OPTN/UNOS Kidney Transplantation Committee
Meeting Summary
May 19, 2014
Conference Call

Richard Formica, Jr., MD, Chair
Mark Aeder, MD, Chair

Discussions of the full committee on May 19, 2014 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.

Review of Public Comment Proposals

1. **Proposal to Modify ABO Determination, Reporting, and Verification Requirements**
   The Committee had some questions regarding the differences between what is being proposed and CMS requirements. UNOS policy staff explained that the two requirements are not exactly aligned (for instance, CMS does not require secondary verification for blood type), but UNOS recently constructed a crosswalk to help with identifying differences. Several committee members expressed the view that education on the changes and tools to help OPTN members comply will be key. In particular, it was suggested that a sample form be provided to transplant programs.

   Several members commented in favor of the Committee's approach with respect to allowing transplant programs define 'qualified health care provider', instead of specifying that the individual be licensed.

2. **Greater Consistency in Candidate and Deceased Donor HLA Typing Requirements Across Organ Types**
   The Committee members supported requiring HLA-DQA and –DPB to be reported for deceased kidney donors. In response to the Histocompatibility Committee's specific request for feedback about how these fields should be programmed, the Committee members indicated a preference for the fields to be added in DonorNet and as unacceptable antigen fields in Waitlist, due to the following:

   - There will be regional and national sharing of kidneys with implementation of the new kidney allocation system (regional/national sharing for high CPRA candidates and regional sharing kidney offers with KDPI greater than 85%) and donors need to be screened using the full list of HLA loci in order to reduce the likelihood of unexpected positive crossmatches.
   - It would be overly burdensome and impractical for transplant programs to have to review extended donor HLA typing information if it is communicated in DonorNet only. The transplant team may overlook the information which has patient safety implications.
   - The OPTN KPD pilot program's UNet application already includes these antigens/unacceptable antigen fields and the deceased kidney donor allocation system should be consistent with the KPD program.

3. **Proposal to Notify Patients Having an Extended Inactive Status**
   The Committee had significant concerns with this proposal. The majority of the members were concerned that it is overly burdensome to require transplant programs to send a letter to every patient that has been inactive for 90 consecutive days and annually, especially when committee members determined there is little correlation between this new requirement and the goal the TCC hopes to achieve (transplant access). The Committee had the following specific comments:

   The Committee agrees that patients are entitled to know when their status has changed on the waiting list. However, the TCC should consider that there are sometimes appropriate and clinical reasons for inactivating kidney candidates for extended periods of time (for example, to allow a period of time for recovery from cancer, for the candidate to achieve a certain degree of weight loss, etc.) and the proposed 90-day rule would be very burdensome for kidney programs with large waiting lists.

   In order to address this new rule, programs may be forced to divert resources from helping patients get to an active status. This change could also potentially make kidney programs reluctant to list patients that they plan to make inactive for a period of time and, therefore, cause the patient to miss out on additional waiting time accrued at inactive status and additional priority points as a result.

   Overall, the Committee agrees with the goals the TCC wishes to achieve but disagrees with the proposed solutions, arguing that they may instead have negative consequences for kidney candidates and transplant programs across the country.

Other Significant Items

4. **Feedback to MPSC on Policy 5.2 Shipping Kidneys on Cassettes**
   The Committee reviewed a request for feedback from the Membership and Professional Standards Committee (MPSC) on the practice of shipping kidneys on cassettes. The MPSC requested feedback on this practice after a discussion about the inability of organ procurement organizations (OPOs) to comply with Policy 5.2, which states that all organs must be packaged in a triple sterile barrier. The MPSC staff presented this information, along with the OPO Committee's response and recommendation that if the perfusion cassette is removed from the machine to be shipped, the kidney should be removed from the cassette and packaged in a triple sterile barrier.

   Members of the Committee agreed with the OPO Committee's conclusion that there is no acceptable way to package a kidney in a triple sterile barrier if the kidney is not removed from the cassette. The Committee members agreed that maintenance of sterility is paramount. In the interest of patient safety and the proper packaging of organs, the Committee recommended that the MPSC amend Policy 5.2 or issue guidance to OPOs to make it clear that the kidney must be removed from the cassette and packaged in a triple sterile barrier if it is no longer being pumped.

5. **Feedback to the Pediatric Transplantation Committee on Pediatric Training and Experience Consideration in the OPTN Bylaws**
   The Committee reviewed a request for feedback from the Pediatric Transplantation Committee on their efforts to:
   - establish a pediatric component for each transplant program intending to transplant patients younger than 18 years of age; and

- establish qualifications for a pediatric primary surgeon and pediatric primary physician at these programs.

While the Committee members agreed that the utmost quality and safety is needed in transplanting pediatric patients, many expressed concerns about provisions in the proposal. The Committee members wondered if there is evidence of a problem with the outcomes associated with pediatric transplants or any recent adverse events that have occurred to spur this change. Members of the Committee also suggested that the Pediatric Committee and MPSC obtain information regarding whether the majority of existing kidney transplant programs can meet the proposed pediatric component requirements. Without knowing the impact, the Committee is concerned that the changes could result in decreased access for some pediatric candidates. It could also result in surgeons doing procedures and managing patients for a procedure that may only come up 5-7 times a year at their center. The Committee had the following specific comments:

- The proposed case volumes for pediatric primary kidney surgeons are too high. The Pediatric Committee has chosen a case volume that is 40% of that for individuals performing adult kidney transplants. However, pediatric transplants comprise a very small percentage of overall transplants. The case volume number should better reflect the percentage of pediatric transplants, otherwise, there could be a decrease in access for these patients.

- Given that certain older pediatric patients can be similar in size to adults, there is no technical or clinically relevant reason for requiring a certain number of kidney transplants in patients 'younger than 18'. From a surgical perspective, the same techniques are used for children similar that would be used with an adult similar in size. In this sense, it may be more appropriate for an adult transplant surgeon with more experience to perform transplants on children similar in size to an adult than it would be for a pediatric transplant surgeon with less experience. There are multiple events, such as surgical and infectious complications, which mirror adult recipients that the transplant team would be able to more efficiently diagnose. It may be clinically relevant to use size in the criteria (patients 20 kg or less at the time of transplant), however, this may also decrease access for those pediatric patients due to the low number of transplants performed on these patients each year.

- The Pediatric Committee should consider whether there are workforce issues that make it difficult to meet the proposed new pediatric primary kidney physician requirements. One member pointed out that there are a limited number of pediatric nephrology fellowships in the country, making it difficult to meet the pediatric nephrology fellowship pathway. This member suggested that the Committee consider allowing pediatric nephrologists to accumulate the experience necessary by working with adult candidates and/or allow experience working alongside a nephrologists serving adult candidates.

If the Pediatric Transplantation Committee continues to pursue these changes, the Kidney Committee members would suggest that a phased implementation approach be considered to ensure that the changes do not decrease access to transplants for pediatric patients.

Upcoming Meeting(s)

- June 30, 2014