OPTN/UNOS Patient Affairs Committee
Meeting Minutes
October 16, 2018
Conference Call

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Introduction

The Patient Affairs Committee (PAC) met via Citrix GoToTraining teleconference on 10/16/2018 to discuss the following agenda items:

1. Fall 2018 Public Comment Proposal Review

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

1. Fall 2018 Public Comment Proposal Review

Unanimously, the PAC wholeheartedly supports a proposal that facilitates broader distribution of not just livers, but all organs, and thus minimizes the significance of geography in allocation. Although there was still some residual confusion about the use of concentric circles in light of the 3 frameworks recently out for public comment; a majority understood the constraints within which the Liver Committee had to make rapid changes. The PAC supports a solution that:

- Prioritizes the sickest candidates first
- Promotes utilization and mitigates discards
- Does not prolong the allocation process
- Considers recipient/graft outcomes

The PAC was evenly split regarding whether the Broader 2 Circle (B2C) or the Acuity-based Model was the better solution.

Those favoring the B2C tended to also work in the transplant or OPO profession, or had other fiduciary experience, so were sensitized to cost concerns. This cohort felt this model balances equity in access and prioritizing the most urgent patients first while optimizing successful organ transplants, avoiding organ wastage and mitigating costs. These members emphasized concerns other transplant professionals have cited pertaining to cost increases. Members acknowledged that although beyond the OPTN's purview, reimbursement should be addressed with all payers, not just by CMS to justify and document that patients, even sicker ones receiving transplants sooner than those under the current allocation system, can return to healthier lifestyles and ultimately reduce their cost of care over an extended period of time. A few members felt the OPTN should broach this subject with third-party payers. However, the average patient has no knowledge of the fiscal impact these changes will have to programs (or OPOs), or the downstream financial effects. The PAC did acknowledge that if the cost increases were so significant that they caused a transplant program closure, this could impact access. In terms of circle size, the PAC continues to seek a firm recognition that the variable of concern is really time, not distance. Should this system be adopted, some members supported a MELD thresholdof 29, based upon increased mortality risk of the other options. Other members supported a higher threshold, such as 32, which is what the OPTN Board of Directors approved in December 2017.

Those who supported the acuity model felt this system would provide a more equitable distribution of livers based upon Median MELD at Transplant (MMaT) and Waitlist Mortality Rates. From a patient perspective, the PAC felt this model was more equitable and in line with

the Final Rule, but acknowledged it appeared the chief downside was cost. They also debated whether outcomes would be better (transplanting sicker patients earlier, before they are too sick to be transplanted or die on the waiting list) or potentially negatively impacted (from the effects of potentially longer ischemic times, or transplanting sicker candidates). Ideally, neither cost nor geography would disadvantage candidates.

There was mixed support for extending the Closed Variance for Allocation of Blood Type O Deceased Donor Livers in Hawaii to Puerto Rico (PR). Those who favored applying the variance to PR felt it was reasonable as the geographic challenges for these non-contiguous states were likely similar. In addition, there was some support for further extending a variance to Alaska and other areas in which there is not a transplant hospital w/in the 500 nautical mile circle (perhaps extending the allocation area to a slightly larger area, e.g. an additional 100 or 200 nautical miles). However, some members felt that PR was not in the same position as Hawaii, and was not at as much of a disadvantage. Others proposed revisiting this question as part of the post-implementation monitoring.

While not directly related to the proposal decision requested, the PAC emphasized education, not only for the transplant community, but particularly for the general public and patients. As the OPTN modifies the geographic distribution for the other organ systems, a proactive messaging strategy would be helpful to ensure public trust in the organ allocation system, promoting equity and fairness, and encouraging donation.

Finally, and not specific to this proposal, the PAC continues to encourage all OPTN committees to write policy proposals at a level an average candidate or recipient would understand. This is essential to more patients submitting feedback. A 79-page proposal written in “professional speak” intimidates and discourages members of the general public from commenting on these policy proposals. If the entire proposal cannot be written in plain language, we would advocate for an accompanying “layman’s abstract” or summary.

PAC members asked the following questions, which were answered to the satisfaction of the group:

- **Q:** Most living donor recipients do not receive their transplant based on their MELD or PELD score, because they are often recipients of directed donations, where the donor names the recipient rather than the recipient being allocated following a match run. The Liver Committee is proposing excluding these donors’ from the calculation of MMaT and MPaT because the scores at transplant for these recipients tend to be outliers. Why?
  A: These are being excluded as these candidates are typically transplanted at a lower MMaT, and may disadvantage other patients if they were included in the system that calculates MMat and MPaT.
- **Q:** How exactly will the B2C vs Acuity model improve mortality rates on waitlists?
  A: The expected survival on the waitlist was calculated to have improved under these model because patients who would have been too sick to be transplant, or were at highest risk to die while waiting, will be transplanted.
- **Q:** How will split livers be allocated?
  A: Exactly as they are today.
- **Q:** What timeframe did the modelling cover?
  A: The modelling included transplants conducted over a year’s time.
- **Q:** If the pediatric list is exhausted nationally, then would the offer come back to adult allocation and start over?
  A: Yes, the offers will be extended to adult candidates after pediatric candidates, as is done today.

- **Q:** If travel is restricted due to weather-related events, is there a contingency distribution model in place so discards do not occur due to weather related incidents? Would the organ then be allocated within a non-fly area 150 miles?
  A: There is not. Usually this is not an issue; it is rare that procurement teams can't get an organ to a potential recipient. Sometimes the patient can't travel. Teams typically have a robust back-up plan so organs do not go to waste.
- **Q:** What is the time table for implementation?
  A: The National Liver Review Board is expected to be implemented in the first quarter of 2019, and the allocation changes will take effect after that.

Upcoming Meeting

- October 16, 2018