

**OPTN/UNOS Kidney Transplantation Committee  
Meeting Minutes  
March 12, 2018  
Chicago, IL**

**Nicole Turgeon, MD, FACS, Chair  
Vincent Casingal, MD, Vice Chair**

**Introduction**

The OPTN/UNOS Kidney Committee met in Chicago, IL on 03/12/2018 to discuss the following agenda items:

1. Public Comment Review: OPTN/UNOS Strategic Plan 2018-2021 (OPTN/UNOS Executive Committee)
2. Public Comment Review: Improving the OPTN/UNOS Committee Structure Concept Paper (OPTN/UNOS Executive Committee)
3. Important Updates for the Kidney Committee
4. En Bloc and Dual Kidney Implementation Questions/Discussion
5. Important Kidney Paired Donation Updates
6. Public Comment Review: Expedited Organ Placement Concept Paper (OPTN/UNOS OPO Committee)
7. Public Comment Review: Change Waiting Time Criteria for Kidney-Pancreas Candidates (OPTN/UNOS Pancreas Committee)
8. Simultaneous Liver-Kidney 6-Month Implementation Update

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

**1. Public Comment Review: OPTN/UNOS Strategic Plan 2018-2021 (OPTN/UNOS Executive Committee)**

The Policy Manager presented the Strategic Plan proposal. The Kidney Committee supports the 2018-2021 strategic plan, but would like the Executive Committee to consider slight changes. There was general consensus in the Kidney Committee that decreasing the outcomes goal from 15% to 10% is not optimal, for strategic planning and public perception. Increasing the number of transplants and the efficiency of getting candidates through the process will have a direct impact on the outcomes goal, but the Committee felt strongly that the outcomes goal should not be decreased. Committee members asked about the 5% difference for some goals from the previous plan to this one, and wonders what direct impact 5% has on the resources of Committee members and UNOS. The current strategic alignment was shown, focusing on current Kidney Committee projects and their resources among the strategic goals.

The Committee thanks the Executive Committee for their commitment to excellence, and seeking substantive comments on the direction of the strategic plan. The Kidney Committee supports the overall direction and measures of the proposed strategic plan, but encourages the Executive Committee to reevaluate the outcomes goal before finalization.

**2. Public Comment Review: Improving the OPTN/UNOS Committee Structure Concept Paper (OPTN/UNOS Executive Committee)**

The Policy Manager presented the Committee Structure Concept Paper. The Kidney Committee supports the aim of the concept paper, which is to increase participation in the policy development process. The Committee did not support the exact concept proposed by the Executive Committee, and discussed various alternatives and solutions. The Committee was receptive to the idea, but ultimately decided that the decisions makers in the concept/process had not changed, and may be more limited.

Adding expert councils that have unlimited number of members will achieve the goal of adding voices to the process, but the Committee wonders how the expert councils will be moderated; how will they function? Without this information, it was hard for the Committee to visualize an effective method of listening to hundreds of members in an expert council. Having such large groups may be detrimental to the forward progress, unless guided with set parameters.

The Committee suggested that expert councils could be advisory panels, made up of smaller groups who have previously not had chances to participate in the process. Those advisory panels could include pioneers of industry to help bring unique and innovative ideas to the forefront (such as insurance payers, financial experts, transportation experts, and industry leaders in solving complex problems). Those advisory councils of industry leaders would serve only in advisory roles; they would not have voting powers due to potential conflict of interests.

The Kidney Committee understands that the Committee structure (for itself) would not change much as a result of the proposed concept, but strongly believes that other committees, such as Minority Affairs, Patient Affairs, and Living Donor Committees, remain committed to providing perspective and able to sponsor projects, whether that be in official committee structure, advisory councils, or both.

### **3. Important Updates for the Kidney Committee**

The Geography Committee Liaison presented an update on the progress of the Ad Hoc Geography Committee. The Committee members asked questions regarding the impact of the Geography Committee recommendations to the organ specific committees. The Kidney Committee Chair, who is also a member of the Geography Committee, commented that only high level geographic organ distribution principles and their alignment to considered organ distribution models will be sent as recommendations. The OPTN/UNOS Board of Directors have the authority to decide next steps. The Geography Committee's charge is to submit recommendations, not propose alternate policies or public comment proposals affecting specific organ distribution.

The discussion about geographic organ distribution spurred conversations around organ distribution of kidneys on pumps. While this concept was out of scope for the Geography Committee, it will be added as a potential new kidney idea to be prioritized with other ideas.

The Kidney Committee Vice Chair presented an update for the Policy Oversight Committee (POC). The update included the POC charge when reviewing new project ideas and public comment proposals. The current update included a new Kidney Committee project: Improving Access for Highly Sensitized and Pediatric Kidney Candidates that was approved and is moving forward in the evidence gathering stage of policy development. The Committee has no questions for the Vice Chair.

The Kidney Committee Chair updated members on the progress of the new kidney project focused on highly sensitized and pediatric candidates. The new project includes two work groups that will work on the two topics simultaneously and form public comment and policy proposals together. The work groups have been formed and will begin to meet in April 2018.

### **4. En Bloc and Dual Kidney Implementation Questions/Discussion**

The Committee discussed key questions for the implementation of the en bloc and dual kidney allocation projects.

- There are differences in criteria for other metrics (such as DCD, KDPI). Does the Committee think that local and import options should exist for en bloc/dual?
  - The Committee agreed that options to take these organs (en bloc and dual separately) stratified by local vs. import was important, given current organ distribution framework of DSA, regional, national.

- What reasons does the Committee want available for when both kidneys from a single deceased donor are not transplanted together as originally accepted?
  - During the previous Committee call in February 2018, the Committee decided on several acceptable reasons: donor size or weight; kidney size or weight; kidney anatomical damage or defect.
  - The Committee agreed to add “Kidney Quality” and “Recipient Issues” as additional reasons.
  - The Committee agreed that one list of reasons was sufficient, and that a separate list of reasons for en bloc and dual was not needed.
  - Given that the drop-down menu will only have reasons, the Committee strongly stated that IT would need to explain the reasons in the help documentation.
- What should the time period between data entry (opt-in/opt-out) and allocation change be?
  - The members used recent examples of allocation implementations to decide on three months time period for centers to enter their opt-in/opt-out choices at the candidate level.
- When en bloc and dual allocation goes live in the system, should the default for accepting en bloc and dual offers at the candidate level be Yes or No?
  - The Committee debated the advantages and disadvantages of both options. Defaulting to Yes does not encourage centers to complete the data entry, but also does not penalize the candidate for a center not entering data. Defaulting to No creates efficiency in the system and gets offers to candidates quickly, which is the main purpose of the project.
  - The Committee agreed to default to No upon implementation with targeted and increased education and communication for the transplant community, since this option is a departure from the IT implementation norm. The en bloc and dual policy language supports this decision, stating that centers must opt-in in order to receive en bloc and dual match offers.
- Are there different acceptance criteria for single versus dual kidneys? These are center defaults, not at the individual level.
  - The Committee ran out of time before agreeing on this decision. Members stated that any acceptance criteria must apply to all centers. Some members mentioned if kidney pumping should be part of acceptance criteria, but pumping information is not always known at time of match offer, and while it is collected in the system, it cannot be used for allocation at this time.

The Committee will continue to discuss important en bloc and dual implementation questions at the next Kidney Committee meeting in April 2018.

## **5. Important Kidney Paired Donation Updates**

The Kidney Committee Chair reviewed the following updates on the Allowing Deceased Donor Kidneys to Initiate KPD Chains project:

- The work group is committed to continuing progress on this project if there is sufficient support/evidence that the “system” benefits – even if that means only a small group of patients fit the criteria.
- The work group is committed to actively seeking patient group input during solution discussions. Including patient groups in the discussion will ensure that values/perceptions held by the Workgroup are in line with reality. There are living donors

on the Workgroup and including broad patient group perspective is more important than having one of two patient representative on the Workgroup to try and represent all patient populations.

- The Workgroup agreed to seek more community input prior to a policy proposal with a more detailed concept paper, hopefully in 2018. The Committee members that disagreed were in favor of moving along at a quicker pace in the project and proceeding to a policy proposal without further concept papers.
- The Workgroup is committed to address blood type concerns with optimization requests and creative solutions with specific criteria.
- The Workgroup reviewed previous discussion points regarding whether the living donor kidney needs to be of similar quality to the deceased donor kidney. The Workgroup was divided on the quality issue and will discuss more fully in later calls.
- The Workgroup is committed to continuing this project even if the number of transplants increased is minimal.
- Considering all the ethical implications, the Workgroup votes to continue forward to the modeling and/or optimization data constraint phase.

The Kidney Committee Chair presented an update on the concept of Global Kidney Exchanges. This concept is not currently being done in kidney transplantation, and several articles were published discussing its ethical and other concerns. The Kidney Committee agreed that there is no official avenue of commenting on this concept by the OPTN. The members asked if perhaps the Ethics Committee would be interested in investigating the ethical concerns of this concept. The Kidney Committee Liaison will follow up with the OPTN/UNOS leadership to inquire into official OPTN statements regarding Global Kidney Exchanges.

#### **6. Public Comment Review: Expedited Organ Placement Concept Paper (OPTN/UNOS OPO Committee)**

The Chair of the OPO Committee presented this concept paper. The Kidney Committee is supportive of expedited organ placement. The Committee thanks the OPO Committee for the chance to provide feedback early in the concept process. This is a topic that involves the entire transplant community. Specific feedback questions were discussed by the Committee:

*Should an allocation system include triggers for expedited placement based on defined donor characteristics?*

The Committee supports expedited placement triggers. The Committee understands that initially this concept is focused on liver allocation, but the Committee decided to develop policy similar to a trigger with the dual kidney allocation project. Current variability in how OPOs handle expedited placement creates inequity and lack of transparency.

*Should an allocation system include triggers for expedited placement based on an event (like organ decline in OR)?*

The Committee supports triggers based on process altering events.

*Should system allow OPO to move to expedited list after well-defined point in allocation process (after X offers to candidates, X hours of scheduled OR time, etc.)?*

The Committee supports expedited placement options after well-defined points in the allocation process. The Committee is interested in further discussions about the details of those well-defined points, as they may change depending on type of organ.

*Once trigger met, should OPO use discretion to place organ?*

The Committee does not support absolute OPO discretion. There must be defined rules/criteria for transparency. Given each organ, stringent policy review would need to take place to ensure that expedited placement at a given point does not go into violation with current policy, such as highly sensitized allocation in KAS.

*Once trigger is met, should list of candidates be limited to those at transplant hospitals with recent history of transplanting organs from similar donors?*

The Committee strongly objects to limiting candidate list to those at transplant hospitals with recent history or transplanting organs from similar donors. With a process like that in place, the other transplant hospitals would have no chance to receive offers or change behaviors.

*Should transplant hospitals be allowed to choose if candidates are on expedited list?*

The Committee supports transplant hospitals selecting candidates to be involved in expedited list. The transplant hospitals, and the candidates' physicians and transplant team, are the ones to make that decision – based on urgency and discussions with the candidates.

*Should system give priority to candidates more likely to accept an organ that has a higher likelihood of discard based on statistical modeling?*

The Committee does not support using statistical modeling to skip candidates and break allocation classifications. The Committee believes that rules/criteria need to be set and the match run should be followed.

*Should DonorNet set acceptance criteria based on hospital's past practices?*

The Committee does not support acceptance criteria based on a transplant hospitals past practices. Turnover at transplant hospitals happen routinely, and with new surgeons and physicians come new practices and behaviors.

#### **7. Public Comment Review: Change Waiting Time Criteria for Kidney-Pancreas Candidates (OPTN/UNOS Pancreas Committee)**

The Chair of the Pancreas Committee presented this proposal. The Kidney Committee thanks the Pancreas Committee for their presentation regarding changing criteria for kidney/pancreas waiting time. The Committee does not support the proposal as written. There were concerns from several committee members about the proposed primary solution of removing the BMI/insulin requirement from the KP waiting time criteria and references to maximum BMI. Given the ever-changing candidate population and increasing registrations with Type 2 diabetes, the Committee recommends taking a more cautious approach to this policy change by increasing the maximum BMI cap for candidates with c-peptide of 2 or greater incrementally and monitoring listing behaviors and outcomes of high BMI recipients. The Committee does not agree that centers should be allowed to police themselves, given the large Type 2 diabetes population. The Committee understands that the Pancreas Committee may be willing to modify the proposal to better reflect the concerns of the community, and the Kidney Committee is interested in continuing the discussion, given the degree of modification.

#### **8. Simultaneous Liver-Kidney (SLK) 6-Month Implementation Update**

The UNOS Research Liaison presented the 6-month implementation update for simultaneous liver-kidney policy changes. The liaison reviewed SLK registrations and transplants since implementation and compared to kidney-alone registrations and transplants. There were questions about eligibility versus ineligibility requirements in the SLK policy. The Committee expressed no pressing concerns about the implementation update. The next update will be a yearly implementation report.

#### **Upcoming Meetings**

- April 9, 2018 Teleconference
- May 14, 2018 Teleconference