OPTN/UNOS Executive Committee
Meeting Minutes
December 3, 2018
Dallas, TX

Sue Dunn, RN, BSN, MBA, Chair
Maryl Johnson, MD, FACC, Vice Chair

Introduction

The OPTN/UNOS Executive Committee (ExCom) met in Dallas, Texas on 12/3/2018 to discuss the following agenda items:

1. Transplantation in Non-Resident/Non-Citizens
2. UNOS Organ Center Kidney Accelerated Placement Concept
3. Report on Constituent Council Pilot
4. OPTN Project Portfolio: Strategic Alignment Update

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

1. Transplantation in Non-Resident/Non-Citizens

Data summary:

During 2016, a total of 57,610 adult and pediatric registrations were added to the US solid organ transplant waiting list. Of those, 746 (1.3 percent) were indicated to be for candidates not residing in the United States, including 321 registrations for candidates in the US specifically for the purpose of transplantation. The percentage of non-US resident registrations in the US for transplant added in 2016 varies by organ, from zero kidney-pancreas registrations to 8.0 percent (16) of intestine registrations. Data was shown giving the number of non-US resident registrations added during 2017 within the IRC Report. 144 programs (56.9 percent) had none while the rest had 1 or above, with 42 programs (16.6 percent) having four or more. Preliminary observations show no difference between percent of non-US residents listed for transplant and percent of non-US residents receiving transplant. The absolute number of wait list additions and deceased donor transplant remains very low. Activity appears to be concentrated within a small number of programs, particularly in Regions 5 and 9. The number of NCNR in the US for reason other than transplant is increasing, while the number of NCNR in the US for transplant has been going down. Most programs do not list non-US residents.

The first issue involves 2013-2015 pediatric liver transplants at centers with the most liver transplants for candidates with citizenship of NCNR travel for transplant. While there is a small number of NCNR transplant, this number may mask a potentially significant local and regional impact. This requires thought on how to properly evaluate such a situation.

The second issue is in the context of Declaration of Istanbul (DOI). Part of the problem is travel for transplantation is becoming part of transplant tourism if it a) involves organ trafficking and/or transplant tourism or b) if the resources devoted to providing transplants to patients outside a country or region undermine the country's ability to provide transplant services for its own population.

In the context of DOI, should ExCom respond to specific complaints about a member sent from overseas regarding potential transplant tourism and violation of DOI? A recent such complaint resulted in ExCom saying that they have no official decision and that no law has been broken, so no inquiry is required. However, this position is unsatisfactory. At the minimum, such a complaint trigger dialogue between transplant center and Ad Hoc International Relations

Committee (AHIRC) to jointly review and understand center-specific NC/NR transplant practices in this regard.

The third issue is a quest for transparency. OPTN Policy 17 refers to ExCom's role in reviewing and reporting NC/NR activities. AHIRC may request that transplant hospitals voluntarily provide additional information about registrations or transplants of non-U.S. citizens or non-U.S. residents, and requires ExCom to publish an annual report of NC/NR activities. The Committee is concerned that the current report does not adequately fulfill this mandate for transparency on transplant activity of NC/NR recipients and results in loss of public trust in this regard.

Summary of discussion:

For clarification, current UNOS/OPTN policy reflects the regulatory mandate that medical criteria be used to determine who is eligible for a transplant. Citizenship is not a medical criterion, which is why there is no policy that prohibits a center from making that decision to the listed candidate.

One member asked if there was any methodology for collecting the data and reporting on patients on a waitlist who become transplanted outside the U.S., and whether the data are available. This question was previously asked by a community member, so the research department will try to estimate the numbers for candidates who are removed from the transplant list by reason of having received a transplant, and yet there is no record of them being transplanted. OPTN does not make rules for the broader community, so patients who get transplanted overseas are not obligated to report to UNOS.

Another question was whether the ExCom should take a closer look at Policy 17.1.B in the context of voluntary reporting. The AHIRC is in the process of submitting a request for voluntary information. In pediatrics, when looking at geographic distribution of where NC/NR candidates are coming from, it is conceivable that the majority of the pediatric liver transplants are being done as status 1b, so possible the limited activity could have significant local impact. However, currently there are no metrics as to whether there is a true impact.

The Chair asked about the timeline for the AHIRC survey, whether ExCom will need to review that, and whether it will look at all NC/NR donors. The final draft will likely be ready within the next month or two, which will focus on liver and kidney only. Currently the plan is not to have ExCom review, but they would be open to any suggestions. Not all NC/NR donor data is available.

Next steps:

ExCom and AHIRC will remain in contact going forward.

2. UNOS Organ Center Kidney Accelerated Placement (KAP) Concept

An introduction of the KAP Concept was presented, which is not fully flushed out at this time.

Data summary:

Discard rates for kidneys in 2016 was 20%, and the number has been increasing annually, so the community has been asking for ways to decreasing discards. Recently National Kidney Foundation (NKF) held a Consensus Conference to decrease kidney discards. A subset at the conference looked at system-level enhancements, publishing results in September 2018. They emphasized the need for a method for allocation to get high KDPI kidneys to centers that are most likely to accept them faster and more efficiently.

Currently organ centers receive 2,200 potential kidney donors for non-mandatory national shares (already been through zero mismatch categories with no success in placing them). These donors have a minimum KDPKI of 80, the average is 41 center (greater than 2,300

patients), and the range is between 1 and 186 centers. Placement time ranges from half hour to almost a full day. If adding OPO placement time prior to kidneys turned over, placement ranges to greater than 58 hours. Placement rate is about 28%.

Research department data is shown next. A chart shows lower KDPI <50, 50-79, and then 80-100. Orange dots indicate two kidneys from one donor, green for one kidney, and blue for zero kidneys transplanted. There is no discernable pattern seen that relates to number of individual candidate offers per donor. The scale is indeed up to 25,000 individual offers. The question is whether at some point the organs could be placed faster and more efficiently, converting blue does to green dots and then green dots to orange dots. This would impact the system greatly.

KAP proposal is to do a proof of concept of what is being called accelerated placement of kidneys through the organ center. The focus would be on increasing placement of hard-to-place kidneys (high KDPI at the bottom of match run). Data will be used to identify donor triggers for accelerated placement. KDPI is a pretty good indicator for when kidneys should be included in this concept.

The concept is to get hard-to-place kidneys more quickly to centers with a history of actually accepting them. What can be learned from this concept is important. The learnings could be expanded to other organs and other committees that are working on expedited placement projects.

The next steps include presenting this to the OPOs, the Kidney Committee and MPSC after more information is obtained on what the concept will look like. Once feedback from them is received, data will be evaluated to look at the full impact on policy and the Final Rule. Once the concept is fully teased out with all of the data, it will be presented to ExCom once again before moving forward to proof of concept period, which will likely last a full year to obtain maximum potential learnings.

Summary of discussion:

One member, who is a donor family member agrees with the need for decreasing discards and expressed appreciation for the concept. There were no further questions or comments.

3. Report on Constituent Council Pilot: Improving OPTN/UNOS Committee Structure Through Enhanced Communication and Engagement

There was a proposal that went out for committee restructure that was discussed and voted on in June. As a result, the policy changed to be more about concept. The concept supports the OPTN strategic plan to promote efficient management of OPTN. Issues that are not dealt with every day are hard to fully appreciate and understand. The intention was to increase input from members in stakeholders that would be different than usual committee structure.

The concept would address the problem of one-size-fits-all by allowing for opportunities for participation, minority representation on committees, diversity in perspective, and connection between the Board and Committees. The solution was to alter committee structure to incorporate better constituency perspective.

The objectives of the proposal that went out before the community ended up as the proof of concept, which are: 1) increased diversity in perspectives and to 2) increase connections between the Board and Committees.

The framework would decrease siloing between Committees, but not change any bylaws, Committees' ability to propose or sponsor projects, or current member status.

Patient Affairs Committee and Transplant Coordinators Committee were involved, creating the Constituent Committees (PACC and TCCC). In PAC, 35 members served as a patient, donor or

recipient family member on Committee or Board. Only 2 of those 35 declined to participate, expanding the Committee to 50. More than half of OPTN Committees lacked a member who was clinical transplant coordinator who interfaced with patients on a regular basis. Of the 9 coordinators that were invited to participate in the proof of concept, 2 declined, expanding TCC from 17 to 24.

A diagram was presented, showing the inner most circle being the Constituent Committee, and next circle our being the official reps of the constituencies. This is the scope of the project, but it could expand to the next circle, being additional members on other home Committees that might have an interest and then future to the universe and beyond.

Themes developed included an increased diversity in perspective on Committees and policy development process, as the patient voice was amplified on calls and it felt like a safe space for members to share ideas and concerns. A second theme was increased connections between Board and Committees, as there was increased cross-communication and exposure, as well as Board members that sat on constituency councils were receptive and vocal.

Other feedback and unintended consequences were looked at. First, the consensus among professional participants was that the patient perspective is not fully informed, as there is little understanding about the scope and detail around donation and transplant process and operations. Secondly, professionals who were involved were more thoughtful and more reflective on the donor family and the recipient perspective. Thirdly, half of the core PAC withdrew or did not engage on calls, feeling overwhelmed with new or vocal participants. Lastly, there were large concerns about losing pediatric voice. However, the Pediatrics Committee piloted this structure on their own accord and had good engagement and some success.

The final survey results show higher success with the PACC and more neutral with TCCC. When members were asked how UNOS should proceed with proof of concept, there is more engagement with PACC than TCCC.

As next steps, only PACC will continue the testing structure under staff guidance and not TCCC. Areas of increased engagement will be explored, as well as increased understanding of complex proposals due to structure.

Summary of discussion:

The proof of concept was a good demonstration of how one size does not fit all. One question was whether consideration was taken to look at best use of structures with the goal of increasing engagement and communication since PACC had success and TCCC did not. UNOS staff clarified that it is not that it did not work with the TCC and would not work with any profession Committee (since Pediatric Committee decided to do it on their own), but it is up to UNOS leadership on whether there should be an ad hoc Committee structure. Amongst patients and families, it did seem successful. Of note, there were two camps in the PAC, those with no professional background and those with. Those without came in with less skepticism.

4. OPTN Project Portfolio: Strategic Alignment Update

A chart of the current portfolio was presented. Alignment is broken down by 40%, 30%, 10%, 10%, and 10% to the approved 2018 strategic goals. Each column represents all projects that meet the strategic alignment. Goal 2 (increase equity in access to transplants) is most over-allocated due to the four geography projects underway.

A graph demonstrating projected strategic alignment was shown. Goal 2 will continue to be over-allocated until the June Board meeting. There will be no projects at this time relating to improving outcomes and first goal will be under-allocated to increase numbers of transplants.

As projects mature and get approved, the focus will be on starting projects in second and third goals.

A graph showing the alignment of the strategic portfolio shows improvement over time. Looking at April 2015 to October 2018, Committees have worked together with Policy Oversight Committee to come closer in alignment with the strategic goals. Spikes in the graph align with Board meetings when Board moves or halts a project, followed by projects moving forward.

There are 8 projects that POC and Executive Board went on to approve since July 2018. Fifty percent of projects were approved, and four were related to policies 3 through 6, which were geography-related projects.

In approved 2018 strategic plan laid out initiatives and metrics recommended to work towards goals tied to those. POC's plan is to review and report on some of these initiatives. The first goal of increasing number of transplants includes the initiative to pursue policies and system tools such as a donor offer filter for more efficient donor/recipient matching. A proposal including new policies for expedited organ placement is being worked on for January public comment.

The second goal of improving equity in access to transplant includes the initiative of improving equity in transplant opportunities for multiorgan and single-organ candidates. The Ethics Committee is developing a white paper regarding ethical principles of multiorgan allocation. Then a framework will be developed which will move on to specific policy changes. A second initiative is to develop a common policy framework for applying the principles of geographic distribution to allocation policies across all organ systems. If approved by the Board, then the POC will start a new subgroup to oversee application of this framework within organ-specific committees.

The goal of promoting efficiency in donation and transplantation includes initiative that by 2021 reducing time from POC project approval to Board approval or end of project.

The goal of improving organization capacity includes initiative to improve volunteer workforce satisfaction and engagement. A survey was just completed on this. Most Committees showed a high degree of satisfaction with their volunteer work and showed members would highly recommend volunteering at UNOS to others. Compared to last year, survey results reflect changes in technology and use of Basecamp for communication. UNOS reached out to the two Committees with the lowest satisfaction.

A second initiative is to increase racial, ethnic, and professional diversity on the Board and Committees.

A final initiative is to improve member and public engagement in development of equitable allocation policies. Three metrics are being looked at regarding this: median number of comments received, number of Committees that are collaborating on each project, and number of stakeholder organizations collaborating on each project.

In 2018 a different way of collecting public comment was piloted, starting with obtaining regional meeting individual comments, not collectively. This resulted in spike of overall number of public comments; therefore, creating a new baseline for public comment. Demographic information along with responses was also collected, allowing breakdown of different demographics.

Evolution of volume of stakeholders being engaged when something is in project was looked at. Number of stakeholder was increased early on. Number of stakeholders and Committees that are actually collaborating on projects is increasing. There has also been a decrease in number of Committees that are submitting formal requests for projects because they're collaborating on existing projects to make those stronger.

5. Open Session Overview

After lunch, open session will start with executive and operation updates. The Chair will report on policy consent agenda and nominated Committee reports. Finance Committee report will include updated budget now that contract is in place with a clearer view of current fiscal year.

Then will be policy updates from liver, which will be the most complicated procedural item at this meeting. There are a couple of amendments to be discussed have now been made available to the members on a new flow chart. The chart will also be used for structuring the conversation. Following liver will be pancreas with proposed amendments to the islet bylaw proposal.

Next will be a series of geography presentations with proposal from the Geography Committee discussing strategic direction of long term of geography. Thoracic Committee will present impact of lung change and Kidney Committee will present the direction they will go with spring public comment. The Systems Performance Committee will present tomorrow.

Upcoming Meetings

- January 16, 2019
- April 15, 2019 @ Chicago

Attendance

- **Committee Members**
  - Sue Dunn
  - Maryl Johnson
  - Deanna Santana
  - Theresa Daly
  - David Reich
  - Yolanda Becker
  - John Schmitz
  - Danyel Gooch
  - Akinlolu Ojo
  - Christopher Anderson
  - Macey Henderson
  - Randee Bloom
- **HRSA Representatives**
  - Cheryl Dammons
  - Frank Holloman
  - Christopher McLaughlin
  - Monica Lin
  - Shannon Dunne
- **SRTR Staff**
  - Ajay Irani
  - Bert Kasiske
  - Jon Snyder
- **OPTN/UNOS Staff**
  - Brian Shepard
  - Steve Harms
  - Maureen McBride
  - Henri Haskell
  - Ryan Ehrensberger
  - David Klassen
  - Jason Livingston
  - Mary D. Ellison
  - Alex Tulchinsky
  - James Alcorn
  - Chelsea Haynes
- **Other Attendees**
  - Jennifer Milton
  - Kishore Iyer