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EDITORIAL

Changing organ allocation policy for kidney transplantation in the United States

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Abstract

The new kidney allocation scheme (KAS) in effect since December 4th 2014 was designed to overcome the shortcomings of previous system. A key feature of the new KAS is preferential allocation of best quality organs to wait-list candidates with the longest predictive survival in a concept called longevity matching. Highly sensitized recipients would get extra points and enjoy widespread sharing of organs in order to increase accessibility to transplant. Wait-list candidates with blood group B will be offered organs from donors with A2 and A2B blood type in order to shorten their wait-list time. Time on the wait list will start from day of listing or date of initiation of dialysis whichever comes first which should benefit candidates with limited resources who might be late to get on the transplant list. Pay back system has been eliminated in the new KAS. These changes in organ allocation policy may lead to increase in median half-life of the allograft and increase the number of transplants; thus resulting in better utilization of a scarce resource. There could be unintended negative consequences which may become evident over time.

Key words: New kidney allocation scheme; Longevity matching; Highly sensitized; Kidney donor profile index; Expected post-transplant survival

Core tip: The new kidney allocation system (KAS) was recently implemented in the United States in an attempt to improve the utilization of deceased donor kidneys. A key feature is preferential allocation of best quality organs to wait-list candidates with the longest predictive survival in a concept called longevity matching. Attempts were also made to improve access to kidney transplantation by giving priority points to highly-sensitized recipients and by giving consideration to dialysis vintage. Simulation model has predicted a modest increase in median allograft and patient life-years with the new KAS. Potential limitations and unintended consequences are also discussed in the article.

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THE NEED FOR A NEW ALLOCATION SYSTEM

Kidney transplantation extends life and improves quality of life for most individuals compared to patients on the waiting list undergoing dialysis[1]. In the United States, an increasing number of candidates on the kidney transplant waiting list without a corresponding increase in the availability of suitable organs have led to a gradual widening of the gap between demand and supply of organs. This along with the shortcomings observed in the organ allocation system during the last two decades led to the development of the new kidney allocation scheme (KAS) for deceased donor (DD) kidney transplantation. New KAS was approved by the organ procurement and transplantation network (OPTN) in June 2013 and subsequently implemented for clinical use starting on December 4th 2014. In the previous allocation system, candidates who accrued the longest waiting time received the kidney transplant irrespective of their expected long-term outcomes. As a result, many older transplant recipients died with a functioning allograft while several younger recipients failed their older donor kidneys with return to waiting list in a short duration[2]. There was less emphasis regarding the level of HLA sensitization of candidates. The minority candidates who have difficulty in navigating the complex transplant process got listed late and hence had to wait longer to receive a transplant, whereas the educated affluent candidates generally got listed as soon as glomerular filtration rate (GFR) is < 20 mL/min and hence had better access to this scarce resource. This resulted in some disparity in allocation of kidneys between various socio-economic and racial groups[3-5]. The candidates with blood type B waited much longer as compared to blood type A[6]. The geographic disparity in different donor serving areas has worsened over time with the increased demand and limited supply of organs[7]. Over the last 10 years, the kidney transplantation committee of united network of organ sharing has worked on identifying and rectifying the limitations of the previous allocation system and designing the new KAS[8].

PRINCIPLES INVOLVED IN DESIGNING A NEW ALLOCATION SYSTEM

The two main principles involved in designing an allocation system are utility and equity[2]. A system that focuses on maximizing the outcomes after the transplant is a utility based system whereas the principle of equity is designed to prioritize equal access of organs to all irrespective of the long-term outcomes. In the context of organ shortage and long waiting times, the previous allocation system was heavily weighed on the principle of equity with less stress on measures of utility such as life years after transplant. If the new allocation system were entirely to focus more on utility, older patients with end stage renal disease would have decreased access to transplant. Thus a balance between equity and utility was necessary in the designing of new KAS, such that there is access for transplant to every one while maximizing the benefit of this scarce resource.

MAIN CHARACTERISTICS OF THE NEW KAS

In the new KAS, an attempt was made to match the donor and recipient characteristics in such a way that the best quality donor kidneys are preferentially given to recipients who are expected to have the longest post-transplant survival[9]. All the available DD kidneys will be given a score ranging from 0%-100% termed kidney donor profile index (KDPI). The 10 factors influencing KDPI are donor age, height, weight, ethnicity, history of hypertension and diabetes, cause of death as cerebro-vascular accident, serum creatinine level, hepatitis C status, and donation after circulatory death (DCD) status. Lower the KDPI score better is the quality of the kidney. Expected post-transplant survival (EPTS) is calculated to risk-stratify all wait-listed patients. EPTS ranges from 0%-100% and takes into account four factors including candidate age, dialysis duration, prior solid organ transplant, and diabetes status. Lower the EPTS score better is the post-transplant survival. The aim is to have patients with the top 20th percentile of EPTS receive organs with $\leqslant$ 20% KDPI in a concept called longevity matching. The formulae for calculating KDPI and EPTS are shown in Table 1. The KDPI is derived by utilizing the donor specific elements from the kidney donor risk index (KDRI) developed by Rao *et al*[10] in 2009. KDRI was validated by applying the formula to first time transplant recipients from 1995 to 2005 in the national Scientific Registry of Transplant Recipients (SRTR) data base. The KDRI was considered to be a substantial improvement in interpreting the graft outcomes based on donor related factors as compared to the expanded criteria donor (ECD) and standard criteria donor (SCD) terminology. The EPTS score was developed by the SRTR upon request from the OPTN Kidney Transplantation Committee. For the sake of simplicity, the committee requested that the score only include the four factors described above. The formula was derived using a Cox proportional hazards model to quantify the associations between the four factors and patient survival after transplant[11].

New KAS allocates kidneys in 4 steps after stratifying the organs based on the KDPI scores: $\leqslant$ 20%, 21%-34%, 35%-85%, > 85%. The recipients are matched based on their EPTS. In each of the

Table 1 Formulae for calculating Kidney Donor Profile Index and expected post-transplant survival

KDPI

KDPI = exp (-0.0194 × I[age < 18 year] × [age - 18 year] + 0.0128 × [age - 40 year] + 0.0107 × I[age > 50 year] + 0.179 × I[race = African American] + 0.126 × I[hypertensive] + 0.130 × I[diabetic] + 0.220 × [SCr - 1 mg/dL] - 0.209 × I[SCr 1.5 mg/dL] × [SCr - 1.5 mg/dL] + 0.0881 × I[cause of death = CVA] - 0.0464 × [{height - 170 cm}/10] - 0.0199 × I[weight < 80 kg] × [{weight - 80 kg}/5] + 0.133 × I[donation after cardiac death] + 0.240 × I[hepatitis C] - 0.0766, where I is equal to 1 if the condition is true and I is equal to 0 if the condition is false

EPTS

EPTS score = 0.047 × MAX (age - 25. 0) - 0.015 × Diabetes × MAX (Age - 25.0) + 0.398 × Prior Organ Transplant - 0.237 × Diabetes × Prior Organ Transplant + 0.315 × log(Years on Dialysis + 1) - 0.099 × Diabetes × log(Years on Dialysis + 1) + 0.130 × (Years on Dialysis = 0) - 0.348 × Diabetes × (Years on Dialysis = 0) + 1.262 × Diabetes

EPTS: Expected post-transplant survival; KDPI: Kidney donor profile index.

Table 2 Points awarded to wait-listed candidates in the new kidney allocation system

Candidate features	Points awarded
The waiting time (date of listing with GFR < 20 mL/min, or date of initiation of dialysis)	1 per year (1/365 per day)
Pediatric candidates at time of match with 0- ABDR mismatch donor	4 (if child is 0-10 yr) 3 (if child is 11-17 yr)
Pediatric candidate at time of match if KDPI < 35%	1
Prior living donor	4
Level of sensitization (cPRA ⩾ 20%)	0-202, see description
Single HLA-DR mismatch with donor	1
Zero HLA-DR mismatch with donor	2

cPRA: Calculated panel reactive antibody; GFR: Glomerular filtration rate; KDPI: Kidney donor profile index; HLA: Human leukocyte antigen.

KDPI class, first preference is given based on HLA sensitization: in patients with calculated panel reactive antibody (cPRA) of 100%, kidney is allocated at local, regional or national level, followed by cPRA of 99% and 98%. The zero HLA mismatch gets the next preference, followed by prior living donors, and then pediatric recipients. If a donor organ with KDPI ⩽ 20% is still unused after running down the list, it will then be offered to candidates with EPTS in the bottom 80%. A kidney with KDPI > 85% not used locally will be offered at a regional level before discarding.

In the new system, the time on the wait list for a candidate starts to accrue from the time of listing when the GFR < 20 mL/min or from the date of initiation of dialysis. The latter should benefit candidates with limited resources who might be late to get on the transplant list to accrue wait time from the date of initiation of dialysis. Points are assigned to each candidate as described in Table 2. In sensitized patients, points are given based on the level of sensitization. Patients with cPRA of 100% are awarded 202 points. Similarly for cPRA of 99%, 98%, 97%, 96% and 95%, points awarded are 50, 24, 17, 12 and 10 respectively. As the cPRA goes down, points are given in a decreasing order till the cPRA reaches a minimum of 20%. More the points accumulated by a candidate, higher the priority for receiving the next compatible kidney offer.

KEY DIFFERENCES BETWEEN NEW KAS AND OLD ALLOCATION POLICY

Many concepts of the new KAS are similar to the old policy but there are some key differences (Table 3). In the new KAS, an attempt is made to move away from the terms such as SCD, ECD and DCD. Instead the KDPI will be a more accurate way of assessing the donor risk index in a graded manner. The wait time for a potential recipient on the list is variable based on the geographic region and availability of organs. Traditionally blood types B and O candidates experienced the longest wait time in every region because blood type B is the least common and blood type O kidneys are also given to other blood type recipients if there is a zero-HLA mismatch. Blood types AB, A, O, and B have mean wait times of 2, 3, 5, and 6 years, respectively[12]. A blood type comprises of A1 and non-A1 (A2) blood sub-types. A2 blood type may be less immunogenic when compared to A1 blood type. Studies have shown increased rate of transplantation with reduced waiting time along with similar graft and patient outcomes when A2 or A2B DD kidneys were transplanted to wait-listed patients with B blood type when compared to B recipients of a B kidney[13-15]. In order to decrease the wait times for blood group B candidates, kidneys from donors with A2 and A2B blood types will be offered to blood group B candidates in the new KAS[9]. In the past, if an organ procurement organization (OPO) from a particular region received a kidney from another OPO because of a combined organ transplant or zero-HLA mismatch kidney, the receiving OPO had to pay-back to the national pool. This pay back system is eliminated now. National priority sharing of organs for highly sensitized patients and those with zero-HLA mismatch will help reduce the geographic disparity and better utilization of scarce resource for optimizing the-long

Table 3 Comparison of old *vs* new allocation policies

Old kidney allocation system (effective 1988 - 12/3/2014)	New kidney allocation system (effective 12/4/2014 onwards)
Wait list time starts from time of listing	Wait list time starts from time of listing or date of initiation of dialysis, whichever comes first
The quality of organs described based on the terms SCD, ECD and DCD kidneys	The quality of organs assessed by a KDPI score (0%-100%)
No metric was involved in allocating kidneys depending on the expected long- term outcomes of the transplant candidates	Longevity matching is used to allocate kidneys depending on the KDPI and EPTS scores
Only 4 priority points were given for HLA sensitization for a cPRA ⩾ 80%	Gradation of priority points given based on HLA sensitization for cPRA ⩾ 20% range from 1-202, which can bring the recipient much higher on the list
Long wait time for blood group B candidates	In order to decrease wait times for B blood group candidates, A2/A2B blood type donors acceptable
Pay back system present	Pay back system eliminated
Priority given to pediatric candidates: share 35 (donor age < 35 yr)	Pediatric candidates still get priority for kidneys with KDPI < 35%
National and regional sharing for sensitized patients was not mandated	National, regional and local priority sharing of organs for highly sensitized patients with cPRA of 100%, 99% and 98% respectively
High discard rate existed for marginal ECD/ DCD kidneys	Regional sharing of marginal kidneys (KDPI > 85%) is proposed

cPRA: Calculated panel reactive antibody; DCD: Donation after circulatory death; ECD: Extended criteria donor; EPTS: Estimated post-transplant survival; KDPI: Kidney donor profile index; SCD: Standard criteria donor.

term outcomes.

PREDICTED OUTCOMES FROM THE CHANGE IN ALLOCATION POLICY

It will take time to understand the real impact of the change in organ allocation policy in DD kidney transplantation. A simulation study was recently published which compared the long-term outcomes of transplant recipients by simulating distribution of organs based on the principles of the old and new kidney allocation policies[16]. Modeling was done using the software system called kidney-pancreas simulated allocation model (KPSAM) which is routinely used by the OPTN committees to assess policy proposals[17]. The characteristics of the recipients and donors were similar in both categories and similar to the actual transplants performed in 2010. The new allocation policy showed an increase in median survival of +0.23 years (an increase of 4.6%) when compared to wait-list candidates. There was also a slight increase in the number of transplants, *i.e.,* 68 more per year (0.58% more transplants per year). The model predicted an increase in the number of transplants by 18% in diabetics and by 11% in recipients with a dialysis vintage > 4 years while using the new allocation system. Median life span post-transplant increased by 0.83 years. The overall prediction was a 7.0% increase in median patient life years per transplant and a 2.8% increase in median allograft life years with the new allocation model. Assuming 11000 DD kidney transplants occur annually; this could result in a net gain of 9130 life-years of patient survival and 2750 years of allograft survival. The model also predicted an increase in the number of transplants for recipients in the age group 18-49 years, whereas the number of transplants would decline by 4.1% in 50-64 year olds and by 2.7% for those ⩾ 65 years. An increase in the rate of transplantation from 12.7% to 17.7% among blood type B candidates was also predicted by the model. A decrease in wait-list mortality predicted with the new allocation system despite an overall decrease in the transplantation rate for patients > 50 years could possibly be due to some unknown assumptions since it is less likely that the wait-list mortality would decrease despite fewer transplants in that age group. Simulation model in this study used various assumptions, and results were generated by the single software KPSAM. The reliability of these predictions in a dynamic environment can be questioned[18]. All the comparisons of the simulation were made to the transplants and outcomes from 2010, but all the outcomes from that year may not be a true reflection of what the results are each year. The practice patterns may change or vary with the changes in allocation policy which will alter the simulated results.

POSSIBLE LIMITATIONS AND UNINTENDED CONSEQUENCES OF THE NEW KAS

It is unclear how the information regarding major determinants of KDPI such as donor hypertension, diabetes mellitus and serum creatinine would be obtained in the setting of DD organ procurement. Blood pressure and blood sugar can increase under the stress of various clinical situations in a terminally ill potential donor and can erroneously give a diagnosis of underlying hypertension and diabetes. Serum creatinine is subjected to change over short period of time in critically ill patients and it is unclear which creatinine will be used for KDPI calculation since a baseline serum creatinine many not be available for most donors at the time of organ procurement. Procurement kidney biopsy findings, which can provide useful predictive information, are not part of KDPI since many kidneys are not biopsied. However, a recent study showed significant correlation between degree of glomerulosclerosis on

procurement biopsy and KDPI score[19]. The average glomerulosclerosis was 3.1% ± 4.4% among donors with a KDPI below 85 and 16.6% ± 11.7% for donors with KDPI ⩾ 85 (P < 0.01). Recipient cardiovascular status, a strong predictor of survival, is not directly incorporated in the calculation of EPTS. There could be other determinants of post-transplant survival that are not included in the computation of EPTS.

Unintended consequences are always a possibility while implementing any new system. For example, potential recipients with EPTS < 20% will have higher likelihood of getting organs with KDPI < 20%, within a relatively short time-frame and such recipients might decide not to pursue living donation. Wait-listed candidates > 50 years of age might feel disadvantaged with the potential decline in the number of transplants in their age groups. The effect of dialysis initiation on pre-emptively wait-listed candidates in the new KAS was reported by Schold *et al*[20]. Their analysis revealed that majority of patients pre-emptively listed are younger, privately insured, highly educated, Caucasian, non-diabetic females who would qualify for the top 20% KDPI organs. Counter intuitively, initiating dialysis in this group while on the waiting-list will lower their EPTS score further by 4%-5% for another 5 mo, which allows them to enjoy the priority status of receiving better quality organs. On the other hand, only very few diabetic patients would have EPTS < 20%, and initiating dialysis in these patients immediately increases their EPTS by about 6%, further disadvantaging them. The new KAS with its proposed local, regional and national sharing of organs may or may not decrease the geographic disparity in kidney transplantation as is expected. The cold ischemia time might increase with distant sharing of organs. Antibodies to HLA-DPB and HLA-DQA are not routinely considered in the cPRA calculation. Wait-listed patients with these unmeasured HLA antibodies might get offers from donors with HLA-DPB and/or HLA-DQA and could result in "unexpected" positive cross-matches and poor outcomes if decided to proceed with transplantation[21]. About 63% of the wait-listed candidates with cPRA > 98% had significant antibodies against HLA DPB or DQA subtypes which disproportionately affected women and minorities[22]. This may prevent the intended higher transplant rates in highly sensitized patients unless HLA DPB and HLA-DQA antibodies are routinely incorporated into cPRA estimation.

CONCLUSION

Donor kidney is a scarce resource and optimal utilization while maintaining equitable distribution is challenging. The changes in the new KAS are created with an aim to minimize the mismatch between allograft and recipient longevity. The new scoring systems of EPTS and KDPI give a gradation for the expected longevity of the potential recipient and allograft respectively. Priority sharing of organs for highly sensitized candidates and considering waiting time from time of initiation of dialysis will be advantageous for these waitlisted candidates. As a tradeoff, the rate of transplants in potential recipients > 50 years of age might decline. Regional sharing of high KDPI organs will hopefully lower the high discard rate of marginal organs. The simulation analysis looks promising but the dynamic practice pattern changes and other unknowns might result in some unanticipated results. We will need more methods to assess the outcomes of this new allocation policy, and with time the transplant community will learn the benefits and shortcomings of the new KAS.

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