The Kidney Allocation System

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KEYWORDS

• Kidney transplant • Organ allocation • Transplant waiting list

KEY POINTS

- The current kidney allocation system is outdated and has not evolved to reflect the changing demographics of patients on the waiting list.
- Without additional donor kidneys, any change in the allocation system shifts kidneys between different patient groups.
- Any changes in the allocation system will be trade-offs between equity and utility.
- The new proposed system will significantly reduce mismatches between possible donor kidney longevity and life expectancy of recipients.

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- The new system more appropriately incorporates the biology of highly sensitized patients into the waiting-time scoring algorithm.
- The new system makes incremental advances toward more geographic sharing.

INTRODUCTION

Dialysis and kidney transplant are the two available active treatment options for the nearly 500,000 individuals in the United States with end-stage renal disease (ESRD). Many patients with ESRD will achieve improved quality and increased quantity of life from a kidney transplant in comparison with maintenance dialysis (Fig. 1).[1–3] ESRD patients can receive a kidney for transplant from a living or a recently deceased donor. The current system for allocation of deceased donor kidneys in the United States has been in place for nearly 3 decades. During this time the demand for kidney transplants has increased dramatically while the supply has remained fairly constant (Fig. 2). Moreover, as the criteria for eligibility for kidney transplants have broadened, the system for allocating kidneys has remained largely unchanged. This situation has resulted in ever increasing waiting times for patients as well as a patchwork of allocation variances designed to address perceived or actual deficiencies. The resulting system of allocation fails to address the differences in wait-listed patients or optimize the use of recovered organs, and is both cumbersome to administer and nearly impossible to modify. As established in the National Organ Transplant Act, the Organ Procurement and Transplantation Network (OPTN) administers the waiting list and develops policy regarding the allocation of deceased donor kidneys.[4] The OPTN contract is currently held by United Network for Organ Sharing.

LIMITATIONS OF THE CURRENT KIDNEY ALLOCATION SYSTEM

Because of the extreme mismatch between the number of listed candidates and the number of organs available for transplant (see Fig. 2), candidates must wait ever longer

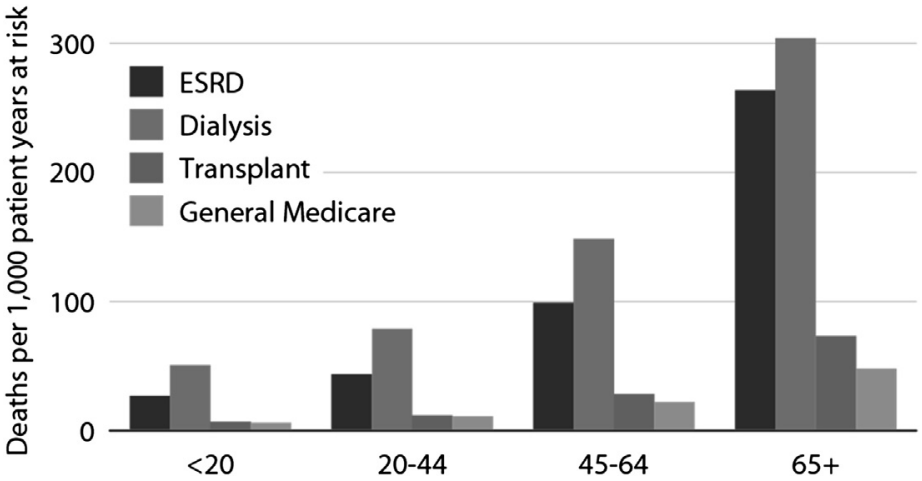

Fig. 1. Death rates of end-stage renal disease (ESRD), dialysis, and transplant patients, and in the general Medicare population, by age.

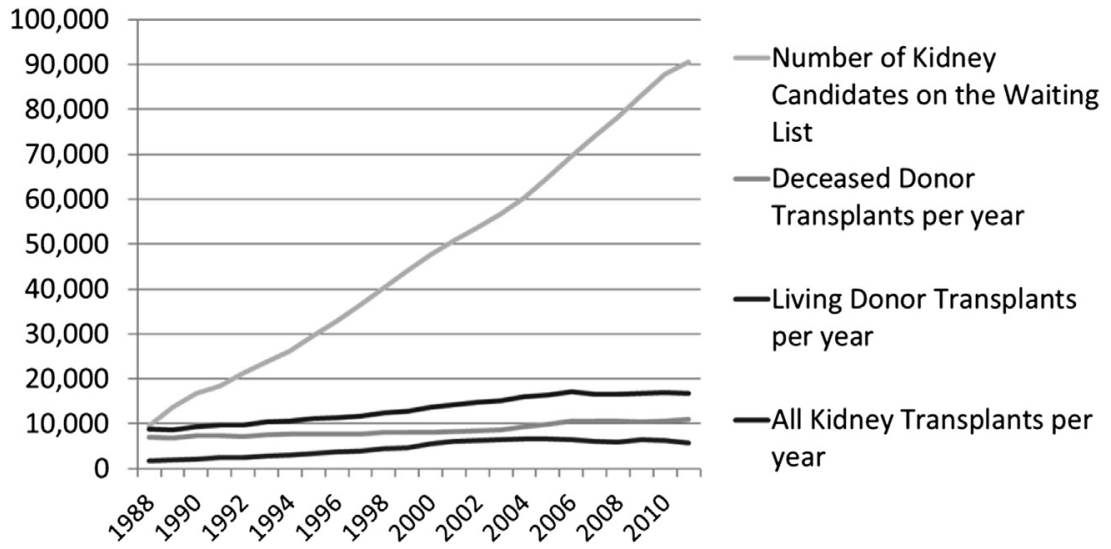

Fig. 2. Kidney transplant waiting list and numbers of transplants performed.

to receive an organ offer. Over time, as the disparity between supply of and demand for organs for transplant has grown, waiting time has become the dominant factor in allocation, surpassing the contribution of biological allocation system criteria, such as degree of immune system sensitization or degree of human leukocyte antigen (HLA) matching. As a result, this allocation system achieves only one goal: performing transplants in candidates who have waited the longest. It does not strive to improve outcomes after transplant, or to reduce mortality on the waiting list. It also fails to account for the fact that survival while on the waiting list is not the same for all candidates.

The main limitations of the current system are:

- Higher than necessary discard rates of kidneys that could benefit candidates on the waiting list
- Variability in access to transplant by candidate blood type and geographic location
- Many kidneys with more potential longevity being allocated to candidates with significantly less potential longevity and vice versa, resulting in unrealized graft years and unnecessarily high retransplant rates
- Inability to make timely modifications to the allocation system in an economical way

A CALL FOR CHANGE

In 2003, the OPTN Board of Directors charged the Kidney Transplantation Committee with reviewing the current kidney allocation policy to identify system limitations and approaches for improvement. For almost 10 years, the Committee worked to develop improved methods for kidney allocation. Two public forums have taken place, in 2007 in Dallas and in 2009 in St Louis (see sentinel events listed below). During these forums, the committee received feedback from interested parties and incorporated recommendations into iterations of its proposal. In addition, the committee circulated a concept paper that detailed various components of a kidney allocation system for discussion and consideration by the transplant community and the general public. This process culminated in the most recent version of the kidney allocation proposal, which was circulated for formal public comment in September 2012.

Date	Sentinel Event
2003	Board requests review of kidney allocation system; public hearings held
2004	Board directs investigation of benefit use in a kidney allocation system
2007	Public forum held in Dallas; main topic life-years from transplant (LYFT, a utility-based system)
2008	Request for information released; main topics kidney donor profile index, LYFT
2009	Public forum held in St Louis; main topics LYFT, kidney donor profile index
2009	Donor/recipient age matching reviewed as possibility
2011	Concept document released; main topics estimated posttransplant survival score, age matching, kidney donor profile index
2011	Age matching no longer under consideration
2012	Public comment proposal
2013	OPTN Board of Directors approves revised kidney allocation policy; implementation forthcoming

SYSTEM GOALS

By design, each organ allocation system attempts to achieve different goals. For example, the liver allocation system was modified in 2002 to allocate livers based on a candidate's probability of dying while on the waiting list. Candidates whose probability of death is higher are offered livers ahead of candidates whose probability is lower. Lungs are allocated similarly, but the lung allocation system takes into account a candidate's chance of dying while on the waiting list and during the first year following transplant.

The design of any allocation system that distributes a scare resource, such as deceased donor organs, must be based on sound ethical principles. The 2 principles primarily at work in the design of an allocation system are utility and equity (justice).[5] An allocation system that focuses on improving outcomes is considered a utility-based system, and a system that prioritizes equal access regardless of need is an equity-based system. These 2 approaches represent the polar ends of the ethical methods used to allocate a scarce resource. In organ allocation, an approach that uses the principle of utility attempts to maximize a desired outcome, such as patient or graft survival, whereas an approach that uses the principle of equity is designed to achieve fairness, which may occur at the expense of outcomes or utility measures. Ideally, everyone who needs a kidney transplant would receive a high-quality kidney and would not have to wait for it. However, the shortage of kidney donors and the changing demographics of candidates on the waiting list have become so extreme in some areas of the country (**Fig. 3**) that achieving equipoise between the principles of equity and utility is becoming ever more difficult. If kidney allocation were more heavily weighted toward achieving equity, utility measures such as life-years after transplant would decline. Alternatively, if kidney allocation were more heavily weighted toward achieving utility (defined here as life-years after transplant), equity measures such as number of transplants received by older candidates would decline (**Fig. 4**). Any redesign of the kidney allocation system must take into account the tension between equity and utility; it must balance access to transplant for everyone who could benefit across the age spectrum while maximizing the benefits of a scarce resource, the donated kidney.

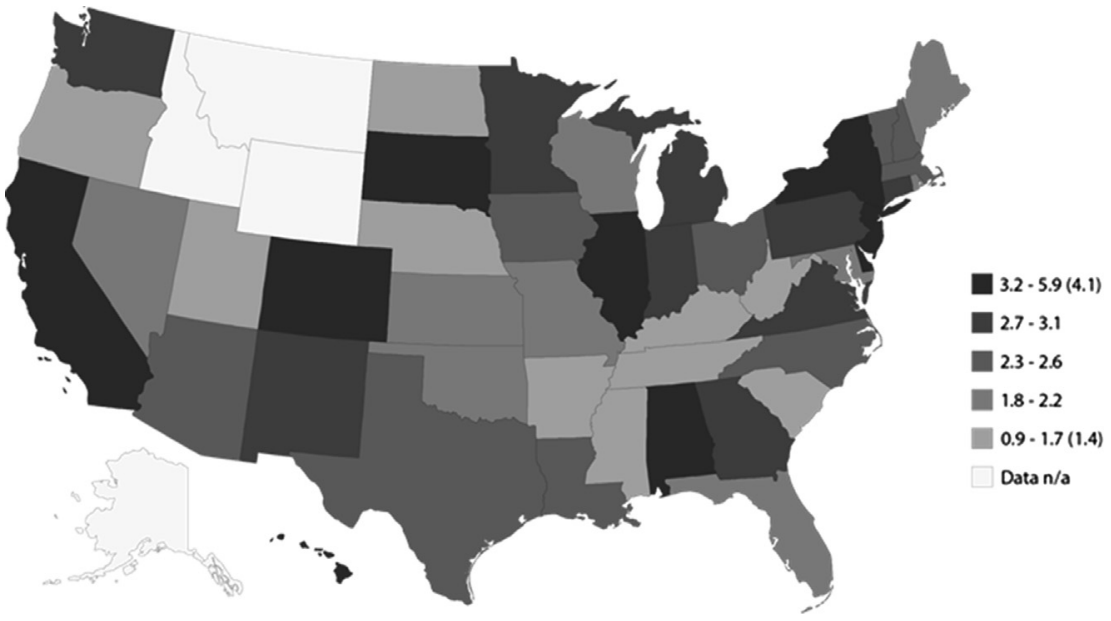

Fig. 3. Patients aged 18 years or older undergoing first-time deceased donor kidney-only transplant in 2010. Unadjusted median waiting times (years) by state of transplant center. (*From* United States Renal Data System. USRDS 2012 annual data report: atlas of chronic kidney disease and end-stage renal disease in the United States. Bethesda (MD): National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2012.)

The following guiding principles were used to redesign the kidney allocation system. These principles were developed in consultation with transplant professionals, patients, donor family members, and members of the general public:

Proposed Goals of New Allocation System	Ethical Principle Addressed
More accurately estimate graft and recipient longevity to maximize the potential survival of every transplanted kidney and to provide acceptable levels of access for candidates on the waiting list	Utility/Equity
Promote posttransplant kidney function for candidates with the longest estimated posttransplant survival who are also the most likely to require additional transplants because of early age of ESRD onset	Utility
Minimize loss of potential functioning years of deceased donor kidney grafts through improved matching	Utility
Improve offer system efficiency and organ use through the introduction of a new scale for kidney quality, the kidney donor profile index	Utility
Reduce differences in transplant access for populations described in the National Organ Transplant Act (eg, candidates from racial/ethnic minority groups, pediatric candidates, and sensitized candidates)	Equity

COMPOSITION OF THE WAITING LIST

The candidate waiting list has grown steadily over the last several decades (see Fig. 2), reaching 95,459 candidates in March 2013. Beyond the sheer number of candidates, the demographics of the waiting list, particularly with respect to age, have

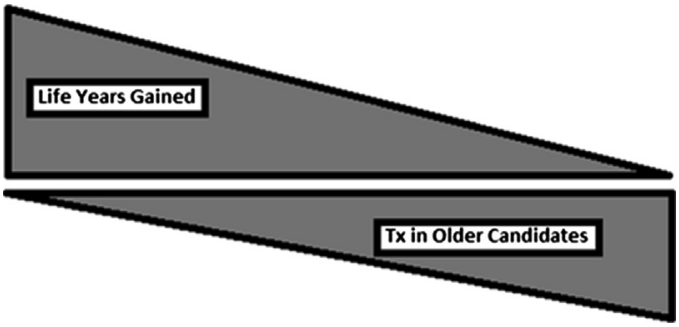

Fig. 4. Balance of utility (life-years gained) and equity (transplants [Tx] performed in older candidates).

changed markedly during this time span. Fig. 5 depicts the shift in the age of kidney recipients (patients who underwent deceased donor transplant) over 2 decades, reflecting the overall change in the composition of the waiting list. For example, in 1990, 3% of deceased donor kidney recipients were older than 65 years, compared with 16% in 2009. Similar increases occurred regarding transplants in recipients older than 50 years, whereas transplants in recipients aged 18 to 50 years steadily decreased. Pediatric candidates receive separate priority on the list and therefore have not been affected by changes in wait-list composition. The aging of candidates on the waiting list poses challenges not only in allocation of organs but also in caring for recipients before and after transplant. The overall distribution of candidates and donors, based on age, is shown in Fig. 6.

ESTIMATED POSTTRANSPLANT SURVIVAL

A tool to estimate the anticipated posttransplant survival of a patient receiving a kidney transplant was developed to help improve the allocation system.[6] By design, this tool uses only 4 variables to stratify patients based on predicted survival: recipient age, diabetic status, time on dialysis, and number of prior solid organ transplants. This tool does not discriminate well between two similar individuals, but it performs

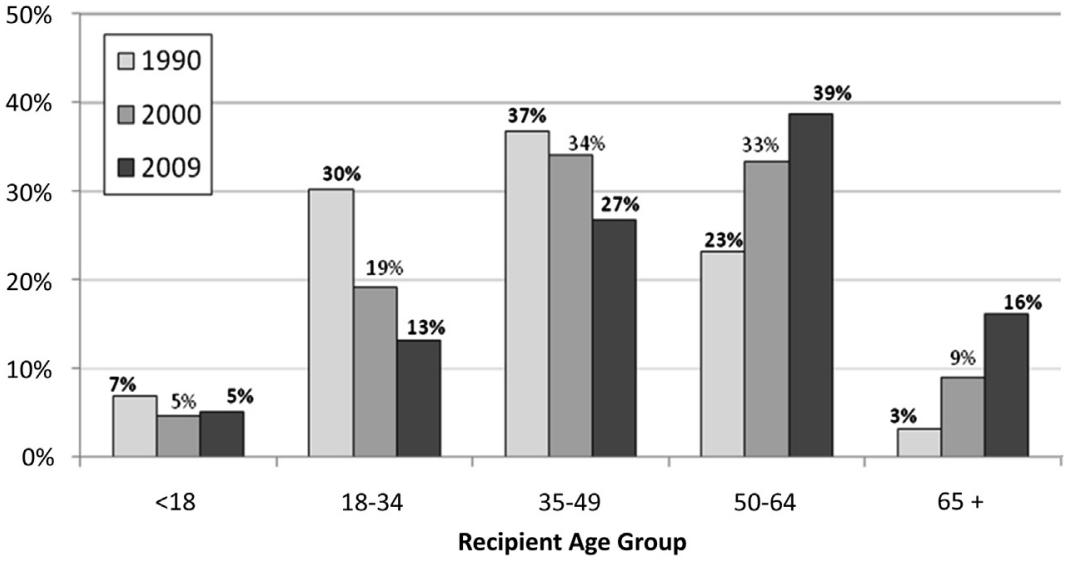

Fig. 5. Recipient age distribution for kidney transplants, United States, 1990, 2000, and 2009. (*Data from* Organ Procurement and Transplantation Network as of November 6, 2009.)

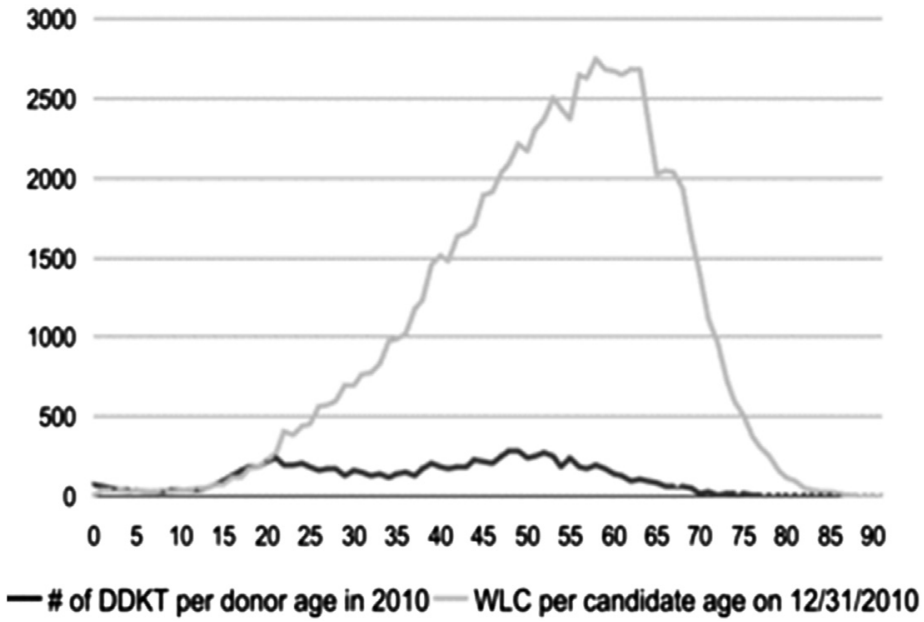

Fig. 6. Overall distribution of candidates and donors by age. DDKT, deceased donor kidney transplants; WLC, wait-list candidates. (*From* Ross LF, Parker W, Veatch RM, et al. Equal opportunity supplemented by fair innings: equity and efficiency in allocating deceased donor kidneys. Am J Transplant 2012;8:2115–24; with permission.)

well when dividing patients into broad categories. A lower estimated posttransplant survival (EPTS) score suggests longer posttransplant survival, and a higher score shorter survival. Examples of EPTS scores for various candidates are shown in Table I.

In the new allocation system, EPTS scores will be used to divide patients on the waiting list into the top 20% of scores and the remaining 80%. These 2 broad categories will be used to distribute kidneys with the longest potential survival to candidates with the longest estimated posttransplant survival, those in the top 20% of EPTS scores.

Table 1
Estimated posttransplant survival vignettes: who is in the top 20%?

Age (y)	Dialysis Duration (y)	Diabetes	Prior Transplants	EPTS (%)
18	0	No	No	1
25	0	No	No	1
18	2	No	No	2
25	5	No	No	5
25	2	No	Yes	7
40	0	No	No	8
18	0	Yes	No	12
25	0	Yes	No	12
40	5	No	No	17
50	0	No	No	18

Based on kidney wait-list registrations as of May 31, 2012. Data prepared by UNOS for the OPTN Kidney Transplantation Committee, October 2012.

Abbreviation: EPTS, estimated posttransplant survival score.

KIDNEY DONOR PROFILE INDEX

The kidney donor profile index (KDPI) was developed to improve risk stratification for survival of deceased donor kidneys. The existing method using standard criteria donor (SCD) and extended criteria donor (ECD) involves substantial overlap between the two groups (Fig. 7). The original intent of the ECD system was to list for ECD kidneys only patients for whom the trade-off of lower graft survival was offset by more rapid transplant. However, because survival of many kidneys designated ECD was better than survival of SCD kidneys, practice patterns changed such that patients were being registered on both lists and, therefore, the decreased waiting time for ECD kidneys was not fully realized.

The kidney donor risk index (KDRI) was developed to provide a more granular index of risk for donor kidneys and to locate them on a continuum.[7] The KDRI adjusts the risk of graft failure for any given donor kidney to the rate of failure for kidneys from donors aged 40 years. The scale runs from a relative risk of 0.5 (better survival), to 4.2 (worse survival). The KDPI transforms the hazard ratio of the KDRI for transplanted kidneys into a linear scale from 0% to 100%, where 0% represents the longest projected survival and 100% the shortest (Fig. 8).

KDPI variables:

- Donor age
- Donor height
- Donor weight
- Donor ethnicity
- History of hypertension
- History of diabetes
- Cause of death
- Serum creatinine
- Hepatitis C virus status
- Donation after circulatory death status

THE PROPOSED SYSTEM

The proposed allocation system will allocate kidneys in 4 sequences. The projected longevity of the kidney as determined by the KDPI will determine which sequence is

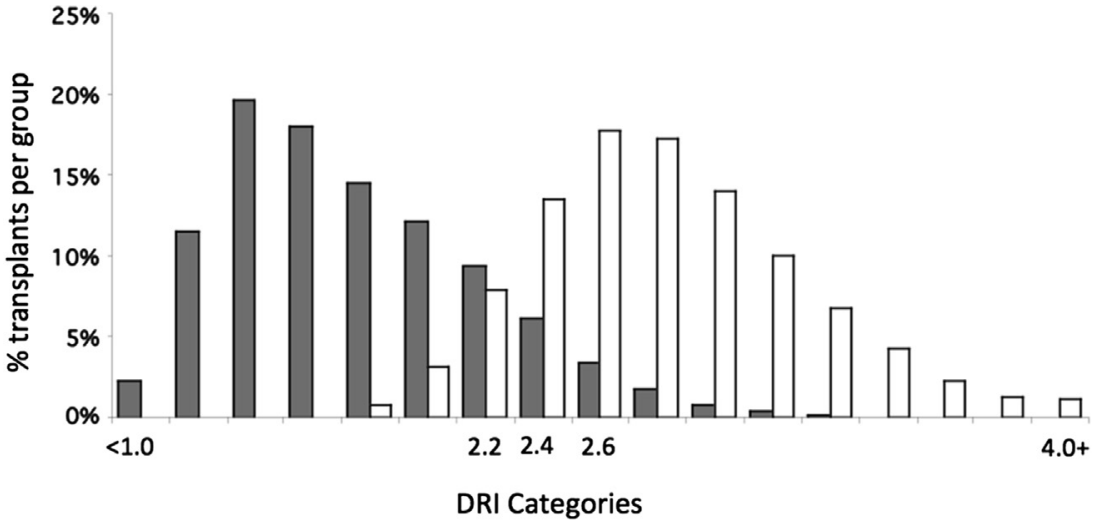

Fig. 7. Overlap of standard criteria and extended criteria donor kidneys. DRI, donor risk index.

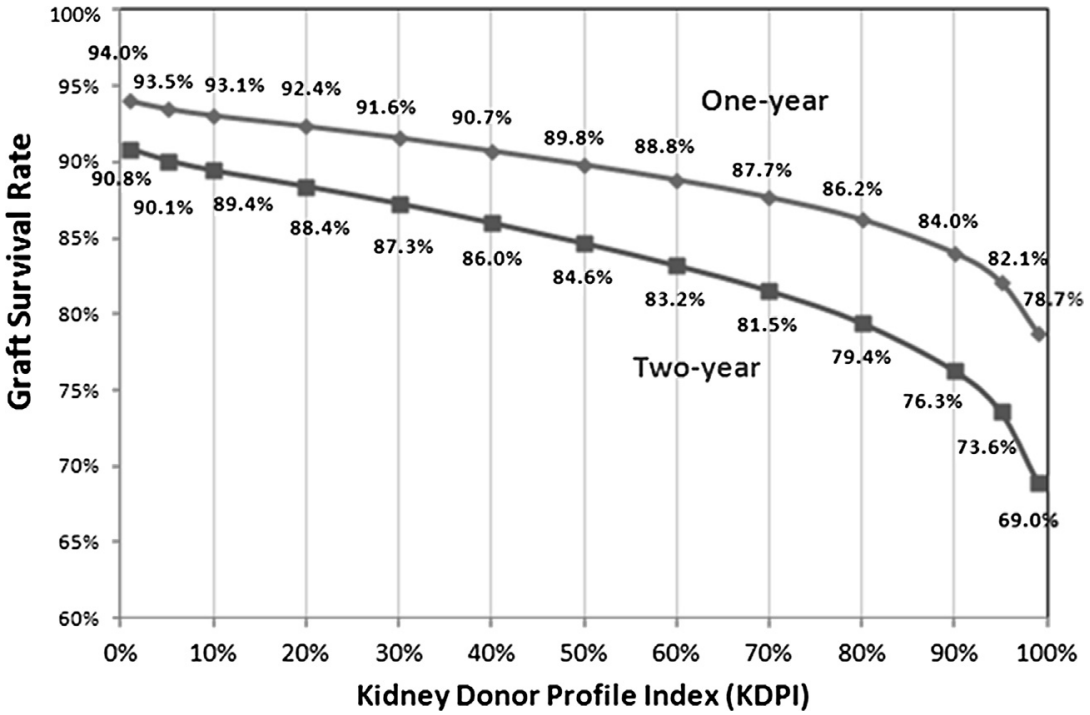

Fig. 8. Estimated graft survival rates by kidney donor profile index. (Source: OPTN.)

initiated. Stratification within the different sequences will be based on several factors used in the current system, primarily waiting time with contributions from HLA-DR matching and points for level of antibody sensitization. This factor was chosen because it is widely accepted by patients and it grounds this allocation system in the ethical principle of equity. Waiting time will be calculated either from time of listing with estimated glomerular filtration rate or creatinine clearance less than 20 mL/min, or from time of dialysis initiation (if dialysis was initiated before listing).

In the current allocation system, sensitized patients, as defined by calculated panel-reactive antibody (CPRA) greater than 80%, receive an additional 4 points on their allocation scores (roughly equivalent to 4 years of waiting time depending on geographic location). Work done by the OPTN Histocompatibility Committee demonstrated that this approach does not reflect the biology of the sensitized population, and that additional points should be awarded to sensitized patients on a continuous sliding scale (Fig. 9). Modeling suggests that this approach will help improve kidney offer rates for candidates with the highest degrees of sensitization, 98% to 100%.

In the new allocation system, as in the current one, all previous living organ donors, of kidneys and of other organs, receive priority for kidney transplant should they ever develop ESRD. This priority applies to first and subsequent transplants. In addition, points will be assigned based on HLA-DR matching, as this helps improve long-term survival without adversely affecting access to kidney transplant in minority populations. Also, in an effort to improve access for minority populations, kidneys from donors with blood type non-A1 (A2) and non-A1B (A2B) will be allocated to recipients in blood group B. Modeling suggests that this results in improved transplant rates for blood group B candidates proportional to their numbers on the waiting list.

Finally, in the new allocation system the ECD program is revised such that only waiting time is used to rank order candidates. ECDs are currently defined as all donors older than 60 years or older than 50 years with 2 of the following: hypertension, death from cerebrovascular accident, or serum creatinine level higher than 1.5 mg/dL. Under the new system, ECDs will be defined as all donors with KDPI greater than 85. This

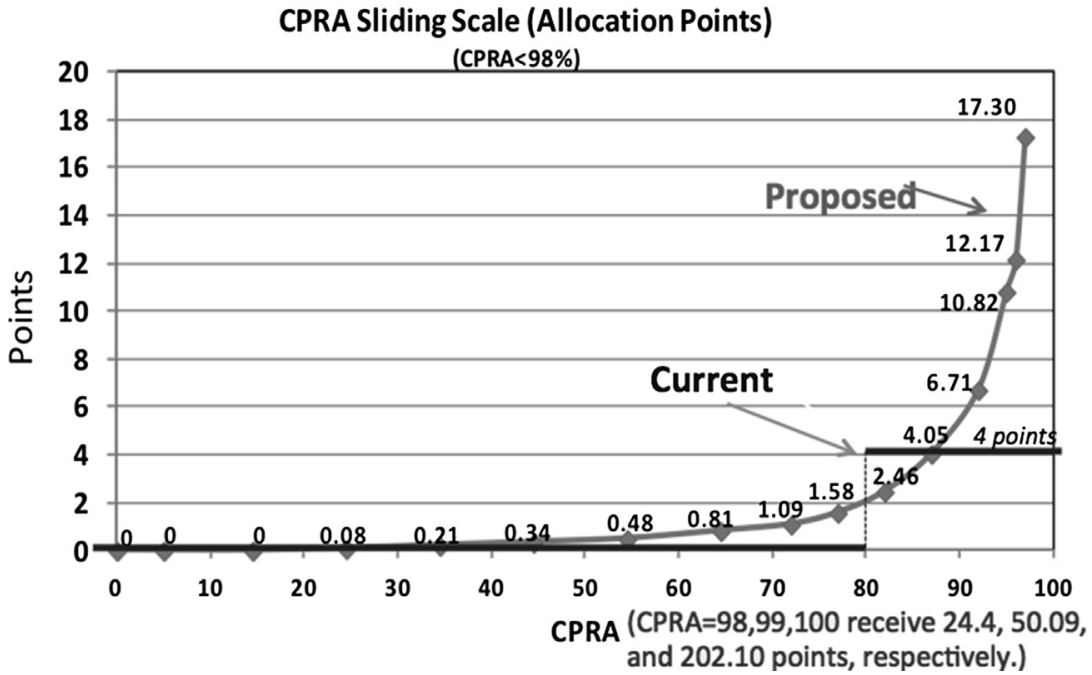

Fig. 9. Sliding scale for allocation points by calculated panel-reactive antibodies (CPRA). (Source: OPTN. Prepared for the Kidney Transplantation Committee, 2011.)

approach should make the timing of the organ offer more predictable and thus allow transplant centers to perform list maintenance in the patient group at most risk. In addition, organs will be offered at the regional level, bypassing local allocation, in an effort to expedite placement and perhaps encourage increased recovery of these organs.

Sequence A: Top 20% KDPI Kidneys to Top 20% EPTS Candidates

In this sequence, the top 20% of kidneys (those with the greatest predicted longevity) will be allocated to candidates in the top 20% of EPTS. Modeling suggests that in all donation service areas, the number of potential recipients in the top 20% of EPTS greatly exceeds the number of donor kidneys in the top 20% of KDPI (based on the large mismatch between supply and demand), so that projected waiting time is less than waiting time for candidates in the remaining 80% but still substantial. Therefore, it is not anticipated that candidates in the top 20% of EPTS will forgo living-donor kidney transplant in anticipation of receiving a deceased donor kidney of longer anticipated survival in a timely fashion; this would be contrary to the experience of pediatric patients once they were given priority for all donors younger than 35 years, the “Share 35” rule. Following implementation of the Share 35 policy, the number of living-donor kidney transplants in pediatric candidates declined noticeably. This decline was presumably related to pediatric candidates being able to receive high-quality deceased donor organs with little or no waiting time.

Sequence B: Kidneys with KDPI Between 20% and 35%, Pediatric Candidates

In the current allocation system, pediatric candidates receive priority for donors younger than 35 years. In the new system, pediatric candidates will receive priority for all kidneys with KDPI less than 35%.

Sequence C: Kidneys with KDPI from 20% to 85%

This allocation sequence will pair kidneys with very good predicted longevity with candidates whose expected survival is good but not as long as the expected survival of

candidates in the top 20% EPTS. For candidates in this sequence, EPTS will not be a factor in allocation. For candidates with EPTS greater than 20%, kidneys will be allocated based on points given for waiting time, HLA-DR matching, and CPRA.

Sequence D: Kidneys with KDPI Greater than 85%, Revamped ECD

Sequence D will be an opt-in system that will likely benefit older candidates or candidates for whom the benefit of decreased time to transplant offsets the risk of decreased graft longevity. Kidneys with KDPI greater than 85% will be allocated solely on the basis of time on the waiting list, and will be offered simultaneously to the local area and the region. This approach represents the first attempt to increase geographic sharing in kidney allocation.

CRITIQUE

Any allocation system that attempts to distribute a limited resource across a variety of interest groups will, by definition, be a list of compromises. Perhaps the biggest compromise in the development of this new kidney allocation system has been diminishing utility, decreasing the number of life-years gained, in an effort to preserve equity for recipients of all ages (Table 2).

Despite this reduction in overall utility, the new allocation system makes significant progress toward eliminating extreme mismatches between donor and recipient longevity. More importantly, modeling suggests that allocating kidneys with greater longevity to recipients expected to live the longest reduces the number of recipients listed for repeat transplant.[8] This tendency could potentially make more kidneys available for transplant by effectively reducing the size of the waiting list.

Another significant advance for kidney allocation is use of a metric of survival. Whereas the EPTS is not good at distinguishing between similar individuals, it is good at dividing potential recipients into 2 broad categories. Similarly, using the KDPI system of ranking donor kidneys is an improvement over the SCD/ECD approach, as it reduces the misclassification inherent in any binary labeling system applied to a continuum of quality. Finally, the new system uses a more scientific approach to highly sensitized patients that more closely follows the biology of compatibility matching. These 3 enhancements, based on actual data and not on perception, help lay the foundation for further improvement in the kidney allocation system because they provide metrics that are fixed and can be analyzed for further refinements to the system, in comparison with a stable baseline. This approach will allow for changes that advance the overall goal of a more balanced and fair system.

Table 2
Utility and equity in the new proposed kidney allocation system compared with previously considered strategies for allocation

	Matching Strategy				
	National Utility	Local Utility	Age + Longevity	Age	Longevity[a]
Gain in life-years from each year of transplant	34,026	25,794	15,223	14,044	8380
Proportion of transplants in recipients aged ≥50 y (%)	10	29	46	45	52

[a] Current proposal.

SUMMARY

The proposed system for allocating kidneys for transplant makes significant progress toward eliminating deficiencies in the current system. In the proposed approach, extreme mismatches in longevity are minimized, highly sensitized patients are given more equal access to transplant, and metrics are applied to assess patient survival and organ quality. Moreover, access to kidney transplant is preserved across the age spectrum. Finally, aspects of the program, such as regional sharing of high KDPI kidneys and fewer patients returning to the waiting list for repeat transplant, have the potential to increase the supply of available kidneys.

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