OPTN/UNOS Kidney Transplantation Committee
Meeting Summary
November 16, 2015
Conference Call

Dr. Mark Aeder, Chair
Dr. Nicole Turgeon, Vice Chair

Discussions of the full committee meeting on November 16, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at http://optn.transplant.hrsa.gov/ .

Committee Projects

1. Simultaneous Liver Kidney (SLK) Allocation

The Kidney Transplantation Committee (the Committee) discussed the most recent recommendations from the SLK working group for changes to the SLK policy language based on public comment feedback. The SLK proposal will be distributed in January 2016 for a second round of public comment.

The Committee discussed the qualifying medical criteria for the SLK safety net component of the proposal. In the proposal distributed for fall 2015 public comment, a liver recipient that did not receive a kidney at the time of their transplant qualified for the SLK safety net if the recipient was either on regularly administered dialysis for ESRD or had a GFR at or below 20 mL/min within 60-365 days post liver transplant. A question was raised by UNOS staff as to whether or not the dialysis criteria should be specifically for ESRD because it would be monitored differently if it is not for ESRD. The SLK working group recommended that the dialysis qualifying medical criteria should not specifically be aligned with a diagnosis for ESRD. If a recipient was on dialysis for 60 days, the recipient would not meet the generally accepted criteria for ESRD. A diagnosis of ESRD generally corresponds to 90 days of dialysis. The Committee agreed that the dialysis criteria should not be specifically tied to a diagnosis of ESRD.

For the GFR qualifying medical criteria, the SLK working group recommended that the program must update and confirm at least once a month that the GFR is at or below 20 mL/min. This recommendation was based off a concern that a post-liver transplant recipient could have an episode of acute kidney injury and have a decrease in GFR to 20 mL/min or below and then receive priority even though kidney function may still improve.

The Committee believed that a monthly requirement to document the GFR would be overly burdensome. Instead, the Committee discussed documenting GFR value at or below 20 mL/min three times. Committee members noted that requiring three GFR values would be inconsistent with kidney allocation policy for accumulating waiting time points, which only requires one documented GFR value at or below 20 mL per minute to begin receiving waiting time points. However, the Committee ultimately decided that the proposal should require a documented GFR value at or below 20 mL/min three consecutive months (within 60-365 days post-liver transplant) as a compromise to limit reporting burden while only giving the SLK safety net priority to the liver recipients that do not regain kidney function. If the liver recipient were to receive a kidney offer after they had their first qualifying GFR, but not all three GFRs, the liver recipient would still receive the offer. The three month GFR requirement would be to maintain eligibility for

the SLK safety net until the liver recipient received a kidney transplant. The Committee has not fully resolved this issue and will need to discuss it again on an upcoming call.

The SLK working group also recommended that the safety net priority remain in Sequence B of KAS (KDPI 21-35%). A few regions had commented that they would like the priority to only apply to Sequences C & D (KDPI 36-100%). The Committee felt that leaving the safety net in Sequence B was important to the liver community and should remain.

The Committee also discussed whether there should be any medical eligibility criteria prior to liver transplant in order to be eligible for the safety net. A few of the regions believed that there should be some sign of kidney dysfunction prior to the liver transplant. The Committee did not believe that a liver candidate would need to show signs of kidney dysfunction prior to their liver transplant in order to qualify for the safety net priority post-liver transplant.

2. Kidney Allocation System (KAS) Clarifications & Clean Up Proposal

The Committee revisited the mandatory share section of kidney allocation policy for inclusion in the public comment proposal. The policy on mandatory sharing outlines the number of match offers and time limits for making offers for 0-ABDR mismatches and 99%-100% CPRA candidates in match classifications 1-10 of the kidney allocation sequences. However, the policy does not direct the OPO on what to do after making the number of offers required in policy if they are not accepted. Operationally, the OPO may enter a bypass code to skip the remaining high CPRA and 0-ABDR mismatches to begin allocating locally after meeting the mandatory share requirements. Initially, the KAS subcommittee proposed adding language to policy that reflect the current practice, but when the Committee reviewed this recommendation at its October meeting it did not agree with this recommendation. The Committee asked that the KAS subcommittee revisit this topic and discuss changes to the policy that would not allow OPOs to skip anyone in the 99-100% CPRA match classifications.

The Committee reviewed the updated recommendations from the KAS subcommittee and data on the use of the bypass code. In the first six months of KAS, 22 OPOs used the bypass code 902 times for 51 donors. For three of the donors, the code was used more than 50 times. Of the 902 times, 53% of the candidates bypassed were non-local with 99-100% CPRA (the others were 0-ABDR mismatches). The bypass code was used for about 1.3% of all recovered donors (approximately 4,000) in the first six months of KAS.

The Committee considered two options presented to the KAS subcommittee. Both options require that the OPOs follow the match run and would inactivate the bypass code. The first option would remove the offer timeliness requirements. Currently, the policy says that these offers have to be made within either 8 hours or 3 hours of procurement depending on the KDPI of the kidney. By removing the time requirements, the OPOs would have more flexibility in the case of a DCD donor or expedited case. However, without a time requirement, the OPO could potentially wait to make the offers until the cold time increases and limit the likelihood of offers being accepted outside of their local DSA. UNOS staff noted that it would be very difficult to determine if this was happening.

The second option maintains an offer timeliness requirement that prompts the OPO to begin making offers. The KAS subcommittee recommended the second option, but could not reach consensus on what the requirement should be. The Committee agreed with

the subcommittee and discussed options for the timeliness requirement. The Committee discussed whether the offers for the mandatory shares should be made pre-procurement, within a certain number of hours of procurement, or when certain donor information became available. Generally, the Committee felt that these offers should be made pre-procurement. An OPO representative raised concerns that requiring offers to be made pre-procurement to all of the mandatory share candidates will increase the number of offers and create unnecessary back up offers that may receive provisional yes responses not reflective of a careful consideration of the offer. Additionally, if the OPO makes an offer to a multi-organ candidate and it is accepted, any offers made to candidates on the kidney-alone match run would need to be rescinded. Committee members believed early notification will be essential and it was better to err on the side of making a lot more offers.

The Committee also discussed adjusting operational parameters to permit OPOs to make more offers. After the match run is generated, the OPO can send offer notifications to centers either 3 or 5 at a time (depending on whether the kidney has been recovered or not) if they are outside the OPOs DSA. The system does not impose an offer notification limit for local offers. The Committee believes that this limit will need to be adjusted to give the OPOs more flexibility to make all mandatory share offers pre-procurement. The Committee did not arrive at consensus on the offer notification limits.

Upcoming Meetings

- December 21, 2015
- January 25, 2016
- February 29, 2016
- March 21, 2016