OPTN/UNOS Ethics Committee
Meeting Minutes
March 15, 2018
Conference Call

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Introduction

The Ethics Committee met via teleconference on March 15, 2018 to discuss the following agenda items:

1. What's new with the Ethics Committee? (Dr. Elisa Gordon)
2. Review and vote on two public comment Proposals
3. Current Ethics Committee Projects and Workgroups

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

1. What's new with the Ethics Committee? (Dr. Elisa Gordon)

Dr. Gordon provided an overview of what's new with the Ethics Committee. Dr. Giuliano Testa is going to step in as the new Region 4 representative, and Ms. Leigh Kades will fill in as an interim liaison.

2. Review and vote on two public comment Proposals

Modifications to the Distribution of Deceased Donor Lungs

Summary of discussion:

The Thoracic Committee Liaison presented the Thoracic Committee's proposal on modifications to the distribution of diseased donor lungs.

She outlined three problems that the proposal would seek to address. First, using the Donation Service Area (DSA) as a unit of distribution in lung allocation may not be consistent with the OPTN Final Rule. Second, removing DSA complicates the heart-lung allocation policy, which has not yet been implemented. Finally, it makes the current policy for sensitized lung candidates impractical.

In terms of background, on November 16, 2017, a "critical comment" was submitted to HHS requesting that DSA be removed from the lung allocation policy and there be distribution to Zone A instead, which at that time was a 500 Nautical Mile (NM). The Final Rule spells out the Secretary's obligation in the event of a critical comment, and according to the process, the OPTN was ordered to review current policy to determine whether the use of DSA in lung allocation policy is consistent with the Final Rule and whether distributing to a 500 NM circle was more consistent with the Final Rule than distributing first to the DSA. The Executive Committee of the Board of Directors consulted with the Thoracic Committee when considering the question, and the Thoracic Committee advised that making such a decision without ample time to study the effects was not preferable. That being said, the Final Rule requires the OPTN to weigh multiple factors in developing allocation policy including geographic considerations. While the Executive Committee determined that it is permissible to consider the benefits of distributing organs more geographically proximate to the donor, the DSA is not an appropriate substitute for geographic proximity. Allocation policies must be rationally determined, consistently applied, and must not create inequities in access to transplant. The Executive Committee found that DSAs, as used in lung allocation policy, are not rational or consistent and

result in inequities. It was determined that distributing to a larger, consistently-shaped geographic unit is more consistent with the Final Rule.

Proposed solutions were adopted on an emergency basis and included removing references to DSA in lung allocation policy, and replacing DSA with 250 NM around the donor hospital. Because it was done on an emergency basis, the changes will only be in effect for one year, until November 24th, 2018, unless the Board takes action to either make the changes permanent, modify them, or terminate them. The Thoracic Committee is also required to retrospectively distribute the change for public comment. After the change, TSAM modeling was requested from the SRTR to compare the potential effect of distributing to the DSA first as compared to a 250 NM zone first and then a 50 NM zone. Overall, the DSA and 250 NM waitlist mortality rates were similar. The minimum and maximum of the two simulations overlapped. When comparing DSA and 500 NM simulations, more differences emerged. Deaths per 100 patient years declined to a greater degree at 500 NM compared to 250 NM or DSA. Overall, transplant rates in the DSA and 250 NM simulations differed slightly or not at all. In the 500 NM simulation, the average rate declined but remained within the range of the simulation. Importantly, the transplant rate for candidates with LAS scores greater than or equal to 40 increased in both the 250 and 500 NM simulations. The simulations suggest that candidates that are more urgent, as demonstrated by higher LAS are being prioritized for transplant in both of the models of broader distribution simulation.

If more urgent candidates are being transplanted, it is important to examine whether these transplants are successful, as measured by increased post-transplant mortality. A system that shifts deaths on the wait lists to deaths post-transplant is one that results in only a minimal benefit to the transplant population. Overall, the one-year post-transplant mortality rates are not impacted dramatically by any of the model distances. When stratified by diagnosis group and region, post-transplant mortality rates within a diagnosis group continued to be similar across all simulations.

The TSAM suggests that distributing adult donor lungs to all candidates within 250 NM of the donor hospital will result in an effect that is very similar to distributing first to the DSA suggesting that the executive committee's action or change is unlikely to result in any immediate or alarming unintended consequences or impacts. In order to realize the benefits of broader distribution, however, the TSAM suggests that it may be preferable to distribute first to a distance beyond 250 NM since patients with higher LAS scores will have a greater opportunity to receive a lung transplant.

Removing the DSA impacted other parts of lung policy, heart-lung allocation, and the policy for sensitized candidates. Current policy is vague and therefore difficult for OPOs to consistently follow. The Thoracic Committee tried to clarify the policy language when they were changing the adult heart allocation policy. The approved but not yet implicated heart-lung allocation policy explicitly mentions the DSA and heavily relies on the distances for sharing hearts and for sharing lungs to be equal, Putting aside the changes to geographic sharing, the approved heart-lung policy will still be difficult for OPOs to follow because it inadvertently suggests skipping over certain heart candidates. Given this, the Thoracic Committee looked at approved but not yet implemented heart policy to figure out how to clarify the intent and provide very precise language for OPOs to follow. If the OPO follows the heart match, the heart will always pull the lung, but if the OPO follows the lung match, the lungs will pull the heart unless there is an urgent heart candidate within a certain geographic distance that needs the heart. The focus was on the lung side of heart-lung allocation to figure out how urgent a heart candidate must be to pull the heart before a heart-lung candidate and how far away from the donor the heart candidate can be. The Thoracic Committee reviewed data comparing the death rate of heart-lung candidates to heart alone and lung alone by heart status and LAS. Previous TSAM results were also

reviewed examining the death rates of heart candidates in the approved but not yet implemented heart policy. Granting priority to heart or heart-lung candidates and heart classifications 1-4 was proposed prior to allocating heart-lung to lung or heart-lung candidates in lung classifications 1-12 for offers from adult donors. A similar contract for allocation of heart-lung blocks from pediatric donors was also proposed.

Current sensitization policy for lung candidates allows all transplant programs and the OPO in the DSA to agree to allow the OPO to offer lungs out of sequence to a candidate they have agreed is highly sensitized. A similar policy exists in current heart policy. The removal of DSA first sharing means that if the policy stays as written, not everyone with the potential to be "skipped" would have the opportunity to agree to it.

The Committee considered multiple options including allowing all parties within any area in which the candidate could be in to agree to prioritize a particular candidate, or allowing sensitized candidates to apply to the Lung Review Board for an exception, or just striking the policy all together. Ultimately, the Committee proposed striking the policy.

In terms of implementing the proposal, transplant programs may see an increase in cost associated with broader sharing. Transplant programs will also be reminded to continue to register heart-lung candidates on all three wait lists: heart, heart-lung, and lung. OPOs may also see an increase in cost associated with broader sharing. Heart-lung allocations should be clear for OPOs, but they will be reminded to generate a batch in which the heart-lung matches are generated simultaneously any time they are trying to allocate heart-lung blocks.

Questions/Concerns:

A question was raised about whether anyone has looked at the difference between 250 NM and 500 NM at the center level comparing land-locked centers versus centers that are close to a coast where the 500 NM would include a lot of ocean. The Thoracic Committee liaison didn't think they had delved into that particular analysis. It was suggested that the centers on a coast may be disadvantaged because the mortality for 500 NM miles would be lower than 250, and the number of used organs would go up. It could be looked at in the broader picture instead of region or center-specific. It could be looked at if the Board permits more time to consider other options.

One thing that the Committee looked at when they looked at the out-of-the-gate data was that lungs are not traveling as far as they used to. The hypothesis was that lungs would start traveling further, and there were concerns about travel costs, but they are not traveling as far as the committee hypothesized.

With regard to low-volume centers, transplant rates may change with the proposed changes, but the wait list mortality rates decreased across all size programs. The transplant rate does not decrease significantly at the smaller programs. It would be a metric that would be monitored closely.

A comment was made that with regard to the "number of transplants performed", the group that's supposed to have greater than 20 always has greater than 20 no matter what number is being talked about. The numbers don't seem to match up. Every time the halo is expanded, everybody's numbers drop. If that's the case, it has to go somewhere. The liaison will circle back with the SRT colleagues for clarification.

Next steps:

- The Committee will consider all feedback that comes in during public comment to determine what recommendation to bring to the board in June.

- If the Committee determines that the 250 NM interim policy is preferable, they will recommend that the Board make it a permanent policy.
- If more time is needed to develop a better solution or to consider other solutions, the Committee may instead recommend that the Board permit the committee to explore other options.
- Recommendations will also be made to the Board about whether to adopt the proposed changes to the heart-lung policy and sensitization policy.

Vote

Do you support the Thoracic Committee's modifications to the distribution of deceased donor lungs public comment proposal?

8 yes; 2 no; 1 abstained.

OPTN Strategic Plan 2018 (Concept Paper)

The liaison to the OPTN/UNOS Board of Directors presented the strategic plan update. The plan was developed beginning with a strategic planning session with committee chairs and board members at the June 2017 board meeting. The feedback was then given to an internal strategic planning group. They integrated with the department goals to draft the strategic plan, which was then provided to the Executive Committee and the Board of Directors for feedback prior to finalizing.

UNOS has been internally reviewing processes and work for continuous improvement. They are taking part in a Baldridge journey, which is a framework for continuous improvement where the organization is asked pointed questions to identify gaps and opportunities for improvement. Three key strength areas were identified in the work of UNOS: match, data, and quality improvement. The goal in creating the plan was to create a narrative reflecting the three core strengths.

The next three-year plan is structured differently from the last. There will no longer be separate plans for UNOS and OPTN. Instead there will be one overarching plan that has shared high-level goals and a description of core activities along with opportunities for growth and new initiatives. Key metrics will be applied to each initiative. The mission statement at the start of the strategic plan sets the stage for the goals and initiatives that are highlighted. The mission is to advance organ availability and transplantation by uniting and supporting our communities for the benefit of patients through education, technology and policy development. The vision is to promote long, healthy, and productive lives for people with organ failure by promoting maximized organ supply, effective and safe care, and equitable organ allocation and access to transplantation. The five core values are stewardship, unity, trust, excellence, and accountability.

The goals and resource allocation benchmarks of the current strategic plan were shared, which are used as a measure of how to distribute internal resources toward moving each of the strategic goals. They assist in determining how to focus efforts in policy development and are considered by the Policy Oversight Committee and Executive Committee in determining which projects to emphasize and which ones should go to public comment. The proposed goals were also shared:

- Increase the number of transplants (40%)
- Provide equity in access to transplants (30%)
- Promote efficiency in donation and transplant (10%)
- Promote living donor and transplant recipient safety (10%)
- Improve waitlisted patient, living donor and transplant recipient outcomes (10%)

The following initiatives are included under increasing transplants:

1. More dynamic donor/recipient matching
2. Expand use of collaborative improvement methodologies/models
3. Examine monitoring approaches for transplant programs/OPOs to focus on increased collaboration and performance improvement
4. Promote knowledge of effective donation/procurement practices
5. Improve ability to perform analysis of refusals

The following initiatives are included under promoting equity:

1. Improve equity in opportunities for multi-organ and single-organ candidates
2. Decrease geographic disparity
3. Increase diversity on the Board/Committees
4. Increase opportunities for volunteer engagement
5. Improve member and public engagement in policy development
6. Develop equity benchmark for each organ
7. Collect additional data on vulnerable populations

The following initiatives are included under promoting efficiency:

1. Modularize and simplify UNet architecture
2. Achieve continuous level of UNet accessibility
3. Improve efficiency in policy development and implementation processes
4. Improve volunteer workforce satisfaction and engagement
5. Improve seamless data exchange between members and UNet

The following initiatives are included under promoting safety:

1. Improve accuracy in HLA reporting
2. Decrease number of safety incidents related to logistics/transport
3. Increase perception of UNOS and MPSC
4. Enhance knowledge sharing
5. Enhance system capability

The following initiatives are included under improving outcomes:

- Improve longevity of organ transplants
- Evaluate effective methods for assessing living donor outcomes.
- Enhance transplant program tools and education
- Expand use of collaborative improvement models
- Develop transplant program tools

Questions/Discussion

A question was raised about what the meaning was in changing the wording from "promoting efficient management of the OPTN" to "promoting efficiency in donation and transplant." It was explained that people thought "promoting efficient management of the OPTN" related to things like running good meetings and not necessarily providing tools that enhance the efficiency of the system. It's a small tweak to better reflect what the intention was, and they will also be devoting additional resources. There was some concern voiced by a committee member, about increasing the resource utilization at the expense of reducing resources allocated to the outcomes. It seemed that perhaps the living donors are getting less and less effort. A committee member agreed with the concerns. It was also suggested that there may need to be additional input into the behavior of OPOs around the country.

Vote

Do you support the OPTN/UNOS 2018 Strategic Plan concept paper?

11 yes; 2 no; 0 abstained.

3. Current Ethics Committee Projects and Workgroups

Manipulation of the Waitlist Priority White Paper

Feedback has been very positive. The white paper will go to the Board in June.

Multi-organ Allocation Guidance Workgroup

There are two workgroups: the Multi-Organ Allocation Guidance Workgroup and the Eligibility for Intellectually Disabled Individuals for Transplant Workgroup. Two to three additional volunteers are needed for each workgroup.

Upcoming Meeting

- April 9, 2018 Full Committee Meeting