OPTN/UNOS Executive Committee
Meeting Summary
04/20/18
Chicago, IL

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Introduction

The Executive Committee met in Chicago on 04/20/2018 to discuss the following agenda items:

1. OPTN/UNOS Geography Committee Update
2. Modifications to Board-approved heart-lung allocation policy (Update)
3. POC Update: Committee Engagement Discussion
4. Committee on Committees Update
5. Mini-Brief: Amend Requirements for Primary Liver Transplant Physician
6. 2018 Strategic Plan Post-Public Comment Update
7. Finance Committee Update
8. Closing Comments

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

1. OPTN/UNOS Geography Committee Update - Committee Chair

The Ad Hoc Committee on Geography was assembled at the end of December and started work in January with a clear charge to define principles for the use of geographic constraints in allocation policy and recommend frameworks for incorporating those principles in alignment with the Final Rule. The committee includes regional and appropriate representation from the entire spectrum of the transplant community with members in leadership positions from each discipline. The committee became aware of the distinction between distribution and allocation and restricted the purview and discussions to distribution as a distinct component of the process.

A recommendations report will go before the Board in June including recommended principles of organ distribution, thematic models that align with those principles, and recommended next steps. The committee requested and received permission to continue through the end of calendar year 2018 in order to provide information and respond to questions and feedback.

The organ distribution principles represent tremendous work with robust discussions and was almost unanimous in terms of support. The overarching statement includes that deceased donors are national resources. The committee recognized the need for geographic constraints to be rationally determined and consistently applied and came up with four constraints; reduce differences in ratio of donor supply and demand, reduce travel time, increase organ utilization and prevent organ wastage, and improve efficiencies of donation and transplant system resources that include economic considerations to minimize additional costs.

The vote was 13 yes 1 no that these be the geographic organ distribution principles to include as part of recommendation to Board of Directors.

Themes of organ distribution models were created; organ distribution based on fixed distance from donor hospital, organ distribution based on mathematical optimization, and organ distribution without geographic boundaries.

The vote was unanimous to put forth these models for further consideration.

Considerations and next steps: at the next committee meeting on May 30, members will vote on whether the recommendations to the Board of Directors in June will request community feedback on proposed principles. The goal is for feedback and ongoing dialogue to identify a preferred distribution framework for use across all organ types. Current organ allocation policies will be analyzed with respect to distribution within policy, and the committee requests to remain active through 2018.

The vote was 13 yes, 0 no, 1 abstain.

Potential controversies include; discussions will involve detailed information and the committee should be prepared with answers; identifying a single distribution model will be challenging as there is no single unifying concept for how allocation policies are created; some committees may not want to change and revise; and once policy is complete how will the Board decide the order in which to implement each organ specific policy.

Plans include our meeting today and another Geography committee teleconference before the June Board meeting. The committee would like to have monthly teleconferences to discuss feedback from the Board and craft a plan for moving forward.

The final product to present at regional meetings should include how we got to where we are as well as why we want to share organs as broadly as possible. The gap analysis will be a staff project as well as a committee project with a clinical angle to it. Geography may include constraints that need to be measured for size and effect and research staff are working on a tool that will help compare constraints across organs. Building current policies as an algorithm would give the committee ways to numerically prepare and present the differences in geographic constraints between the organs for the Board meeting.

The community must understand that the risk of lawsuit(s) is real and the gap analysis needs to be done quickly. The results of that analysis will provide immediate defensible support should there be a lawsuit and the ability to prioritize legal risk for which organ-specific policies don’t meet the Final Rule criteria based on the identified principles.

Debate over the overarching principle recognizing organs as a national resource can be avoided as it is already federal law. The way the final rule is drafted it needs the gap analysis to show why constraint is necessary for that organ. We assert that the first order is that deceased donor organs are a national resource and we need to be very clear in communicating that we start with this principle. Discussing legal ramifications and adding examples to the document as well as making education available for regional meetings could clear up misunderstandings about the meaning of the final rule. If there are well-reasoned principles and frameworks consistently applied the lawsuits will go nowhere.

The committee and Board should understand that they will be asked to make choices for which there is no consensus. There will be an aggressive communications plan; consistent talking points and a reference document will be helpful. There may be value in conducting workshops at the regional meetings.

There is a systems summit scheduled for October. There will be three workgroups; the OPOs, the transplant centers, and the intersection between the two. Work is being done as policies are identified to consider ways to implement, we will discuss how interaction occurs and maximize it in alignment with the final rule, especially where organ wastage is concerned.

2. **Modifications to Board-approved heart-lung allocation policy (Update) -** UNOS Policy Staff

Since the heart-lung guidance document on the OPTN website was no longer consistent with policy, the document was removed on March 8th. The Thoracic Committee was asked to consider a temporary solution as a bridge until changes for heart-lung go into effect this fall.

Three options were considered; doing nothing because policy is in place, keep current policy but strike the second part allowing heart to pull lung, and including public comment proposal language. The decision was made to keep current policy until the revised heart-lung policy is implemented. There are currently 3,111 active heart candidates and 1,247 active lung candidates.

The committee voted to use language that went out for public comment with minor clarifications allowing a center to request exception, with peer review medical judgement deciding whether the exception would be granted. This needs to be discussed and clarified further offline.

3. **POC Update: Committee Engagement Discussion -** Committee Chair

The Policy Oversight Committee (POC) provided recommendations to the Executive Committee to approve two projects; improving access for pediatric and highly sensitized kidney candidates and reducing pediatric liver wait list mortality. The Executive Committee asked that parameters be developed for projects that should or could require co-sponsorship. Both projects were reviewed and it was determined that co-sponsorship was not necessary for either project. Our recommendation was for collaboration where the workgroups vote to send the proposal to the sponsoring committee instead of two co-sponsoring committees, and the sponsoring committee will have the final vote to send for public comment or Board consideration.

POC came up with guidelines for projects that might require co-sponsorship. First, co-sponsorship should be limited to a project where only two committees have similar stake in a proposal; second, when there is mutual agreement between two committees that co-sponsorship would be beneficial; and third, both committees would be engaged for the entire life cycle of the project.

A recommendation was made for a slide to be added asking for feedback from Vice Chairs on specific topics. It was proposed that Vice Chairs listen to committee phone conferences, allowing them to be more informed and engaged, and as an opportunity to equip Vice Chairs with more in-depth communication. They expressed frustration with the inability to provide their own subject matter expertise when reviewing projects and we are now asking them for anything else they would like to add. The proposal offers a forum to voice concerns and includes outgoing and incoming chairs in alignment with orientation. Vice Chairs feel that this participation increases collaboration such that co-sponsorship may be not necessary. Alerting POC of issues earlier may alleviate concerns about their role and responsibility related to decision-making at levels above the POC.

Co-sponsoring projects was the only framework available in the past and it was determined inefficient. Now, when staff assembles a proposal for the POC it will indicate the need for co-sponsor, and explain the collaborative process. Complex projects should have workgroups under the sponsoring committee. The main difference between co-sponsoring and collaborating committees is that a co-sponsoring committee will give a second formal vote. A collaborating committee involves outside committee involvement on a single document voted on by the sponsoring committee.

A practical component was added to the project request form indicating specific collaborators and explaining the collaborative process as a required portion of the project charter. Currently

most committees lay out a collaborative or co-sponsor plan in the timeline and milestones portion of the project review. There is a survey that POC members go through when evaluating projects that includes questions related to appropriateness of the project plans for collaboration.

The POC gathers in two weeks to do their annual assessment of the portfolio and the discussion will be structured to talk thematically rather than project by project. We will discuss consensus building and how we are constructing plans and project oversight. We want to emphasize how we confirm that sufficient review has occurred and there is an operational plan articulated.

We all appreciate the work of all the committees and look forward to increased collaboration and communication that can help us especially as we consider the recommendations of the geography committee. We will lean heavily on each collaborative group to get this message out and get it right.

Thank you to everyone for all the hard work.

4. Committee on Committees Update - Committee Chair

This work was done to look at committee structure and how we can get more people involved, increase the engagement of the community, and help them understand what UNOS is about. In June of 2016 this group was chartered to look at the volunteer workforce and if changes could be made to it. We considered restructure options with representation by people who have been involved in this process over many decades.

The concept submitted for public comment received 352 responses and 157 comments slightly tipped in favor of support of the concept. Only five comments were received from deceased donor families. This should be reason number one to continue to find new ways to engage the community we serve. It was noted that deceased donor families experience the system at the time of donation which isn't part of the policy comments and we should investigate whether the lack of feedback from deceased donor families exists across all policy proposals.

Negative response numbers from transplant physicians may be skewed due to a crossover and may have been counted twice. Living donor practitioners pointed out a concern about more seats being created for living donors but not living donor practitioners. The living donor committee did not receive much feedback from patients on the survey but more seats were created for physicians and surgeons. There was agreement that the concept would increase broad participation and there were specific comments that it could create silos and decrease participation by the pediatric community.

Concerns about the inability of the proposed expert councils to sponsor proposals were a continuing reference. There wasn’t good understanding that a core committee or core group was responsible within the expert councils for reviewing policies and making formal comments or that there were two layers within expert councils. In-person meetings were deemed as important.

Next steps: the group will meet Monday to consider public comment and the final scheduled meeting is May 23rd. We would like to conduct an operational proof of concept with the goal to determine how to empower a constituent voice and improve intra-committee communication, increase collaboration and communication among committees through the cross-pollination of the volunteers. The Patient Affairs Committee (PAC) has volunteered to participate. They will invite official patient representatives from other standing committees to participate in the PAC teleconferences and potentially in person. Staff and committee leadership are working to create a charge, operational framework, goals and metrics for evaluating success, and recommended next steps. PAC will also test tools to garner broader community engagement. We would like to

invite a second committee to participate in the proof of concept. If approved, the timeline will be July 1 to December 30, 2018.

Effective support and evaluation of success are still being developed, but should include input from all affected committee leadership, current and invited participants, and staff.

This proposal was not open-ended and ongoing. The committee would like to test it through at least one public comment cycle and learn from that to use in next the iteration. The Committee on Committees was tasked for two years that ends June 30, 2018. The Executive Committee should now take ownership with the committee available for support.

5. Mini-Brief: Amend Requirements for Primary Liver Transplant Physician – UNOS Staff

The changes put forth are a clarification of OPTN bylaws Appendix F4, which is the primary liver transplant surgeon requirement. The current language provides an option for a pediatric liver transplant program to be approved if there is board certified pediatrician who meets the primary liver transplant physician requirements or if the primary liver transplant surgeon meets the adult requirements and there is a pediatric gastroenterologist involved in the care of ped liver recipient.

This is different than what Board approved for key personnel at a pediatric transplant program, which includes three options for those individuals. The clarification is addresses that the language on the books is a recommendation in the absence of key personnel requirements at pediatric programs. This recommendation is not enforceable and was superseded by a 2015 pediatric proposal. Leadership of the MPSC and the Liver Committee support this clarification, indicating that it would reduce the administrative burden, add clarity, and achieve all the aims of the clarification. Implementation of this change would be in line with implementation of the larger pediatric membership requirements.

VOTE – There was a motion and a second to place this on the agenda for the May 2nd Board meeting with recommendation for approval. The vote was unanimous.

6. 2018 Strategic Plan Post-Public Comment Update - UNOS CEO

This plan has fewer initiatives than the previous plan but adds specific metrics that these initiatives hope to achieve. We will consider annual updates on department and committee level projects being implemented that effect broad initiatives intended to move those specific metrics. This will give us a better platform for a reporting progress on the initiatives. Feedback received indicates that the community thinks there should be a strategic plan with important initiatives to guide our work going forward that includes effective practices, reevaluating the metrics, sharing information out of MPSC, geography, and policy efficiency. There is an attempt to make system tools function in a way that drives us through the waitlist quickly and more efficiently.

Themes to be discussed evaluate whether policy tools drive better outcomes and can we make that a big portion of our work as suggested in the previous plan. We have been undersubscribed in the outcomes section but outcomes are not included in our scope. A measure was proposed for outcomes in decreasing pediatric waitlist mortality. A community discussion could occur and we could measure pediatric waitlist mortality separately but that would be big step without a discussion of who else it affects. It was noted that waitlist mortality should be decreased without singling out pediatrics. There should be a generic acknowledgement that there are underserved populations, and address in the strategic plan that we are going to pay attention to their outcomes across the board and ensure that our initiatives take those potential underserved populations into account in policy and process development.

There is a new initiative that involves promoting effective long-term outcomes, but there is no metric and there was discussion about outcomes including developmental concerns for kids who don't receive transplants earlier in life. There are limitations of UNOS, but there is a general issue with the fact that we are still limited to analyzing short-term survival rates in terms of metrics. It is thought that an impact on development of delaying access to organs should be component of the allocation decision-making and that may be the argument for a priority for children in the context that end-stage organ disease impacts development in children.

Part of the discussion for the October System Performance Summit will look at whether the correct types of things are being measured. The plan can be adapted to any policy changes. Metrics can also help with communication back to the entire community and a model can be developed that includes high-level goals and initiatives approved in the plan, ongoing projects designed to move those metrics, and our current and historical status on those metrics.

We need to increase community education, and where it exists can be made clearer for sharing best practices, discussing lessons learned from the MPSC, and using education and communication tools to inform the community is in included in the plan.

There is a proposed edit to the mission statement to make sure it's clear that patients are part of the community. We were not able to incorporate increasing VCA transplants as requested by the VCA Committee. There are definitional issues to work through but wanting to see the number of these transplants increased is covered in the overall goal.

There is more clarifying language around how tools in donor/recipient matching can aid in more effectively and efficiently moving through the list to get to the desired candidate faster. Metrics were added to reduce barriers to living donation and to reduce time from donor consent to recovery. This should be carefully evaluated as the collection and entry of the data may not be consistent. The most important evaluation is whether we are making the best use of every donor in front of us.

Language was clarified regarding reducing data burden through APIs. There is ongoing discussion regarding the best way to collect and analyze data for improving living donor outcomes. The wording in the second initiative will be made clearer.

There is a suggestion to maintain or increase one-year graft survival rate and to increase five-year graft survival rate or refer to patient survival rather than graft survival. A measurable point in time is needed to turn the metrics into a dashboard.

Goal one for metrics is increasing transplants. Edits were made based on comments, review, and what's achievable. It is still early in driving a metrics-based work approach. There will be a dashboard for assessing initiatives regardless of whether they're reflected in a metric. Equity metrics examine actual results and the processes we used to achieve them. One of the ways we can drive an equitable system is to include all stakeholders in the system so you see both sides of that in this set. There is some metric selection left to do on what the outside benchmark looks like as there's not one number that covers it all. Demographics of groups are different but we could target both groups towards progress. The understanding in the community of what equity and access means is variable, specifically access to transplant, and there is a plan to clarify that.

The third bullet regarding 10% increase in size of pool intends to measure the willingness of volunteers to participate. In the long-term we should look for more entry level opportunities and we need to create opportunities for people to enter. There are more people participating in public comment, more people wanting to volunteer on our groups, and more people having an official assignment. Measuring that level and measuring willingness to participate and our ability to place them in something that is more than self-selected will be measured through the bio

form they fill out. We want to respect offers we get and take advantage of people's willingness to participate in the system but at the same time, it is felt we could be a bit selective if we have a pool large enough for that to happen. We can identify opportunities for volunteers to participate in outside of committee service that would be effective and meaningful.

Efficiency is to be promoted not only in IT but also in the speed of the policy development process, making sure the system is available to move projects quickly from development to completion. A review of requests received over the last couple of years was conducted and the 30 most common data requests can now be found online, which frees time for the research team to do more difficult analytics with higher value add.

Safety goals shown are created around MPSC for its impact on the community and how we are driving improvement through MPSC with three different ways to show we are learning and sharing with the community. The percentage of MPSC work devoted to performance and process improvement is 100% but the focus should be about collaborative performance improvement. The new membership system in development is going to help take a more comprehensive view at process improvement benchmarks for centers and OPOs to be able to look at a member's entire experience or to be able to look at compliance with an individual policy across membership. That tool is not yet available but is in development.

There is an internal dashboard working through learning stages and there are plans to make it Board-facing to allow you to see progress made on the strategic initiatives.

For outcomes, overall peds mortality will be tracked. The Peds committee will pay attention to it but not as an overall strategic plan goal. If we are successful at the Summit this fall in identifying other outcomes to track, we do not have to wait three years to edit the Strategic Plan.

We need to carefully evaluate why policy compliance is so low. The question or approach to the topic might need to be asked differently. The living donor follow-up policy goal can be to improve the long-term follow-up of living donors. The initiative is to find ways to make follow-up more effective. The rules need to be written in ways that makes sense for those that have to follow them.

Suggested changes will be incorporated and the final will be shared with the committee for a vote before the Board meeting.

7. Finance Committee Update - Treasurer

The committee met yesterday and a draft budget was presented by Matt Lovetro that did not incorporate any potential impact of the contract bid and the committee approved the draft. There will be no change to the registration fees.

Sun Trust provided an in-depth and insightful presentation about the performance of the reserve fund. The committee provided approval for the investment policy and went into details about basic financial strategy for next year. With the potential for new work, the committee has established a baseline so we can react quickly. Changes will be incorporated to make the discussion quick and easy but cannot be incorporated until changes mandated by the HRSA contract are complete. There will be a last-minute budget process but work conducted by the committee yesterday put us in a position where the changes will be limited.

8. Closing comments

Thank you to staff for putting together the strategic plan and thank you to everyone for your time.