabetes, history of IV drug use, and DCD status. Transplant programs will appear first that have transplanted at least one kidney from a donor that has all the characteristics together. The offer characteristics qualification thresholds were briefly presented.

Once key donor characteristics that differentiate the acceptance of the high KDPI national offer kidneys are identified, based on all kidney transplants at the local, regional, and national levels performed in the prior two years, transplant programs qualify as an accelerated center as a match if they have transplanted the kidney from a donor with similar characteristics as that current donor that is on the match. This is determined for each match real-time and the cohort is updated monthly.

The KAP concept and project was referenced in an executive order signed on 7/10/19. On that order, Goal #3 was to increase access to kidney transplants. In addition, information about the project was posted on the OPTN website on 7/18/19, with implementation being on 7/18/19. It was also presented at regional meetings in August and September.

One Committee Member questioned how to prioritize among multiple centers who have used such kidneys. It was clarified that either a center has transplanted such kidneys or has not, not how many they have done. If they have transplanted, then their candidates appear first in the same order as the current match. Then operationally, offers are made to centers down to the end of the list. If no one accepts it, it is offered to all candidates at that point. It is rearranging the candidates in order at the accelerated centers first. Currently, distance and time are not factored into the priority because it is going to the national level.

A five-member council has reviewed the first 90 days of KAP so far. Their charge was to a priori define what the stopping criteria would be for the project and assess whether or not there are any concerns that need to be addressed. They will also determine project measures of success at one year, as well as review evaluation of the project quarterly to identify areas of concern. At project end, they will provide a recommendation on this methodology in terms of next steps and broader use for other organs/policy.

Looking at the first 90 days of KAP project (7/18/19 to 10/16/19), there were 3,348 match runs, with 746 being KAP-eligible and 339 having KAP applied/Organ Center attempting national-level placement. Of the 339 donors, 56 had a KAP-related acceptance, so 66 kidneys were placed during the accelerated portion of KAP and 5 kidneys were placed after all accelerated centers refused the organ.

During the first 90 days, dual and en bloc kidney changes were also implemented. Therefore, the Organ Center staff had to field calls explaining KAP, as well as the dual and en bloc kidney changes, thereby requiring added time to making offers and a match for the Organ Center.

Overall, KAP has seen increased utilization. In addition, there was no decreased time spent offering kidneys or associated cold ischemia time thus far and these kidneys were being offered to and accepted by candidates at considerably more aggressive centers more often than expected, namely those centers with larger waiting lists and that accept offers from high KDRI and greater than 100 offer donors.

In terms of outcomes of the accelerated match accepted kidneys, there were 22 more kidneys accepted during the first 90 days of KAP, compared to comparable time period prior to KAP. Also, there were 47% of accepted kidneys that did not end in transplant during pre-KAP time period, which decreased to 31% during KAP time period. Candidates accepting these organs are receiving the transplant more often.

In terms of characteristics of the kidney transplant programs that are accepting the high KDPI national offer kidneys during the KAP time period, the observed-to-expected offer acceptance ratios are substantially different between centers that are and are not accepting these kidneys. However, the median time from waitlisted to transplant is not very different currently. In the first 90 days, 29 centers have accepted these kidneys.

When looking at all donors and matches that had KAP applied, in terms of time attributable on the match to cold ischemia time, distribution is similar. But if only considering matches that had acceptance during KAP, numbers are even more similar from pre-KAP to during the KAP time period.

In summary, the KAP methodology is allocating to centers that are more likely to accept and transplant hard-to-place kidneys, so that candidates accepting kidneys are transplanted more often and these are not being seen as open offers or center offers, which was a concern. There has been no decrease in time spent offering kidneys or associated cold ischemia time at this point, but the council has no major concerns with the project at this stage. They will continue to monitor the match offer time and cold ischemia time.

One Committee Member commented that since many of the kidneys that are marginal or are being pumped and coming from farther away with national offers, looking at the pump parameters is often part of the match criteria. The fact that they're on a pump gives more time for the center to prepare, so the ischemia time for kidneys shouldn't be a negative. In addition, kidneys are often transported via commercial flights that can be delayed. These two factors can affect the data and are inherent to kidney transplants.

The Committee Chair commented that there can be other downstream effects from kidneys that don't go through the KAP process, and as people learn how to manage the less desirable kidneys. Efficiency with the KAP project is probably difficult to quantify at this time, but the question was whether KAP has made any difference from the Organ Center perspective. The KAP structure is that if no accelerated center accepts the kidneys, the Organ Center continues down the match list. They have been able to place five kidneys after continuing down the list, but over time, that will continue to be looked at by the council.

Outcomes data is not available yet, as it is still early. Specifically, diabetic glomerulosclerosis outcomes will be incorporated into the outcomes reports in the future.

One purpose of the KAP project is to consider whether the methodology and structure can be used for other organs. The council will consider the knowledge learned from this project and discuss how it can be expanded outside just the Organ Center, and where it will make the most sense and broadest impact.

Upcoming Meetings

- January 16, 2020 at 3pm ET
- April 20, 2020 at Chicago, IL

Attendance

- **Committee Members**
  - Maryl Johnson, Chair
  - David Mulligan, Vice Chair
  - Deanna Santana
  - Sue Dunn
  - Robert Goodman
  - Theresa Daly
  - Denise Alveranga
  - Luis Fernandez
  - Mary Francois
  - Walter Herczyk
  - Joseph Hillenburg
  - Sharon Bartosh
  - Brian Shepard, OPTN Executive Director (non-voting)
- **HRSA Representatives (non-voting/ex officio members)**
  - Cheryl Dammons
  - Frank Holloman
  - Emily Levine
  - Chris McLaughlin
  - Shannon Dunne
- **SRTR Staff**
  - Jon Snyder
  - Ajay Israni
- **Other Attendees**
  - Alex Glazier, OPTN Policy Oversight Committee Chair