OPTN Executive Committee
Meeting Minutes
August 1, 2019
Conference Call

Introduction

The OPTN Executive Committee ("EC") met via teleconference on 08/01/2019 to discuss the following agenda items:

1. Policy Oversight Committee (POC) – Introduction to the Policy Oversight Committee
2. Policy Oversight Committee – Review of Proposals Recommended by POC for Fall 2019 Public Comment
3. Setting Strategic Policy Priorities
4. Clarification #1 of 2: Clarification to Policy 9.5: HCC Downstaging Protocol for Standard Exceptions from the Liver & Intestine Transplantation Committee
5. OPTN Policy Clarification #2 of 2: Amendment to Align Region 8 Split Liver Variance to Current Policy from the Liver & Intestine Transplantation Committee
6. Transplant for Individuals with Intellectual Disabilities White Paper: Memorandum to the HRSA DoT COR
7. TAC and LDC Response to CMS Memorandum Regarding Transplant Program Survey Activity Transition's Guidelines on Independent Living Donor Advocates (ILDA)
8. Conflicts of Interest Policy
9. OPTN Systems Performance Committee: Project Plan Update

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

1. Policy Oversight Committee (POC) – Introduction to the Policy Oversight Committee

An introduction to the POC will be presented, followed by a review of proposals recommended by POC for Fall 2019 Public Comment. Finally, an update will be made on the POC status regarding setting strategic policy priorities.

The POC is comprised of all Vice Chairs of each committee. The POC overview began with an OPTN contract requirement review. The POC has emerging OPTN leadership as its members, as well as the broad spectrum of all Committee stakeholders; together, they are developing the existing policy portfolios. The POC is required to both advise and support the OPTN in various ways; the focus is on prioritizing policies in a strategic way to move the system forward in a coordinated fashion for the benefit of all stakeholders. Also, POC work is to be done in alignment with contract requirements to proactively add value to the entire system.

2. Policy Oversight Committee – Review of Proposals Recommended by POC for Fall 2019 Public Comment

A review of proposals was recommended by POC for Fall 2019 Public Comment. Before each public comment period, the EC reviews and approves which committee proposals will be distributed for community and public input. The POC performs an extensive review of the proposals and presented a recommendation to the EC prior to the vote.

The Fall 2019 public comment review accomplished by the POC was highlighted. The POC has an evolving role that includes early identification of big picture concerns to allow for a smoother public comment process, as well as timing of review to allow for response to feedback. The POC is focused on looking for red flags and is uniquely able to address such areas as clinical, financial, legal, procedural, and political, given its broad spectrum of stakeholder Committees on the POC. There still remains opportunity for improvement in the POC role, and work-in-progress includes both timing of POC meetings, as well as for reviewing PC documents, so as to deliver the most value to the EC and ultimately to the system. For now, the review process set up review includes: review for significant concerns earlier in the cycle than what POC has done before; review for whether any identified issues were appropriately addressed; and determination on release for public comment. Shift of thought is from wordsmithing or commenting on the substance of a proposal itself, to being the entity to provide a sounding board in the bigger context of the whole system. The POC strategic plan alignment of public comment proposals encompasses: increase the number of transplants, to include expedited placement of livers; increase equity in access to transplants, to include removal of DSA and region from pancreas and kidney allocation policy, as well as continuous distribution of lungs; and promote the efficient management of the OPTN.

The POC reviewed key components of eight projects and received feedback, with no significant concerns. The POC reviewed and voted to move seven of eight public comment documents. Continuous Distribution of Lungs Concept Paper was reviewed by POC members with no comments to prevent its release; the paper is well done and "ready for primetime." The POC's recommendation includes: remove DSA and region from pancreas and kidney allocation; modify appointment process for histocompatibility Vice Chair; update the definition of preexisting liver disease; expedited placement of livers; modify data submission policies; data collection to evaluate logistical impact of broader distribution; and continuous distribution of lungs.

The Executive Committee voted to unanimously approve these projects for public comment.

Summary of discussion

- This overview regarding POC's future direction to become strategically located in bringing policies forward to EC, the community, and ultimately the Board is a step in the right direction.
- Voice vote will follow opportunity to opine; motion for approval will be accepted.
- Motion called for, and made, to include distributing these eight projects forward to the public comment cycle to begin tomorrow.
- All members except for two are present on call to vote; unanimous approval.

3. Setting Strategic Policy Priorities

The POC reviewed proposed policy priorities for various factors. POC previously presented to EC regarding the new direction of POC setting strategic policy priorities, with the goal to enable movement of a more coordinated portfolio of policies that are interrelated.

Factors to consider and parse out when identifying potential strategy policy priorities include: impact multiple organ systems; impact multiple member types; require broad expertise from multiple committees and stakeholder organizations; require change to multiple policies to provide consistent approach; potential to result in large-scale improvement to deliver big benefit to the community; ripe ideas are to be prioritized work versus still-conceptual ideas; and ability to address through OPTN policy.

Ideally, of the potential strategic policy priorities identified by the POC, 2-3 priorities would be recommended to the EC that meet all factors outlined in Slide 17. EC would approve work consistent in those 2-3 recommendations. In reviewing the eight priorities against these factors, the POC recently

identified three to develop into recommendation for the next 18-24 months: more efficient donor/recipient matching to increase utilization; continuous distribution, which is already underway; and improved equity for multiorgan and single organ candidates. Future priorities to consider that are not yet ripe for EC discussion: more consistent framework for incorporating longevity into organ allocation; and improved equity for access to transplant registration.

Summary of discussion

The Chair opened the floor for comments. A commendation was made to POC for work done; it is spot on and heading in right direction. While there is internal consideration of prioritizations, policy oversight also may be considered as a nodal point for input from external organizations that are involved in those strategic priorities, not only professional societies but also transportation companies, etc., to develop new pathways. POC is a perfect point for embracing this external relationship as well as integrating internal relationships for greater cohesiveness. Regarding more efficient donor/recipient matching, there is indeed a component broader than that of OPTN.

Next steps

The POC will refine recommendation and seek EC approval in October; the POC will solicit project ideas at Fall, in-person Committee meetings, also look at existing proposals; POC prioritizes ideas and constructs project plan at in-person meeting; and approval of portfolio of projects and suggested timeframes aligned with priorities to allow for coordination between Committee work, and drive improvements.

4. Policy Clarification #1

The exception pathway for hepatoma candidates with lesions larger than 2 cm and treated by local-regional therapy was outlined. Current policy states that for up to three lesions, each must be less than 3 cm, and total lesion size must not exceed 8 cm. This is an invalid requirement: candidates with three lesions would always have total lesion size greater than 8 cm. The clarification to language matches the intent of POC and the clinical criteria: Candidates are eligible for standard MELD exception if, before completing local-regional therapy, they have lesions that meet one of the following criteria: (i) one lesion greater than 5 cm but less than or equal to 8 cm; (ii) up to three lesions with at least one lesion greater than 3 cm, and each lesion must be less than 5 cm, and total diameter must be less than or equal to 8 cm; or (iii) up to five lesions each less than 3 cm, and total diameter less than or equal to 8 cm. This change in language would simply accommodate for a correction in logic.

A member of the Committee asked if this is required to be retrospective in any manner, any issues with previous cases which could be considered to be out of compliance. The Liver Committee Chair responded to say that there was a lookback at waitlist to see whether candidates were impacted by the current language in the policy; one patient that was impacted wound up being approved by RRB. Such cases could be put through as exceptions and likely be accommodated; the intent of the language differs from how it was actually written.

Action Item resolution: Motion requested and received to move the resolution. All aye; zero opposed; zero abstentions.

5. OPTN Policy Clarification #2 of 2: Amendment to Align Region 8 Split Liver Variance to Current Policy from the Liver & Intestine Transplantation Committee

This change is required based on legal implementation issues. The Board approved a variance for split liver at June 2019 meeting, which was drafted based on acuity circles, but authorized the EC to revert to regional allocation if still in place at time of implementation of 9/1/2019. Variance overview allows

Region 8 programs to offer the second segment of a split liver to a candidate at their own transplant program, or the affiliated pediatric program, provided that segment has been offered out to a patient with a MELD score of 35 or higher in a Status 1 patient within 500 nautical miles of the donor hospital. The proposed change: The second segment of liver would be offered to transplant programs within the same region of the donor hospital, rather than 500 nautical miles. This change pertains to issues related to differences in regional allocation versus acuity circles.

The resolution is written such that changes shall expire upon notice to members and implementation of policy changes related to allocation that were approved by the Board in 2018.

The resolution will align the split liver variance with current liver allocation policy. If current application policy changed, this split variance would revert back to the 500 nautical mile cutoff.

Motion requested and received to move the resolution. All aye; zero opposed; zero abstentions.

6. Action Item: Transplant for Individuals with Intellectual Disabilities White Paper: Memorandum to the HRSA DoT COR

This action item pertains to Memorandum to HRSA regarding the Intellectual Disabilities Project.

The Ethics Committee worked on the Intellectual Disabilities Project from April 2018 through March 2019. The OPTN Ethics Committee drafted a memorandum to the HRSA Department of Transplantation Contracting Officer Representative (COR) for the OPTN. The memorandum is intended to be shared with the United State Department of Health and Human Services (HHS) Office for Civil Rights (OCR) as they continue their analysis of transplantation for individuals with intellectual disabilities, for use as a potential resource. The Committee identified equity as a potential issue in intellectual disability and transplant eligibility, and it may affect access and variability across practices and across centers, and may impact equity and access to transplant for these individuals.

The Ethics Committee had been working on this, and HRSA felt it would be helpful to have that memo sent forward to them as something to use in ongoing discussions about this topic.

-Any questions or concerns or discussion points?

-Question: Will this initiative address intellectual disability both in adults and in children? It would be favorable if pediatrics were addressed within this initiative. Response: The workgroup have stopped work on this project; the project in general addressed patients with intellectual disabilities and related concerns, did not nuance the differences between adults and pediatrics. There will not be a work product besides the memo, which will now go to HRSA as a resource, nor additional product going out for public comment. Question follow-up: Questioner was confused, did not see any actual recommendations or guidelines coming out of the Ethics Committee related to the handling of decisions regarding patients with intellectual disabilities. Response: In general, the purpose of memo is to look at, and to advise on, issues specific to transplantation from the ethical perspective, not necessarily to provide recommendation. Response: Discussion offline can take place later to give background.

-This work would provide broad concept of issues to HRSA for its ongoing internal discussions.

-Slide 31 – Action Item resolution. Motion requested and received to move the resolution. All aye; zero opposed; zero abstentions.

7. Action Item: TAC and LDC Response to CMS Memorandum Regarding Transplant Program Survey Activity Transition's Guidelines on Independent Living Donor Advocates (ILDA)

This memorandum to CMS is in response to published guidelines. In 2018, CMS announced its plans to pull back duplicative oversight.

The CMS plans were largely a part of the Patients Before Paperwork Act which in March were coupled to new interpretive guidelines that had not gone through a public comment cycle. As such, certain items were not aligned with current OPTN policy. TAC partnered with the Living Donor community to address this concern, as well as provided a memo for EC's review, consideration, and approval to send to CMS. AST has already submitted a response as well.

Regarding CMS interpretative guidelines, OPTN points of concern include: associated hospitals; interview/education; and conflict of interest. Regarding associated hospitals, the concern is that a transplant program that is receiving a living donor kidney from a KPD exchange retains all responsibility for compliance with the management of the living donor when under arrangement with other hospitals; this is not what OPTN current Bylaws provide. The whole purpose of having certified transplant programs is for standards to be the same across each transplant program in the United States. The OPTN response states that it is unrealistic to expect a recipient's transplant program would be able to manage such oversight. The interview/education concern relates to the ILDA itself. The role of the ILDA is essential, to respect and protect the rights of the living donor. The new guideline specifies that the ILDA or ILDA team must interview every potential living donor prior to initiation of an evaluation, which is out of line with the OPTN work process and policy; it also does not define what an interview is, nor initiation of evaluation is. The role of the ILDA is also to help assess the donor's ability to comprehend the donor process, yet this ability cannot be assessed if education has not occurred. Further, the guidelines appear to requires that the ILDA must not be associated with a transplant program in any capacity. Programs have done a great job to ensure there are provisions in place that protect and preserve against any unwarranted and nefarious bias or influence; having the ILDA outside of the transplant program and without any knowledge of transplantation does not put them in a position to effectively support the potential living donor.

Motion requested to approve proceeding with sending this letter to CMS; motion received to move the resolution. All aye; zero opposed; zero abstentions.

8. Conflicts of Interest Policy

The UNOS General Counsel delivered a presentation on the current conflicts of interest policy. This section needed more discussion time and was thus placed on agenda for another EC call. It would help start discussion on conflicts of interest and long-term efforts on the OPTN to conduct its business free of actual and perceived conflicts of interest.

The General Counsel addressed the current state of the approach to conflicts of interest, the definitions and policies previously in place, and aimed to identify conflict of interest which can be improved upon, that is not addressed in the current conflict of interest policy. As part of the new OPTN contract, the Board attestation document describes that Board members have a first and foremost duty of loyalty to the OPTN, and that they are committed to carrying out the responsibilities of the Charter and Bylaws.

A conflicts of interest provision as Article 2.7 has always existed in OPTN Bylaws. The provision is high-level and aspirational and states all things that would be expected. OPTN policy holds that all Directors avoid conflicts of interest and the appearance of same.

Four issues to consider before this discussion is continued in later meetings include: should there be a type of conflict that might be an absolute bar to service on the Board, something egregious; should we more carefully define what types of conflict require only a transactional analysis and remedy, an issue-specific analysis; are there additional tools that would assist the Board in identifying and managing conflicts of interest; and are there behaviors that are allowed under the current policy which should be prohibited? What other guidance can be given to the community on how to manage these conflicts, and what guidance can be given to the Board on how it can better manage conflicts?

Consider these four questions prior to the EC October call and send in feedback so as to have a structured discussion about how to proceed with the conflict of interest issue in a deliberative manner moving forward.

9. OPTN Systems Performance Committee: Project Plan Update

The SPC made a number of recommendations to the Board, which, along with Committee Chairs, did breakout sessions and prioritized those things which they thought would have the biggest impact on the community. SPC combined the Board's prioritization with practical implementation concerns and costs and order of work kind of issues, and have provided access to the report. Concerns are divided into three areas: match efficiency, transparency, and communication. Within each area, such as making the match more efficient, they are in order of the earliest delivery to the latest, rather than from top to bottom in the entire report from earliest to latest. Notes were made regarding whether finishing a particular pilot was important before the next phase of something else was initiated. Some things were extremely difficult to do or were simply not ranked very high by the Board in their analysis. Some of this work is already in progress. The SPC work is being actively reviewed, and the Committee will talk further about whether there is anything which the EC feels is not in the right place, or is given the right level of priority or timing; adjustments can be made to this plan going forward.