OPTN/UNOS Kidney Transplantation Committee
Meeting Summary
August 15, 2016
Conference Call

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

Discussions of the full committee on August 15, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov.

Review of Public Comment Proposals

1. Modification of Existing and Potential New Requirements for the Informed Consent of Potential Living Donors (Living Donor Committee)

The Living Donor Committee presented its proposal to modify or create new requirements for living donor informed consent. In February 2013, the OPTN/UNOS implemented the current requirements for the informed consent of living kidney donors. Informed consent requirements for living liver, pancreas, intestine and lung donors followed in 2014. Since initial implementation, several developments support the need to update and clarify the current informed consent policy requirements including:

- Publication of new evidence on living kidney donor health outcomes
- Consensus-based recommendations from professional societies that the new information regarding the health outcomes for living kidney donors should be disclosed as part of the informed consent process
- Release of living donor program-specific reports (PSRs) by the Scientific Registry of Transplant Recipients (SRTR)
- Reports from living donor program site surveys identifying areas of existing policy language that have been frequently misunderstood by living donor recovery programs

The Living Donor Committee proposes clarifying existing requirements and adding other new requirements. The proposal also includes related changes to the informed consent requirements for kidney paired donation, and modification and elimination of some related OPTN Bylaws requirements.

This proposal has been distributed for public comment August 15 – October 15, 2016.

The following summarizes the questions and discussion among committee members about the proposal:

Committee members supported the updates to inform on the increased risks of end stage renal disease and pregnancy complications after donation and clarifications related to privacy law restrictions and circumstances under which candidate health information may or may not be shared.

Was the Joint Societies Work Group involved in the development of this project? No, the Joint Societies did not feel that it was necessary to participate in the development of this policy. However, the proposed policy was sent for pre-public comment feedback to two of the societies that participates in the Work Group - the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS). The

Living Donor Committee considered this feedback before finalizing the proposed policy language.

Will these changes require additional documentation to comply with the new policy? The intent is to just update existing informed consent documentation with the new requirements. Members were very concerned that these new requirements could increase member burden.

Does this proposal have any changes to donor acceptance criteria? No, clarifications are limited to candidate selection criteria.

A committee member asked about the Living Donor Committee's role in addressing informed consent for donors. Informed consent for donors has had a long history of development and a mandate from HRSA to develop living donor informed consent and medical and psychosocial evaluation policies. The reason for changes to these policies is to reflect new developments in the field and change outdated material.

Several committee members did not support the proposed new requirements to disclose national and center-specific 1-year follow-up rates. Transplant centers invest a great amount of resources to reach out to living donors in order to meet follow-up requirements for living donors, but living donors do not always respond. Because the follow-up rates are based on whether the follow-up is actually completed and do not account for the transplant center's attempts or efforts, members felt that the rates are not indicative of the transplant center's dedication to its living donors. Members felt that this was an element that could distract from the more important issues to discuss with patients such as the safety of donating.

The Living Donor Committee feels that follow-up rates are already publicly available through program specific reports (PSRs), but this policy requirement would help educate donors as the PSRs are not something that patients usually use as a resource.

The Committee will submit a comment on the proposal on the OPTN website that reflects this discussion and any subsequent input from committee members received following the call.

Other Significant Items

2. Review of New Offer Acceptance Models for Program Specific Reports (PSRs)

The SRTR contract with HRSA states that the PSRs shall include certain information on acceptance and utilization of organs. There are three commonly suggested metrics for evaluating pre-transplant organ utilization: transplant rate, organ acceptance, and offer acceptance. The Kidney Committee was asked to provide feedback on offer acceptance model changes:

- Input on model structure and donor and candidate factors for risk adjustment
- Information of interest for public and private reporting

Committee members were asked to identify any other risk factors not included on the list below:

- Donor Factors: KDRI, offered as en bloc or paired, completed biopsy, DCD donor, CDC high-risk
- Donor-Candidate Factors: Ratio of body surface area, distance between recovering and candidate hospitals, number of HLA mismatches

- Candidate Factor: EPTS, age, BMI, blood type, kidney disease, CPRA at the beginning of the cohort

The SRTR noted that they could not account for cold ischemic time. The model will adjust for the number of previous offers made.

Committee members suggested the following additions:

- Time of offer from cross clamp
- Warm time for DCD (i.e. time of withdrawal of life support to time of cross clamp)
- Pump parameters
- Candidate factors that identify potential recipients for high KDPI kidneys (e.g. waiting time, other medical issues)
- Adjusting the model to look at pre-procurement offers

Committee members were asked to provide feedback on two different approaches for reporting offer acceptance behavior:

- Public PSRs – summarize overall offer acceptance behavior
- Private CUSUM-type reports – provide more detailed information for quality improvement efforts. Programs can identify sudden changes in offer acceptance behaviors, offer acceptance for specific types of donors, rejected offers that the model gave a high probability of acceptance

Committee members suggested the following for the CUSUM reports:

- Breaking out the programs that do not accept offers for high KDPI kidneys.
- Factoring the waiting time of similar areas of the country. Programs that have a 10 year waiting time may be more likely to accept offers than those with shorter waiting times.
- Accounting for offers that are turned down by some centers but are quickly accepted farther down the match run. Programs may complain that their transplant volume is lower, but further analysis shows that these centers have received offers but are turning them down.

A committee member asked if these reports would be use by CMS to flag members. The SRTR did not believe so, but noted that CMS operates separately from the SRTR. A couple of members noted that if these reports were reviewed by private insurers or used by CMS, it could change or limit how transplant centers set offer acceptance criteria.

3. Update on Member Fiscal Impact Pilot

The Committee did not have time to review this agenda item.

Upcoming Meetings

- September 19, 2016
- October 20, 2016
- November 21, 2016