# OPTN Kidney Transplantation Committee
## Meeting Summary
## April 2, 2020
## Conference Call

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

### Introduction

The OPTN Kidney Transplantation Committee (the Committee) met via Citrix GoTo teleconference on 04/02/2020 to discuss the following agenda items:

1. Alaska Public Comment Sentiment Analysis & Vote
2. Update to Kidney Donor Profile Index (KDPI) & Estimated Post Transplant Survival (EPTS)
3. Wait Time Modifications for Non-Dialysis Patients During COVID-19 Crisis
4. Medical Urgency Public Comment Sentiment Analysis & Vote

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

### 1. Alaska Public Comment Sentiment Analysis & Vote

The Committee reviewed the public comment sentiment towards the proposal and voted on final policy language.

Data summary:

The proposal was supported in all regions. The proposal was supported by the Minority Affairs, Organ Procurement Organization (OPO) and Operations and Safety Committees. The proposal was supported by Association of Organ Procurement Organizations (AOPO), American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), and American Nephrology Nurses Association (ANNA).

Summary of discussion:

One member commented that in Region 7 there was unanimous support and that this is a very straightforward proposal.

The committee voted unanimously to support the proposal being sent to the OPTN Board.

Next steps:

The proposal will be sent to the OPTN Board at the June Board meeting.

### 2. Update to Kidney Donor Profile Index (KDPI) & Estimated Post Transplant Survival (EPTS)

The UNOS research department presented their annual update of the KDPI and EPTS tables for the Committee's review and approval.

Summary of discussion:

One member asked if there was research that analyzed the trends of KDPI. A UNOS staff member replied that a retrospective review had been done about ten years ago by a group outside of UNOS.

The Committee took a vote on the new KDPI tables. The vote was unanimously in support.

One Committee member noted that it seemed trends had been shifting in a consistent direction for some time. The Committee member wondered if there should be a hard threshold rather than a relative one. A UNOS staff member explained that decision is a clinical one that the Committee could discuss and make. One committee member asked for clarification if the distribution for the 2019 data had a statistically significant difference from the data in 2018. The UNOS staff member clarified that the EPTS data was not statistically significantly different but the KDPI data was. One member asked what the total number of patients are that fall in the new 20% threshold. The UNOS presenter explained that it is hard to estimate how many patients will be impacted by this change due to the constant changes in the waitlist, however the percentage is likely around 1%.

Another member asked regarding the cause for the shift in EPTS value and wondered if it is the same for the past few years. Another member wondered how many more people would now meet the threshold compared to 2018 or 2014. The UNOS presenter did not have exact figures, however they explained that the overall number of patients on the waiting list is also growing every year and it would be expected for the number of patients qualifying for the 20% threshold of EPTS would also grow proportionally. The UNOS presenter stated that the Committee could dete3rmine if they wanted to continue prioritizing the top 20% of the wait list or if they wanted there to be a set threshold.

The Committee took a vote on the new EPTS tables. The vote was unanimously in support.

**3. Wait Time Modifications for Non-Dialysis Patients During COVID-19 Crisis**

The Committee provided input on proposed emergency modifications to policy in order to address the needs of patients during the pandemic.

Data summary:

OPTN Policy 8.4 contains requirements for initiating kidney waiting time

- For adult candidates not on regularly administered dialysis, a creatinine clearance or GFR <=20 is required
- Pediatric candidates do not have clinical criteria, but must complete full registration

The COVID-19 crisis is deterring or preventing candidates from outpatient laboratory testing

Preemptive (non-dialysis) candidates are a sizable part of the kidney waitlist

- Roughly 20% of current kidney candidates on the wait list at any given time were added to the list without being on dialysis
- Approximately 1,000 non-dialysis new registrations per month nationally

The purpose of the proposal is to not disadvantage potential candidates who can't get tested due to the COVID-19 crisis and create a pathway for waiting time modifications for these candidates once they are added to the wait list.

The current proposal:

- Transplant programs can submit a wait time modification request to reset wait time start date, once all registration testing has been completed
- OPTN will set new wait time start date, using a process similar to the one used under OPTN policy 3.7
- The application for modification will require certification that the COVID-19 crisis prevented normal registration

Summary of discussion:

One member commented that their program is doing virtual assessments and that getting the patient's glomerular filtration rate (GFR) is not as difficult as getting the patient's human leukocyte antigen (HLA) type. The member wondered what happens in the instance that a patient on initial intake has a GFR of 22 but cannot finish the evaluation due to the pandemic. The Committee Vice Chair expressed that the current proposed language was very fuzzy regarding what to do in the circumstance of a patient who did not have a qualifying GFR before a program had interruptions to their assessments but had a qualifying GFR after the pandemic and that it would be difficult to guess which date the patient had a qualifying GFR. Due to this the Vice Chair suggested the policy allow all patients with GFR measurement under 25 within the last six months to modify their waiting time to backdate to the date of decision to list. Another member stated that it would be difficult to guess when a patient's GFR fell under the qualifying threshold of 20 and that each patient's GFR decline can vary so widely that the suggested modification may not be the most fair given that some patients GFR measurements take months to fall under a certain threshold when others take weeks.

The Vice Chair suggested that the Committee could recommend that programs first take patients GFR before all else and then the modification could back date wait time to a qualifying GFR measurement rather than the date of a selection committee. Another member agreed with that suggestion.

One member said that the impact of the policy depends on how long the pandemic impacts wait time and three months may not be significant enough to warrant a new modification policy. The Vice Chair disagreed and indicated that it would be helpful for patients who currently have a qualifying GFR but have not finished their evaluations to be listed. In addition, the Vice Chair felt this policy could help from a logistical processing standpoint due to the amount of backlog that will build over the coming months.

One member worried that asking physicians to estimate a date of when their patient had a qualifying GFR would not be accurate and incentivize abuse of the system by estimating the maximum amount of time possible. The Vice Chair expressed the belief that some type of policy to allow those with current qualifying GFR measurements to modify their wait time is necessary but agreed that it could be too problematic to ask physicians to estimate dates for candidates who do not currently have a qualifying GFR.

The Chair spoke in support of some type of policy due to the fact that some tests would be postponed for close to 6 months. The Chair agreed that while there may be risk of people gaming the system, it shouldn't deter a policy entirely.

One member suggested that if a patient had a GFR lower than 20 by December 31st, they should get all their accumulated waiting time but if not then they would not get the waiting time. Another member commented that this suggestion seemed a little complicated and that they also had concerns about gaming.

One UNOS staff member asked for clarification on the committee's desires for the emergency policy. Two members felt that the policy should not include an option for physicians to estimate when a patient had a qualifying GFR. One member supported the idea that the patient can begin accumulating wait time from the time that an internal selection committee approves the patient for listing with as much documentation as possible. A UNOS staff member asked if the committee or a subcommittee would review these patients for wait time approval or if policy would have such explicit documentation requirements that non-clinical UNOS staff could review these requests. The Chair felt that if language was explicit enough and signed off by a medical or surgical director the UNOS non-clinical staff could review the requests.

A UNOS staff member provided the following summary of the proposed policy. The policy would address patients who have a qualifying GFR but are not able to be listed at the moment because they have not

completed the evaluation process. This policy would allow the program to submit an application for modification to backdate the waiting time to the date of the GFR measurement. This application would need the signature of the patient's doctor or surgeon and would be reviewed by UNOS staff.

One member asked what would happen in the scenario that a patient had a qualifying GFR in December of 2019 and their initial evaluation was scheduled for March 2020 but due to the pandemic was not seen and reviewed until September 2020. The member asked when the patient's waiting time would begin. The Vice Chair expressed that many centers have moved to virtual telehealth appointments and potentially even virtual meetings for selection committees which would prevent this kind of scenario. The first member expressed that if centers do not offer virtual selection committees or evaluations then the patients could be disadvantaged. The Chair felt this policy would not back date before the date of approval by the Executive Committee. A UNOS staff member suggested a set period of time between a qualifying GFR and review by a selection committee such as 90 days.

The Chair questioned why GFR was the main measure for this policy. A UNOS staff member explained that in order for this policy to be consistent with current wait time policy, a qualifying GFR measurement is key.

A nephrologist member mentioned that some patients may be disadvantaged because they are not attending the appointments that would measure GFR and lead to a referral for transplant. Another member asked if backdating to the date of a qualifying GFR measurement would be consistent with current policy. A UNOS staff member explained that policy allows candidates to begin accumulating wait time from the GFR measurement date only if the candidate has already been registered on the wait list. The Committee agreed that the modification policy should only backdate to the date of the approval of an internal selection committee for a candidate that has a qualifying GFR rather than the date of the qualifying GFR measurement.

Another member spoke in concern of patients that may be disadvantaged by not being referred to transplant programs. The member felt that backdating to the date of a qualifying GFR measurement would be the best way to mitigate patient disadvantage. The Committee Vice Chair felt that it was outside of the scope of this particular proposal. Another member was concerned that backdating the waiting time that far may risk gaming of the system.

Next steps:

The proposal will be presented to the OPTN Executive Committee for approval.

**4. Medical Urgency Public Comment Sentiment Analysis & Vote**

Data summary:

**Regional Sentiment**

All regions supported the proposal, albeit with varying levels of support. Notably Region 3 and Region 8 had a large percentage of members who voted neutral or oppose.

Membership and Professional Standards (MPSC), Patient Affairs (PAC) and Pancreas Committees all reviewed the proposal. MPSC and Pancreas Committees supported the proposal while PAC opposed the proposal.

**Society Sentiment**

**American Society of Transplant Surgeons (ASTS)**

The American Society of Transplant Surgeons (ASTS) supports this policy proposal. It defines the criteria for medical urgency in kidney transplantation in a more comprehensive and coherent fashion to address

the needs of these unique patients. ASTS believes the priority for the new classification for medical urgency should be confined to the 250 Nautical Mile (NM) circle.

ASTS also contend that priority should be given only to medically urgent candidates inside the circle to: 1) avoid delayed graft function in patients with poor dialysis access and 2) minimize cold ischemic time. As this is relatively unusual, the majority of these patients would be transplanted promptly using only the 250NM circle.

Lastly, documentation to ensure patients are properly assessed for this classification should include: 1) recent notes from interventional radiology or surgery with imaging confirming thrombosis or severe, untreatable stenosis of the vascular structures and 2) evidence the patient has received a translumbar or transhepatic catheter.

**North American Transplant Coordinators Organization (NATCO)**

NATCO supports the efforts to address the obsolescence of current policies addressing medically urgent candidates {…} with strong consideration given to utilizing a prospective review process in place of a retrospective review. NATCO feels priority placement seems appropriate.

NATCO strongly recommends that the process of retrospective review be replaced with a system of prospective review to include examination of documentation by appropriately qualified physicians appointed to an expert review board, or by a sub-committee of the Kidney Transplantation Committee.

NATCO recommends a Status 1A classification, similar to that used in liver allocation, could be assigned to candidates who are completely out of dialysis access.

**American Society of Transplantation (AST)**

AST is cautiously supportive of efforts to standardize the rare instances of “medical urgency”. There is no support for any priority outside of the 250NM circle. AST has concern regarding the retrospective nature of the review of the ‘Medically Urgent” status. AST is concerned that the proposal as written, does not allow for a child with failure of dialysis access (therefore meeting the definition of “medically urgent”) to gain any priority over a child who is listed but stable on dialysis. In addition, the definition doesn’t explicitly consider that pediatric patients are poor candidates for lower extremity dialysis access

**Association of Organ Procurement Organizations (AOPO)**

AOPO supports the proposed criteria for a medically urgent patient as proposed and commends the Kidney Transplantation Committee for establishing a consistent definition to be applied nationally.

AOPO supports the proposed placement of medically urgent candidates, with donor KDPI establishing the match run classification of the medically urgent candidate. AOPO further supports the proposal that, when two medically urgent candidates appear on the match run, the patient with the greater number of days as a medically urgent candidate receive higher priority.

AOPO agrees with the Committee’s current proposal to allocate to medically urgent candidates only within the 250 nm circle and does not support expanding allocation of medically urgent candidates further.

AOPO respectfully asks for monitoring of the policy change to include the number of candidates listed as medically urgent and the trends in those listings; the number of candidates transplanted as medically urgent; outcomes of such transplants; and the percentage of time any organ allocated under this policy was used in the intended recipient.

**Board Sentiment**

A UNOS staff member provided an overview of the board preview call.

Some board members had concerns that a retrospective review process is not sufficient for these cases. Some board members had concerns as to whether exhaustion of complete loss of vascular access to dialysis is possible as several had never seen a case. Some board members had concerns about including "imminent loss" of access in definition. It was noted that some centers do not perform the translumbar and transhepatic IV catheters. Members felt that this term could cause further "gaming". One board member suggested two classifications, one for complete exhaustion and one for imminent.

**Themes in Public Comment:**

There were the following concerns with the medical urgency definition:

- Concerns with including "imminent loss" options for several reasons
    - Some centers don't have expertise to perform the translumbar and/or transhepatic IVC catheter methods
    - Concerns about "gaming" increase when including "imminent loss" definition (this was especially feedback relayed by patients as well as other member types)
- Concerns with definition not being pediatric-specific
    - Definition doesn't explicitly consider that pediatric patients are poor candidates for lower extremity dialysis access
- Concerns with "Medical Urgency" definition altogether
    - Several comments from practitioners that have never seen complete exhaustion of dialysis
- PAC recommends changing the name of medical urgency to "elevated medical priority"

There were the following concerns with the medical urgency priority:

- Concerns that priority doesn't consider local pediatric candidates that are medically urgent
    - It was suggested to prioritize medically urgent local pediatrics over non-medically urgent local pediatrics
- It was suggested that if these cases are truly rare, perhaps priority should be higher
    - Suggestions that medical urgency priority should be placed above local pediatrics and living donors

There were the following concerns about medical urgency oversight:

- Concerns about a retrospective review process
    - Concerns that this will not address "gaming"
    - Concerns that a retrospective review process will not effectively address medically urgent candidates that turn down offers
    - Several suggestions for a prospective review process for these cases
- There were suggestions for documentation
    - Documentation to ensure patients are properly assessed for this classification should include 1) recent notes from interventional radiology or surgery with imaging confirming thrombosis or sever, untreatable stenosis of the vascular structures and 2) evidence the patient has received a translumbar or transhepatic catheter
    - Some believe an independent review from a second transplant program should be necessary

<u>Summary of discussion:</u>

One member noted that there seemed to be several concerns that the committee needed to address.

The Chair acknowledged that two common themes received in feedback were worries about gaming and a desire for a prospective review. The Vice Chair noted that the subcommittee which created this proposal tried very hard to balance out the strictness of the definition of medical urgency and the level of priority assigned while understanding that because each DSA currently determines medical urgency differently, it is impossible to have one consensus definition. For that reason, the Vice Chair felt that it would be unlikely to find a definition that would please everyone but rather the committee sought to find one that was palatable to both extremes. In response to the board feedback, the Vice Chair indicated that the current definition was chosen precisely because meeting the total exhaustion requirements would be very rare.

One member commented that in Region 2 there was a lot of concern about gaming the system and so the community expressed support for a strict definition wherein a patient must have exhausted all access to dialysis. In addition, the Region 2 community preferred the idea of a prospective review.

Another member pointed out that some of the challenge with the current definition which requires total exhausted access is the medical expertise necessary to place trans hepatic or trans lumbar access can vary between centers. Some centers may not have the medical skill to be able to place all the areas for dialysis access and thus may rule a patient as having exhausted all dialysis access although another physician may be able to provide dialysis access. Another member agreed that this issue was raised in Region 10 and it was suggested that programs could reach out to neighboring centers for help placing these more challenging catheters.

A UNOS staff member asked the Committee for feedback regarding why a medically urgent policy is necessary. The Chair responded that the general support indicates that such a policy is necessary and the current dilemma is regarding the “imminent loss” term included in the definition, as well as the debate between a prospective vs. a retrospective review. One member shared that Region 5 also had concerns about gaming as well as a desire for a prospective review. The member expressed that one way to address these concerns would be to provide more specific oversight with review of these applications and specific consequences for improper behavior. A UNOS staff member agreed and explained that the current policy language said the Committee “may review” and could be changed to “will review”. In addition, current policy language noted that the Membership and Professional Standards Committee (MPSC) may investigate should there be suspicions of improper behavior.

The Chair asked if the proposal would have more support if they changed the review process to prospective. Three other committee members agreed that prospective review would likely receive more support. Another committee member pointed out that a prospective review would be best accomplished if reviewed by the Committee rather than the programs in the area but that could put a responsibility burden on the Committee.

One member questioned if narrowing the requirements would still lead to gaming. The Chair expressed the belief that even with narrow requirements there could be a risk of gaming. One committee member expressed reservations against having the Committee members in charge of determining medical urgency status and the potential risk of a patient dying while waiting for the Committee to review their application. A UNOS staff member wondered if the Committee removed the term “imminent” from the definition but still left the review as retrospective if there would be more support for the proposal.

One committee member asked if there was gaming of the medically urgent classification now. The Vice Chair explained that since the requirements of the classification are different based on DSA there is no data about this at the time. One committee member believed that removing the term “imminent” from the definition may make the proposal more palatable without increasing the risk of gaming the system.

One committee member shared that part of the reason that the term "imminent" was included in the definition is due to the varying requirements in the DSAs, some of which are very narrow. Specifically in New York, the current medical urgency classification application is called a "compassionate request" and that while there are quite a few, they are typically approved by all the programs.

One member noted that in Region 10 there was feedback that while medically urgent candidates need a kidney, they may not need the best quality of kidney and therefore could be prioritized higher within Sequence C and D. One committee member noted that pediatric candidates who qualified for the medically urgent classification received no benefit due to the fact that the classification is prioritized lower than all pediatrics.

One committee member suggested that there could be a time period associated with the medical urgency designation, such as three weeks, after which the status would be withdrawn. One committee member agreed but suggested that the program would need to reapply. Several committee members agreed but suggested a shorter time such as two weeks. One member pointed out that the liver time frame is one week.

A UNOS staff member asked if there were changes the Committee would like to make to the definition, for instance addressing the pediatric feedback regarding contraindication for lower extremity access. A couple of committee members expressed that it would be better left up to the centers to identify and note the contraindications themselves. One committee member spoke in support of adding language making it clear that this definition is for adults and there is an option for pediatric physicians to note if their patients are contraindicated for lower extremity access.

The Chair asked UNOS staff about next steps and the timeline for the Board. A UNOS staff member explained that the proposal was slated to go to the Board in June and the Committee should vote on language at their next meeting. The Chair asked if the proposal would need to go out for public comment again if the proposal was switched to a prospective review. The Chair also asked if creating a pediatric medical priority classification would be a new separate proposal or within the purview of this project. A UNOS staff member replied that establishing the systems framework for a prospective review would be challenging and likely the proposal would need to go out for public comment again, due in part because of the increased logistics. Another UNOS staff member noted that changing the definition of medical urgency would not require another public comment cycle.

The Chair noted that the Committee felt ideally the review would be prospective but wasn't necessary. The Committee feels positive about the definition but would feel better if it was possible to review the data at regular intervals such as six months or one year. Additionally, the Chair felt very strongly that there be some medically urgent system in place when the new allocation policy goes into effect even if the policy is not perfect.

The Committee discussed the possibility of adding in a specific medical urgency designation for pediatric patients. This designation would fall before other pediatric patients in the 250 NM circle. Several committee members supported the idea and suggested the OPTN Pediatric Committee review the changes to the proposal for its feedback.

One member asked what the consequences would be given for improper behavior as the Committee still planned on a retrospective review rather than a prospective review. A UNOS staff member noted that in addition to the Committee reviewing medical urgency designations that the MPSC would also be reviewing applications.

A UNOS staffer outlined the current areas of consensus among the Committee:

- No changes to the current definition of medical urgency

- Maintain a retrospective review process with regular review by the Committee (ex. 6 months or annually)
    - This will have a language change from “may review” to “will review”
- Add a new classification for pediatric medically urgent patients which would occur only in sequences A and B
- Transplant nephrologist and transplant surgeon approval required
- The medically urgent classification is applied when the data is entered into UNet
- The documentation must be submitted to the OPTN within 7 business days
- The cases that do not meet the definition will be reviewed to the MPSC

The Committee discussed noting in the language that pediatrics is a contraindication. Several committee members were opposed to the idea and felt that call should be up to the discretion of the pediatric patient’s physician. Other committee members felt it would be helpful especially for physicians who may not be as familiar.

A committee member suggested placing medically urgent patients at the top of the list on Sequence C above a 100% highly sensitized patient. The Chair disagreed due to the rare likelihood that a medically urgent patient would need a Sequence C kidney. This topic will be revisited on the next call. One committee member suggested adding to the policy language the term “adult patient”. A few members spoke in support of such a change.

**Upcoming Meetings**

- April 20, 2020

**Attendance**

- **Committee Members**
  - Deirdre Sawinski
  - Dev Desai
  - Andrew Weiss
  - Nicole Turgeon
  - Julia Steinke
  - Erica Simonich
  - Nick Salkowski
  - Vinaya Rao
  - Martha Pavlakis
  - Cathi Murphey
  - Ernesto Molmenti
  - Deepak Mital
  - Lisa Matthias
  - Jim Kim
  - Mary Killackey
  - Peter Kennealey
  - Valinda Jones
  - Ajay Israni
  - Joe Ferreira
  - Amy Evenson
  - Vincent Casingal
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
- **UNOS Staff**
  - Scott Castro
  - Tina Rhoades
  - Kiana Stewart
  - Matthew Prentice
  - Roger Brown
  - Julia Chipko
  - Shannon Edwards
  - Chelsea Haynes
  - Ruthanne Leishman
  - Lauren Mauk
  - Sara Moriarty
  - Rebecca Murdock
  - Jennifer Musick
  - Joel Newman
  - Amanda Robinson
  - Wes Stein
  - Ben Wolford

- Betsy Gans
- Nicole Benjamin