

## **OPTN Kidney Transplantation Committee**

### **Meeting Summary**

**April 20, 2020**

**Conference Call**

**Vincent Casingal, MD, Chair**  
**Martha Pavlakis, MD, Vice Chair**

### **Introduction**

The Committee met via teleconference on 04/20/2020 to discuss the following agenda items:

1. Medical Urgency Discussion, Language Review and Vote

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

#### **1. Medical Urgency Discussion, Language Review and Vote**

UNOS staff gave an overview of the Committee's previous discussions and the current remaining topics for the medical urgency proposal, followed by Committee discussion.

#### Data summary:

A summary of the previous call on 4/2/2020:

- The Committee reviewed comprehensive analysis of public comment feedback
- The Committee decided to leave "imminent loss" definition in proposal
- The Committee decided that medical urgency priority was appropriate across classifications
- The Committee decided that retrospective review was most appropriate and decided to change language from Committee "may review" to "will review"

The Committee still needs to resolve the following questions:

- Can we add a "Medically Urgent Local Pediatric" classification?
- Should language be added to indicate that pediatric candidates may contraindicate?
- Should we change the name to "Elevated Medical Priority?" Does it add value?
- Should a candidate have to qualify for primary waiting time in order to qualify for medical urgency?
- Should time at medical urgency status be transferrable among transplant centers, similar to primary waiting time?

The staff provided an update on the sentiment of board members following board outreach.

Board members had the following concerns:

- Other organs have a review board
- People will abuse a retrospective process because it will not be enough of a deterrent
- The current definition applies only to exceptionally rare cases and patients that are not able to have vascular access will not have good outcomes with a transplant
- There would be enough time for a small body of people to prospectively review and "cross examine" if attempts did not seem sufficient

- A lot of people will try to use this process who would not normally have gone through the current process because it is easy and available
- The current policy does not have strong enough language and it will be abused

Summary of discussion:

The Chair commented that they believed the current proposal had enough oversight to inhibit gaming.

Another member expressed that they felt very wary about the idea of a review board where members who were not familiar with the case and patient would begin to weigh in on the details to determine classification of medical urgency.

A member of UNOS staff shared that several board members expressed concerns and there was a likelihood that there may be an amendment introduced at the board meeting if the proposal went forward as is.

One member of the Committee asked if the Committee should craft the proposal based on what they felt was best or on what a few board members would like.

The previous UNOS staff member replied that the Committee should vote on what they felt was best while also keeping in mind that part of the policy development process is approval by the board and therefore the Committee should consider how to approach these concerns.

The Vice Chair commented that it is important to remember that the current medical urgency process is done on a local level and is based on trust between centers in the donor service area (DSA) and that much of the fears of gaming and abuse of a national system is due to the expansion of that process from the local level. The Vice Chair expressed that they did not believe this would actually lead to more gaming and that with time the community would recognize that in time as well.

Another member of the Committee asked what logistical implications would be for a prospective review.

Another member of the Committee expressed that they did not feel it was a problem to switch to a prospective review and if that made the proposal more favorable to the board and community then the Committee should consider switching. Another member expressed that while a national review board system would have more volume than any individual DSA that the amount of concern in the community about gaming and a lack of oversight or consequences merited considering a switch to a prospective review.

One member commented that it may be unreasonable to have one national review board review every case and rather suggested the Committee consider a system that allowed a different review board for programs within a certain radius, such as 250 NM, as they would be the ones most affected. A member of UNOS staff indicated that in the new allocation system, there would be so many different allocation circles some of which overlap that it would be too complicated to manage and operationalize a different review board for every potential circle.

Another member shared that over the course of twelve years in their area of the country, there has not been a case that has been applied for medical urgency that did not receive it. The member asked if anyone else on the Committee was familiar with a case that did not receive medical urgency.

The Chair commented that the current concern is that local medical urgency is a prospective review and that process discouraged members from attempting to game the system, however the concern is once the review process switches to retrospective that members may attempt to abuse the new system. The Chair also shared that the Committee should not make policy motivated by fear of gaming but rather policy that makes sense. The Chair noted that the subcommittee had discussed a prospective review and

some of the complications of a prospective review including the composition of a review committee, how to respond quickly to the applications in real time, and the desire to limit the classification to patients who did not have the time to wait for a review.

The Vice Chair shared their perspective as a member of the subcommittee. One of the concerns that led to a retrospective process is the amount of time it would take for a national committee to review a case compared to a smaller DSA that could be more nimble and responsive. The subcommittee worried that in a hypothetical scenario where a patient's application was submitted on a Friday afternoon of a holiday weekend, approval could take four or five days and there could be the potential for the patient to miss out on organ offers while waiting for approval or even die.

Another member commented that in their area of the country the medical urgency approval has taken four to five days for approval. Additionally, the member noted that the current national liver review board is able to review cases in about two to three days. This member noted that other critical organ systems are able to implement a prospective organ review including heart and that a prospective review makes more sense for this proposal.

One member shared that they had once turned down a request for medical urgency because the patient had not lost all dialysis access. The member shared that they believed some members might try to apply for the medical urgency classification when their patient did not meet all the criteria. The member shared that if this definition was so narrow that the classification would be rare then the Committee did not have to worry about being overwhelmed by cases in a prospective system.

The Chair noted that their experience with the national liver review board was different and some cases were much lengthier. The Chair also noted that initially there were concerns about the operational logistics involved in the Organ Center that pushed the Committee away from a prospective review.

A member of UNOS staff responded that operationalization of policies is always difficult and something that the Committee would need to consider, however it should not be the sole reason the Committee does not pursue that option. The staff member recommended that the Committee should determine policy on what they felt was right and then resulting operational concerns could be addressed. In addition, the staff member emphasized that this was feedback from two board members and not the entire opinion of the board.

The Vice Chair explained that they did not have any clinical objections to a prospective review but that the concerns about operationalization and the logistics of reviewing the cases had been the largest deterrent toward this approach, however if these concerns could be addressed then they supported changing the system. Two members of the Committee agreed with this sentiment.

A member from HRSA suggested that the Committee could address the communities concerns about gaming by introducing a form of "informal probation" for programs who submitted two or more applications that did not meet the criteria within a given time frame. The programs placed on "informal probation" would have then be switched to a prospective review program so to implement stronger screening. The member felt this would allow the Committee to avoid all the logistical concerns with a permanent medical review board while also implementing stronger deterrents for those who would abuse the system.

A member of UNOS staff reminded the Committee that in addition to the prospective review, there were additional concerns about the current medical urgency definition from members of the board.

The Chair asked what would be the policy development implications if the Committee switched to a prospective review and how that would play into the implementation of the new allocation system in December. A member of UNOS staff explained that the Committee should determine what they felt was

the best approach and then the logistical implications could be determined later. Another member of UNOS staff asked if a change to prospective review would lead to another public comment proposal and cycle. The first staff member replied that it would need to be determined whether a prospective review is a “logical outgrowth” of the public comment proposal.

The Vice Chair asked what the next step for the Committee would be. The Chair wondered if the Committee could vote on the prospective versus retrospective review.

A member UNOS staff explained that with the current poll question, yes would represent support for proceeding with a retrospective review or no would represent a desire to modify the proposal, potentially for a prospective review.

Committee Poll:

**Do you support sending the Medical Urgency proposal to the OPTN Board for consideration?**

65% - Yes (11 responses)

35% - No (6 responses)

The Chair felt there was enough support that the Committee could move forward with the proposal with a retrospective review system. Vice Chair pointed out that while the Committee was divided that there was a majority that favored moving forward with a retrospective process but noted that there is always a possibility that the board could amend the proposal.

#### **Intra-classification medical priority**

A UNOS staff member posed the following question for committee feedback: Does the Committee believe that this is an appropriate and sensible approach to give priority to medically urgent candidates over non-medically urgent candidates within classification that have a higher priority than the Medical Urgency classification? Should classifications three and four (national offers for 100% highly sensitized candidates) also have intra-classification priority?

Two members indicated support for adding medical priority for the six classifications above the general medical urgency classification. The Chair also indicated support, noting that while the concept seemed complex it was intuitive.

A UNOS staff member posed the following question for committee feedback: Is there a possibility that a candidate contraindicates to all forms of dialysis access, does not have a qualifying GFR but should still be considered medically urgent?

Several committee members expressed support that a candidate must qualify for primary waiting time in order to qualify for medical urgency. There was no opposition from any committee members.

A UNOS staff member posed the following question for committee feedback: Should time at medical urgency status be transferrable among transplant centers, similar to primary waiting time?

Two members answered that no a patient shouldn't take their time with them to a new center. One member wondered if a patient really is medically urgent if they have the time to re-list at a different center. Another member shared that they could envision a scenario in which a patient's health insurance changed and caused them to switch centers.

Another member asked what would happen in the scenario that a patient was multi-listed. The member wondered if the patient would receive the medical urgency priority at all the centers at which they are listed or only one center. A UNOS staff member shared that the policy language would not need to explicitly address this situation but it is important information to know for programming.

Next steps:

UNOS staff will contact the Committee to find a date in the next week to finish the discussion and vote on policy language for the proposal.

**Upcoming Meeting**

- To Be Determined