OPTN/UNOS Kidney Transplantation Committee Meeting Summary June 20, 2016 Conference Call

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

Discussions of the full committee on June 20, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov.

Committee Projects

1. Repairing OPTN KPD Chains

The Committee was informed that the OPTN/UNOS Executive Committee approved their request to begin a project that allows for repairs to OPTN KPD exchanges that fall apart.

2. Allowing Deceased Donor Chains in the OPTN KPD Pilot Program

The Committee was informed that the OPTN/UNOS Executive Committee approved their request to re-visit a project that would allow deceased donor chains in the OPTN KPD.

Committee Projects Pending Implementation

3. Simultaneous Liver Kidney Allocation (SLK) Project

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 June call, the Committee was informed that the SLK proposal was approved by the OPTN/UNOS Board of Directors (the Board) on June 7, 2016. Date of implementation is to be determined based on programming.

4. 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.

During the June call, the Committee was informed that this proposal was approved by the Board on June 6, 2016 as a part of the non-discussion/consent agenda. Two changes to policy will require changes to computer programming and the date of implementation is to be determined. These changes will include inactivating a bypass

code and correcting come match classification labels. All other approved changes will be effective September 1, 2016.

Other Significant Items

5. Discussion on Letter from LifeSource on Pre-Procurement Tissue Typing Blood Samples

The LifeSource Kidney/Pancreas Committee (LifeSource) requested that the Kidney Committee consider revising policy to require that exporting OPOs offer pre-procurement tissue typing blood samples as soon as possible after a preliminary offer is accepted for the highest CPRA candidates. LifeSource suggested that samples be offered for preliminary crossmatch testing for at least the top two ranked highly sensitized (99-100%) CPRA) candidates on the kidney match run. LifeSource believes that while not all centers will accept the option to conduct a pre-procurement crossmatch, many centers will and it will help decrease the risk of urgent reallocation and prolonged total cold ischemia time (CIT). Because some OPOs choose to send blood only at the time the kidney is shipped, rather than pre-procurement, CIT is often unnecessarily extended. Having the ability to facilitate prospective crossmatches sooner should help minimize CIT in some cases and prevent unnecessary shipping of kidneys in cases where the crossmatch result is positive. LifeSource believes that changing practice would benefit both the high CPRA kidney candidates and other candidates who currently miss out on offers when kidneys are shipped only to be reallocated in the importing DSA when the crossmatch result is positive.

During the June call, the Committee considered this request. The Committee also rereviewed KAS data from the 12-month report for offer rates, acceptance rates, and
transplant rates for highly sensitized candidates. Overall, acceptance rates and
transplant rates have increased for CPRA 99-100% candidates. Additionally, post-KAS
implementation, there has been an increase in the number of non-local acceptances for
CPRA 99-100% candidates but a decrease in percentage of kidneys not transplanted
into these acceptors. When the kidney is accepted but is not transplanted into its
originally intended candidate, approximately one third of the kidneys were discarded,
while the remaining two-thirds were transplanted into another recipient. It was also noted
that only about 25% of match runs have more than two candidates on the match run in
for the match classifications for 99-100% CPRA.

The Committee was asked to consider whether this in an issue that needs to be addressed at this time and whether this issue should be addressed by the Kidney Committee, OPO Committee, or other group.

Most committee members agreed that this is an issue worth addressing. Main points of the discussion were:

- Because shipping has increased post-KAS implementation with broader sharing across the nation, it is important to minimize CIT and its impact on delayed graft function.
- OPO practices are not uniform. Some OPOs refuse to ship blood in advance of the kidney.
- Transplant centers may not want to perform crossmatches in advance of the kidney.
- Virtual crossmatch is a very predictive tool but is not 100% accurate.
- Addressing this issue could help decrease the number of discarded kidneys that are not transplanted into their intended recipient due to CIT.

However, the Committee generally agreed that this issue should be handled by the OPO Committee with representation from the Kidney Committee and Histocompatibility Committees. The Committee also suggested that the issue be included in the OPO's ongoing project on system's optimization. However, committee members participating in the work group assigned to this project noted that this issue would only impact kidney allocation and that project is intended to address issues impacting all types of organ allocation. There was some concern that bringing this issue to the system's optimization project could potentially detract from the overall goals of that project. The Committee also recognized that requiring these samples in policy may not be logistically feasible. Instead, the Committee generally favored developing a guidance document or best practices over developing formal policy. The Committee will send a memo to the OPO Committee, including the letter from LifeSource, for consideration.

6. Discussion on Letter from Living Legacy Foundation of Maryland

The Living Legacy Foundation of Maryland (Living Legacy) sent an email requesting that the OTPN or UNOS address the OPO practice of granting waivers to transplant centers. For example, if a transplant center accepts an organ offer with cross-match waivers, the organ will be sent to the center and if the recipient has a positive cross-match, the center is not financially responsible for the organ. Anatomical and biopsy waivers also exist. Full waivers means that the transplant center is not obligated to pay the standard acquisition charge (SAC) unless the center transplants the organ, they can decline for any reason. Living Legacy believes that OPOs are making organ offers that have differing waiver rights assigned to them and this practice is neither fair nor equitable allocation practices and it disadvantages patients at centers when the OPO does not grant a waiver. Living Legacy believes that if an OPO chooses to offer an organ with waivers, then it should be required to offer all centers the same waiver.

The Committee was asked to consider whether this in an issue that needs to be addressed at this time and whether this issue should be addressed by the Kidney Committee, OPO Committee, or other group. The Committee was advised that OPTN policy does not usually address the financial arrangements between OPOs and transplant centers.

Committee members acknowledged that there are differential practices among OPOs in how they grant waivers and this is cause for concern, but noted that waivers can help facilitate the acceptance of marginal organs that can be difficult to place. Generally, the Committee believes that this is not an area that the OPTN would normally be involved and the Committee is not in the position to create policy or guidance on OPO business practices. A committee member also noted that there also may be variation in clinical judgement where some transplant centers may feel comfortable accepting an organ without a waiver, but others may not. Establishing a uniform practice for the OPOs offer waivers and transplant centers to request these waivers would be very difficult. Generally, members felt that this is outside of the scope of the Committee and waivers are granted for organs other than kidneys. Therefore, the Committee requested that this issue be referred to OPO Committee and the Association of Organ Procurement Organizations (AOPO) for consideration.

Upcoming Meetings

- July 19, 2016
- August 15, 2016
- September 19, 2016

• October 20, 2016