ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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United Network for Organ Sharing
700 N 4th Street
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Attention: Kidney Transplantation Committee Liaison

To Whom It May Concern:

On behalf of the American Society of Nephrology (ASN), a not-for-profit organization of more than 12,000 physicians and scientists dedicated to promoting excellence in the care of patients with kidney disease, thank you for the opportunity to provide comment on the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) "Concepts for Kidney Allocation Document." Foremost among ASN's concerns is ensuring available kidneys provide the maximum benefit to society.

ASN has a number of serious reservations regarding the existing national kidney allocation algorithm (see addendum) and endorses efforts to improve the current kidney allocation system. ASN submits the following recommendations to OPTN/UNOS.

ASN strongly endorses the concepts of:

- Adopting a kidney donor profile index (KDPI) that would provide a more granular, accurate, and clinically useful assessment of each deceased donor kidney than does the current dichotomy between standard criteria –and expanded criteria donor kidneys.[1]

- Matching survival potential between donated organs and the potential recipients of those organs to improve post-transplant survival and minimize repeat transplantation.

ASN strongly endorses the principle that the kidney allocation system should treat similar patients similarly. This principle is not articulated in the concept document. Thus, ASN does not endorse the creation of a sharp boundary that would divide candidates into just two groups based upon projected post-transplant survival.

The society advocates the following additional allocation strategies:

A. The post-transplant survival models employed by the OPTN have been validated by comparing split-half sample predictions ($R^2 \geq 0.994$) and, if utilized appropriately, are viable metrics for use in kidney allocation.[2] They are highly accurate at distinguishing candidates with dissimilar survival potential, but cannot be employed to precisely rank candidates with very similar survival potential.[3] The concept document proposes allocating the 20% of deceased-donor kidneys with the longest potential survival to the 20% of waitlisted candidates with the longest estimated post-transplant survival (EPTS), creating a precise division of opportunity for candidates based upon this calculation.

Candidates falling within similar EPTS percentiles will be expected to have quite similar EPTS. Following the principle that that the kidney allocation system should treat similar patients similarly, ASN favors the development of an allocation algorithm that provides a continuous ranking of allocation priority so that similar patients are given similar allocation priority.

B. Allocation based upon incremental survival prioritizes both medical urgency and EPTS. It accomplishes this goal by providing higher priority if the candidate's estimated waitlist lifetime is shorter or if the candidate's EPTS is expected to be longer**.** ASN advocates prioritizing allocation based upon incremental survival to foster allocation to younger diabetic kidney transplant candidates who stand to gain the largest number of years of post-transplant survival, but who are limited in access to organs by allocation policies based solely on the expected duration of post-transplant survival.

C. African Americans, patients whose transplant costs are reimbursed solely through public insurance, and candidates with lower socioeconomic status, are waitlisted an average of 18 months later than educated, privately insured, or white kidney transplant candidates.[4] As a partial remedy for waitlisting disparities, ASN recommends that waiting time for all candidates be calculated from the earlier of the following milestones: 1) the date of first maintenance dialysis for those candidates who have initiated dialysis prior to wait-listing; or 2) when the GFR falls below 20 ml/min for those candidates who are waitlisted prior to beginning dialysis.

D. In the current allocation system, priority for sensitization against the potential deceased donor organ-pool is now limited to highly sensitized candidates with panel reactive antibody levels that exceed 79 percent. Proportionate priority should be extended to candidates with lesser, but still clinically significant, levels of sensitization, to permit them access to kidney transplant comparable to that offered more highly sensitized candidates. ASN agrees with the current standard of excluding PRA from the EPTS calculation.

E. As waiting times vary considerably between Donor Service Areas, ASN recommends that allocation boundaries be reconfigured to minimize geographic differences in the prevalence of ESRD and organ donor potential.

ASN supports efforts to improve the current kidney allocation system. With a limited number of organs available, the society encourages changes that best ensure the maximum number of life years per graft.

Again, thank you for allowing ASN to comment on the Concept Document for Kidney Allocation. The society would be pleased to discuss these comments with OPTN/UNOS if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Public Affairs, Paul C. Smedberg, at psmedberg@asn-online.org.

Sincerely,

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President

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Addendum:

ASN has a number of serious reservations regarding the existing national kidney allocation algorithm, and the society endorses efforts to improve the current system. Among these concerns are:

I. The weights assigned to the existing allocation priorities are not objective; they do not reflect the biological effect of these priorities on outcomes (for example, one year of waiting time is assigned the same allocation priority as one HLA-DR mismatch; 4 points are awarded for a PRA of 80% but no points for a PRA 79%).
II. With the exception of ECD, the existing algorithm does not account for differences in potential survival of recipients and donated organs. Based on the current allocation rules and donor pool, simulation models have demonstrated the potential to gain more than 35,000 years of post-transplant survival and more than 10,000 years of incremental post-transplant survival (i.e. years of life that would not have been achieved without the benefit of transplant) from each year of deceased donor kidney allocation. [2,3] In addition, mismatched survival potential between organ and recipient contributes to high rates of repeat transplantation.
III. Waiting time varies considerably between DSAs based upon the prevalence of end-stage kidney disease (in general higher in large urban populations), the efficiency of the OPO in identifying, consenting and recovering organs from donors, the opportunities within the DSA for transplant referrals and waitlisting, and the acceptance and discard practices of individual transplant centers. As a consequence, median time to kidney transplant in the United States varies markedly by DSA and blood type, ranging from 26 days to 8.23 years.
IV. The method for calculating waiting time in most of the US contributes to system-wide inequities in access to transplantation by race/ethnicity and socioeconomic status.
V. Allocation rules are inconsistent across Donor Service Areas due to the existence of alternative local allocation priorities.
VI. The allocation algorithm does not provide uniform access to sensitized patients in that the 4 points provided for sensitization against 80% of the donor pool offer a different advantage in each DSA, depending on DSA waiting time and candidate blood type
VII. There is no priority offered to moderately sensitized candidates

References:

1. Rao, Panduranga S, Schaubel, Guidinger DE, Andreoni MK, Wolfe KA, Merion RA, Port RM, Sung FK, Randall S: A comprehensive risk quantification score for deceased donor kidneys: the kidney donor risk index. Transplantation. 88(2):231-6, 2009.
2. Wolfe RA, McCullough KP, Schaubel DE, Kalbfleisch JD, Murray S, Stegall MD, Leichtman AB: Calculating life years from transplant (LYFT): methods for kidney and kidney-pancreas candidates. *American Journal of Transplantation*. 8(4 Pt 2):997-1011, 2008.
3. Wolfe RA, McCullough KP, Leichtman AB: Predictability of Survival Models Comprising the LYFT Calculation. American Journal of Transplantation. 9(7):1523-7, 2009.
4. Keith D, Ashby VB, Port FK, Leichtman AB: Insurance type and minority status associated with large disparities in prelisting dialysis among candidates for kidney transplantation. *Clinical Journal of the American Society of Nephrology*: 3(2):463-70, 2008.