

**OPTN/UNOS Ethics Committee
Meeting Minutes
October 29, 2018
Chicago, IL**

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Introduction

The Ethics Committee (the Committee) met in Chicago, IL on 10/29/2018 to discuss the following agenda items:

1. Policy Oversight Committee Update
2. Liver and Intestinal Organ Transplantation Committee Proposal – Special Public Comment
3. Patient Affairs and Transplant Coordinator Councils – Proof of Concept Update
4. Living Vascularized Composite Allograft Donation – Update on Potential Project and Collaboration
5. Ad Hoc Geography Committee Update
6. MOT Break out group
7. CAT break out session
8. New Project Ideas

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

1. Policy Oversight Committee Update

The Committee discussed an overview of the new geography allocation proposals, their alignment in the strategic goals, and their approval of the Policy Oversight Committee's (POC) approval.

Data summary:

The current OPTN/UNOS strategic plan breakdown of allocation of resources is as follows:

- 40% increase transplants
- 30% provide equity
- 10% improve outcomes
- 10% promote safety
- 10% promote efficiency

The current actual breakdown of resources is as follows:

- 24.8% increase transplants
- 51.4% increase equity
 - 12.15% Liver Distribution
 - 7.88% Kidney/Pancreas Distribution
 - 5.23% Thoracic Distribution
 - 3.28% VCA Distribution
- 13.4% improve outcomes
- 4.9% promote safety
- 5.5% promote efficiency

Summary of discussion:

One committee member noted that while the strategic plan intends to dedicate 30% of resources to equity, the other 70% could be categorized as focused on utility. The member felt that the ideal standard for resources should be a minimum of 50% equity and 50% utility, which was an issue discussed by the Committee at previous meetings. One committee member made note that it is possible for the Ethics Committee to become more involved in other committee's proposals that they feel align with their goals in an effort to increase projects dedicated to equity.

One committee member noted that the strategic goals are created and reevaluated every 3 years. As 2019 marks the beginning of the newest strategic goals, they will be reset by the Executive Board in 2022. A member of OPTN/UNOS staff inquired how the committee member would categorize the issue of increasing patient safety. The member confirmed that because safety is focused on minimalizing risk and danger, safety efforts fall into the utility category.

Next steps:

The Committee will continue to receive updates on the POC at regular intervals.

2. Liver and Intestinal Organ Transplantation Committee Proposal – Special Public Comment

The Committee discussed a presentation on the two liver geographic allocation models out for special public comment and their origins.

Data summary:

There are two current proposed geographic liver models labeled B2C and Acuity Circles. Both use 150, 250 and 500 nautical mile circles around the donor hospital. Both have sharing thresholds, however the sharing pattern is different for candidates with a MELD/PELD above a certain threshold. Both cap standard exception scores. Both prioritize pediatric candidates for pediatric donors and give less weight to proximity for pediatric donors. Both give more weight to proximity for DCD and donors at least 70 years old. Both prioritize pediatric candidates for pediatric donor livers. A lower sharing threshold includes more candidates in broader distribution and modeling suggests that a lower threshold (35-32) results in more flying, decrease in variance in MMaT, and positive impact on waitlist mortality. Overall demographic subgroups (age, sex, and race/ethnicity) were similar between the modeled scenarios and the total population with one exception. The pediatric subgroup saw reductions in MMaT and increases in transplant rate that were better than the improvements for the overall population. The trends for the socio-economic status characteristics (education, insurance type, cumulative community risk score, and urbanicity) subgroups were similar between the modeled scenarios and the total population. The B2C model differs by prioritizing pediatric candidates above all adult candidates and not extending local priority for pediatric candidates in smaller circles.

Summary of discussion:

One committee member asked if the concentric circles model would still be based off the location of the original DSA hospital, which was confirmed. Another member asked for clarification on a graphic depicting the varying distance of 150 to 300 nautical miles. One committee member brought up a concern of an increased cost for candidates and recipients to travel across state lines due to increasing the large radius of nautical miles and whether insurance costs could also increase. Another committee member confirmed that the burden of increased travel would not fall on recipients but rather on transplant programs to transport the organs to the recipient's hospital. Another committee member expressed the concern heard from transplant programs about the possibility of doubling the distance and therefore increasing costs for air travel.

One committee member highlighted that multiple criteria of the Final Rule shaped this proposal. A committee member stated that they felt the previous geographic allocation was not compatible with the Final Rule and that from an ethical standpoint, the cost should not prohibit moving forward on a more equitable model. A different committee member advocated for considering a population-based model for determining the distance threshold between the options of 150, 300 and 500 miles due to the fact that rural areas will always have increased travel time. One committee member pointed out that distance is a difficult measuring standard because 200 miles looks very different on the East Coast vs. the West Coast vs. Puerto Rico vs. the Midwest. The member felt it was worrisome to use distance because if the circles are too small, it would only re-distribute the inequity to different geographic locations. The member felt that our current geographic allocation method meets most of the requirements of the Final Rule and the specific geographic criterion is the only aspect in need of updating. The member felt that improving geographic compliance with the Final Rule could have a negative impact on other criteria of the Final Rule that deal with utility.

One committee member commented on the difference between equality and equity and that the goal is not to set a distance standard that just enforced equality while sacrificing true equity. One committee member expressed concern that certain vulnerable groups, such as rural groups, may be disadvantaged by the geographic proposal and that it was important to analyze which populations would be advantaged and which would be disadvantaged. One committee member questioned why the lawsuit was pushing a geographic change so quickly and what the consequences of this lawsuit would be. An OPTN/UNOS staff explained that because the current DSA geographic allocation policy was found to be noncompliant with the Final Rule, a lawsuit could lead to entities other than OPTN/UNOS members determining the appropriate geographic boundaries to include in allocation. Removing this decision making capacity could have a negative impact on the entire community, which is uniquely qualified to address transplant-related challenges using input from OPTN/UNOS committees and feedback from members of the community.

A member then inquired which of the proposed geographic distance thresholds were best for the patient. OPTN/UNOS staff responded that it depended on the patient's location, their current health condition, and other factors. Due to these varying factors, no one plan would universally benefit all patients. Due to the limited time, the OPTN/UNOS liaison proposed that any additional committee members who wished to add a comment should make them as part of the special comment period and the liaison would identify them and use their input when synthesizing the overall response of the Ethics Committee. One member asked for clarification on a graphic depicting the lowest MELD/PELD, which was clarified by an OPTN/UNOS staff member.

Next steps:

The Committee liaison will summarize Committee comments on the liver proposal; these comments will be posted on the OPTN website as a public comment. The Liver Committee will consider this and other comments in their post-public comment review.

3. Patient Affairs and Transplant Coordinator Councils – Proof of Concept Update

The Committee received an overview of a proof of concept piloted by the Transplant Coordinators Committee and Patient Affairs Committee that would model how to expand committee participation.

Patient Affairs Constituent Council (PACC) Survey Results

Feedback from the Patient Affairs Constituent Council was about half positive and half negative. There was a range of engagement for members. The majority strongly agreed or agreed:

- OPTN/UNOS staff makes you feel your role is important and valuable
- Volunteer leadership makes you feel that your role is important and valuable
- You are called upon to offer your patient/donor family perspective in Committee discussions
- You feel comfortable speaking up to offer your personal patient/donor family perspective
- You feel comfortable speaking on behalf of your patient/donor family perspective

Most members felt that they could explain their Committee's projects and policy proposals in layman's terms. The majority felt that the patient's/donor family member's voice is heard, with 1/3 feeling neutral. Most felt that patients/donor families had a chance to participate in OPTN/UNOS policy development. There was a majority of negative feedback on Basecamp, also not many consistent posters.

Transplant Coordinator Constituent Council (TCCC)

Overall fewer members provided feedback or participated in the survey, with responses showing more neutral or negative feedback from the coordinators. A majority of the coordinators did not feel strongly engaged as committee members and had negative feedback about Basecamp. A majority strongly agreed or agreed:

- OPTN/UNOS staff makes you feel your role is important and valuable
- Volunteer leadership makes you feel that your role is important and valuable
- You are called upon to offer your transplant coordinator perspective in Committee discussions
- You feel comfortable speaking up to offer your personal transplant coordinator perspective
- You feel comfortable speaking on behalf of your transplant coordinator perspective

Unlike the PACC, all TCCC members reported at least occasionally voicing an opinion as opposed to almost never or when called upon. Most members felt that they could explain their Committee's projects and policy proposals in layman's terms. The majority felt that the transplant coordinator's voice is well-represented in the policy development process, with 1/3 feeling neutral. Most felt that transplant coordinators had a chance to participate in OPTN/UNOS policy development. There was a majority of negative feedback on Basecamp and little to no dialogue between meetings.

Summary of discussion:

One committee member brought up the floating idea of OPTN/UNOS ambassadors. No other comments were made by committee members.

Next steps:

The Executive Committee will evaluate the committees' feedback on the proof of concept and determine next steps.

4. Living Vascularized Composite Allograft Donation – Update on Potential Project and Collaboration

The Vascularized Composite Allograft (VCA) and Living Donor Committees are exploring the possibility of collaborating on a project proposal concerning adding policy language concerning VCA transplants to sections of policy related to living donation.

Data summary:

VCA transplants begun in 1998 and were primarily for either upper limb unilateral or abdominal wall until 2009. In the recent last three years, there has been a significant increase in uterine

donations by living donors. In September of 2018 additional guidance on uterus transplantation was released by the American Society for Reproductive Medicine.

Summary of discussion:

Overall discussion focused around the questions of the ethical implications of a lack of policy language specific to VCA transplants. One committee member noted that without language holding VCA research to the requirements in OPTN/UNOS *Policy 14: Living Donation*, it would be possible for donors to not receive a psychosocial evaluation or provide informed consent forms and felt strongly a lack of these basic standards was problematic. One OPTN/UNOS staff member noted that all centers do some type of informed consent per an OPTN/UNOS requirement but the specifics of the informed consent requirement may vary according each center. A committee member asked if there was required follow up with recipients. In the case of uterus donation it is dependent on the center. Another committee member brought up a possible need for an evaluation on the psychosocial burden on recipients of uterine transplants. One committee member asked if there was a consensus for applying policy 14 language and requirements to VCA transplants. The committee was in consensus that VCA should be included in policy 14 living donation informed consent requirements.

An OPTN/UNOS staff brought the second part of the proposal on the applications of OPTN/UNOS *Policy 18: Data Submission Requirements* to VCA to the committee's attention for consideration. The staff member related that the VCA committee was currently against adding language to require VCA transplants to abide by additional data submission requirements as there is a great concern the community at large may reject such a proposal. One committee member questioned that whether or not modifying data submission requirements was the best approach it is important to track transplant outcomes for safety and further discussion should determine which outcome measures need to be captured.

Next steps:

The VCA liaison will relay the Committee's feedback to the VCA Committee.

5. Ad Hoc Geography Committee Update

In June 2018 the Board of Directors approved five principles of geographic distribution and three geographic frameworks that align with those principles. The principles are that deceased donor organs are a national resource and should be distributed as broadly as possible, reduce inherent differences in supply and demand, reduce travel time that affects cold time, increase organ utilization and prevent wastage, and increase efficiency and transplant system resources.

The three frameworks that align with those principles are fixed distance from donor hospital, mathematical optimization, and continuous distribution and are out for public comment now.

- Fixed distance from donor hospital creates fixed geographic areas with distance between donor hospital and transplant candidate's hospital. This allows for wider distribution, particularly for medically urgent patients. Disadvantages are it still uses fixed boundaries and differences in population density may affect similar matching patients.
- Mathematically optimized boundaries are based on data and formula with one or more specific goals such as having consistent ratio of donors to potential recipients within each distribution area. It provides consistent results that can be scaled and monitored and take into account overlapping neighborhoods. Disadvantages would be fixed boundaries again which might not be uniform.
- Continuous distribution uses a statistical formula that combines important clinical factors such as medical urgency, likelihood of graft survival, as well as proximity to donor hospital to give the candidate a distribution score. The score would prioritize candidates

and determine where they would appear on the match run, allowing organ offers to be matched more efficiently to the candidates with highest medical priority. The disadvantage is that the concept is new and difficult to understand.

Data summary:

92 total comments with overall mixed support. The comment breakdown was as follows:

- 46% Transplant Hospital
- 22% Organ Procurement Organizations
- 1% Histocompatibility Lab
- 20% Patients
- 11% Non-members

All the various member types preferred the Continuous Distribution framework by large margins besides the public organizations, which were evenly split among the Continuous Distribution and Fixed Distance Circles frameworks.

Fixed Concentric Circles Feedback

- Has worked well in thoracic allocation and decreased CITs
- Easiest to implement and understand within the patient community
- A moderate concentric circle approach could spur broader sharing and could be introduced without devastating disruption and travel costs, effective compromise without significant transformation
- Does not properly account for donor/recipient compatibility or optimize outcomes
- Could disadvantage centers in less-densely populated areas
- May unnecessarily limit the ability of high urgency waitlisted patients, who reside just beyond the defined fixed distance from the donor hospital, to gain access to donor organs.

Mathematically Derived Districts Feedback

- Appears to be the most data-driven and customizable
- Implements objective criteria and removes inherent discrimination
- Concerns of how such a model would be communicated to the community at large and understood by patients
- May unnecessarily limit the ability of high urgency waitlisted patients, who reside just beyond the defined fixed distance from the donor hospital to gain access to donor organs.

Continuous Distribution Feedback

- Provides the most flexibility for organ-specific medical factors
- Presents greater equity with the elimination of “cliffs”
- Provides patients with the greatest assurance of equality throughout the system
- Concerns with un-intended consequences of such a transformation change
- Concerns with the manipulation of medical urgency points within this proposed system
- Concerns over increased organ transportation and associated costs

General Feedback

- None of the models account for differences in listing practices or OPO performance
- Concerns that socioeconomic variables are not being adequately considered
- Protecting priority for pediatric recipients needs to be considered regardless of framework

- If allocation is based on the donor hospital, it would not take into account the difference in geography if organs are taken to an outside perfusion facility
- Justification for a common model across all organ allocation policies has not been made sufficiently clear to the greater community

Geography Committee final vote was 87% for Continuous Distribution and 13% for Concentric Circles.

Summary of discussion:

Committee members had a few questions of clarification regarding the weighting system for the criteria of the continuous distribution model and how strongly distance would be weighed. One committee member expressed that he strongly felt distance should not be weighted by individual mile but rather by significant distance thresholds that represent a significant decline in transplant success.

One member asked why the liver geographic allocation policy proposal was taking a fixed distance approach if that model was the least popular of the three new proposed geography models and questioned why there are geographic policies en route to implementation if other, possibly better, models are currently being proposed. An OPTN/UNOS staff member explained that the current allocation proposals of liver and thoracic are considered short term plans to move towards a more equitable model than the previous DSA model while the newer proposed models are ones intended to be refined over a long amount of time and implemented sometime farther in the future as a final solution.

Next steps:

The Committee will continue to receive updates about this proposal as it is reviewed by the Board in December.

6. MOT Break out group

The MOT Work Group reviewed data on an MOT analysis and discussed next steps.

Summary of Data and Discussion:

Below is a summary of the data analysis findings and feedback from the MOT Work Group:

- Found significantly more white recipients for MOT overall compared to KI
 - Question for writing group and/or research analyst: do we think this is because female and minority candidates have less medical need for MOT, or is there a potential disparity in access for being considered for MOT?
 - Yes – this indicates that minorities on the kidney alone list are being disadvantaged.
- More MOT recipients overall had CPRA of 0% compared to kidney alone, which had more high CPRA recipients
 - This indicates there could be cherry picking the kidney or cherry picking the donor.
- More recipients in the 50-64 age range for MOT overall compared to kidney alone
 - This indicates that MOT receiving priority over single organ transplant (SOT) could have impact from longevity standpoint
 - This is also a utility issue

- MOT had a significantly higher eGFR median and mean compared to KI alone (eGFR is a measure of kidney function, the lower eGFR indicates worse kidney function)
 - This indicates that SOT kidney recipients had worse kidney function when transplanted
 - To be eligible for kidney have to have GFR of 20 or less. So the MOT mean is 25, better than anybody on the kidney list.
 - eGFR isn't a good indicator with liver of how good the organ is.
 - One idea mentioned is to prioritize MOT if the single organ transplant doesn't work. For a heart transplant, kidney graft function may be worse following the transplant, so the allocation system could prioritize candidates that need an additional organ for a certain period of time (say, 3 months) following a single organ transplant.
- SES using zip code median income (which has limitations but is the best proxy we had at our disposal) found MOT had higher median and mean income compared to KI alone overall
 - Take home: MOT more likely to come from zip codes with higher income zip codes.
 - The Work Group asked for p-values to indicate the statistical significance of this finding. The research liaison will provide.
- Waiting time for kidney alone was significantly longer than for MOT overall (712 vs 45 days)
- MOT had higher death rate per 100 patient years compared to kidney alone (36.4 vs 8.8, respectively)
- In terms of geography, MOT had similar % of local (about 69%), more regional (27 vs 13%) and fewer national (4 vs 17%) compared to kidney alone

The section on regionalization should be updated based on this data.

Next steps:

The Work Group will work on updating the draft MOT paper and the Committee liaison will schedule a call to discuss the MOT analysis and draft paper further.

7. CAT break out session

Summary of discussion:

The group held a discussion about the different representations and variations of disabilities. It is difficult to assess and quantify the mortality differences between an infant with ESRD and someone with an intellectual disability. While organ policies don't discriminate against the disabled they do discriminate against high mortality. Members asked why this is. Generally, someone with significantly reduced life expectancy – such as trisomy 18 – will also have other contra-indications. This issue is about ensuring equal access to transplantation; for example, issues such as cancer also engender closer looks at the innate contra-indications. Reasons concerning utility will cause transplant centers to perhaps naturally discriminate.

The workgroup agreed it is necessary to define what is meant by intellectual disabled, and then further break this down by adult versus pediatric. This needs to avoid becoming amorphous and really target the realities faced within transplant centers. If current policy takes predicted life

expectancy into account, can the presence of intellectual disabilities indicated by shorter life expectancy also be taken into account? Historically, there has been lower priority for such individuals when allocating organs. A portion of the paper could address how this issue interacts with social bias.

The oldest recipient of a transplant was 88. Oldest donor for kidney was 78. Determining with which patients to move forward to transplantation often depends on center-to-center. Centers are currently looking more at survival than life expectancy when dealing with organ allocation. Workgroup members discussed the following questions:

- How could policy even the playing field, especially when there is so much disparity between patients and their situations?
- What kind of resources does the American Disability Act already cover? Further, what should it cover that it doesn't currently?
- How can the Committee call attention to this issue to state legislatures? – The workgroup noted that while it is desirable to inspire change on a legislative level, it is essential to keep the white paper focused on OPTN/UNOS members (organ procurement organizations, transplant centers, and histocompatibility labs)?
- Does the group need to plan another survey to get updated data from centers? What data would be needed?

Next Steps:

Workgroup members discussed requesting more data from OPTN/UNOS in the future once the needs of the paper have been more solidified.

8. New Project Ideas

The Committee discussed possible new project ideas to work on in the future.

Summary of discussion:

One Committee member suggested a project regarding the ethical concerns of those performing tests to determine whether a patient is braindead. Another project idea was the ethical implications of failing to follow the policy development process. One committee member brought up the Philadelphia case of a young lung transplant recipient whose transplantation of adult lungs was essentially ordered by a judge following a lawsuit of her parents. An OPTN/UNOS staff brought up the tenuous ground of weighing in on a judge's right to determine legal cases and therefore change policy. One committee member suggested a paper based on the "value of due process". An OPTN/UNOS staff suggested focusing on the process of policy making rather than the legal term "due process" in opposition to a judge's legal right. One Committee member felt it worthwhile to ensure that there be an ethical document to provide if legal reviews of compliance with the Final Rule happened in the future. An OPTN/UNOS staff member commented that based on their own background in law judges are often very empowered to rule based on precedence and their own judgement. OPTN/UNOS staff will follow up on the implications of pursuing such a project.

A committee member suggested the issue of living donors donating to a recipient more than one generation older, especially considering familial and cultural pressures. Another committee member spoke in support. One committee member pointed out that a two generational gap could be as little as 18 years. One committee member mentioned that with paired donations, many donors could end up indirectly donating to a recipient two generations above.

A committee member suggested discussing the issue of donation "vouchers" and the ethical implications of individuals charitably donating and gifting the voucher to friends or family. Another committee member indicated the belief that a voucher program like that could not only

flood the market but also create a type of organ market. It was questioned if it were possible to incentivize altruistic donation without creating those consequences. One committee member indicated that incentivizing donation is different than removing disincentives.

Next Steps:

The Committee liaison will document new project ideas in the project forms, for the Committee to review at a later time.

Upcoming Meeting

- Teleconference November 29, 2018 (teleconference)