

OPTN Kidney Transplantation Committee

Meeting Summary

April 22, 2020

Conference Call

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

Introduction

The Committee met via teleconference on 04/22/2020 to discuss the following agenda items:

1. Medical Urgency Discussion, Language Review & Vote
2. Medical Urgency and Alaska Transition Procedure Discussion
3. Geography Transition Procedure Discussion

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

1. Medical Urgency Discussion, Language Review & Vote

UNOS staff gave a brief overview of the Committee's previous deliberations and the current policy language for the Committee's approval.

Data summary:

The following short summary from the previous meetings was provided:

- 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, changing language from Committee "may" review to the Committee "will" review
- The Committee voted to move forward with retrospective review and proposal as written
- The Committee agreed that intra-classification priority of medically urgent candidates was sensible
- The Committee agreed that candidates should be eligible for waiting time in order to be eligible for medical urgency

UNOS staff presented the following questions for the Committee's consideration:

- Should language be added to indicate that pediatric candidates may contraindicate?
- Should we change the name to "Elevated Medical Priority?" Does it add value?

Summary of discussion:

The Chair commented how the initial policy language was crafted to allow for pediatric programs to determine if there was a contraindication to lower extremity access but that if the language was unclear, the Committee could add more specific language.

The Vice Chair explained that there had been a concern from the pediatric community that some less experienced teams may believe that they must attempt dialysis access from all areas indicated in the language before qualifying for the medical urgency definition.

A UNOS staff member explained that the Committee could also choose to include specific educational guidance for this topic upon the policy implementation instead of adding policy language.

One member noted that most two year old patients can't receive dialysis in either their upper or lower extremities, and that the drafted policy language currently contains the clause "or has a contraindication to". Two members of the committee who work with pediatric patients explained that most pediatric transplant physicians would understand that certain areas of dialysis access are naturally contraindicated in their patients without need for additional language but that this issue could be discussed in the education.

Multiple members supported addressing this issue with educational guidance rather than any change to policy language. The Chair confirmed that the Committee agreed to leaving the drafted policy language as is and providing additional explanation through educational guidance upon implementation.

A member of UNOS staff drew the attention of the Committee to the feedback from the PAC regarding the term "medical urgency" in preference for "elevated medical priority".

The Chair commented that the Committee was in favor of keeping the term "medical urgency" as it maintains consistency with the previous classification done at the donor service area (DSA) level and that it maintains a type of clinical specificity that is lost with "elevated medical priority".

A member of UNOS staff raised a feedback question: "Why does the Committee feel that the definition as written is appropriate?"

The Chair commented that the goal of the policy is to keep the general idea of current medical urgency policy but to make it compatible with the removal of DSA from kidney allocation.

A member of UNOS staff raised a feedback question: "Why is the imminent loss definition necessary?"

The Vice Chair continued to note that this new policy would be attempting to reconcile the varied local requirements by DSA. They noted that in the New England region, the requirements were extremely strict but that other regions had less stringent requirements. The subcommittee felt that this definition was a happy medium between the strict and the flexible requirements around the country. Specifically the requirement of "imminent loss" exists in certain regions currently and allows for those regions to continue with familiar requirements. Additionally, the Vice Chair added that the subcommittee felt that complete exhaustion would be a difficult national policy to enforce. The inclusion of imminent allows for patients who are on their last limb of dialysis access without including patients who do not have an urgent need. The Vice Chair elaborated that there are circumstances where patients are able to receive some dialysis through catheters as a last resort but are really struggling. Furthermore, the Vice Chair noted that the current definition allows for physicians to make clinical judgements regarding their patients.

The Vice Chair also spoke in favor of keeping the current term of "medical urgency" over "elevated medical priority" as changing the terminology seems unnecessary and inconsistent with standard terminology.

One committee member wondered if policy language was going to include any time limits for the medical urgency classification. A member of UNOS staff explained that after implementation of the policy and case reviews by the Committee, they could determine if any time limits are warranted.

After reviewing the policy language, the Committee took a vote on the proposal.

Do you support the Medical Urgency proposal moving forward for OPTN Board Consideration?

- Yes, 94% (15 responses)

- No, 6% (1 response)

Next steps:

The proposal will be presented to the OPTN Board of Directors in June.

2. Medical Urgency and Alaska Transition Procedure Discussion

A UNOS staff member explained a Final Rule requirement regarding consideration of transition procedures, followed by Committee discussion.

Data summary:

A UNOS staff member presented the context of a Final Rule requirement regarding transition procedures.

42 CFR 121.8(d)(1): “When the OPTN revises organ allocation policies under this section, it shall consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies. The transition procedures shall be transmitted to the Secretary for review together with the revised allocation policies.”

Summary of discussion:

A member of UNOS staff gave an example of a transition plan that was used for the SLK policy wherein programs could add in patient information into the system before implementation so they would not lose their status. The staff member explained that allowing programs to input patient’s information before implementation is one example of a transition procedure the Committee could consider.

One member commented that patients could be backdated to when they were approved for the medically urgent classification by their DSA rather than having time begin accruing on January first with implementation of the new system.

Another member commented that those patients who had been previously listed for medical urgency should be prioritized and therefore backdated for waiting time. Several members also agreed. One member wondered if there would be discrepancies due to the fact that each DSA has different requirements and thus some candidates may have completely exhausted all dialysis access whereas others still maintain some access.

A UNOS staff member commented that it would be up to the discretion of the Committee whether patients who previously met the requirements in their DSA would need to meet the new policy requirements or not. One member commented that it would be difficult to allow some patients to maintain their status based on the former local requirements while other patients must meet the new requirements under the new policy at the same time. A couple of members wondered if it would be unfair to patients who previously qualified for medical urgency at their DSA to lose the classification due to the new policy.

A UNOS staff member explained that it was up to the discretion of the Committee to decide if a transition plan is needed and the Final Rule only requires the Committee to consider it.

A member commented that this situation may resemble when the SLK policy requirements changed and wondered how the transition dealt with patients who previously met requirements but did not meet the ones in the new policy language. A UNOS staff member said they can follow up on that.

The Chair wondered if the Committee could get data from the various DSAs regarding how many patients are currently listed as medically urgent as that could give insight as to how many patients could be impacted.

A UNOS staff member asked the Committee for their opinions regarding a transition procedure for the Alaska policy.

Committee members commented that it does not seem that any transition policy would be necessary in this instance particularly because there are no transplant programs in Alaska. Another member commented that most if not all of the organs are currently being transported via the Seattle-Tacoma airport, as suggested in the new policy, and therefore this policy would not have as great an impact on a specific patient population.

Next steps:

The Committee will continue discussing transition procedures for the medical urgency proposal pending approval by the OPTN Board of Directors at their June 2020 meeting.

3. Geography Transition Procedure Discussion

The Committee reviewed and discussed next steps for the Board approved kidney allocation policy eliminating the use of DSA and regions.

Summary of Discussion:

The Kidney Transplantation Committee's Eliminate the Use of Donation Service Area (DSA) and Region in Kidney Allocation policy proposal was passed by the OPTN Board of Directors in December 2019. The anticipated implementation of the policy will be in December 2020.

The Final Rule requires that when the OPTN revises organ allocation policies, it should "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies."¹ . Although the Committee discussed the impact the revised policy may have on patients, the Committee wanted to discuss the following questions and determine if a transition procedure should be considered:

- Are there any populations that may be treated less favorably under this new allocation policy than they would have been treated under the DSA based policy?
- If so, is a transition plan for these populations necessary?

A member noted that this policy would not particularly impact any specific patient population and suggested that a transition procedure would therefore not be necessary. Another member spoke up in agreement. Committee members commented that it did not seem that this proposal would benefit from a transition procedure.

Next Steps:

The Committee's conclusion that transition procedures for this policy is not required will be synthesized and packaged with the feedback received by the OPTN Pancreas Transplantation Committee and be reported to the OPTN Board of Directors for their consideration at their June 2020 meeting.

¹ 42 C.F.R. §121.8(d).

Upcoming Meeting

- May 18, 2020