AST Timely Topics in Transplantation Webinar Series

Questions and answers from the January 21 webinar on the new UNOS kidney allocation policy, presented by Dr. John Friedewald.

Answers provided by Gena Boyle, MPA, Policy Manager, UNOS

Q: Are there UNOS resources to help individual centers model the effect of the new system on their particular waitlist population?

A: Yes. Throughout the course of 2014, UNOS will be releasing a number of resources that will help transplant programs assess the effects of the candidates on their list. In March 2014, UNOS will release an EPTS calculator that will help programs experiment with different combinations of the four candidate factors to evaluate their impact and generate profiles of patients with varying EPTS scores.

In addition, programs will be able to view a "candidate points report" in UNet^{SM} in the summer of 2014. This report will include information about the points listed for each candidate (based on CPRA, pediatric or adult status, waiting time, prior living donor status, etc.) and will serve as a tool for programs in evaluating how patients listed at their center will be ordered. It will not, however, indicate where that program's candidates will be prioritized in comparison to candidates at other local or national programs.

Q: When will the donors DQ testing be posted?

A: At this time, no new HLA fields have been approved by the OPTN Board of Directors. The OPTN/UNOS Histocompatibility Committee is distributing for public comment a proposal that would require HLA-DQA and HLA-DPB to be reported on deceased donors prior to organ offers. If public comment is favorable, the Committee will request that the Board approve this change in November 2014.

Q: How was the pediatric consideration of KDPI <35% derived and considered equivalent to the Share 35 program?

A: The Scientific Registry of Transplants Recipients (SRTR) performed modeling on this change to kidney allocation for pediatric candidates. SRTR's simulation modeling forecasted that pediatric candidates would maintain approximately the same level of access that is experienced under the current system. The OPTN/UNOS Pediatric Committee was in agreement with this recommendation.

Q: What is the basis of KDPI group cut off values of 20, 35 and 85%?

The KDPI cutoff of 20% was selected as a starting point for introducing the concept of longevity matching for a relatively small percentage of kidney allocations. Simulation modeling performed by the SRTR showed that prioritizing the Top 20% of kidneys (per KDPI) to the Top 20% of candidates (per EPTS) resulted in substantial gains in life years from the existing supply of kidneys, while still allowing waiting time to play a large role in allocation. Selecting too small of a group of patients – for example, the Top 1% or Top 5%, instead of Top 20% of EPTS -- was thought to potentially create a disincentive for living donation, since the waiting time for these candidates would be very short. Under the new allocation system, patients in the Top 20% will be prioritized but are still expected to have significant waiting time. The new allocation system is being designed to be flexible, to allow both the KDPI and EPTS cutoffs to be modified, as needed, based on future data analyses and recommendations from the OPTN Kidney Transplantation Committee.

The 35% KDPI cutoff was chosen to provide pediatric candidates approximately the same level of access to kidneys as they receive in the current system. Please see above response for more details.

The 85% KDPI cutoff was chosen to identify a similar percentage of kidneys as the current ECD designation. Approximately 15% of deceased donor kidney transplants used are ECD kidneys, and about 20% of recovered kidneys are ECDs. Even though the KDPI cutoff was selected to match ECD volume, it is important to recognize that KDPI is a different and more accurate measure of donor quality than ECD/SCD. Some KDPI>85% kidneys are actually

SCD kidneys that are expected to have reduced longevity, while some kidneys with KDPI≤85% are actually ECD's that are expected to perform better than a typical ECD kidney.

Q: Will there be a crossmatch waiver for the new allocation for 99-100 CPRA patient offers?

A: The new policy does not include a crossmatch waiver.

In the new allocation system, candidates will receive increased sharing priority (regional sharing for CPRA 99% and national sharing for CPRA 100%) if the candidate's physician or surgeon and the HLA laboratory director have reviewed and signed a written approval of the unacceptable antigens listed for a candidate.
When a candidate's CPRA score is greater than 98%, a message about the required approval and an approval form with signature fields will display in UNet℠. If both signatures are not entered in the system, the candidate will not be eligible for this additional sharing priority. Programs who do not want to see any regional or national offers for a candidate in this category can simply choose not to provide this approval.

Q: If time on the list is greater than dialysis time, will a current patient still get the points for the pre-emptive listing when the new system is activated?

A: Yes. Patients already on the waiting list will not lose any waiting time points with the new KAS. For preemptively listed adult candidates, waiting time will begin to accrue once any of the three qualifying criteria have been met (eGFR<=20 ml/min, CrCl<=20 ml/min, start of chronic maintenance dialysis).

Q: The new KAS will move all highly sensitized patients to the top of the waitlist in a given transplant center?

A: Only very highly sensitized candidates will receive additional sharing priority (regional for 99% CPRA and national for 100% CPRA). Donor offers for these candidates will still be screened based on donor acceptance criteria and there are still going to be candidates that are very hard to match. In addition, prioritization is assigned based on other factors (for example, waiting time) and it will really just depend on what each center's list looks like.

Q: Can we expect nationally that OPO's will send blood out nationally for the 100 CPRA candidates that come up for an offer?

A: The new policy does not require this specifically.

Q: Was an analysis performed in an attempt to estimate impact on costs associated with a broader share of kidneys regionally and nationally?

A: Though a cost analysis was not conducted, simulation modeling by the SRTR showed that the increase in shipping of kidneys due to the new policy is expected to be modest. Approximately 20% of kidneys are currently shared outside of the local DSA; under the new system, about 25% of kidneys are expected to be allocated outside of the DSA.

Q: Will region 1 patients who are pre-dialysis and are listed/registered based on GFR < 20 receive waiting time prior to full implementation of new system in December 2014?

A: Region 1 currently participates in an Alternative Allocation System (AAS) that allows candidates to receive waiting time points based upon the time the candidate has been on dialysis. However, time cannot be accrued prior to the listing date. Region 1's AAS does not include a provision for accruing waiting time based on GFR criteria.
Upon implementation, all kidney candidates will begin waiting time points once on dialysis or at the point after listing that the program reports that the candidate meets the GFR or creatinine level criteria (an actual or estimated value at or below 20 min/mil). The system will not backdate waiting time prior to listing for GFR value criteria.

Q: How will this affect patients with recurrent disease ie FSGS?

A: The KAS will have no change in policy compared to the current policy regarding patients with recurrent disease.

Q:The cutoff/definition of unacceptable antigens are varied by transplant center. How do we deal with these variations in national sharing?

A: The Kidney Committee has long held the view that the cutoff/definition of unacceptable antigens should be decided on a center basis, as they are medical and clinical practice decisions. This variation exists in deceased donor kidney allocation today. The new policy does not address the issue specifically.

National sharing will only apply to those candidates with a CPRA 100%. The Kidney Committee will monitor the new allocation system once it is in effect to determine whether there are negative consequences associated with national sharing for highly sensitized candidates.

Q: Do patients who undergo desensitization lose their extra points if an unacceptable antigen is removed?

A: The new policy does not address candidates who are undergoing desensitization. If unacceptable antigens are removed, the candidate will lose any CPRA points associated with those particular unacceptable antigens. The OPTN/UNOS Histocompatibility, Kidney Transplantation, and Minority Affairs Committees have formed a workgroup to discuss possible new policies to address this issue going forward, but no changes are proposed at this time.

Q: For the 99 and 100 PRA sign off by tissue typing and surgeon will this be electronic?

A: Yes, when a candidate's CPRA score is greater than 98%, a message about the required approval and an approval form with signature fields will display in UNet℠. Transplant programs and their affiliated laboratories will be able to print the approver sheet once the required approvals are complete. The transplant program should print the approver sheet and maintain documentation in the patient's record.

Q: Can you comment on the impact of ABOi transplants and paired donation on this new kidney allocation?

A: The new allocation system does not incorporate ABO incompatible transplantation, although it does include allocation of subtype compatible kidneys by allowing qualifying blood type B candidates to receive offers from donors with blood type A2 and A2B.

While the current supply of deceased kidney donors has remained relatively flat in recent years, kidney paired donation has become an important advancement with the potential to increase the supply of available kidneys (through expanded opportunities for living donation). If kidney paired donation continues to grow, it has the potential to reduce the demand for deceased donor kidneys and mitigate the widening gap between supply and demand for candidates on the deceased donor waitlist.

Q: Do you anticipate increased use of depleting induction agents as a result of this new policy implementation?

A: The choice of induction agent is always a choice left up to individual transplant centers and clinicians.