# OPTN/UNOS Kidney Transplantation Committee Meeting Minutes March 20, 2017 Chicago, IL

# Mark Aeder MD, FACS, Chair Nicole Turgeon, MD, FACS, Vice Chair

#### Introduction

The Kidney Transplantation Committee met in Chicago, IL on 3/20/2017 to discuss the following agenda items:

- 1. Improving En Bloc Kidney Allocation Project
- 2. Improving Dual Kidney Allocation Project
- 3. Annual Updates to Estimated Post Transplant Survival (EPTS) and Kidney Donor Risk Index (KDRI)-to- Kidney Donor Profile Index (KDPI) Mapping Tables
- 4. State of the OPTN Kidney Paired Donation Pilot Program (KPDPP) Annual Update
- 5. Allowing Deceased Donor-Initiated Kidney Paired Donation Project
- 6. Repairing OPTN Kidney Paired Donation (KPD) Chains Project
- 7. Two-Year Kidney Allocation System (KAS) Update Preview
- 8. Policy Oversight Committee (POC) Update
- 9. External Project Updates
  - a. Simultaneous Liver Kidney (SLK) Implementation Update
  - b. Minority Affairs Committee (MAC) A2/A2B to B Project
  - c. Kidney Donor Profiles Project
  - d. Systems Optimization Project
- 10. New Project Brainstorming

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

#### 1. Improving En Bloc Kidney Allocation Project

All but two of the Committee's Regional Representatives have presented the En Bloc Allocation project at their regional meetings, with Regions 3 and 9 presenting the coming days. Six regions approved the proposal and two have opposed. The Committee has also presented the proposal to eight different OPTN/UNOS Committees and received feedback from several. The Vice Chair reminded the Committee that the goal of the project - to increase utilization of en bloc kidneys without impacting single transplants - as well as how the Work Group's arrived at the proposed solution. Feedback thus far has indicated overwhelming support for mandating a donor weight-based threshold at which en blocs are to be mandatorily allocated, overturning the original provision of a donor weight range in which en blocs may be allocated.

#### Summary of discussion:

The Vice Chair opened the floor for discussion on selecting a donor weight threshold for mandating en bloc allocation. OPTN data show quantity of en bloc transplants at various donor weights, and the Vice Chair asked the group to carefully consider the impact of any given threshold. If 10kg is chosen, for example, a significant amount of centers using en blocs will never see those numbers, according to the data. It is important to consider this issue nationally and not just for one's own region or center. A number of centers do use en blocs at the 15 and 20kg donor weight range.

One member commented that her initial reaction was that 15kg seemed to be the right cutoff for allocation. At 14 and 15kg, about half were used en bloc and, presumably, the other half were used singly - so about 150 kidneys from these two donor weights were en bloc. The Chair noted, however, that data on retrieval of these kidneys is not available - there is no way to know whether these were recovered en bloc and split, for example. The Vice Chair noted that at a threshold of 15kg, the assumption is that those above 15kg will be used singly - though data show that this is not the case. One member asked why we assume these kidneys above the threshold will not be used. Wouldn't the single centers accept them? The Vice Chair commented that while the local centers are most likely the ones to be using them en bloc. Behaviorally, if the en bloc centers won't use them, then it will take longer to place them because singly their KDPIs are higher and many single centers will not accept them as they are more technically complicated to transplant, similar to how behavior is seen for other types of high KDPI kidneys. The pediatric at-large member of the Committee commented that centers are also hesitant to use small pediatric kidneys due to the risk of both arterial or venous thrombosis.

The Chair commented that the Maluf paper, cited throughout the en bloc proposal, indicates that about 20% of kidneys are at 20kg donor weight. The Committee, of course, only has information on actual utilization and not on kidneys not recovered. A donor weight of 20kg could maximize utilization and increase recovery of smaller pediatric kidneys so that local en bloc centers, who would have the ability to "opt in" to receive offers with an enhancement to UNet, could have faster access to them.

The Committee acknowledged that regional meeting feedback indicated that many members disagree with the provision in the proposed policy stating that a surgeon splitting en blocs must return the second kidney to the host OPO for allocation according to Policy 5.9. The Work Group felt strongly that this provision is necessary to prevent gaming of this allocation policy. Furthermore, the Committee and the Work Group agree that the en bloc and dual kidney allocation projects should both be in alignment with existing OPTN Policy 5.9: Released Organs.

#### 2. Improving Dual Kidney Allocation project

The Improving Dual Kidney Allocation project Work Group opted to develop a concept paper for public comment during the spring 2017 cycle. The Work Group sought feedback on three different concepts developed with the intention of increasing utilization of high KDPI kidneys. The Concept Paper was announced at regional meetings and presented to the OPTN/UNOS Minority Affairs, Transplant Coordinators, Transplant Administrators, OPO and Operations & Safety Committees. Several related societies were asked to comment as well but have not done so to date.

#### Summary of Discussion

The Chair provided a brief overview of the goal of the project as well as the three concepts developed by the Work Group. The solutions all include some similar components as minimum requirements for any chosen policy, including the provision to split kidneys according to Policy 5.9 as well as a requirement that any final solution incorporate a single match run (as opposed to multiple). The Chair encouraged members of the Committee to engage their organizations in commenting on the concept paper. The Chair has also sent a request for comment to the top seven highest-volume dual kidney centers in the nation.

The Chair reiterated that the goal of the project is to facilitate placement of high KDPI kidneys that are typically difficult to place quickly using a standard match run. Centers that would accept duals could opt-in to receive these offers and those that routinely do not choose to accept high KDPI kidneys would not see them at all.

#### Next Steps

The Dual Kidney Work Group will resume its meeting series in April after the close of public comment. The Work Group will consider public comment, select a final concept and draft a proposal for fall public comment.

# 3. Annual Updates to Estimated Post Transplant Survival (EPTS) and Kidney Donor Risk Index (KDRI)-to- Kidney Donor Profile Index (KDPI) Mapping Tables

UNOS staff presented the annual updates to the EPTS/KDPI mapping tables. Each donor's KDRI is converted annually to a KDPI using a mapping table. The mapping table is based on all 2015 donors or those donors recovered in the previous calendar year. EPTS works very similarly and, as per policy, UNOS is required to review and update these annually. This update covers 2016 donors.

Policy states that UNOS determines KDPI using the OPTN Contractor's KDRI to KDPI mapping table, reviewed annually by the Committee and implemented by the UNOS IT department by June 1 each calendar year. The same is true for EPTS. UNOS staff showed a snapshot of the current table for donors recovered for the purpose of transplantation in 2015. KDRI is normalized such that the median donor has a KDRI of 1. UNOS staff perform analysis on how KDRI-to-KDPI changes year to year. KDRI is generally stable over time. There has been a gradual decrease of KDRI in the median, 75th and 95th percentiles. An analysis shows that the 2016 data is no different than the 2015 data - the *p* value is not statistically significant. UNOS staff then presented the updated table and requested approval.

One member asked what would occur should the slight decline observed each year continues inexorably. Given that there is a general observed trend of shying away from high KDPI organs in the community, will this impact KDPI values over time such that it could lead to less utilization of high KDPI kidneys? The Chair agreed that this is an important question, and that there are a number of factors impacting the use of high KDPI and otherwise marginal kidneys. Another member noted that as the community becomes more conservative in its use of high KDPI kidneys, the mapping tables will reflect this and shift each year as part of a "labeling effect," theoretically using less each year. The opiod epidemic has added a number of younger donors to the donor pool.

A candidate's EPTS score indicates the percentage of adult kidney candidates on the waitlist with higher estimated post-transplant longevity. There is a common misconception that the EPTS factors in a candidate's position on the waitlist, when in reality it is based on a recent snapshot of the waitlist. The EPTS tables presented today will be updated to reflect EPTS scores as of December 2016. The top 20% of the table is slightly easier to meet this year than last year, which is a continuation of a trend observed in previous years. Upon implementation, slightly more candidates will be eligible for the top 20%, as the raw EPTS score needed to meet this percentile increased from just under 1.5 to just over 1.51. UNOS staff then presented the proposed EPTS mapping table. One member asked whether the new mapping table results in a total increase in people in the top 20%, and UNOS staff replied that this is the case.

#### Next Steps

UNOS IT will implement the tables for a June 1 release.

#### 4. State of the OPTN Kidney Paired Donation Pilot Program (KPDPP) Annual Update

UNOS staff provided an update on the status of the OPTN KDPPP. At a national level, KPD started in the US in 2002 and has consistently seen approximately 600 transplants per year, or 11% of all US kidney living donation. The KDPPP facilitated 43 transplants, or 7% of all living donor transplants. The KDPPP has seen a slight increase in A donors and a slight decrease in O donors since implementation of the new Histocompatibility policy. These changes in blood type, CRPA and other factors have resulted in a pool that is difficult to match. The program has seen, however, that the policy is working as expected by decreasing the number of crossmatch-related refusals.

One member asked how many altruistic donors initiate chains and whether this is a contributing factor to the volume of transplants in the KDPPP program. The KDPPP has very few non-directed donors - 24 in total thus far. Compatible pairs are not permitted in the KDPPP program as the National Organ Transplant Act defines KPD as for biologically incompatible pairs, though they permitted in other national KPD programs. If a center wants to enter a pair who is ABO compatible but a size mismatch, they may do so however, as "incompatibility" is not limited to ABO/HLA matching.

Another member asked if UNOS has determined what percent of the candidate pool has a CPRA of 99% and above, and of those, have they determined how many have "true" 100% CPRAs (vs. 99.6% and above). The Vice Chair commented that the population of high CPRA candidates is very similar to those of other national programs, so it is unlikely that this difficulty is unique to the OPTN program.

A Committee member asked whether the OPTN sees this data as a success or disappointing. The Vice Chair responded to say that while number of matches is one form of success, giving candidates opportunities that they may not otherwise have is a far greater one for the OPTN, and that staff are constantly looking at how to improve access to KPD. Part of struggle is the long lead time required to make changes and innovations to the program.

Another Committee member commented that logistical inefficiencies should also be examined, and the Vice Chair agreed. Two other members noted it would be helpful to know which centers are cross-listed with other (non-OPTN) programs. UNOS staff responded to say that of the data publicly available at the end of 2015, 12 programs are registered with the OPTN KPDPP, the National Kidney Registry (NKR) and the Alliance for Paired Donation (APD); are with the OPTN and NKR; and 41 are with the OPTN and APD. The OPTN does not have information on whether these hospitals are actually active with any given external program.

#### 5. Allowing Deceased Donor-Initiated Kidney Paired Donation Project

The Vice Chair presented the Deceased Donor-Initiated Chains project. The charge of the project is to develop methods for allowed deceased donor kidneys to initiate paired exchanges. The project idea has been in consideration at UNOS for a number of years, but with increased interest from the community last year (including four inquiries to UNOS from member institutions and an announcement from Walter Reed noting their intention to create a deceased donor chain), the Committee decided to initiate a Work Group in the fall of 2016. The group has opted to publish a pre-public comment document in the fall of 2017 to request community feedback on this topic. The document will describe the three known methods for creating deceased-donor initiated paired exchange (donor-driven, candidate-driven, and list exchange chains), review recent literature, and describe any applicable parameters for future projects.

The Deceased Donor Chains Work Group meets monthly and will continue to report to the Kidney Committee regularly.

#### 6. Repairing OPTN Kidney Paired Donation (KPD) Chains Project

The Vice Chair then presented the KPD Repairs project. The goal of the project is to allow more flexibility for the OPTN KPDPP in repairing exchanges that have broken. Currently, only one type of repair - truncation - is allowed in policy. The proposed language developed by the Work Group is designed to maintain transparency in operations but also to allow for more options for repairing exchange. The draft policy language was presented to the Committee.

One member asked if centers that frequently terminate exchanges are penalized in any way. UNOS staff said that while there is no penalty, they do follow up with centers to attempt to address any recurring refusals. A member of the Committee who also serves on the Work Group noted that the discussion on how best to address this issue was rather long and the broad language presented was determined to be the best way to promote flexibility for the program.

The Committee voted unanimously to approve the language.

#### 7. Two-Year Kidney Allocation System (KAS) Update Preview

UNOS staff presented a preview of the KAS Two Year Monitoring report. All of the same characteristics reviewed in the 1 Year and 18 Month reports will be included in this report, which will be presented at the Kidney Committee's April meeting. New or updated data elements include:

- Waiting List analysis, including active and inactive switching within 60 days of listing
- Existing metrics include stratification by region
- Additional CPRA cross-tabulations, on request from the fall meeting
- Additional metrics for delayed graft function, including a descriptive analysis of recipients with DGF
- Pumping added to many transplant utilization analyses (from December Board discussion)
- One-year post-transplant survival outcomes, including additional stratifications
- Relisting rates within one year under KAS

This report will also include a comparison between one year and two years post-KAS.

#### 8. Policy Oversight Committee (POC) Update

The POC has been focusing on alignment of projects with the OPTN Strategic Plan while also considering resource prioritization and stakeholder engagement. Currently, OPTN Strategic Goal 1 (increasing the number of transplants) is over allocated, so the POC is looking at projects that can address all five strategic goals.

The POC will review all active projects in July of 2017 and validate whether they meet current standards. The Committee will make recommendations to the Executive Committee as to whether these projects are ready for public comment.

## 9. External Project Updates

a. Simultaneous Liver Kidney (SLK) Implementation Update

UNOS staff provided an update to the Committee on the Simultaneous Liver-Kidney (SLK) Project Implementation.

The Committee Chair asked whether any of the Regional Representatives received any comments from the community during their regional meetings on the SLK project update they delivered.

One Regional Representative noted that there is confusion about grandfathering patients into the new policy. She offered the example of a patient that received a liver transplant in 2014, went immediately into kidney failure and was subsequently then listed for a kidney transplant within the same year. Today, that patient would have been completing their third year on the wait list. UNOS staff responded to say that that patient would be eligible for the "Safety Net" classification under the new system providing they meet eligibility criteria and are able to furnish the requisite documentation.

## b. Minority Affairs Committee (MAC) A2/A2B to B Project

A member of the Minority Affairs Committee's (MAC) A2/A2B to B project Subcommittee presented an update to the Committee.

Since the implementation of KAS, 18 month data revealed significant underutilization of the A2/A2B to B provision, seeking to address disadvantage to blood group B candidates. MAC formed a work group to better understand why this was occurring. The group sent a survey to 230 transplant administrators and garnered a response rate of 22% of those surveyed. The group is producing a guidance document that addresses the concerns expressed in those responses. The document should be finished in late spring for presentation in the summer of 2017, public comment in the fall and the Board in December.

Transplant Administrators described a number of barriers and their reported solutions, if applicable, that the work group is synthesizing for inclusion in the document as best practices. The goal is to provide centers with education and support in the hope that they will be more comfortable with A2/A2B to B transplants.

An At-Large noted that perspective of a blood bank or transfusion medicine professional on the work group would be critical to weigh in on titer levels and methodologies as they often vary between blood blanks and laboratories. Often there is confusion between transplant centers and their blood banks in this particular area so as to ensure that technicians are all on the same page. The Chair also noted that developing "centers of excellence" within regions may do well to help standardize these practices.

#### c. Kidney Donor Profiles Project

UNOS IT staff presented the Kidney Donor Profiles (KDP) Project.

The KDP project is being managed by the UNOS Customer Innovations group and was initiated on the suggestion of a kidney surgeon in the community.

Donor profiles are intended to allow transplant hospitals to use criteria in combination to more precisely specify what organ offers they will accept, reducing unwanted offers and cold ischemic time and increasing organ acceptance.

Customer Innovations projects are developed via user requests and reviewed by the UNOS IT intake process. For projects without a policy impact, the UNOS IT Customer Council assesses the idea for value and priority. If the project presents a new strategic business or technological project to UNOS, it becomes an Innovations Project and a senior IT staff member will drive the project.

The Donor Profiles project idea originated from a kidney surgeon and UNOS volunteer that requested this functionality. A working group, including one member of the Kidney Committee, met over the past summer to gather initial requirements and develop a prototype. The UNOS Business Analyst is requesting a Kidney Committee surgeon volunteer to join the work group.

The Vice Chair expressed concern over how larger centers will be able to make use of the tool given the large scope of data entry that would be required of transplant coordinators. A member

commented that aggressive programs who have same acceptance criteria no matter where a donor is may find this useful, though the program is probably not as useful as a smaller center who changes criteria based on donor location. Another member agreed and thinks this will help where DonorNet fails. A few times a year, phone calls come in for organ offers for organs over 20 hours old, even though criteria set already not to accept anything over 16 hours from outside the region. Another Regional Representative commented that she comes from a small center but doesn't think coordinators would be able to handle intricacy of this type of wait list management. A fourth member from a large volume center noted that DonorNet does the job most of the time, but won't serve programs that pay a contractor to take the offer calls for them.

#### d. Systems Optimizations Project

The Work Group was developed from the OPO Committee with the goal of reviewing efficient placement of organs. Much of the discussion has surrounded the transition between a provisional yes to organ acceptance and setting OR time. After a number of meetings, the focus has been on thoracic and liver placement and revisions to timing for organ offers and acceptances. The Group has decided on the following central goals:

- i. Reduce time limits to respond to electronic organ offers.
- ii. Time limit of 1 hour to make final decision once all required information provided.
- ii. Limit the number of offers that can be accepted for one candidate at a time.

UNOS staff reiterated that this project is taking 2 parallel paths: policy and technology. The impact of this project is wide-ranging. The Work Group itself is focusing on policy solutions while the Innovations team will focus on non-policy, technology-based solutions.

The Group will draft policy for fall public comment.

#### 10. New Project Brainstorming

The Committee reviewed new project ideas submitted in advance of the meeting. As a next step, the Committee will identify a list of finalist projects for consideration. These new project ideas will be brought to the 2017-2018 Committee once the new terms begin in July.

The Chair adjourned the meeting at 3:00PM CST.

#### **Upcoming Meetings**

April 19, 2017 May15, 2017 June 12, 2017