

OPTN/UNOS Kidney Transplantation Committee
Meeting Summary
December 21, 2015
Conference Call

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

Discussions of the full committee on December 21, 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. Kidney Allocation System (KAS) Clarifications & Clean Up

The Kidney Transplantation Committee (the Committee) reviewed remaining policy clarifications for inclusion in the KAS Clarifications and Clean Up proposal which will be sent for public comment in January 2016. The Committee discussed the following remaining issues:

- Correcting match classification labels
- Informed consent for KDPI greater than 85% for multi-organ candidates
- Mandatory sharing policy

The Committee reviewed additional corrections to match classification labels for allocation of kidneys with a KDPI less than or equal to 20%. These changes do not affect the allocation order and are only clerical changes.

The Committee discussed Policy 5.3.C and Policy 8.5.C: Informed Consent for Kidneys Based on KDPI Greater than 85%. These policies state that prior to receiving an offer for a kidney with a KDPI score greater than 85%, transplant programs must obtain written, informed consent from each kidney candidate willing to receive offers for kidneys in this category. UNOS staff have interpreted that these policies also applies to multi-organ candidates that are listed for a kidney because the policy does not specifically exclude multi-organ candidates. The Committee was asked to clarify this policy further by specifically stating that this requirement also applies to multi-organ offers that include a kidney. In previous discussions, the Committee had been evenly split about whether the requirement should apply to multi-organ candidates because multi-organ candidates have different considerations from kidney-alone candidates and the other organ drives the allocation instead of the kidney. A Kidney Allocation System Post-Implementation Subcommittee (Subcommittee) had recommended that this requirement apply to multi-organ offers that include a kidney but suggested that it may be more appropriate to allow consent to be obtained up until the time of transplant rather than requiring it prior to receiving offers. The Committee generally favored extending the period for obtaining consent to up until the time of transplant. However, because of the division among the Committee members about whether written, informed consent must be obtained from multi-organ candidates, the Committee is asking for specific public comment feedback.

The Committee agreed to add clarification to the policy in the public comment proposal consistent with how the policy has been interpreted (i.e. that the informed consent requirement also applies to multi-organ candidates). The public comment proposal will request feedback from the transplant community to the following questions: (1) does the transplant community believe the informed consent requirement should apply to multi-

organ candidates and (2) if so, should consent be obtained prior to receiving offers or prior to transplant. The Committee will consider this public comment feedback to assess whether the informed consent requirement should be changed before making its ultimate recommendations to the OPTN/UNOS Board of Directors for final approval.

The Committee discussed removing the mandatory share policy. This policy requires that for 0-ABDR mismatches and candidates with a CPRA greater than or equal to 99% in classifications 1-10 of the allocation sequences OPOs make at least:

- 10 offers within 8 hours of procurement for donor kidneys with a KDPI score less than or equal to 85%
- 5 offers within 3 hours of procurement for donor kidneys with a KDPI score greater than 85%.

The current policy does not direct the OPOs on what to do after these minimum number of offers have been made. In practice, OPOs can use a UNet bypass code to skip the remaining candidates in these classifications and begin making local offers. The Committee has debated what changes should be made to this policy. Ultimately, the Subcommittee recommended a compromise that would remove the timing requirements but require OPOs to follow the match run (i.e., would not allow the OPOs to skip these classifications due to this bypass reason, which does not require the OPO to provide a justification). The UNet bypass code associated with this policy would be inactivated. The OPOs would no longer have a time constraint for making offers within 8 or 3 hours of procurement. The OPOs could still use other currently available bypass codes (i.e. expedited placement, donor medical urgency) to bypass candidates if absolutely necessary, but using these codes require the OPO to provide a reason. UNOS staff review the match runs on a rolling basis and the Membership and Professional Standards Committee may review these cases for potential violations. OPO members of the Committee believed that this was a good solution because using the other currently available bypass codes require justification. It will be in the OPOs best interest to begin making offers as soon as possible so that they do not have to use these other bypass codes. The Committee agreed with this recommendation.

The Committee voted in favor of including these changes in the KAS Clarifications and Clean Up public comment proposal with one abstention.

2. Simultaneous Liver Kidney (SLK) Project

The Committee reviewed the final language for inclusion in the SLK proposal's second round of public comment. Proposed policy changes will establish:

- Medical criteria for liver candidates to receive a kidney at the same time as their liver offer (Pediatric candidates will not need to meet this criteria. In order to receive an SLK offer, the candidate will need to be registered on the waiting list for both organs prior to turning 18 years old. The OPO would be required to offer the SLK to all local, regional, and national candidates less than 18 years old at the time registration.)
- A safety net priority in KAS for liver recipients that do not receive a kidney at the time of their transplant and do not regain kidney function

Liver-kidney allocation would be an exception to the general allocation of multi-organ combinations policy. These policy changes do not address the broader issue of multi-organ allocation.

The OPO Committee had requested that the policy make it clear that SLKs do not have to be offered before other multi-organ combinations. The proposed changes do not

require the OPO to make SLK offers instead of other multi-organ combinations that include a kidney. The OPO still has the discretion to decide which multi-organ combinations to offer.

Policy changes also describe when it is required, prohibited, or permissible for the host OPO when allocating the kidney with the liver from the same deceased donor. Programming will indicate to OPOs whether the liver candidate meets medical criteria eligibility and if offering the kidney is required, prohibited, or permissible on the match run.

Medical Eligibility Criteria

The Committee discussed changes to the medical eligibility criteria for chronic kidney disease (CKD). In the fall 2015 public comment proposal, one way a transplant program could document this diagnosis was to show that at the time of registration, the candidate's most recent measured or calculated creatinine clearance (CrCl) or GFR was less than or equal to 35 mL/min. Several members of the OPTN/UNOS Board of Directors, who felt this GFR value was too high, recommended reducing the CrCl or GFR value to 20 mL/min. These members believed that if left at 35 mL/min, this could increase the number of SLK transplants to candidates who might recover kidney function after receiving their liver transplant. The SLK Working Group did not agree with this value, but recommending reducing it to 30 mL/min. If the GFR value were 20 mL/min, the SLK Working Group felt that may reflect end-stage renal disease (ESRD) rather than chronic kidney disease. The Committee agreed to the SLK Working Group's recommendation.

The Committee reviewed the medical eligibility criteria for sustained acute kidney injury. Previously, the proposal implied that the transplant program would have to report on the 7th day for six weeks that the candidate either was on dialysis or had a CrCL or GFR less than or equal to 25 mL/min. The policy now makes it clear that the transplant program will have to report at least once every 7 days for 6 weeks. Programming will allow transplant programs to enter this information retrospectively. Committee members also discussed concerns raised by the Liver Transplantation Committee (Liver Committee) that the calculated GFR may not be an accurate reflection of acute kidney injury in certain liver patients. Although the Liver Committee was concerned, they did not offer an alternative to consider. The Committee did not decide to make any changes at this time.

A Committee member requested an edit to the metabolic disease medical criteria to clerical change to clarify that the diagnosis of atypical HUS from mutations should be from factor H or factor I. As proposed, the policy says "factor H and *possibly* factor I." The change would remove the word "possibly." The other committee members agreed and this change will be included in the SLK proposal.

Originally, the candidate's nephrologist would need to confirm a diagnosis of CKD, sustained acute injury, or metabolic disease in UNet, but the medical criteria required in policy would be maintained in the medical record. Going forward, UNOS plans to program data entry fields in UNet for both the diagnosis and the medical criteria to make the policy easier to monitor and analyze data to determine if the medical criteria is appropriate.

The day the policy is implemented, existing SLK candidates will have to meet the medical eligibility criteria. UNOS will program these new data fields in advance so that transplant centers can enter this data prior to implementation. The Committee still needs

to decide how far in advance these fields should be made available so that eligible candidates can receive offers the day of implementation.

SLK Safety Net Priority

The Committee discussed changes to the eligibility requirements for prioritization for liver recipients on the kidney waiting list that do not receive a kidney transplant at the time of their liver transplant. As proposed, these liver recipients could qualify for priority on the kidney waiting list if they register on the kidney waiting list prior to the one-year anniversary of their liver transplant. The liver recipient would also have to show that they had a CrCL or GFR less than or equal to 20 mL/min or that they were on regularly administer dialysis during the 60-365 day timeframe following their liver transplant. In order for the candidate to retain this priority, the Committee decided that the transplant hospital would have to report this qualifying criteria at least once every 30 days for three consecutive months. Once the candidate qualified, the candidate would receive priority on the kidney waiting list indefinitely. If a candidate initially qualified at month 11 following liver transplant, the candidate will still need to meet this qualifying criteria in months 12, 13, and 14 in order to retain the priority. Programming will allow this information to be reported retrospectively.

Upon implementation, all liver recipients (within the past 365 days) on the kidney waiting list will be potentially eligible for this priority except for an SLK recipient. An SLK recipient could only be eligible for priority if the kidney experienced immediate and permanent non-function within 90 days post-transplant.

The Committee approved the final language for the SLK proposal which will be distributed for public comment in January 2016.

Other Significant Items

3. SLK Supplementary Data Request

During the OPTN/UNOS Board of Director's (the Board) Meeting on December 1-2, 2015, the SLK proposal was presented as part of a break out session for board members. Several board members requested additional data to complement previously performed analysis. Board members were concerned that the medical eligibility criteria would increase the number of SLK transplants and transplants to liver recipients that later need a kidney. After discussing the board member feedback with Committee leadership, UNOS staff suggested that the Committee make a supplementary data request to support the proposal. The purpose of requesting this data will be to increase the transplant community and Board's comfort level with the proposed policy changes. The Committee discussed performing the following analysis:

- Estimate the percentage of current SLK recipients that would not qualify under the proposed medical criteria
- Providing an assessment of (a) expected volume of use of potential safety net and (b) differences in likelihood of not regaining kidney function by different degrees of medical eligibility criteria

The purpose of this analysis would be to estimate the potential increase or decrease for SLK transplants and the impact to kidney-alone candidates. Committee members were concerned that limitations in the type of data collected could impair the analysis from providing a full assessment. Committee members noted that the results will need to include the limitations to the analysis when presented. Additionally, committee members discussed whether analysis should not only include SLK recipients that would not qualify

under the proposed medical criteria, but also the number of liver-alone recipients that would have qualified. Ultimately, the Committee voted not to include the liver-alone recipients in the analysis, but after a robust debate about the merits of performing additional analyses, approved the data request as drafted by the UNOS research department. Committee members requested that the results be presented to the Committee prior to the regional meetings.

Upcoming Meetings

- January 25, 2016
- February 29, 2016
- March 21, 2016
- April 18, 2016