

**OPTN/UNOS Patient Affairs Committee
Meeting Minutes
March 12, 2018
Richmond, VA**

**Kristie Lemmon, MBA, Chair
Darnell Waun, MSN, RN, Vice Chair**

Introduction

The Patient Affairs Committee (Committee) met in Richmond, VA on 03/12/2018 to discuss the following agenda items:

1. Spring 2018 Public Comment Proposal Review
2. National Survey of Organ Donation Attitudes and Practices (NSODAP)
3. Scientific Registry of Transplant Recipients (SRTR) Website Update
4. OPTN/UNOS Ad Hoc Geography Committee Update

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

1. Spring 2018 Public Comment Proposal Review

The Committee reviewed three proposals out for public comment.

Modifications to the Distribution of Deceased Donor Lungs

The Committee commends the Thoracic Committee efforts to attempt to make lung allocation policy more consistent with the OPTN Final Rule, provide more equity in access to transplantation regardless of a candidate's geography, and to clarify and make more transparent the heart-lung allocation policy. The Committee asked the following questions, and were satisfied with the Thoracic Committee representative's answers:

- **Q:** Are the modeled outcomes better when lungs are shared more broadly (500 nautical miles), versus the implemented 250 nautical mile change?

A: The model projects that the deaths per 100 patient years on the waitlist declined to a greater degree at 500 NM compared to 250 NM or DSA. The presenter noted that the cohort used for modeling is all candidates, recipients, and donors from 2009 to 2011, and thus may be a limitation of the analysis.

- **Q:** Doesn't it make sense, for consistency, to extend distributing for lungs to 500 nautical miles, as the approved-but-not-yet-implemented changes to heart policy offers broader distributing up to 500 nautical miles for the most urgent statuses?

A: The same issues the Committee considered when debating how broadly to share hearts are relevant to lungs: cold ischemic time, potential for increased discards, and greater travel time. Unfortunately, the Committee has yet to discuss and evaluate unintended consequences of this policy change. It's also important to note that the broader distributing for hearts in the approved-but-not-yet-implemented changes is limited to the most urgent candidates; currently, the change in lung distribution is applicable to *all* lung candidates.

- **Q:** Is it true that it does not appear the change has had an adverse effect on post-transplant mortality?

A: The TSAM demonstrates that overall, one-year post-transplant mortality rates are not impacted dramatically by any of the modeled distances. Moreover, when stratified by diagnosis group, and when stratified by region, post-transplant mortality rates within a diagnosis group continued to be similar across all simulations.

- **Q:** One member asked, in looking at the average distance from donor hospital to transplant center for lung transplants (Figure 3 in proposal) that in certain areas of the country, it appeared that lungs were traveling quite far. Wouldn't a patient listed at a center in a more remote area of the country want to support a broader distributing scheme to improve access? If that's the case, should the Thoracic Committee consider distributing even more broadly than 250 nautical miles?

This question wasn't answered, as the Committee continued discussion.

- **Q:** Has the Committee reviewed data on the actual effect of the change on patients and centers not located in major metropolitan areas since the changes were made in November?

A: Yes, the Committee reviewed out-of-the-gate data in February. Nationally, the distribution of the LAS at transplant does not seem to be changing. Early metrics also suggest no apparent change in the number of lungs recovered, number of adult lung transplants, utilization rate, or number of removals from the waiting list due to too sick to transplant or death. There is evidence of a decrease in the percent of lung transplants that travel further than 250 NM.

- **Q:** When the sunset date expires, will the policy revert back to what it was if no decision was made?

A: The next steps for the Thoracic Committee is to review all public comment feedback and make a recommendation to the Board of Directors in June whether to make the 250 nautical mile interim policy permanent, modify it, or request an extension on the sunset date to keep this interim change in place while the Thoracic Committee thoroughly vets all options and any potential consequences.

- **Q:** If survival prediction models were based upon an older cohort, are decisions being based on outdated models, given the advancement of technology and surgical procedures since that timeframe? How does current volume of lung/heart lung waitlist patients compare to the cohort used in the models?

A: Even using an older cohort, the TSAM can still provide insights on how different rule sets might behave in relation to each other. The important information to get out of TSAM for any metric is not a particular rate or count, but relative difference. UNOS staff was unaware of any significant volume change of waitlisted candidates within the timeframe used in the modeling, but there was a significant policy change. Updates to the lung allocation score (LAS) was approved by the Board of Directors in 2012 and implemented in 2015. These changes changed the distribution of the LAS amongst

candidates, because it better accounted for medical urgency in certain diagnoses groups.

- **Q:** Is sensitization as big an issue among lung candidates as other organ candidates (i.e. kidney)?

- **A:** Unfortunately, the lung community has not defined what sensitization means because lung transplant programs are not required to report unacceptable antigens to the OPTN. This is an issue the Thoracic Committee hopes to address at some point.

The Vice Chair asked the Committee if they understood the genesis of how this policy change was selected and implemented and the timeframe in which policy was changed. He asked Committee members whether they felt the Thoracic Committee had sufficient time to do their due diligence in developing a policy that was well-vetted and evidence-based. One Committee member, representing an OPO, did not favor the 250 nautical mile solution because he felt it was arbitrary, and encouraged the Thoracic Committee to consider a point system similar to the Liver Committee's solution of proximity points to mitigate concerns regarding increased travel. There was consensus that the Thoracic Committee be granted the time to consider alternatives, request modeling, and solicit additional feedback through public comment. In addition, the Committee does not favor striking the policy for sensitized candidates without a clear, consistent, well-defined alternative, despite the lack of a definition of sensitization for lung candidates.

2018-2021 OPTN/UNOS Strategic Plan

The Committee commends the Executive Committee's efforts in drafting the next OPTN strategic plan. They supported the plan with minor language changes to goal 1. They felt that overall, the metrics and resource allocations seemed reasonable. The Committee also suggested distributing results on an annual basis so the community may track our performance. However, they cautioned not to forsake effectiveness for efficiency. Some concern was expressed about the phrasing of goal 1: Increasing the number of transplants. Committee members felt like this verbiage could be clarified to emphasize that increasing the number of transplants should not come at the expense of good outcomes. They suggested rewording the goal to "optimizing transplant" or increasing the number of "successful" transplants.

The Committee encouraged more emphasis on living donation under the first strategic goal and to leverage studies or initiatives others in the community are doing to improve living donor outcomes (e.g. "Whole Donor Study"¹).

The Committee prioritized the following five goals:

- Expand the use of collaborative improvement methodologies and models
- Promote knowledge of and increase implementation of effective donation and procurement practices
- Reduce geographic disparity in access to transplant
- Improve longevity of organ transplants
- Improve efficiency in the policy development and implementation process

¹ Wellness and Health Outcomes in Live Kidney Donors (WHOLE). Epidemiology Research Group in Organ Transplantation. Johns Hopkins University School of Medicine.

Concept paper on improving the OPTN UNOS committee structure

The OPTN/UNOS Patient Affairs Committee (Committee) commends the Executive Committee's desire to increase engagement with the OPTN from diverse constituencies, including transplant candidates, recipients, living donors, recipient families and donor families. Everything the OPTN/UNOS does either directly or indirectly impacts transplant patients and their families so concepts that enhance patient involvement are worthwhile. While the Committee supports this goal, members had reservations about whether restructuring the OPTN/UNOS committee system will actually increase patient engagement or amplify the patient [1] voice.

The Committee supports utilizing the current committee, or constituent council, as a training ground for patient representatives who ultimately might decide to continue service with the OPTN. In addition, there was support in improving communication and collaboration between committees and the Board of Directors. The Committee noted that Board members can currently volunteer to be a "Visiting Board Member" to any committee, but the expectations and responsibilities of this role are unclear.

The Committee acknowledges that the proposed strategy was narrow in scope and does not attempt to address what members felt was the most significant hurdle in engaging patients: simply, a majority of patients have no knowledge of UNOS or the OPTN, and for them, "engaging" with the transplant community stops at their transplant center or for donor families, the OPO. Even being aware of UNOS doesn't guarantee a patient understands UNOS' role as the OPTN or how the OPTN operates and develops policy (i.e. through Committees). Therefore, the Committee focused feedback on engaging patients who might find themselves on an OPTN/UNOS Committee or expert council.

The Committee echoes the concerns raised by other constituent committees and does not support the following aspects of the proposal:

- Taking away the ability for expert councils to sponsor projects will decrease engagement and voice, not increase. Several of the constituent committees who would be relegated to an expert council have sponsored several policy proposals, guidance documents, white papers, and other products that necessitate Policy Oversight and Executive Committee input and approval. The Committee was unsure how this change would increase engagement.
- Taking away opportunity to meet face-to-face will decrease engagement, networking opportunities and may impact consensus-building. The face-to-face meetings are essential to develop not only a patient's understanding of the transplant world beyond their center, but the relationships to each other that they don't have another forum to do this in. Patients do not have a professional organization or many options to interact with others like them.
- Siloing the different "perspectives" from each other. The Committee feels that one of its strengths is its diversity of perspectives, and members value learning from each other. This includes the physicians and surgeons who serve on the Committee and often help explain clinical concepts, terms, processes, etc.

The Committee could not reach consensus about whether doing away with regional representatives would be beneficial or detrimental. Those that supported keeping regional representation on an expert council cited concerns around ensuring geographic diversity; having regional representatives ensures that this diversity is achieved. This group supported more patient participation at regional meetings. Those who supported doing away with regional representation on the expert councils cited the freedom to recruit whomever the council wanted;

therefore, the council could ensure geographic diversity, organ representation and specific expertise. These members noted the regional nomination process has not worked for the Committee in the past. It has resulted in appointment of many non-patients, as noted in the proposal, to the extent that at any given time, a majority of members are professionals, or may represent multiple perspectives (transplant professional AND patient). This faction also felt that regional meetings are intimidating; the patient regional representatives don't know what their role is, they aren't acknowledged and few, if any, of the professionals attending are aware there is a patient in the room. However, without regional representation, would expert council members be expected or required to attend regional meetings? If not, it seems like a large segment of the transplant community would be missing from the dialogue that occurs in these forums.

The Committee voiced other concerns:

- There is no evidence as to whether patient engagement would increase or improve with this concept. Was a root cause analysis of the problems done prior to concept paper? Were other solutions considered?
- What value do patients get from volunteering with the OPTN?
- Volunteer time: members of the core council would serve on two groups, much like the Vice Chairs serve on their respective committees and the Policy Oversight Committee. The time commitment that would be required seems demanding.
- Constituent committee projects: Committee members were not convinced an organ-specific committee will prioritize patient-centric projects (like education products) over more complex and resource intensive policy projects. Even constituent council members voicing support for such a project as a "block" may not be enough to convince an organ-specific committee to take on such a project.
- UNOS has been perceived as being reluctant to truly engage with individual patients, including developing patient education: Prioritize patient education and information projects and allocate resources accordingly – this will help with brand awareness. The OPTN/UNOS is losing out on being the primary source of information about policy and processes unique to the OPTN/UNOS. Other organizations are (or will) step in to fill the gap (AST is also prioritizing patient engagement efforts; they have a full-time "Patient Engagement Program Manager", hosted an in-person "Patient Summit" and facilitate interaction via social media).

The Committee suggests the following as alternatives to consider:

- Instead of overhauling the committee structure in one fell swoop, with no evidence that it would meet the goals laid out, take a slower, more measured approach and try piloting the concept with an existing committee
- Keep the current committee structure and add adjunct expert councils. They should increase opportunities to participate
- Create standing spots on committees/expert councils for patient advocacy groups, similar to AST/ASTS representatives on the Board
- Before committing to a total restructuring of the OPTN/UNOS committee system, the Committee encouraged UNOS to start by maximizing patient input and engagement within their current committee structure. The Committee feels that the solution does not lie exclusively in changing the structure of the committee system, but more so in the recruitment, preparation, and education of patient representatives.

- RECRUITMENT
 - Passively relying on transplant programs and OPOs to refer patients to serve on committees may not be the most effective way to recruit patients, although one Committee member suggested designating transplant programs or OPOs who refer patient candidates as “Patient Engagement Centers of Excellence”
 - There are currently few, if any, transplant candidates on committees. May be especially challenging to recruit these patients to serve the OPTN/UNOS
 - What is the outreach plan to recruit patients with the background UNOS is looking for? How will UNOS/OPTN recruit a more diverse participant pool?
 - Keep committee alum engaged, but how?
 - Meet patients where they are (social media, Transplant Games, support groups, patient advocacy groups) in the languages they use
- EDUCATION:
 - Patients require much more intensive orientation and onboarding. What is currently offered is not sufficient
 - An in-person orientation for all patient representatives would be extremely beneficial
 - Patient representatives really need a policy/policy-development boot camp
- PREPARATION:
 - OPTN/UNOS leadership should communicate expectations regarding interacting with patient representatives to UNOS staff, Committee Chairs and Committee members
 - Liaisons and/or Committee Chair should have standing calls with patient representatives
 - Provide an acronym glossary to all patients
 - Quick check-in at beginning of in-person meeting to reinforce how important patient role is on Committee
 - The clinical nature of most committee meeting discussions are not inclusive nor patient-friendly. There could be ten patient representatives serving on a subject-matter committee; that doesn’t mean they will feel any more comfortable to speak up and offer an opinion. Patients do not understand what is being discussed and do not feel they can contribute to the conversation
 - Finally, how does UNOS expect patients to participate in public comment if proposals are not written at a literacy level most patients can comprehend? The Committee suggests developing an unbiased “layman’s abstract” and “layman’s proposal presentation” so that patients understand the goals and merits of each proposal and feel confident enough to post comment. Ideally, this format would be translated into

other languages, reflective of those spoken by the affected patient populations

2. National Survey of Organ Donation Attitudes and Practices (NSODAP)

The Health Resources and Services Administration (HRSA) requested comment regarding the changes to the National Survey of Organ Donation Attitudes and Practices from the Committee. The Committee commented that although word choice has improved in some questions, other language was too formal, awkward and might be perceived as confrontational. They also felt the survey was too long, but didn't offer suggestions on which questions to cut. Members questioned whether the mix of quantitative and qualitative questions was purposeful. Members suggested differentiation between deceased donation and living donation and asking a question about whether parents would honor their (minor) child's donor designation decision. Finally, the Committee advised outlining the goals of the survey clearly in the beginning.

3. Scientific Registry of Transplant Recipients (SRTR) Website Update

The Scientific Registry of Transplant Recipients (SRTR) launched its brand new website in December 2016. Last spring, the SRTR shared the website with the Committee to garner feedback. They presented updates to the website, including prototypes for future updates, based on patient feedback throughout the year. Committee members commended SRTR for the changes made, commenting that the site was easier to navigate. In addition, the visual cues, pop-ups and other descriptors should facilitate understanding. One member cautioned that while the revisions to the site should empower patients, it's only helpful if the patient understands the information. She recommended adding a disclaimer to the site that advised patients to discuss search results with their medical provider. Transplant centers can also use this tool when educating patients. The Committee was supportive of the changes made and the additional tools provided.

4. OPTN/UNOS Ad Hoc Geography Committee Update

The Ad Hoc Geography Committee was formed during the December 2017 Board of Directors meeting. With recent projects altering several organ distribution policies, the ad hoc committee was formed to take a comprehensive look across the organs at organ distribution as a whole. The Committee was provided an update on the Geography's Committee's work to date. The donor family representative shared that donor families might agree that organs are local resources versus national, as if their loved one's organs were placed locally, that might make meeting the recipients more convenient. One member commented that the principle highlighting demand following supply seemed impractical, inequitable and may increase waitlist mortality. Another member commended the Geography Committee's work thus far and asked what the next steps would be. UNOS staff advised that the Geography Committee would narrow the list of principles down over future meetings and move on to considering models or frameworks.

Upcoming Meetings

- March, 2018