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See related article, "Explaining the Racial Difference in AKI Incidence," on pages 1834–1841.

# Simulating the New Kidney Allocation Policy in the United States: Modest Gains and Many Unknowns

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For over a decade, the transplant community has deliberated over potential changes to the system for allocating deceased donor kidneys in the United States. Largely stimulated by the scarcity of deceased donor organs relative to the rapidly growing cohort of candidates, transplant leadership has considered whether policy revisions could better achieve the prominent goals of organ allocation: utility and equity. The culmination of this work is a new kidney allocation system that was approved by the Organ Procurement and Transplantation Network (OPTN) and is anticipated to take effect in calendar year 2014.[1] Fundamental changes to allocation include enhanced access to transplant and greater availability of high-quality kidneys to patients with the greatest life expectancy and increased allocation priority for sensitized candidates. In addition, under the new policy, waiting time will now be calculated from the date of ESRD onset for patients who initiated dialysis before listing instead of from the date of placement on the waiting list alone.[2] In this issue of *JASN*, the Scientific Registry of Transplant Recipients (SRTR) presents simulated effects of this new allocation policy on the United States kidney transplant population.[3] Overall, the results suggest that the policy will achieve modest gains in survival and better access to transplant for some disadvantaged groups. The study also underscores the significant complexity of organ allocation with many unknowns and potential unintended consequences of the new policy. In addition, the study draws attention to our dependence on these simulations for decision making that ultimately has profound ramifications.

Measuring the success of kidney allocation policy requires some agreement about reasonable benchmarks. Specifically, the challenge lies in deciding how to measure and balance the principles of utility and equity when comparing two allocation policies. In conducting the simulation, the authors assessed utility by estimating the median improvement in survival per kidney transplant recipient (compared with dialysis) in the old and new allocation systems and predicted an increased median survival of +0.23 years (or a 4.6% increase) per transplant with the new system. In addition, the simulation results compared other indicators of utility such as median lifespan, allograft years of life, and death on the waiting list, which suggested modest gains or little change with the new allocation system.

Unfortunately, compared with utility, measurements of equity are much less straightforward.[4] One approach is to examine how access to transplant varies between groups of patients, with particular focus on disadvantaged individuals such as sensitized patients. As compared to actual distribution of recipients in 2010, results of the simulated new policy indicated an increased likelihood of transplantation among patients with elevated panel reactive antibody, fewer 0-HLA mismatched transplants (7.3% versus 5.9%, respectively), and a decrease in kidneys shared beyond the local procurement area (20.4% versus 16.9%, respectively). The new policy also predicted a decrease in the number of recipients older than 50 (2010 actual, $n=6155$; simulated new policy, $n=5777$), but an increase in the number of recipients with diabetes as a primary diagnosis (2010 actual, $n=2626$; simulated new policy, $n=3206$) and recipients with more than four years of dialysis (2010 actual, $n=1251$; simulated new policy, $n=1407$). There were no marked differences in the total number of transplants or racial composition of recipients despite numerous studies

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that indicate that minority groups have longer durations of dialysis before listing compared with Caucasians.[5,6] Cumulatively, the net results of the simulation of the new policy indicate a slight increase in the total number of graft-years associated with transplants and a shift in the composition of candidates who are most likely to receive these organs.

The most heated debates about the new kidney allocation policy will likely revolve around whether it is more equitable than the existing system. The new system eliminates the "first-come, first-served" approach toward prioritizing candidates based on waiting time, an approach that favored wealthier, more educated, and better-connected patients who were more successful navigating the wait-listing process, as well as those who were more proactive in pursuing their goal of receiving a transplant. The policy change promotes equity by allowing certain disadvantaged patients to receive priority from the time they started dialysis.[7] However, the improvements in median survival with the new policy are largely driven by reducing the percentage of older patients who receive transplants, because older age is a very strong predictor of death and shorter life expectancy reduces transplant priority in the new policy. From one perspective, this shift in kidney allocation is equitable because it gives more young patients the opportunity to live until old age, whereas older candidates have already enjoyed that opportunity.[8,9] From another perspective, the use of life expectancy in allocation seems inherently inequitable by placing differential value on patients on the basis of demographic characteristics.[10] In predicting the effects on different candidate groups, the current simulation provides a preview of how the new policy may shift the balance of utility and equity.

Policy development in the field of transplantation relies heavily on simulated results to forecast the effects of interventions such as changes in organ allocation. The article by Israni *et al.* draws attention to potential perils inherent in relying solely on such simulations, generated by a single software system known as the Kidney-Pancreas Simulated Allocation Model (KPSAM).[3] Unfortunately, we know little about the reliability of the estimates that derive from these simulations, the inputs and assumptions made, or whether there are alternative algorithms that might be considered for estimating effects. In essence, the KPSAM is a black box with uncertain variability yet tremendous effect on policy decisions. In this study, it is notable that simulations estimated within the same calendar year (2010) generally were concordant with actual transplant outcomes. However, there were a few important exceptions, which included a 23% undercount of kidney transplants shared outside the local procurement area, a 37% overestimation of preemptive transplants, and a 14% underestimation of deaths on the waiting list among patients aged >50 years. A curious finding of the simulation was that despite the fact that fewer patients over the age 50 were expected to be transplanted as compared to actual recipients in 2010 (5777 versus 6155 respectively), wait list mortality was expected to decline 14% in the same group. Whether this finding is the result of insufficient follow-up in the simulation or other unknown assumptions, it is highly unlikely that a significant reduction in transplant rates will not raise the probability of death on the waiting list for older candidates. Taken together, these findings highlight the need for wider use of KPSAM software by groups outside the SRTR to validate results. Furthermore, the transplant community should consider development of alternative simulation software with the potential to yield more accurate estimates of the effects of transplant policy.

We must also acknowledge that even if simulations were perfectly reflective of the effect of a new allocation system in a static environment, the greatest unknowns may be changes in behavior that are induced by the policy itself. For example, with the new policy, transplant centers will likely have more difficulty predicting patients' time to transplantation and may therefore change their criteria for candidacy and approach to wait list management. As a second example, although policy makers had no intention to create disincentives for living donation (which probably occurred as a result of the Share 35 policy), it is not beyond the realm of possibility that patients with short waiting times and access to the highest-quality deceased donor kidneys may forego living donor transplantation.[10] In addition, the simulation indicated that although there is only moderate regional variation in the availability of "top 20%" donations, the effects within certain centers might be more dramatic and change organ acceptance decisions.

There are certainly other assumptions of the simulation that merit scrutiny and ongoing evaluation. As expected, the simulation estimated a significant increase in the proportion of patients with extended dialysis time to receive a transplant. However, at least two studies based on national data have demonstrated that the effects of dialysis time are markedly different when separated into the time intervals before versus after placement on the waiting list.[11,12] These studies indicated that prelisting dialysis time is a much stronger predictor of post-transplant mortality and graft loss compared with dialysis time after listing. This observation may be explained if the effects of dialysis time before wait listing represent not only the detrimental effects of dialysis on health but also the factors associated with delayed access to or quality of care or a higher prevalence of unmeasured morbidities. Under the new policy, many patients will have experienced longer times on dialysis before wait listing, and therefore may have a higher risk of death than the simulation predicted. As a result, the new allocation policy may result in smaller improvements in life-years than the simulation predicted. As another example, donor quality has been shown to have a variable effect based on recipient characteristics.[13,14] The redistribution of kidneys based on quality, along with the significant interaction between donor and recipient characteristics, may lead to different post-transplant outcomes not accounted for in the current simulations. Finally, the simulation did not address the possibility that a decrease in HLA matching with the new policy may have long-term detrimental effects to patients' likelihood of retransplantation as a result of increased sensitization.[15]

For nephrologists who refer to transplant centers, this preview of the revised allocation policy has valuable lessons.

First, patients who have lingered on dialysis without getting wait listed should be educated that they can now receive allocation priority for that dialysis time and potentially have rapid access to transplantation. Importantly, referring nephrologists should not forego preemptive referrals because preemptive listings will still benefit candidates; in addition, live donor kidney transplantation remains the optimal treatment for many individuals with ESRD. Second, patients referred for transplantation may now receive different counseling and a different approach to the medical work-up depending on their age and other characteristics. For young patients without diabetes and without a prior transplant, a rapid work-up will make sense given the potential to be classified as top 20% candidates and the potential short time to receive a transplant. Nephrologists may provide value to patients by educating them about new vernacular and concepts associated with the new allocation policy such as the kidney donor risk index and estimated post-transplant survival. Finally, nephrologists may need to answer uncomfortable questions about the indirect use of age in organ allocation. Although the new OPTN policy is equitable from one perspective, the allocation of a scarce resource always involves difficult choices and older patients may feel that the revised policy has unfairly affected them.

In the end, this analysis provides an important framework for the community to anticipate the plausible effects of a major change in allocation policy. Compared with the *status quo*, we can welcome some improvements in overall graft survival within the transplant population and better opportunities for some disadvantaged patients (*e.g.*, those with a high panel reactive antibody) as well as certain tradeoffs, including diminished access to transplant for older candidates. However, there are also likely to be unanticipated changes in patient, provider, and payer behavior, as well as unforeseen secular changes. Given the enormous ramifications of these simulations, we urgently need new methods to evaluate effects of modifications to policies in the field of transplantation. Ultimately, as our understanding of the effect of the new allocation system grows, the transplant community will need transparent and efficient methods to communicate the effects of these policy changes to our patients.

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## DISCLOSURES

P.P.R. serves as vice chair of the United Network for Organ Sharing Ethics Committee and as a member of the Policy Oversight Committee.

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