

OPTN/UNOS Pediatric Transplantation Committee
Meeting Minutes
September 19, 2018
Conference Call

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Introduction

The Pediatric Transplantation Committee (PTC) met via teleconference on 09/19/2018 to discuss the following agenda items:

1. Task Force Updates
2. Public Comment - Frameworks for Organ Distribution

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

1. Task Force Updates

Summary of discussion:

Liver Committee

The Vice-Chair will join the Liver Committee's next conference call to address any issues on the liver distribution from the pediatric perspective. Leadership has maintained a good relationship with the Liver Committee Chair. Points to be presented will be that the Pediatric Committee include:

- support of wider sharing and looks forward to reviewing the LSAM reports as expected soon; wider sharing is common in pediatrics because of the fewer programs and should be wider than for adults
- capping of MELD or PELD should not apply to pediatrics
- status 1B patients who have a high waitlist mortality should be distinguished from those with chronic liver or metabolic disease (came up in the context of removing the 30-day wait period for patients with status 1B status after being listed with a PELD of 30).

The Liver Committee will be voting on a proposal for public comment on 9/27/2018. Formal public comment will be 10/8/18 to 11/1/2018. Task Force representatives are scheduling time to join the Liver Committee's October conference call due to anticipated amount of interest in the proposal.

Members appreciated the update and asked, was whether there was any thought of pediatric status 1Bs just going to national sharing? What was discussed was the pediatric donor livers under the age of 17 would be shared at a wider range right away before going nationally, so starting at 500/600 miles for status 1B and then going to PELD at that region before going national. After the modeling is received, Task Force members will evaluate the impact. The time to review this would be during the public comment period.

UNOS staff reminded the Committee that the LSAM report is due 10/24/2018 and will be posted in Basecamp for review. Current modeling requests are also available on Basecamp, and comments on the modeling can be posted to accordingly. In addition, any additional data or comments peds has for the Liver Committee or vice versa can be discussed via Basecamp.

Kidney Committee

UNOS staff reminded members the KPSAM request is available on Basecamp. There will be ongoing discussions while they wait for the results of the modeling that the task force members should be engaged in. Those discussions include geographically distant donor hospitals and transplant programs (Hawaii, Alaska, and Puerto Rico), as well as simultaneous liver-kidney allocation. Public comment period for this proposal modeling will be in January 2019.

One Committee member who joined a few of the Kidney Committee calls commented that they were looking at modeling for giving additional proximity points. Another Committee member felt that it is difficult for her to have a comment or feedback without modeling and data on how pediatrics is affected. Another member commented that there has been more published about the erosion of pediatric priority in kidney allocation over the years. The kidney allocation system (KAS) and multi-organ transplant likely plays a part in access for pediatric candidates waiting for a solitary kidney transplant. The question was whether the Committee was interested in addressing that or whether they were just trying to develop another unit of distribution in the current system. UNOS staff responded that the current effort was to look at different distribution models only. The multi-organ transplant discussion is not a focus of this project at this time and would need to be addressed by within a different project.

Task Force members shared some disappointment that the Kidney Committee's focus now is very narrow. UNOS staff reminded the Committee the purpose of the current project was to address the use of donation service areas (DSAs) and regions in organ distribution. Embedding a complex issue such as pediatric kidney transplant access may not be possible due to the current project's short timeline and the diligence needed to carefully address the topic. Task force members on the KP working group are encouraged to bring up the pediatric and multi-organ topics to help make sure the points are raised.

One suggestion was that the Pediatric Committee create principles or guidelines to be used as a template. 1) Excluding liver donation, children do better with a pediatric organ. 2) Pediatric organs are more tolerant to travel. 3) No matter how large the transplant program, pediatric waiting lists vary with respect to its ability to use a particular pediatric organ. Guidelines will be necessary because the modeling will be irrelevant.

Thoracic Committee

Thoracic Committee is moving forward with a modeling request for the November timeframe. Discussions will begin 11/1/2018 where they will discuss distances, heart/lung policy changes, and assessing impact to pediatric candidates. Anyone from the thoracic Task Force who can join that Thoracic Committee's conference call is encouraged to do so.

The timeline for each of the committees' geography discussions, modeling and public comment periods were summarized. Public comment for the distribution frameworks will conclude first in October and for liver and intestine will conclude at the end of October. Kidney-Pancreas and Thoracic will be out for public comment in January after their modeling comes back. VCA is also moving forward with a proposal to be out for public comment at that same time.

2. Public Comment - Frameworks for Organ Distribution

The Committee heard a presentation on the Geography Committee's concept document re: potential frameworks for organ distribution.

Summary of discussion:

The ask of this committee is: which of the three distribution frameworks the Pediatric Committee feels would best serve the organ transplant community?

UNOS staff shared a brief history behind DSAs and regions, and how the passage of the National Organ Transplant Act (NOTA) in 1984 changed the landscape of donation and transplantation.

Prior to 1993, the OPOs had a lot of subdivisions and mergers, but there was no national-level review or criteria about geographic boundaries in organ allocation. After 1993, the DSA boundaries considered allocation local and any sharing agreements followed a defined process that was geographically driven. Currently there are 58 DSAs; there is a wide range of sizes and population density in DSAs, as well as the number of transplant programs in each individual area.

In November 2017, a lawsuit was filed stating that lung distribution using DSAs was not consistent with the OPTN Final Rule. The Final Rule states the candidate's place of residence or listing cannot be used in organ allocation, with some exceptions (numbers 1 through 5). Any allocation policies must follow the Final Rule and must be based on medical judgment, best use of organs, preserves and maintains transplant program's ability to accept or decline an offer, reduces organ wastage, promotes efficiency and patient access to transplantation. This resulted in the 250 NM circles centered from the donor hospital for lung distribution. Then in 2018 a lawsuit was filed stating the same argument, but for liver distribution.

OPTN has always had an emphasis on consensus-driven policy development, taking into consideration the input of the medical community and the Board of Directors (BOD) to make the informed decision. OPO and transplant hospital relationships were derived from DSA and regional structure, so the medical community looks at the relationships when considering proposals. However DSAs and regions were never designed for organ allocation. They were considered to be reasonable proxies for distance.

The Geography Committee identified three distribution frameworks consistent with the Final Rule:

- Fixed distance from donor hospital - Creates geographic areas based on the donor hospital and the transplant candidate's hospital. This may allow for wider distribution and other characteristics such as medical urgency. The advantages are that it is easy to explain and extends the distribution area when considering medical urgency. The disadvantages are fixed boundaries including areas near coasts and national borders, as well as population density may affect patients with similar matching characteristics.
- Mathematically optimized borders - Boundaries are based on a statistical formula designed to achieve the best results based on one or more specific goals of the proposal such as a consistent ratio of donors to potential recipients within each distribution area. This framework is more complex and requires a lot of data, modeling and careful discussion. Distribution areas could range from a limited number of larger districts to a smaller number of localized neighborhoods. Shape could also be customized to account for issues of demographics, geography or clinical factors and neighborhood boundaries could overlap if factors share common characteristics. Advantages include it provides consistent results and can be monitored and scaled. Disadvantages include that it is difficult to explain.
- Continuous distribution - Candidates receive a score based on statistical formula combining important clinical factors that may include medical urgency, likelihood of graft survival, and proximity to the donor location. It uses no geographical boundaries. The candidates who best meet the combination of factors would receive highest priority.

There is a video explaining the three geographical frameworks in more detail and with animations that is available on the Pediatric Committee's Basecamp site for Committee members to review.

The Committee Chair pointed out that when looking at Continuous Distribution model slide, the colors indicate a priority characteristic that can be included. To the kidney discussion, for example, if the community decided that being a child was an important criterion for pediatric kidney that can be assigned a certain weight on the composite score. The Geography Committee specifically named pediatrics as a variable that could conceptually be included. However, one comment was that the feeling on the Kidney Committee is that KAS already gives pediatrics priority, so the priority for pediatrics is built into where they fall in the sequence for KAS. But if modeling shows children are not advantaged, then the argument can be made that just changing the distribution area and not changing KAS regarding pediatrics is not enough.

The Kidney Committee is currently looking mostly at the Continuous Distribution model. This framework, however, is a longer-term recommendation after implementation of some shorter-term solution that is compliant with the Final Rule. The models that are currently being done by the organ-specific committees are for fixed circle approaches, as posted in Basecamp, which may evolve to a better outcome in the future.

One suggestion was to include in the formal response to the Geography Committee should be the pediatric priority options discussed at this meeting. The Chair asked members to think about the frameworks as to which would allow for the most equitable distribution framework and put aside the current consideration of KAS and pediatrics.

Next steps:

Each member should review the Geography Committee's proposal and share their thoughts with the Committee leadership on which of the three would be most appropriate in relation to pediatrics within the next week or so. Leadership will submit a formal response from the Pediatric Committee.

Upcoming Meetings

- 3rd Wednesday of every month, 4-5 pm EST
- November 6, 2018, in-person meeting in Chicago
- March 19, 2019, in-person meeting in Richmond