OPTN/UNOS Kidney Transplantation Committee
Meeting Summary
May 16, 2016
Conference Call

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

Discussions of the full committee on May 16, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov/.

Committee Projects

1. Kidney Allocation System (KAS) Clarifications and Clean Up

KAS was implemented on December 4, 2014. Since that time, the Committee and UNOS staff have identified several clarifications that are needed in the policy language. The Committee had previously developed a proposal and distributed it for public comment in early 2016. During the Committee's meeting on April 18, 2016, the Committee reviewed public comment feedback and voted to send the proposal to the OPTN/UNOS Board of Directors (the Board) for approval at the Board's June 2016 meeting. There was only one revision to the proposal. During the May call, the Committee received an update on activities since the Committee voted on the proposal. Since the Committee voted on the proposal, committee leadership sent a formal response to the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) that addresses their comments and explains the Committee's final decisions. The proposal will be presented to a subset of the Board's members in advance of the June 2016 meeting. There have not been any requests for amendments to the proposal at this time.

2. Simultaneous Liver Kidney Allocation (SLK)

The intent of the SLK project is to provide medical eligibility criteria to allocate a kidney with a liver from the same donor, provide clear SLK allocation rules for OPOs, and create a "safety net" for liver recipients who are dialysis dependent or have significant kidney dysfunction within a year of their liver transplant. In December 2016, the Committee voted to recommend distributing a revised SLK proposal for a second round of public comment beginning in January 2016. During the April 18, 2016 meeting, the Committee reviewed public comment feedback and voted to send the proposal to the Board for approval at the Board's June 2016 meeting.

During the Committee's May call, the Committee received an update on the proposal since the Committee voted. Since the April meeting, committee leadership sent a formal response to the AST and ASTS that addresses their comments and explains the Committee's final decisions. The proposal will be presented to a subset of the Board's members in advance of the June 2016 meeting. However, one of the Board member's has requested an amendment to the proposed policy changes.

The amendment would change the medical eligibility criteria to allocate a kidney with a liver from the same donor. As approved by the Committee, a transplant nephrologist must confirm that the candidates has chronic kidney disease, sustained acute kidney injury, or metabolic disease to allocate the kidney with the liver from the same donor. If the candidate has chronic kidney disease, the transplant hospital must show that the

candidate is on dialysis for ESRD or that the most recent eGFR/CrCL is at or below 30 mL/min at or after registration on the kidney waiting list. The amendment would reduce the 30 mL/min to 20 mL/min. The rationale for this amendment is so that the medical eligibility criteria for SLK mirrors the waiting time criteria for kidney-alone candidates.

The Committee was advised that Committee leadership is speaking to Board members to explain the impact of passing this amendment and educate members on the proposal that may not have expertise in kidney policy. There is concern among the Committee that this change could undo years of progress and compromise on the proposal. Neither the Liver nor Kidney Committees support this amendment. This change was discussed but not supported in the regions.

Any further developments will be communicated to the Committee.

Other Significant Items

3. Presentation on Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types

The Chair of the Pancreas Transplantation Committee (Pancreas Committee) presented an update on their project to broaden allocation of pancreas transplants across compatible ABO blood types. The following is a summary of the presentation:

Problem: Pancreas transplants continue to decline and the majority of pancreata are transplanted through simultaneous pancreas-kidney transplants (SPK). Current policy has blood type restrictions that prevent clinically compatible SPK transplants.

Project Objective: Revise blood type restrictions on kidney-pancreas allocation to increase SPK transplants and increase utilized pancreata. This will increase equity in access to transplants for candidates across blood types.

Timeline of Events: In September of 2015, it was discovered that the current programming for Kidney-Pancreas Allocation by Blood Type does not match current Policy 11.4.D. Current policy states that Blood type B Deceased Donors are to be only allocated to Blood type B candidates. Programming however, allowed for blood type B deceased donors to be allocated to B and AB/A_1B/A_2B Candidates. In early October 2015, the leadership of the Pancreas, Kidney, and Minority Affairs Committees met by conference call to discuss the issue. The committees were presented data on the number of kidney-pancreas transplants by blood type in the last year, as well as current waitlist numbers by blood type. The options considered for moving forward were; changing policy to match programming, changing programming to match policy, or changing both policy and programming. Concern was expressed over the effect on kidney transplants if policy was changed to expand KP allocation to allow B donors to be allocated to AB recipients. It was agreed among all parties that the discrepancy between policy and programming needed to be fixed. It was decided that the most immediate action would be to change programming to mirror current policy. Programming was changed to match policy on November 4, 2015.

Action: The Pancreas Committee is developing a proposal that would allow all compatible blood types to kidney-pancreas candidates. The Pancreas Committee feels that current policy limits the opportunities by not allowing all compatible blood types for kidney-pancreas transplants. There is a known survival advantage to receiving both a kidney and a pancreas rather than a pancreas-alone transplant.

The Pancreas Committee has requested modeling from the Scientific Registry of Transplant Recipients (SRTR) to determine the potential influence of allowing all

compatible blood types to kidney-pancreas candidates. All analysis will contain subgroup analysis to determine if specific blood type candidates or different ethnicities would be disadvantage by making a blood type compatibility change. The SRTR will also evaluate potential waiting list and post-transplant outcome differences.

The Committee had the following questions:

- Will the changes apply to regional and national sharing? The changes will apply to local allocation and possibly regional sharing. Currently, regional sharing for kidney-pancreas is not mandated by policy. There are no plans to include these changes for national sharing.
- Is the SRTR modeling going to include analysis on the potential effect on the kidney-alone list? SRTR modeling will include this analysis.

The Committee discussed whether the proposal could potentially divert some high-quality kidneys away from the kidney-alone list. However, committee members believe that this volume will be very low. This volume is somewhat impacted by the increasing number of donors that are dying from drug overdose which may make organs unsuitable for a pancreas transplant or a kidney-pancreas transplant. Using a marginal pancreas could jeopardize the patient. The SRTR noted that 50% of type 1 diabetics on the kidney-pancreas waiting list die within 5 years of being listed. Overall, committee members felt that the Committee should not do anything to inhibit SPK transplants.

4. Update on Policy Oversight Committee (POC) Meeting

During its April 18, 2016 meeting, the Committee requested that two kidney paired donation (KPD) projects be submitted to the POC for review and approval. One project is designed to create policy that will allow exchanges in the OPTN's Kidney Paired Donation Pilot Program (OPTN KPD) to be repaired when one or more pairs involved in exchange can no longer proceed with transplant. The second project is exploring how to utilize deceased donors and the kidney-alone waiting list with KPD. The Committee was informed that the POC had reviewed and approved both projects. The POC will send on these recommendations to the Executive Committee for final approval in June 2016. If approved by the Executive Committee, the Committee will use the KPD Work Group to work on the repairs project and create a new work group to develop the other project.

5. Update to the CPRA Calculator

The Committee reviewed the updates to the online CPRA calculator. The CPRA calculator is an informational tool that can be used to assess the CPRA value used for allocation. The calculator will now also display a more detailed CPRA value based on the unacceptable antigens entered. For example, the CPRA value use for allocation may be listed as 100%, but the detailed CPRA value is 99.57%. This update was programmed based on numerous requests from OPTN members.

Upcoming Meeting

- June 20, 2016