Curr Transpl Rep (2016) 3:39–44
DOI 10.1007/s40472-016-0093-x

OPTN POLICY (K ANDREONI, SECTION EDITOR)

Changing the Kidney Allocation System: a 20-Year History

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Published online: 30 January 2016

Abstract The development of the current kidney allocation policy took almost a decade to complete and required compromise on many levels. The history of this process provides an excellent case study of how public policy is made. The final product of this process is a policy that balances utility and equity and establishes priorities for the allocation of a scarce national resource—deceased donor kidneys. While it may be imperfect, it is a dramatic improvement from the prior system and provides a framework for further revisions in the future.

Keywords Kidney transplant · Allocation

Introduction

The original kidney allocation system (KAS) which was introduced with the formation of United Network for Organ Sharing (UNOS) in 1987 was not conceived as a unified allocation policy and did not substantially change over the prior two decades [1]. It was based on the current best practices and incorporated other legacy encumbrances, noted as variances, which were unique to a particular geographic area. Initially, this allocation system, primarily based on HLA matching, time waiting, and geographic proximity, was successful in providing kidney transplantation to the limited number of recipient candidates with the available deceased donors, with short wait list times and improving outcomes. Over the next decade, with the introduction of improved immunosuppressive protocols, new immunosuppressive medications, and improved preservation solutions, the patient population accepted for transplant consideration and candidate list grew rapidly while improvements in trauma care, declining rates of accidental (especially vehicular) deaths, and improved health habits led to a decrease in the number of historically "ideal young donors" for kidney donation. The result was an ever increasing waiting time for listed patients and the development of pronounced differences in waiting time in different areas of the country.

As the short- and long-term outcomes of kidney transplant recipients improved, data emerged demonstrating the superiority of kidney transplantation compared to dialysis in improving the long-term survival of patients with end-stage renal disease [2]. Then, in 1999, a New England Journal of Medicine article concluded that regardless of chronologic age or the etiology of the renal failure, there was a survival benefit offered by kidney transplantation as compared to remaining on dialysis [3••]. This finding resulted in further growth of the wait list, primarily in the 50 to 64 and greater than 65 age groups, and it became necessary to consider kidneys from donors that were previously characterized as "less than ideal" because the donor was older than age 60, died of a cerebral vascular accident (CVA), or had other associated chronic conditions such as hypertension. With this new classification of donors, named expanded criteria donors (ECD)

This article is part of the Topical Collection on *OPTN Policy*

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[4], it was realized that although these kidneys had a shorter duration of function compared to the ideal young donor, they functioned well for many patients allowing them to enjoy many years, if not the rest of their life, free from dialysis.

The premise behind the ECD program was to trade off a potential decrease in years of expected kidney function in return for a more rapid kidney transplant opportunity. However, the scoring system used to define an ECD kidney was imperfect and many kidneys that were labeled ECD actually functioned like kidneys defined as standard criteria donor kidneys (SCD). Moreover, some SCD kidneys had a shorter duration of function compared with ECD kidneys. As a result, patients were added to both lists as physicians attempted to match the expected donor organ function with their expected survival for each recipient. This led to marked organ acceptance differences between individual transplant programs based on less than optimal medical assumptions, resulting in a further deterioration in the kidney allocation system.

In 2005, the Organ Procurement and Transplantation Network (OPTN)/UNOS Board authorized the initiation of a process to significantly revise the national kidney allocation system (Table 1). Many of the organs were being allocated based on factors that were no longer as important due to medical advances in preservation and immunotherapy, and the system was encumbered by numerous local variances, many of which had been in effect since the inception of the national system. The new KAS would not be creating new donor organs but a reallocation of the existing kidneys, in effect, providing a more optimal rationing of the increasing limited resource to effectively and efficiently maximize utilization through a transparent system stressing utility and maximal access.

The first attempt at improving the KAS took 3 years of modeling (using 30 different proposed sets of allocation rules) by the Kidney Committee and resulted in the concept of "life years from transplantation" or LYFT [6••]. LYFT introduced the idea of more broadly sharing kidneys on a national scale, addressing the long-standing parochialism of local organ ownership. The national share concept quickly ran into wide opposition, and this was scaled back to a LYFT algorithm without a national share. Modeling of this allocation system succeeded by repeatedly showing a significant increase in the number of total life years gained from transplantation with the current donor pool. The main barrier was that although the system was effective in achieving the goals of utility, the LYFT algorithm was also very complicated and difficult to explain to patients. Additionally, the modeling showing the success of the overall system did so at a projected severe disadvantage to certain subgroups of candidates, particularly older individuals and those with diabetes. This culminated in January 2009 with a UNOS sponsored forum in St. Louis where the public voiced its strong opposition to this LYFT-based proposal.

After the defeat of LYFT, the Kidney Committee returned to craft a new KAS, retaining some of the progressive ideas including incorporating donor and recipient factors, national share for the most highly sensitized patients, eliminating paybacks, incorporating the existing local variances for blood type B candidates to be prioritized for blood type A_2/A_2B donor kidneys, and including prelisting dialysis time into candidate waiting time calculations.

This led to a new concept called age and longevity matching. The idea behind age matching was that an organ would be allocated to recipient based upon the age of the donor. For example, if the donor was 45 years old, the kidney would be allocated to an individual as young as 30 years of age and as old as 60 years of age. This was called age plus or minus 15 years. The first iteration of this approach also included optimized survival matching where the top 20 % of the organs based on longevity were allocated to individuals expected to live the longest following transplantation. This ran into some opposition and the system was reduced to simply age matching alone whereby organs were allocated based upon the donors age +/−15 years.

The feedback on this proposed allocation system was instructive. The system was proposed to the general public in the form of a concept document released without the accompaniment of media or public announcements explaining the project. There was no committee perspective framing the proposal. As a result, the public misinterpretation and negative reaction to the proposal was present shortly after introduction. Prior to formal public comment, there was opposition mounted by special interest groups who incorrectly believed the new system would remove access completely for patients of a certain age. This was further complicated by a meeting with the Office of Civil Rights (OCR) who voiced a concern that this would not stand up to legal scrutiny because age matching could be consider a violation of civil rights. The OCR did, however, add two constructive observations: first was, if age was to be used as a single metric, there must be a rationale as to why 15 versus 14 versus 16 years was chosen. Second, the system could use age as a biological factor if it also brought in other variables to help refine the process. At this point, the process of redesigning the kidney allocation system came full circle.

With the decision to use age as a biological factor, the concept of estimated post-transplant survival (EPTS) was born. EPTS relies upon four variables: age, number of prior transplants, diabetic status, and time on dialysis [7]. Ironically, these were the four most statistically important variables used in the LYFT system.

At about this time, Rao et al. published a concept called kidney donor risk index (KDRI), a method to stratify kidneys based on expected graft survival relative to the entire donor organ pool. This metric used 10 variables found to be predictive of function after transplantation [8••]. For use in organ

Table 1 Sentinel events in the development of the kidney allocation proposal [5]

Date	Sentinel event
2003	OPTN Board of Directors instructs the Kidney Allocation Review Subcommittee (KARS) to conduct a 360° review of the current kidney allocation system. This review included a series of public hearings to better understand the limitations of the current system and possible approaches for improvement.
2004	OPTN Board of Directors instructs KARS to examine the use of net lifetime survival benefit in a revised allocation system.
2005	KARS merges with the OPTN Kidney Transplantation Committee to begin formal policy development process.
2007	Public Forum held in Dallas, TX, to review the use of life years from transplant (LYFT) in an allocation system.
September 2008	Request for information (RFI) issued detailing the concepts of life years from transplant (LYFT), kidney donor profile index (KDPI), and changes to the waiting time calculation to include time on dialysis prior to listing.
January 2009	Public forum held in Saint Louis, MO, to review concepts circulated in September 2008. Participants included representatives from the following organizations:
	American Association of Kidney Patients
	American Society of Histocompatibility and Immunogenetics
	American Society of Transplant Surgeons
	American Society of Transplantation
	National Association of Transplant Coordinators
	National Kidney Foundation
	Renal Support Network
2009	At the recommendation of forum participants, the Committee considers age matching as a way to address concerns about system complexity.
February 2011	Concept document is released detailing the use of estimated post-transplant survival (EPTS), age matching within 15 years of donor and recipient, and kidney donor profile index (KDPI).
August 2011	Committee receives feedback suggesting that age matching does not meet the requirements of the 1979 Age Discrimination Act since it uses age as an arbitrary determinant in allocation.
2011–2012	Committee considers alternatives to age matching.
September 2012	Committee issues a proposal for public comment.

Source: OPTN/UNOS, provided for OPTN Kidney Transplantation Committee, 2012

allocation, this was modified to the kidney donor profile index (KDPI). This allowed transplantable kidneys to be graded on a scale of 0 to 100 where zero is a kidney that is expected to last the longest compared to all other transplantable kidneys [9]. By using these two new concepts, EPTS and KDPI, the concept of longevity matching could be realized.

Longevity matching was many years in development. The first issues were policy considerations. There was a mandate to have increased priority for certain groups such as the highly sensitized candidate, children, minorities, and prior organ donors. Longevity matching also addressed one troubling aspect of kidney allocation, that much older and sicker candidates could receive a kidney from a young donor, thereby losing out on years of potential organ function. The new allocation system allowed for matching donor kidneys with the longest expected function with recipients who are expected to live the longest.

Finally, with the implementation of this modified KAS, all pre-existing variances were eliminated to allow the new system to be a blank slate, a benefit for future assessments. This eliminated legacy variances developed over time in the different donor service areas and regions in an effort to address what were felt to be local disparities in organ allocation. This resulted in a system that was so heterogeneous, large, and unwieldy that no meaningful incremental changes could be made without prohibitively large IT expenditures.

The New Kidney Allocation System

The KAS was designed in an effort to address the deficiencies of the prior systems. These deficiencies had become so glaring that change to the system was impossible without a complete overhaul [10]. In the prior system, waiting time had become the primary driver of allocation and there was no accounting

for medical need or urgency, the difficulties faced by highly sensitized patients, the fact not all patients can wait the same amount of time, and no consideration of the needs of younger adult patients.

In KAS, allocation of the kidney will be driven by the expected duration of function of that specific donor organ. Kidneys will the longest expected duration of function will be allocated to those individuals with the longest expected lifetime after transplantation and after initial allocation to multi-organ recipients and children. The majority of the kidneys will be allocated in a fashion similar to the current method, meaning that time waiting will be the primary unit of allocation. This was in response to public feedback and a significant amount of compromise design to balance utility, number of life years gained from kidney transplantation, with equity, access to transplantation for those individuals over age 50 (Table 2). Finally, those kidneys with the shortest expected duration of survival, similar the prior extended criteria donor system, will be allocated in a simplified system, using only waiting time to a combined local and regional list.

Longevity Matching

In KAS, longevity matching will pair those donor kidneys with top 20 % expected duration of survival with those recipients that fall within the top 20 % for expected survival after transplantation (EPTS). The majority of the kidneys, those with KDPI 21 to 84 %, will be allocated in a fashion that is similar to the current system. Finally, those kidneys with KDPI 85 % and higher will be allocated on a combined local and region list and will be the basis of a modernized ECD system. It is important to note that within all categories, similar to the prior allocation system, waiting time will be the primary determinant of the order of allocation along with points for HLA DR matching and level of sensitization.

High KDPI Kidney Allocation

As mentioned above, the overlap in expected survival undermined the efficacy of the prior ECD system. The new "ECD" was designed with the intent of improving organ outcome predictability as well as potentially promoting greater organ recovery. The KPDI method of classifying deceased donor kidney does not result in a disconnection between classification and graft survival, and therefore, there is no reason to list a recipient for a kidney with KDPI 86 % or greater unless they will benefit from a more rapid time to transplant and can tolerate potentially shorter graft survival.

Additionally, the allocation of kidneys with KDPI 86 % and greater to a regional list may incentivize organ recovery. Currently, there is disparity on ECD recovery as there are organ procurement organizations (OPOs) in which the utilization of ECD kidneys is very low, and these OPOs are often adjacent to those with very high usage of ECD kidneys. As an OPO's incentive for organ recovery is based on the probability of that organ being placed and not influenced by a the fact it is utilized by a transplant center with in its distribution area, the creation of a market for these kidney in an adjacent (regional) area may promote more recovery. Additionally, the recovery and placement of organs outside the OPO may cause a change in behavior of the programs within that OPO to begin to utilize these organs. At the time of this writing, this remains an experimental hypothesis.

Finally, by allocating these high KDPI kidneys nearly exclusively by accumulated waiting time, management of these often older candidates with complex medical histories should be easier for transplant centers because their anticipated time to transplantation could be more predictable. This will vary by region but should reach a predictable equilibrium.

Waiting Time Calculation

In kidney transplantation as opposed to other solid organ transplantation, there is no accounting for the severity of candidate illness in organ allocation. This is due to the success of maintenance dialysis therapy in forestalling death from end-stage renal disease. The prior allocation system did not account for the accumulated dialysis time prior to the time of listing such that if candidate listing occurred years after dialysis initiation, the patient suffered from the negative consequences of more dialysis exposure. Moreover, those individuals who on average had more dialysis exposure prior to listing were often from racially and socio-economically disadvantaged groups. The KAS now will credit waiting time from

Table 2 Comparison life years gained from kidney transplant and the percentage of transplants going to recipients over the age of 50 of the different kidney allocation proposals [5]

	National sharing + LYFT	LYFT	Age matching + longevity matching	Age matching	Longevity matching
Gain in life years	34,026	25,794	15,223	14,044	8380
Proportion of kidneys transplanted into recipients >50 years old	10	29	46	45	52

Source: OPTN/UNOS, provided for OPTN Kidney Transplantation Committee, 2012

the date of listing with eGFR less than or equal to 20 ml/min or from the confirmed date of dialysis initiation.

Highly Sensitized Patients

In the prior allocation systems, those recipients with a calculated panel reactive antibody (CPRA) level of 80 % or greater received and additional four allocation points. This had two unintended consequences. First, it resulted in inappropriately high rates of transplantation for individuals in the CPRA 85 to 95 % ranges, likely over-advantaged than those in the CPRA 80 to 84 % range, and did nothing to help those individuals who are truly disadvantaged, those with CPRA greater than 98 %. In an analysis of time to next offer, recipients with CPRA 100 % had to wait an average of 13 years. It also resulted in transplant programs not entering all unacceptable antigens into UNET for recipients who they assumed would not achieve a CPRA score of 80 % (and the additional four points). This contributed to a relatively large number of unexpected positive cross matches based on inaccurate virtual cross matching.

In the new KAS, recipients are assigned a point score to more accurately reflect the biological reality of their degree of sensitization. Patients with CPRA 100 % will be prioritized for organ offers from the national donor pool while those with CPRA 99 % will receive regional priority and those with 98 % local priority ahead of most candidates. Additionally, enough points will be allocated to ensure that from the time of listing, they will be "at the top of the list" in any category so that recovered kidneys will be screened against them for a potential match.

Blood Group A_2 and A_2B Donor Kidneys Allocated to Blood Group B Recipients

The national median waiting time is longest for patients with blood type B. Moreover, because blood type B tends to occur more frequently in minority populations and because blood type B is rare among the organ donor pool, these groups are at a disadvantage [11]. In 2001, the OPTN Board of Directors approved a variance to enable the transplantation of blood type A_2 (technically, "non-A_1") and A_2B (technically, "non-A_1B") deceased donor kidneys into blood type B candidates. The goal of this variance was to increase the rate of transplantation in blood type B candidates by allocating these kidneys to them without negatively impacting post-transplant outcomes. Since implementation, nine OPOs have participated in this variance. Published studies demonstrate that A_2 and A_2B kidneys transplanted into appropriate blood type B recipients have comparable survival rates to blood type B and O donor organs and that this practice has shortened waiting times for blood type B candidates [12, 13]. Therefore, in an effort to increase access to transplant for blood group B candidates, in the new KAS, donors of blood type non-A1 and non-A1B will be allocated to blood type B candidates who will participate in this program.

Conclusion

The new KAS, which became effective on December 4, 2014, was the result of the work of five OPTN/UNOS Kidney Transplantation Chairs and their respective committees. It took nearly a decade to design and reflects both striving for an ideal system and the understanding that a project so large and affecting a large and diverse patient population requires compromise. While not perfect, early data indicates that the new system is achieving the stated goals without unexpectedly disadvantaging any one group. The KAS was designed in a way to make modification easy in response to future trends. Most importantly, the new KAS was designed using allocation principles that already had acceptance by the transplant community and can be applied, with little change, to a future allocation system that shares kidneys over larger geographic areas. The new KAS erases the arbitrary way kidney allocation was done in this country for nearly two decades and it establishes a new benchmark for which to compare future proposals to address racial, economic, and geographic disparity in access to kidney transplantation.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no competing interests.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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