OPTN Policy Oversight Committee
Meeting Summary
December 9, 2020
Conference Call

Alexandra Glazier, JD, Chair
Nicole Turgeon, MD, Vice Chair

Introduction

The Policy Oversight Committee (POC) met via Citrix GoTo teleconference on 12/09/2020 to discuss the following agenda items:

1. OPTN Board Meeting Update
2. Update on Refusal Codes/Late Turndown Project
3. Multi-organ Transplantation Discussion
4. Update on Image Sharing Projects

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

1. OPTN Board Meeting Update

Biannually, the Chair presents an update to the OPTN Board of Directors on the work of the POC. On 12/07/2020, the Chair presented on the POC's work from the last six months, particularly the efficient matching workgroups. The Chair said it was a privilege to present that work and to show the significant amount of progress that has been made, and thanked all the POC members who contributed to this work to address pain points in the organ allocation system. The Chair also updated the Board on the POC's work to revamp its processes for project approval and post-implementation monitoring in ways that will add more value to the OPTN.

2. Update on Refusal Codes/Late Turndown Project

The Vice Chair (VC) of the Data Advisory Committee (DAC) presented an update on the refusal codes/late turndown project.

Summary of discussion:

Refusal Codes

In 2018, one refusal code accounted for almost 70% of all organ offer refusal reasons, and six refusal codes accounted for 96% of all refusal reasons. The purpose of this project is to improve the specificity of the refusal codes so that refusal code data will better inform the OPTN of challenges hindering organ acceptance. The workgroup has identified 37 refusal codes, as compared to the current set of 28, along with improvements for the user experience to make it easier for users to find and use the appropriate code. The Chair asked how the DAC will respond if it becomes clear following implementation that a code is being used as a catch-all. The DAC VC said the DAC is considering an annual review to identify and address any issues. A member asked if the refusal codes related to increased risk will be updated since the Board approved changes to OPTN policy corresponding to the updated Public Health Service

(PHS) guidelines.[1] The DAC VC confirmed that the DAC will revisit the language for these codes based on the PHS changes, noting that the workgroup also proposed combining increased risk characteristics and social risk in one refusal code.

The Chair asked about the timeline to finalize the proposal. The DAC plans to reach out to the organ-specific committees to make sure the proposal is not missing anything. The Chair said the POC can help facilitate cross-committee collaboration if need be. UNOS staff said that the public comment requirements do not apply since this is not a policy proposal, but the changes will have a big impact on the community, so the OPTN will facilitate some sort of broad request for feedback before the project is implemented. This will not be a prolonged process, so the goal will be to get the feedback back to the DAC, finalize the refusal codes, and program the refusal codes, hopefully within a couple of months.

Late Turndowns

There is currently no OPTN data collection on late turndown of organ offers, but data collection will help to clarify the scope of the problem and how the OPTN can avoid late turndowns. The DAC will start this work by defining the problem to figure out what information needs to be captured, based on the impact on transplantation and allocation. The Chair said that this work is really foundational to the efficient matching policy portfolio and asked when it will be getting underway. The DAC VC said the refusal code and late turndown efforts are interrelated. The data elements collected for late turndown need to be informed in part by the refusal codes. The DAC expects to wrap up the refusal code work by February, and then turn their attention to late turndowns. The DAC is not planning to wait for the community feedback on refusal codes to start the work on late turndown data collection. The Chair asked if the POC can help get this work started immediately or in January to ensure it could go out for the next public comment cycle in summer of 2021. The DAC VC agreed to share with the DAC that this work is a priority and the DAC should aim to start this work in January.

Next steps:

The proposed refusal codes will be shared with the organ-specific committees, and then more broadly with the transplant community. The DAC VC will work with UNOS staff to develop a plan to start the late turndown work sooner.

3. Multi-organ Transplantation Discussion

The POC discussed multi-organ transplantation (MOT) and how policy development in this area should be coordinated with work on continuous distribution (CD) and other strategic policy priorities.

Summary of discussion:

UNOS staff explained that MOT provides substantial benefits to certain recipients, including avoiding serial surgeries, but additional policy development is needed to determine prioritization between MOT candidates and single-organ candidates. This work may include:

- Eligibility criteria – who qualifies for the second organ – for various organ combinations
- Allocation threshold and geographical unit for qualifying candidate criteria related to the primary organ
- Safety nets for patients who receive a single organ but qualify to be listed for an organ shortly after transplant

[1] "Align OPTN Policy with U.S. Public Health Service Guideline, 2020," Notice of OPTN Policy Changes, accessed December 18, 2020: https://optn.transplant.hrsa.gov/media/4250/align_202phsguideline_202012_policynotice.pdf

- Match run prioritization, particularly between single organ and MOT candidates

The Chair said it is incumbent on the POC to figure out how to parse out the work in the most efficient manner so that the work gets completed and the right people are involved. This work will look different than it might have a few years ago, now that the OPTN is working on shifting organs to a CD framework. The Chair noted that the Kidney Committee has started work on CD and kidney is the linchpin of a lot of the MOT work. The Vice Chair agreed that the purpose of the conversation with the POC is to talk through how to operationalize the MOT work with CD, along with the moral and ethical conversations that need to accompany this policy development.

The VC of the Kidney Committee (Kidney VC) said CD development is going to span years. It does not make sense to sequence the MOT work before CD implementation for all organs, because it would need to be reworked sequentially as each organ goes through CD. Working on MOT during CD development means that the MOT work would be done before some organs shift to CD, and during or after CD for some organs, since this work is in progress for lung, kidney, and pancreas, but has not yet started for other organs. If the Kidney Committee works on MOT during CD development, that may help organize MOT for other organs. It does not make sense to sequence the MOT after all of the CD work because it will delay the MOT work for too long, and the OPTN probably needs to be doing that work now.

The VC of the Operations and Safety Committee (OSC VC) said the work that has been completed for liver-kidney allocation, particularly qualifying criteria, is helpful for shifting the organs to a CD framework. There is no reason to slow down the MOT work. There is also an organ procurement aspect to consider. For example, if transplant programs are traveling more under the CD allocation systems, the OPTN should consider the logistical implications for MOT, like the timing if separate teams are flying in to procure both thoracic and abdominal organs from one donor for one candidate.

Members supported continuing MOT work during CD development. The VC of the Pancreas Committee (Pancreas VC) said there is a need for the MOT work to be completed prior to all organs shifting to CD, since some members of the community were hoping to have a heart-kidney allocation scheme in place by now. The Chair asked if it would work to address heart-kidney combinations as part of the kidney CD project, or whether there need to be an interim step in advance of implementing CD for kidney. The Pancreas VC said it would be ideal to establish heart-kidney criteria soon. UNOS staff noted that a proposal slated for public comment in January 2021 includes criteria for heart-kidney and lung-kidney.

The DAC VC said the MOT work needs to happen in parallel with CD. It does not make sense to have a heart-kidney or liver-kidney allocation process that is at odds with the prioritization for kidney allocation. The population of MOT candidates has grown, and MOT allocation should not be separate from the kidney allocation process. For example, current policy prioritizes allocating kidneys with Kidney Donor Profile Index (KDPI) scores under 20% to candidates with an Estimated Post Transplant Survival (EPTS) score of 20% or less, so that higher quality kidneys are allocated to candidates who are expected to experience more years of graft function. Yet among kidneys with a KDPI less than or equal to 20% that are transplanted into recipients with an EPTS *greater than* 20%, about 66% of those kidneys are allocated preferentially to MOT candidates.[2,3] A member agreed that delaying this work until after CD

[2] S. Ali Husain, Kristen L King, Geoffrey K. Dube, et al. "Regional Disparities in Transplantation with Deceased Donor Kidneys with Kidney Donor Profile Index Less than 20% Among Candidates with Top 20% Estimated Post Transplant Survival," *Progress in Transplantation* 29, no. 4 (2019): 354-360, https://doi.org/10.1177/1526924819874699

[3] Nearly 60% of MOT candidates receive kidneys with a KDPI between 0-20%, but this represents only about 22% of all kidneys with a KDPI 0-20% that are allocated. In other words, the majority of kidneys (about 78%) with a KDPI between 0-20% are allocated to single-organ candidates. Source: "Examining Kidney Priority for Multi-Organ Candidates Compared to Pediatric Kidney-Alone Candidates," OPTN, December 16, 2020.

will not be acceptable to many stakeholders, including the pediatric community, which has been concerned about the effects of MOT on pediatric access for over a decade. The POC VC agreed that this is important and said that the ethical and moral questions that need to be addressed in MOT include considering when a single kidney would need to be allocated above an MOT combination.

The Chair asked if the MOT work is urgent enough that the OPTN needs to develop an interim solution, since there might be a 12- to 18-month gap between when additional MOT work could be completed – not including implementation – and implementing continuous distribution for kidney, which is tentatively slated for 2023. The Kidney VC suggested that the workgroups start working on the eligibility criteria since that is the core piece from a clinician standpoint, and there is a lot of data to evaluate to develop those criteria. The OSC VC said that work should include the safety net too, since that gives transplant programs the license to take more risk with different levels of kidney dysfunction.

The Chair asked if there should be a cross-committee workgroup or steering committee to start reviewing the data on eligibility criteria now. This group would advise the Kidney Committee and other organ committees as they work on CD. The Chair suggested starting this work in January 2021 and asked UNOS staff how to get this work underway. UNOS staff asked if the existing MOT Policy Review Workgroup is the right group to carry this work forward, or if the POC recommends establishing a new group that is more robust or has broader representation. The VC of the Organ Procurement Organization Committee (OPO VC), who is also the chair of the MOT workgroup, said that the workgroup had representation from the organ-specific committees and they all worked well together. The OPO VC did not see any reason why this group cannot keep moving the work forward.

The Chair summarized that the POC does not want to delay the MOT work, and the OPTN should use some sort of cross-committee workgroup to start addressing eligibility criteria now. That workgroup will partner with the Kidney Committee to get MOT work done in parallel with kidney CD, and then will consider how to address each of the other components of MOT. A member asked which committees are represented on the workgroup currently. UNOS staff offered to send the POC the current list of workgroup members for review to seek suggestions on who should be included, if there are any gaps. The Chair said that Kidney Committee leadership should be connected to this group as well.

Next steps:

UNOS staff will work with POC leadership on refining the process for coordinating MOT and CD work.

4. Update on Image Sharing Projects

UNOS staff presented an update on UNet℠ image sharing projects.

Summary of discussion:

In 2019, UNOS integrated new features into DonorNet® as part of an image sharing pilot project. These updates are being rolled out nationally to all OPOs via a phased approach which should be completed by end of March 2021. UNOS IT is working on a number of other image sharing features, including:

- Integration with image interpretation services
- Mobile access to imaging studies
- Image archive and restoration
- Volumetric assessment of organs using 3D imaging
- Receipt of image studies directly from donor hospitals
- Biopsy image sharing and interpretation
- Streaming video of organ recovery procedures

The Chair said these updates will help improve many aspects of allocation in terms of efficiency and facilitating local recovery. The VC of the Vascularized Composite Allograft (VCA) Committee said there is strong interest from the VCA Committee in 3D imaging, for example, for faces and limbs. The OPO VC said that all of these projects will make the job easier for OPOs, and asked for the implementation timelines. UNOS staff said these features are in various stages of development. Some of these projects started in 2019 and took a backseat to the national rollout of the baseline image sharing capability. UNOS IT hopes to offer most of these features within 2021, though the streaming video and image archive and restoration projects may take longer. The OPO VC expressed strong support for the biopsy imaging and interpretation feature, and said that the streaming video would be helpful for thoracic organ recovery.

Upcoming Meetings

- January 8, 2021
- February 10, 2021

Attendance

- **Committee Members**
  - Alexandra Glazier, Chair
  - Nicole Turgeon, Vice Chair
  - Sandra Amaral
  - Marie Budev
  - Lara Danziger-Isakov
  - Alden Doyle
  - Garrett Erdle
  - Andrew Flescher
  - Rachel Forbes
  - Barry Friedman
  - Heung Bae Kim
  - John Lunz
  - Stacy McKean
  - Sumit Mohan
  - Martha Pavlakis
  - Emily Perito
  - Kim Rallis, Visiting Board Member
  - Kurt Shutterly
- **HRSA Representatives**
  - Vanessa Arriola
  - Marilyn Levi
  - Shannon Taitt
  - Robert Walsh
- **SRTR Staff**
  - Ajay Israni
  - Jon Snyder
- **UNOS Staff**
  - Brian Shepard, UNOS CEO
  - Kristine Althaus
  - Sally Aungier
  - Nicole Benjamin
  - Matt Cafarella
  - Laura Cartwright
  - Julia Chipko
  - Craig Connors
  - Shannon Edwards
  - Randall Fenderson
  - Chelsea Haynes
  - Robert Hunter
  - Adel Husayni
  - Sarah Konigsburg
  - Maureen McBride
  - Meghan McDermott
  - Eric Messick
  - Elizabeth Miller

- Rebecca Murdock
- Kelley Poff
- Matt Prentice
- Amy Putnam
- Tina Rhoades
- Leah Slife
- Peter Sokol
- Susie Sprinson
- Kaitlin Swanner
- Susan Tlusty
- Kim Uccellini
- Ross Walton
- Sara Rose Wells