OPTN Executive Committee
Meeting Summary
June 9, 2019
Richmond, VA

Sue Dunn, RN, BSN, MBA, Chair

Introduction

The Executive Committee met in Richmond, Virginia on 06/09/2019 to discuss the following agenda items:

The agenda item titles should exactly match the agenda item titles in the body

1. Kidney-Pancreas ("KP") Community Engagement Strategy
2. Data Advisory Committee ("DAC"): Modify Data Submissions Project Update
3. Policy Oversight Committee ("POC") Report Preview

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

1. Kidney-Pancreas ("KP") Community Engagement Strategy

Summary of discussion:

The Executive Committee heard a presentation on the timeline, communications, and outreach for upcoming proposals on kidney and pancreas distribution. The presentation will include specific strategies to clearly communicate and maximize stakeholder engagement, incorporate community feedback, and articulate the resulting policy recommendations.

Tomorrow's presentation will outline steps taken along the way and give an update on current and future plans. A policy proposal does not yet exist, but we await modeling and will present our strategy for communicating with stakeholders. The kidney and pancreas workgroup targeted several audiences: committee and workgroup members; transplant professionals; stakeholder organizations; patients and families. KP Committee/workgroup is comprised of representatives from Pancreas, Kidney, and other important stakeholders including Pediatric, OPO, and Minority Affairs. Each committee independently had the opportunity to provide feedback to the KP Committee. This meeting schedule indicates both combined as well as individual committee meetings. Kidney and Pancreas each have four meetings, including one in-person meeting for each committee (June 25th); the dual committee has two meetings, including day-after reflection on the in-person meetings. Workgroup members have been invited to attend as well. To gather support and educate people on policy proposal, targeted transplant professionals include: medical and surgical directors of programs; transplant administrators; OPO leadership; lab directors; Kidney and Pancreas Committee alumni; community leaders. Traditional stakeholder organizations and societies to be targeted include: American Society of Transplantation; American Society of Transplant Surgeons; Association of Organ Procurement Organizations; North American Transplant Coordinators Organization; International Pancreas and Islet Transplant Association; relevant associations/organizations.

Engagement of patients and families is of utmost importance. Targeted outreach will include the Patient Affairs Committee; committee patient and donor family representatives; regional meeting attendees; and direct patient outreach. The Committees' goals include providing accurate and timely information to

the community to identify and respond to concerns; engage the community in the process early and maintain engagement; provide transparency on the proposal path to date; seek feedback from both the Board and the community to ensure a better product. The public concept cycle allowed for feedback to be solicited. Post-public comment analysis will be completed and presented to the Board in December. Methodology includes traditional webinars, plus one webinar to target medical and surgical directors with the hope of developing champions. Other methods include: sending emails to committee alumni and updating the key OPTN members at certain milestones; creating Transplant Pro and Tech News newsletters; providing updates on the Geographic Organ Distribution page; and providing outreach by committee leadership and UNOS staff to community members to help with understanding the policy proposal. This particular policy proposal will have additional breakouts where UNOS staff will be present to take notes. Also, regional representative preparation will allow reps to become well-versed as they present to, and field questions from, the community.

The Chair thanked the Kidney Committee Chair for presenting such a well-defined communications and engagement plan and then opened the floor for discussion. The Kidney Chair reminded attendees that all committee meetings are open to Board members and the public. Question/comment: on a Board briefing call, one Board member expressed interest in getting to see committee modeling; a special communication should be made to sitting Board members to follow the process in the same way. Information will be shared with the Board upon the June 25th meetings to allow for tracking and participation in the conversation as it moves through the regional process and towards the December meeting.

Specific strategies to clearly communicate and maximize stakeholder engagement, incorporate community feedback, and articulate the resulting policy recommendations will be implemented.

2. Data Advisory Committee ("DAC"): Modify Data Submissions Project Update

Summary of discussion:

The Executive Committee was updated on the DAC project to modify data submissions policies, and was asked to provide early feedback as the leadership arm of the OPTN Board. The project originated in both a lack of a singular requirement for timely data submission, which has led to member confusion, as well as the ability of members to change data indefinitely after it has been formally submitted, which impacts data used for analysis. The committee wanted to address data integrity, accuracy, and timeliness of data that is submitted.

The project focuses on TIEDI (informational electronic data interchange) records. Eight such data collection instruments are utilized; six of these denote events where data is likely complete and available when the form is due. Data shown included the the forms that were submitted by the expected date and within 90 days of the expected date. Deceased Donor Registration submissions are close to 100% for each of three quarters in year 2018. Blue lines represent, respectively, donor and recipient histocompatibility collection instruments, and are somewhat lower than the percentages that OPOs were meeting, but did climb back to 90+% by 90 days after submission date. Green bars represent transplant hospitals: the darker green bars inside are in 60s-80s% at the time that submission is required, but climb close to 95-100% within 90 days of expected date. One specific example is the Transplant Recipient Registration (TRR) data collection instrument, which is due 60 days after the transplant hospital removes the recipient from the waiting list. A large number of forms were submitted prior to the due date as the information was available, yet some forms were still being modified up to 800 days after the due date. Proposed policy changes are twofold: first, changes to deadlines would include elimination of Policy 18.4 Data Submissions Standards, leaving only one section which contains data submission due dates, thereby allowing for greater consistency; plus, an extension of submission

timeframes for certain data of TIEDI forms would be incorporated. Also, a data lock would be made to data that has been officially submitted; a process will be implemented for changing submitted data. Data reporting requirements for the committee to the Board would be established. As in this screenshot, members will provide an explanation and approver's name.

Next steps: DAC votes on the proposed language on June 17, 2019; public comment August – October 2019; proposal brought to Board in December 2019; and the implementation date is still TBD based on exactly how the lock and data collection would occur.

A committee member asked what thoughts do clinical colleagues around the table have regarding these two specific issues, the lock and the timeframe? Moving the timeline will likely help a great deal with the later changes: even at 30 days, we sometimes don't have the necessary data and a later submission will be needed once data is final; 90 days will help greatly. Ideally, auditing of data will occur within a 90-day window prior to final submission.

Another committee asked whether any analysis was done on changes/spikes in October and April as many transplant centers review their data when SRTR gives their release? The data has not been analyzed, but there is awareness of such activity. An in-depth analysis was done and presented to the DAC when kidney models were released a couple years ago: many changes related to new elements within the models, yet other changes were also occurring, enough to be concerning in terms of the direction of changes, always making patients look riskier than initially.

The Chair commented that there seems to be good energy about moving this project forward. Public comment will be heard in August.

3. **Policy Oversight Committee ("POC") Report Preview**

Summary of discussion:

The Executive Committee saw a report preview setting forth a new direction and new ways that the POC will be working.

The role of the POC is currently focused on reviewing policies on an individual basis, looking at policies on their own bottom, focusing on resource and goal category scoring to ensure a balanced scorecard in terms of range of policies going through the development process. The POC currently does not set or look at larger strategic policy direction for the suite of policies that are going through the process, and has not had a robust process for considering regulatory requirements and other legal parameters that are important to ensure policies are compliant.

The POC is considering how it can deliver more value to the OPTN in the future. Certain components from the new contract relate specifically to POC's development of its future vision. The POC would like to enhance its strategic oversight in support of the policy development process and would like to increase oversight in the work being done by the committees in developing policy. The POC could add value by working more closely with HRSA to define what criteria should be used to determine if a policy may be recommended to be enforceable; this must be an ongoing conversation for the next 1-2 months. The POC will work to identify strategic policy priorities, which do not pertain to balanced scorecard resource allocation as per strategic categories, but rather to whether there is a larger directive to identify and ensure better consistency and alignment across policy development. This would allow for the OPTN to take on larger issues in a concerted manner, but is not meant to encumber the natural need for other types of policy development.

This preview to the Executive Committee is important as the POC works on making recommendations for strategic policy priorities. The first step is engagement of the stakeholder. The Vice Chairs who comprise the POC would work with their committees and stakeholder constituents to identify areas that would benefit from this type of coordinated policy development process, and bring these ideas to the POC for vetting, then to the Executive Committee to set priorities moving forward. The ideas would go back to the POC and committee leadership to solicit projects, then move through the policy development process. Ideally, this process will be continual; having Vice Chairs on POC will ensure that leadership is in the Chair position when policy proposals go through the draft process and ultimately to public comment. A ramp-up period will make this functional and efficient, but over time, it should pay dividends to the OPTN to make larger policy changes in a more coordinated fashion. There will be more detail to this preview at tomorrow's Board meeting. This group should expect recommendations from the POC within the next couple months.

The Committee Chair opened the floor for discussion and asked whether the Executive Committee had items for inclusion before the broader Board. One member asked whether there is some way to capture ideas as they come up, bring them forth, categorize them and make new recommendations, particularly those that might work for more than one committee at the same time? The POC Chair responded that projects and ideas are grouped into themes, but ultimately, there is not unlimited resources, and thus, prioritization is set, which means that not every great idea will necessarily move forward; in looking at what has already been thought of and developed, some natural themes could be looked at that may have already emerged that would make sense to present to this group as priority possibilities. The project portfolio looks at every step in the policy development process from a funnel view. In the initial "idea phase," there are 270 policy project ideas in the portfolio; it's a challenge to systematically determine which should be worked on. Hopefully, a more systematic approach to determine which ideas get turned into proposals will be developed. Another member commented that this concept is presented to the larger Board, this should be considered a layer on top of what is being done, not replacing what is being done. The POC Chair respinded that that is indeed important to incorporate into tomorrow's presentation. This process provides prioritization regarding selection of what ideas move forward in a more coordinated manner; some ideas can seem to align, but the Vice Chairs will return to the committee and offer priorities that are being considered, and gather other ideas that would align. Now is the time to do so because of the ability to have consistency across committees. It also gives the message that strategic planning continues throughout the year. Another committee member asked whether there was discussion on the importance of how to make the offer system move faster. The POC Chair responded that yes, that conversation is ongoing. For examples, the portfolio currently includes projects looking at timing of a kidney to an organ center, how to target centers that are more likely to take a kidney; predicting whether an organ offer is likely to be taken by a transplant center; looking at whether kidneys of a certain quality should be offered to the first 20 people on the list who should not be taking that kidney; looking at whether there are certain values and approaches that should underlie these things. Having the Committee of Committees be the place for this conversation has real potential for driving big picture improvement in a way to get the most bang for the buck.

A member asked whether white papers still go through POC, and if so, why; or, is there a separate pathway to debulk what happens at POC? The POC Chair responded that yes, they do go through the POC, but the conversation of how or if this concept would change that in any way has not taken place. There may be a need for a white paper to kick off a strategic policy priority; multiorgan is potentially a great example of that for which we have the white paper coming through now. White papers and guidance documents would be a good example of products that would be sponsored by a committee and would not necessarily have to meet a thematic goal. Looking at a resource allocation piece, the question becomes, is the system or the committees or staff being overburdened?

The POC Chair concluded her presentation by saying that there will be more detail to this preview at tomorrow's Board meeting. This group should expect recommendations from the POC within the next couple months.

The Chair thanked the Committee members for attending and adjourned the meeting.

Upcoming Meeting

- September 16, 2019