OPTN/UNOS Kidney Transplantation Committee
Meeting Summary
January 25, 2016
Conference Call

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

Discussions of the full committee on January 25, 2016 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 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 and create a "safety net" for liver recipients that do not receive a kidney at the time of their liver transplant but later experience renal failure. In December 2016, the Committee voted to distribute a SLK proposal for public comment beginning in January 2016. During this same conference call, the Committee requested supplementary data on (1) the estimated percentage of current SLK recipients that would not qualify under the new medical eligibility criteria, (2) the expected volume of use of potential safety net, and (3) the differences in likelihood of not regaining kidney function by different degrees of medical eligibility criteria. The Committee reviewed preliminary results on the first request.

The analysis showed that approximately 19% of previous SLK recipients would not have qualified under proposed medical eligibility criteria. These results are similar to previous research which had estimated that 15-30% of SLK recipients would not have qualified for the SLK transplant.

Committee members discussed whether there was any way to tell the likelihood of a liver patient that did not qualify for SLK receiving a kidney following their liver transplant. The second part of the analysis, which is pending completion, will look at liver recipients that experienced ESRD within 1 year post-liver transplant. A committee member noted that the purpose of including a safety net is help those patients that do not receive a kidney with their liver, but later show signs of kidney dysfunction. Transplant centers will also need to report the GFR value for the diagnosis of chronic kidney disease which will allow the committee to assess whether there needs to be any adjustments to the medical eligibility criteria.

Implemented Committee Projects

2. Kidney Allocation System (KAS)

KAS was implemented on December 4, 2014. The Committee has reviewed the early trends and results on an ongoing basis since implementation. The Committee was asked to approve a 1 year KAS data analysis request compiled by the UNOS research department. The purpose of this analysis is to provide pre- and post-KAS metrics to help the committee assess KAS performance relative to its goals. Many of the same metrics

that were included in earlier reports will be included in the 1 year analysis. New metrics (stratified by patient characteristics) will be added to the analysis including:

- 6 month, post-transplant outcomes (graft survival and patient survival rates) and creatinine measurements
- Waitlist mortality rates (death rates per patient-year) including death while on the waiting list and death after listing. Death after listing refers to patients who registered on the waiting list but were removed from the list and passed away shortly after. These are considered waiting list deaths.

The new cohorts for this data will be 12 months both pre- and post-KAS implementation.

The Committee requested the following changes to the proposed data request:

- Stratify the recipient data by the number of previous transplants.
- Include analysis of organ discard rates by match runs that identify non-local 99-100% CPRA candidates. The Committee would like to know if there is a higher likelihood of discard which could be attributable to the logistics of national sharing, shipping blood, and arranging crossmatches. This information would be helpful in determining whether there should be a strategy for getting the materials to make the allocation process as efficient as possible.

A recent analysis by UNOS researchers noted that the offers made to the highly sensitized had a lower the discard rate. These patients have very high acceptance rates compared to most other groups of patients. The Committee may review this analysis rather than making it a part of the 1 year data analysis request.

The Committee approved the data request. The 1 year report will be completed in March 2016 and presented to the Committee at its in-person meeting on April 18, 2016 in Chicago.

Other Significant Items

3. Imminent Death Donation Report (Ethics Committee)

The Ethics Committee has requested formal feedback from the Kidney Committee on a draft report examining the ethical considerations, logistical, and policy issues of Imminent Death Donation (IDD). IDD refers to the recovery of a living donor organ immediately prior to impending and planned withdrawal of ventilator support that is expected to result in the patient's death. This report specifically focuses an individual with a devastating neurological injury that is considered irreversible, but is not considered brain dead. This individual is unable to participate in decision-making and a surrogate has already made the decision to withdraw care. The surrogate would make the decision for this person to donate either as a donation after cardiac death (DCD) donor or prior to withdrawal of care (i.e. IDD). Under current OPTN policy, this person would be considered a living donor. The report refers to these donors at Live Donation Prior to Planned Withdrawal (LD-PPW). The Ethics Committee is recommending that the potential for LD-PPW and the associated risks be better understood before considering policy development in order to support the utility of this potential new donation practice. The Chair of the Ethics Committee presented a number of ethical and operational considerations that have been identified:

Ethical Considerations

- Potential for perception that LD-PPW erodes the Dead Donor Rule (i.e. organ donors must be dead before procurement begins or organ procurement itself must not cause the death of the donor)
- Appropriateness of a surrogate to consent the patient to organ donation. Because the patient would be a living donor, the patient would not be able to provide informed consent for living donation. These patients could be considered a vulnerable population because that could not make decisions for themselves.

Operational Considerations

- Identifying appropriate candidates for LD-PPW rather than DCD
- Existing living donor informed consent and medical evaluation policies would need to be modified to permit LD-PPW and LD-PPW could only occur in OPTN living donor member hospitals
- OPOs are responsible for deceased donor authorization, medical evaluation, organ recovery and allocation while living donor hospitals are responsible for the informed consent process, medical evaluation, organ recovery and placement of living donor organs. However, these roles may need to change for LD-PPW.
- Because the death in these patients is anticipated, outcome data would need to be segregated from other living donation so that it would not negatively impact a transplant program's living donor outcome metrics.

Other Considerations

- Potential for eroding public trust
- Potential to be welcomed by some families it LD-PPW was perceived as another viable approach to supporting surrogate preferences since not all DCD donors progress to death in time for organs to be viable for transplant

The presentation also addressed the potential benefits and harms to allowing LD-PPW:

- Potential for increased availability of organs
- Reduced organ ischemic time with better recipient outcomes
- Fulfilling a patient's previously indicated or documented decision to be an organ donor
- Emotional benefit to donor family's grief process
- Avoid wasted hospital resources, reduce costs and staff frustration when DCD does not occur
- Difficulty in accurately predicting whether potential DCD donors will become actual donors
- If a potential donor does meet DCD criteria, that donor could donate multiple organs. Therefore, it is possible that LD-PPW could negatively impact the current volume of organs available for transplant.

The Ethics Committee is asking several committees to review the report and provide feedback. This feedback will be considered before presenting this topic to the OPTN/UNOS Board of Directors (the Board). If the Board is supportive of continued work on this project, the Ethics Committee will consider releasing a concept paper for public comment and will ask the Scientific Registry of Transplant Recipients (SRTR) to provide modeling to understand how LD-PPW might impact the total number of organs available for transplant.

The Committee generally felt that the Ethics Committee should continue to explore this idea. Individual committee members had the following comments/questions:

- Pursuing LD-PPW could create serious risk of eroding public trust and the potential benefit of increasing the number of organs recovered may not outweigh this risk. The general public may feel that this is a realization of their greatest fear – that their organs would be taken from them when by some miracle they might recover.
- Anesthesiologists should be included in any future development to assess when a patient would be recovered from a nephrectomy to then begin extubating.
- Are any other nations pursuing this option for donation? The Ethics Committee is not aware of any other nations practicing LD-PPW at this time.
- Does LD-PPW put anyone at risk for violation of state laws? The Ethics Committee did not know of any risk at this time.
- What is the reason that cases do not progress to DCD donation? After extubation, the potential DCD donor does not expire within the prescribed timeframe defined by the OPO and donor hospital to allow for viable organs to be recovered.
- Would LD-PPW allow for a liver to be recovered without violating the Dead Donor Rule? At this time, the Ethics Committee believes that initially the recoveries would be limited to one kidney.

There were several questions that the Committee felt should be considered as part of further development:

- How would it be reported on a cost report?
- How would this donation be used (ex. non-directed donor going to waitlist at donor hospital, OPO-driven list)?
- Has there been any consideration to include language in the first person registry of informed consent?

Upcoming Meetings

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