OPTN/UNOS Minority Affairs Committee
Meeting Minutes
March 5, 2018
Chicago, IL

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Introduction

The Minority Affairs Committee (hereafter, the Committee) met in Chicago on 03/05/2018 to discuss the following agenda items:

1. Committee Member Updates
2. Ad Hoc Geography Committee Update
3. Active Projects Update
4. Project Brainstorming
5. Spring Public Comment Presentations

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

1. Committee Member Updates

The Committee heard an update and watched a video on the recovery from Hurricane Maria in Puerto Rico from a committee member from that region. The Committee also heard updates from committee members on news relevant to the Minority Affairs Committee in their regions.

2. Ad Hoc Geography Committee Update

The Geography Committee was formed as an ad hoc committee at the December 2017 Board meeting to take a comprehensive look at organ distribution. The intent is to recommend organ distribution principles, frameworks, and models that are aligned with the Final Rule and may be used when analyzing and reviewing specific organ policies and donor service areas (DSAs). These guiding principles will help to assure consistent application of geographic distribution of organs. The Geography Committee is only focusing on high level recommendations for geographic organ distribution to be provided to the Board and the Board will decide on subsequent work.

Work is still in progress and the Geography Committee is in midst of gaining consensus on principles, frameworks, and models with continued revisions and fine-tuning. A Minority Affairs Committee member asked whether the performance of OPOs was accounted for in the review of geographic distribution of organs. The presenter explained that the current principles are purposefully high level and broad to account for a range of options for different organs to approach distribution. The Board of Directors will consider what to do with these broad principles once the Geography Committee establishes which principles are most relevant and important.

3. Active Projects Update

<u>Non-A1 Educational Offering</u>

The Non-A1 educational offering went out March 1st and communications with the community have included publications, newsletters, and listservs. The offering can be found on UNOS Connect and is about 9 minutes long. Since the educational offering was only recently released, it is too soon for metrics to be developed and updates will be provided when more information is

available. The educational offering references and links to the guidance documents which also serve to communicate with the kidney community about the utilization of Non-A1 kidneys.

MAC Checklist for OPTN Projects

The goal of the checklist is to help committees preemptively think about populations that may be affected by potential policy changes and to help these committees think about potential impacts earlier in the process. It was decided to present this as strongly advised to committees to utilize this checklist, although some Committee members expressed support for making the checklist mandatory. Making it a requirement would involve changing the Bylaws and other issues that are beyond the scope of the creation of the checklist. However, UNOS staff strongly recommended including references to NOTA (National Organ Transplantation Act, which authorizes the OPTN to consider vulnerable populations in the formation of policy) in the checklist document. Using the checklist will be an expectation for committees in pursuing Policy Oversight Committee (POC)-approved projects.

There has been an idea to develop PowerPoint slides aligned with this checklist for committees to use as they present their project to the Minority Affairs Committee. The hope is for this to be useful and efficient in the project approval process. Key populations are listed along with added items related to addressing geographic disparities. Committees are asked how policies may affect candidates living in rural, urban, or urbanized clusters in noncontiguous U.S territories, in economically deprived areas and to think about other populations not included on the list that would be affected by their proposal. The plan is to pilot this checklist in early summer for new committee projects and fully implement it in the fall.

4. Project Brainstorming

The Committee discussed options to pursue for new projects. The strategic goals that the new project should align with are: increase the number of transplants, provide equity in access to transplants, improve outcomes for waitlisted patient, living donor, and transplant recipients, promote living donor and transplant recipient safety, and promote the efficient management of the OPTN.

The Committee's charge is to consider aspects of procurement, allocation, and transplantation that impacts minority and disadvantaged populations. The Committee provides input and recommendations to ensure these issues are addressed with regard to minority populations. The Committee found no formal definition of minority in OPTN policy nor does the Minority Affairs Committee charter define minority.

During this session, Committee members joined small groups to brainstorm and consider new project ideas.

Ideas presented for consideration included:

- A policy proposal to give prioritization to foreign nationals on the donor waiting list for kidneys
- A proposal for extending aid to distribution outside of DSA when these organs are allocated
- Concept projects to establish best practices for post-living donation monitoring and establishing best practices for encouraging non-directed donations, as these donations may have a particularly beneficial impact on minority populations.
- Creation of a universal transplant site that provides information prelisting and how programs can provide the best transplant care and get appropriate resources for patients.

    - This site would serve as a “best practices” website for programs and a resource for patients to make informed decisions. The Committee considered this project idea in relation to the disparity of access that impacts different populations.
- Looking at access to care by linking by zip codes similar to the geographical disparity research
    - The Committee expressed interest addressing the geographic disparity that can impact access to transplant. There was discussion of coordinating UNOS/SRTR data, which doesn’t include economic information, with Census data. There are difficulties in time and cost associated with integrating data this way. Another possible challenge could be looking at the impact on patients that don’t get listed, since UNOS doesn’t collect this data, focusing on patients on the waitlist and those transplanted.
- Look at geography and whether there's a way to measure access to care based on population density and economics on a U.S.-wide scale
- Look at access to transplant in noncontiguous states of the U.S. to see if there's a difference that would result in a potential benefit from assigning additional allocation points to people in those areas

All ideas will be taken back and discussed for feasibility and further recommendations.

5. Spring Public Comment Presentations

Broader Sharing of Lungs – Thoracic Committee

The problems that the Thoracic Committee seeks to address with this proposal is that DSA in lung allocation may not be consistent with OPTN Final Rule, removing DSA complicates heart-lung allocation policy, and removing DSA makes current policy for sensitized lung candidates impractical.

Proposed solutions are to remove references to DSA and replace any reference to DSA with 250 NM (nautical miles) from donor hospital; make the policy more explicit and adopt similar model for allocation of heart/lungs from pediatric donors; and remove current policy for sensitized lung candidates. TSAM (Thoracic Simulated Allocation Model) data reviewed modeling for different distribution schemes, analyzing lung transplant rates based on lung allocation score and the ratio between deaths on waitlist and one-year survival following transplant.

The Thoracic Committee will continue to seek public comment feedback and make recommendations to the Board in June regarding options for distributing lungs. The Board will have to determine whether or not to make the 250 NM radius a permanent change. The Thoracic Committee believes they can develop a better system with more time and they may ask the Board to delay the expiration date and permit the Committee to continue to look for the best solutions.

VOTE: There was no opposition to this proposal.

The Minority Affairs Committee unanimously supported the change in lung allocation from 500 miles to 250 miles. Despite lack of opposition to the already-implemented change, committee members expressed concern that there may not have been adequate modeling produced in advance of the change. The SRTR did provide some modeling, but members may not have had adequate time to review the projected results.

Proposal to Change Waiting Time Criteria for Kidney-Pancreas Candidates –Pancreas Committee

Current kidney-pancreas (KP) waiting time policy requires candidates to be on insulin, and have a BMI (body mass index) of less than 30 kg/m^2 if C-peptide is above 2 in order to accrue time. The KP waiting time criteria restricts a high BMI, Type 2 candidate's ability to accrue waiting time which affects the ability to potentially get a transplant. The Pancreas Committee reviews the maximum allowable BMI every 6 months in relation to the percent of active KP candidates with C-peptide > 2 and BMI below or equal to the maximum.

Subsequent analyses by the Committee indicated the maximum BMI should be raised further because low C-peptide, high BMI candidates represented less than 10% of total listed cohort. It is also noted that no BMI weight restrictions are imposed by UNOS for other organs. It is felt this policy unfairly limits the access to transplants for certain populations of candidates. Substantial evidence indicates Type 2 candidates can be successfully transplanted have high BMIs greater than 30, specifically Asian, African American, and Hispanic populations who typically represent greater proportion of Type 2 patients on the SPK waiting list.

The Pancreas Committee recommends the removal of the BMI/insulin requirement from the KP waiting time criteria. This will allow Type 1 and Type 2 diabetic candidates with high BMIs to be treated equally in their ability to accrue waiting time. It is important to note candidates still need to be diagnosed with diabetes or have pancreatic exocrine sufficiency with renal insufficiency and meet criteria for a kidney transplant waiting time to be registered for a KP transplant. The recommendation allows for discretion of transplant team with respect to the BMI of the recipient. There is no need for additional restrictions because programs are already reviewed for outcomes. Changing KP waiting time criteria aligns with the first OPTN strategic goal and may have beneficial impact on increasing number of transplants. The recommendation would also remove the burden and confusion of a BMI review every six months.

VOTE: There were 6 votes in opposition

The Minority Affairs Committee voted in support of the proposal (8 support, 6 oppose, 0 abstain). The Committee has concerns, however, about the proposal's potential impact on both organ allocation and long term survival rates. If type II high BMI candidates receive a greater percentage of available kidneys, healthier candidates will be on the waitlist longer. It is uncertain if Type II high BMI recipients will remain insulin free in the long term, potentially causing survival rates to remain as is or decrease.

Manipulation of the Waitlist Priority of the Organ Allocation System through the Escalation of Medical Therapies –Ethics Committee

This paper seeks to address concerns raised regarding raising patients' priority on the waitlist through escalation of care. There is no existing OPTN/UNOS guidance or formal position on this practice on how providers should balance competing concerns. This paper assessed whether there are ethical violations and what the best and most ethical approach to proceeding is. It is beyond the scope of the Ethics Committee to advocate or propose safeguards or policies. This paper provides an ethical analysis of escalating care for the purposes of increasing waitlist priority and can serve as guidance for transplant providers who may be confronted with this. The focus is limited to the practices or interventions that are not medically required, but are initiated, maintained, or escalated for the sole purpose of increasing a candidate's waitlist priority.

The Ethics Committee believes it incumbent upon the OPTN/UNOS and the transplant community, more broadly, to ensure providers understand the expectations for upholding the

principles of organ allocation. This is now out for public comment and it is anticipated the Board of Directors will review in June.

VOTE: The Committee supported the proposal unanimously, but noted that they also supported use of safeguards against unnecessary medical interventions. The guidance would benefit from some accountability among providers. This would be important for minorities that have historically distrusted medical institutions.

Next Steps

Next steps will include follow-up on new project ideas. The new liaison will be contacting everyone with regards to scheduling meetings. Nothing is currently on the calendar but meetings should continue in the same expected timeframes. There will be an in-person meeting in September, an in-person in March, and every other month on a Monday from 1 to 3 p.m. There might be one more checklist meeting to go over any changes or edits to review feedback discussed today.