

**OPTN/UNOS Kidney Committee
Meeting Summary
October 20, 2016
Chicago, IL**

**Mark Aeder, MD, Chair
Nicole Turgeon, MD, FACS, Vice Chair**

Discussions of the full committee on October 20, 2016 are summarized below. All committee meeting summaries are available at <https://optn.transplant.hrsa.gov>.

Committee Projects

1. En Bloc Kidney Transplant Project Update (Voting Item)

The Committee received an update on the status of this project from the En Bloc Work Group Project Liaison. The purpose of this project is to increase the utilization of pediatric en bloc kidneys. The Work Group proposed creating policy to provide specific direction for host OPOs offering kidneys from deceased donors weighing less than 15 kg and those between 15 and 25 kg. En bloc kidneys will only be offered to candidates at transplant centers that indicate they are willing to accept them.

The Committee voted unanimously to approve the proposed policy language and proceed to public comment in January 2017.

2. Double Kidney Project Update

The Committee received an update on the status of the project from the Double Kidney Group Project. The purpose of this project is to increase the utilization of kidneys with high KDPIs, frequently from older patients, that are not suitable for single transplant. The Work Group proposed a two-tier allocation scheme for double kidneys based on medical criteria and designed to minimize cold ischemia time.

Pre-recovery criteria	Post-recovery criteria
<ul style="list-style-type: none">• Donor of at least 70 years <i>or</i>• Less than 70 years <i>and</i> KDPI greater than 90 <i>and</i> creatinine clearance less than 60 mL/min.	<ul style="list-style-type: none">• Glomerulosclerosis greater than 20% <i>or</i>• Creatinine clearance less than 65 mL/min. <i>and</i> failure to place kidneys singly 6 hours post cross-clamp

Some on the Committee were supportive of this concept, while others expressed concern that so many dependent criteria would be complicated and difficult to enact. They expressed a need for clear directives for OPOs to follow. The Subcommittee will continue to work on this proposal. The Committee did not come to a clear consensus, so the Work Group will continue to consider options. It is unlikely to go out for public comment in January 2017.

Other Significant Items

3. Kidney Paired Donation (KPD) Work Group Update

The Vice Chair presented an update on the KPD Work Group progress to date.

KPD Improvement Plan

UNOS staff conducted a series of interviews with transplant centers to gather feedback for an improvement plan. Based on this feedback, UNOS staff will focus on education about the program, understanding and reducing refusals of match offers and gathering and sharing best practices for the donor pre-select tool, which will eventually result in computer programming to improve the tool. An advisory council will also convene to discuss changes that can be made to the system or operational improvements that do not require formal policy changes. Council membership has not yet been developed.

A member asked if there are data to explain the increase in donor issues leading to chain breaks as reported in the presentation. UNOS staff are looking into decline reasons as part of the improvement plan – there are some donors that are declined due to age, BMI, medical history, etc. The team is looking into whether there are trends behind the number of declines.

KPD Project Review

Repairing OPTN KPD Exchanges: Currently, there is only one method of repairing OPTN KPD chains. Policy permits chains to be “truncated” where the chain is shortened up until the point of refusal or break. Policy does not allow a chain to be reevaluated to see if other repair types are possible. The KPD Work Group has been developing this project. To date, the KPD Work Group suggests writing a broad policy that allows for multiple types of repairs to allow for future medical and technical advances. Chain repair types under consideration include leap frogging (e.g. skipping over the break in the chain), substitution of 1 or more pairs to fill the break, reordering of remaining pairs, and truncation. The Work Group will examine IT solutions that can support these types of repairs, if incorporated into policy. The KPD Work Group believes that full automation is ideal.

Allowing Deceased Donor Chains: Deceased donor-initiated chains (DD chains) are currently not permitted by policy. This project will seek to develop policy that will allow DD chains. A DD Chains Work Group has been formed to focus specifically on this project, The DD Chains Work Group membership has been finalized and includes members of AST, AOPO, ASTS and NATCO, as well as recipient and living donor representation. The first monthly meeting is October 26.

At the request of Kidney Committee leadership, the Ethics Committee has provided a memo outlining specific concerns regarding DD chains. The concerns include: depletion of DD blood type O, unequal distribution among ethnic minority groups, deceased donor kidneys being ultimately better quality than the organ being donated back to the wait list, and the risk of living donors declining to donate.

This project will begin with a Request for Information (RFI) to ask for feedback from the kidney transplant community to generate ideas and consensus building for allowing DD chains. Based on this feedback, the DD Chains Work Group may ask for the Kidney Committee to sponsor a variance which would be distributed for public comment and presented to the OPTN Board of Directors for approval. Variances are experimental policies that test methods of improving allocation.

A committee member expressed a concern about disadvantaging certain blood type groups. Most paired exchange programs have a lot of O candidates with a lot of A,B, or AB donors. This member's center attempted allowing donors simply to donate to the list and then sending the next deceased donor to the next sensitized O candidate, but there was concern of disadvantaging the O blood group deceased donor pool. Another committee member expressed that any data or modeling that can be done surrounding this issue will be key, though they acknowledged this data may be challenging to acquire. A committee member participating on the DD Chains Work Group acknowledged that often chains end in donating to AB candidates and that this issue will be considered thoroughly as part of this project.

The Committee supported the proposed development plan for this project.

4. Update on the OPO Committee Systems Optimization Project

The Systems Optimization project was established following Liver Redistricting Subcommittee work looking at increasing donation and utilization. The goal of this project is to evaluate and recommend policy designed to increase efficiency of organ allocation and to prevent loss or misallocation of organs. The OPO Committee is sponsoring this project and has put together a multi-disciplinary Work Group that includes Kidney Committee members. One of these members provided an update on the project progress including the use of the "provisional yes," barriers to efficient placement, the impact of center-specific behavior on evaluating and accepting organ offers, and limitations in DonorNet. The Work Group has developed several recommendations to improve efficiencies in the process, largely surrounding the use of technology to get better information to centers sooner so the "provisional yes" is not such a barrier to placement. A list of proposed changes has been submitted for IT implementation and a subgroup is meeting to determine timeline and feasibility for OPOs.

Additionally, the Work Group has proposed shortening the allowable response time for acknowledging an organ offer post-procurement from 1 hour to 30 minutes. This recommendation will need to be supported by the OPO Committee and would require a policy change.

Did Kidney Committee have any specific feedback for System Optimizations that should be included here?

5. Update on the Minority Affairs Committee (MAC) Project on A2/A2B Deceased Donor Kidney Transplants to Blood Type B Recipients

A member of the Committee presented an update on the Minority Affairs Committee's (MAC) A/A2B to B transplant Work Group's project, which is seeking to assess programs currently conducting A2/A2B transplants in blood type B recipients.

The Work Group conducted a survey to assess why transplant centers do (or do not) conduct these types of transplants. The response rate for this survey was 22% (234 centers). Most centers that currently perform these transplants were already doing so prior to KAS implementation.

Based on the data collected from the survey, the Work Group will be developing a guidance document and webinar designed to help transplant centers develop policy and protocols. One committee member commented that there is a tendency of blood banks to push back on doing this work in the absence of best practices. Another member asked if there are examples of transplant centers and blood banks finding differing results in testing. This member has found that their blood bank was finding higher than expected titers in most patients, inconsistent with the center's data. The presenting member

responded that the validation of results is critical, as results may vary depending on the methods used in testing. Many blood banks use a standard method seeking only IgM antibodies, which can result in grossly high antibodies, but banks should instead be looking for IgG antibodies. The Vice Chair added that a new machine is now available that makes easier for blood banks to conduct testing, though they increase titer levels. Traditional 1:8 ratios are now running at 1:16 on this method.

Variability can also be one to two full dilutions, which is why testing must be conducted repeatedly.

6. SRTR Geographic Disparities Update

A representative from the SRTR provided an update on its analysis of geographic variations in kidney allocation. This study came as a request from HRSA in 2012 and has been underway over the course of the past year.

HRSA requested this data as it was concerned that the geographic disparities in access to transplant were violating the Final Rule and asked organ-specific committees to identify specific measures of fairness through which these disparities could be measured. Previously, the Kidney Committee formed a subgroup to investigate specific metrics, including offer rate, transplant rate, supply and demand ratios for certain groups, median time to transplant by blood type, and the number of new and instant listings. The SRTR is reinitiating work this year on HRSA's request, looking at a year of pre- and post-KAS data. The SRTR's presentation reported on results from this analysis.

A committee member cautioned that examination of geographic disparities should not be to the exclusion of other types of disparities (gender, age, ethnicity, etc.) More time may be necessary to collect post-KAS data that would best help the Committee address these disparities as listing patterns are actively changing.

7. KAS Data Review & Discussion

A member of the UNOS Research team presented a review of 18-month post-KAS implementation data and feedback from the regional meetings. Highlights from the presentation include:

- Distribution of transplants has not varied much by blood type. A2/A2B to B blood type transplants have, however, increased by a factor of 5, though numbers are still small. Discard rates have also increased, and the increase was most evident for high KDPI kidneys.
- Many very highly sensitized patients and patients with high dialysis time have been transplanted since KAS was implemented in December 2014. Transplants to these groups have been tapering over the last 18 months, suggesting a possible leveling off of the bolus effects.
- Deceased donor transplants have increased 7%.
- Early recipient survival outcomes are trending positively, though slightly lower than pre-KAS, and longer-term outcomes will be analyzed when more data is available.

The Committee also received a summary of regional feedback. Committee members offered the following comments:

- One committee member asked if parsing discard rates for high KDPI kidneys (e.g. 95% and above) would show decreased discards. Overall, transplants are up 4% across the most common factors – focus must now shift to addressing underutilized kidneys, as the data suggests. Furthermore, KDPI is only one factor when deciding

when to accept a kidney.

- The Pediatric Committee reviewed this data and noted its concern for patients 5 years of age and under given that the pediatric transplant rates did not change much except in Region 5. It was noted that the Pediatric Committee had requested additional data at their meeting for this population, as Members discussed Region 5 as of particular concern the possibility of higher export rates, bolus effects and multi-organ impact for each region.
- Another member noted interest in seeing demographic data of CPRAs of 99- 100% for the upcoming KAS report.
- One member noted that, around the same time as KAS implementation, Region 5 OPOs all agreed to voluntarily share kidneys with extra-renal organs, including pancreas, liver and heart, which they speculated may have had an impact on the decrease in transplants overall for pediatric patients. Members of the Committee discussed speculation that the increased discard rate of high KDPI kidneys indicates a failure of regional sharing implemented under KAS. Centers are now less likely to place a kidney on a pump than before, leading to a higher likelihood of discard for kidneys being shipped. One of the intentions of regional sharing is that the aggressive centers would be more likely to accept a high KDPI kidney from their region, which would in effect expedite placement for a given OPO.

The Committee ultimately decided to suggest two data points for inclusion in the 2 year post-KAS report: discard rates by more granular KDPI levels and expanded demographics for high CPRA patients.

8. Discussion on Vascularized Composite Allograft (VCA) Multi-Organ Transplants

The Committee reviewed information on multi-organ transplants that involved candidates listed for a kidney and a VCA. Currently, policy does not prohibit allocating a VCA organ as a second organ off of a kidney match, nor does it prohibit a allocating a kidney off of a VCA match. Either would be permitted after the required multi-organ offers for kidney (following local hearts, lungs, livers, and pancreas). At this time, the total number of candidates waitlisted and transplants is very small.

SRTR noted that they are working with the Membership and Professional Standards Committee (MPSC) to start looking at multi-organ models for outcomes reviews, such as liver-kidney, now that there are more cases. Reporting will soon be available of all of the different combinations of multi-organ transplants, possibly by the next cycle.

The Committee stated that its preference is that kidneys should be allocated according to prioritization on the kidney waitlist when in combination with a VCA organ. This issue should be addressed through a larger policy project that addresses multi-organ allocation as a whole.

Upcoming Meetings

- November 21, 2016
- December 19, 2016
- January 9, 2017