

OPTN/UNOS Kidney Transplantation Committee
Meeting Summary
September 29, 2014
Chicago, Illinois

Richard Formica, MD (Chair)
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Discussions of the full committee on September 29, 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>.

Committee Projects

1. Kidney Paired Donation (KPD) Histocompatibility

The Committee distributed for public comment (March-June 2014) proposed new histocompatibility testing policies for the OPTN KPD program. UNOS staff provided an overview of the public comments received on the proposal. The Committee discussed the comments and made three changes to the proposal:

- The public comment proposal required programs to inactivate their candidate in the OPTN KPD program if an unacceptable positive crossmatch occurred that precludes transplant with a matched donor. During the public comment period, the Committee asked for specific feedback about whether or not the program should be required to inactivate the candidate or if UNOS should automatically make the candidate ineligible. The overwhelming feedback received was that UNOS should automatically make the candidate ineligible. The Committee adopted this change in the proposal.
- The Committee removed a requirement for someone from the histocompatibility laboratory to verify the accuracy of the unacceptable antigens each time they are entered. The Committee was concerned this was going to be a very burdensome requirement, because programs would be required to document the verification in the medical record. Instead, the Committee amended the proposal to require that the physician or surgeon (or their designee) and the histocompatibility laboratory director (or their designee) review any unacceptable antigens listed for the candidate before the candidate appears on their first KPD match run.
- Finally, the Committee discussed the proposed requirement that all candidates be tested for antibodies every 90 days. The Committee members wanted to allow programs some flexibility in this requirement, so the proposal was amended to add a plus or minus 20 day window to the requirement. This is consistent with the KAS policy to confirm that Blood Type B candidates are still eligible for access to A2/A2B kidney offers.

The Committee voted unanimously (18-Y, 0-N, 0-A) to recommend the amended proposal be approved by the Board of Directors at their November 12, 2014 meeting. If approved, all of the changes would become effective when IT programming is complete and the OPTN membership has been notified.

2. Marking Kidney Laterality

A total of 21 cases of switched kidney laterality have been self-reported to UNOS since 2012. In 5 of these cases, one or both of the switched kidneys was not transplanted due (at least in part) to the laterality switch. There are currently no guidelines or policies on marking kidney laterality and this creates confusion for receiving transplant centers across different DSAs. This issue was the third highest ranked failure mode identified during the Failure Modes Effects and Criticality Analysis (FMEA) conducted by Northwestern University on the current deceased donor organ procurement process as part of the Electronic Tracking and Transport (ETT) Project.

A working group comprised of representatives from the Kidney Transplantation, Operations and Safety, and Organ Procurement Organization Committees held a conference call in early August to discuss the issue. The workgroup agreed that switched laterality is a problem that results in discards and should be addressed. The workgroup discussed solutions to the problem, particularly whether policy changes or guidance may be needed for marking kidney laterality. The majority of the workgroup did not feel that policy changes are needed at this time. However, they did agree that official OPTN guidance on the issue may be appropriate. They requested feedback from the OPO Committee before moving forward with official guidance.

The chair of the working group presented the Committee with an update on the discussion and feedback from the OPO Committee. The OPO Committee indicated support for moving forward with a guidance document on marking kidney laterality. Many of the OPO Committee members reported that their institutions began this practice after having a switched laterality incident. However, some members said their efforts to enact a policy in their institution was not supported.

The OPO Committee suggested that the guidance put forth the following as the best practice:

- OPOs should work with their local surgeons to develop a policy for marking laterality.
- OPOs should indicate laterality by marking the *left* kidney *in situ* (but leaving it up to the OPO as exactly what they use to mark it)

The Committee made the decision to draft a guidance document for the Board of Directors to consider at the June 1, 2015 Board meeting.

3. Simultaneous Liver Kidney (SLK) Project

The Committee received an update on the discussion and data review from the first two SLK working group calls. The Committee members expressed support for moving forward with a public comment proposal in summer 2015.

Committee Projects Pending Implementation

4. Revised Kidney Allocation System (KAS)

The Committee reviewed the results of data requested at April meeting and incorporated into KAS educational materials. The Committee requested additional data to better compare deceased donor kidney longevity to that of a living donor kidney. These data are intended to be used by physicians in talking to patients about kidney offers and acceptance.

The Committee also received an update on KAS education efforts and a progress report on how kidney programs are doing with updating their EPTS data elements. The Committee also briefly reviewed the KAS data monitoring plan, which will be more closely monitored by the KAS Implementation Subcommittee beginning in January 2015.

Review of Public Comment Proposals

5. Definition of Pancreas Graft Failure

The Committee reviewed the Pancreas Transplantation Committee's proposal to create a separate definition of pancreas graft failure. In general, the Committee members did not have any concerns with the definition of pancreas graft failure.

The Committee reviewed the general definition of graft failure in OPTN policy (used for assessing kidney program performance), along with the definition of 'immediate and permanent non-function' (used for reinstating waiting time for kidney candidates). There are some differences in these definitions, and the Committee discussed whether the differences are appropriate for each definitions use in OPTN policy.

The Committee offered the feedback that the current definition of graft failure is sufficient and appropriate for assessing kidney program performance. They did, however, request to further discuss the definition of immediate and permanent non-function of a transplanted kidney, due to the fact that interpretation of the current policy means that programs must report a graft failure in order to reinstate a candidate's waiting time. The Committee will continue to discuss what clarifications may be needed to this policy, including whether candidates who request waiting time reinstatement based on GFR/CrCl values at or below 20 ml/min within 90 days of a transplant should be granted reinstatement without the program reporting the transplant to the OPTN as a graft failure.

Other Significant Items

6. Request from Membership and Professional Standards Committee (MPSC) for Feedback on Medical Urgency Policy

In August, the MPSC sent a memo to the Kidney Committee leadership requesting the Committee's review of OPTN policy pertaining to medically urgent kidney candidates. The MPSC recently reviewed a case where an OPO bypassed a number of national O-ABDR mismatch and local pediatric candidates for a medically urgent local candidate in the DSA.

The Committee reviewed the policy language around medical urgency that will take effect with the new KAS. The Committee agreed that the policy should be clarified to define medical urgency. There was some support for specifying that a kidney candidate is medically urgent when they are on their last vascular access for dialysis, but the Committee could not come to consensus during this first conversation. The Committee will continue to discuss what clarifications may be needed to this policy, including how medically urgent candidates should be prioritized if they meet the definition.

7. Increasing Utilization of Double Kidney Allocation

Though dual kidney transplantation has been shown to provide a substantial survival advantage over single kidney transplantation, in particular from deceased donors with high KDPI values, currently only about 1% (approximately 100 per year) of kidney transplants are duals. With discard rates for high KDPI kidneys at or exceeding 50%, expanding the prevalence of dual kidney transplantation may be a way to increase the number of kidney transplants by reducing the number of discards.

The Committee reviewed the current policy criteria for allocating dual kidneys and the programming for dual allocation that will be in place with the new kidney allocation system on December 4. Some members expressed concern that the current policy and programming are suboptimal and need revision in order to expand the use of dual kidney transplantation.

The Committee will continue to review and discuss proposed changes beginning in January 2015 (after the implementation of the new kidney allocation system).

Upcoming Meetings

- October 20, 2014
- November 17, 2014
- December 8, 2014