

IMPROVEMENTS TO THE KIDNEY ALLOCATION SYSTEM—COMING 2014

Organ Procurement and Transplantation Network (OPTN) has approved a substantial change to the deceased donor kidney allocation system scheduled to be implemented in 2014.

The objectives of the changes are:

- ▶ Increase the life years for deceased donor kidneys that are transplanted by adding allocation priority for longevity matching for potential recipients with an estimated survival in the top 20%. It is projected that the change in allocation will result in 8000 additional transplant life-years and decrease the need for re-transplantation.
- ▶ Improve access to transplantation for moderately and highly sensitized candidates on the waiting list.
- ▶ Improve access to transplantation for ethnic minorities.
- ▶ Improve efficiency and utilization of deceased donor kidneys by providing more granular information regarding organ quality.

Reasons for change:

- The previous kidney allocation system had significant limitations due to over-reliance on the time on the waiting list as the primary driver of kidney allocation.
- There are high rates of discard of kidneys that may benefit a subset of potential transplant recipients.
- There is variability in patient access based on geographical, socio-economical and biological differences.
- The observed mismatch between survival of the patient and potential survival of the allograft has resulted in high rates of death with a functioning transplant or repeat transplantation in certain populations, reducing the opportunity to maximize life-years gained from the deceased kidney donor pool.

While no organ allocation policy can resolve the existing shortage of kidneys, the new allocation system intends to optimize equitable access to kidney transplantation to all recipients while maximizing the transplantation benefit for recipients with the greatest possible survival.



IMPROVEMENTS TO THE KIDNEY ALLOCATION SYSTEM—COMING 2014

CONTINUED

The major components of the new system include:

- ▶ Kidney Donor Profile Index (KDPI) is an estimate of a deceased donor kidney's expected survival. The KDPI will replace the current categorical classification of deceased donor kidneys into standard or expanded criteria.
- ▶ It groups the allocation of available deceased donor kidneys into 4 categories: i) kidneys with a KDPI of $\leq 20\%$, ii) those with a KDPI of > 20 and $< 35\%$, iii) those with a KDPI of ≥ 35 and $\leq 85\%$, and iv) those with a KDPI of $> 85\%$.
- ▶ Undertakes longevity matching of donor kidneys with a KDPI $\leq 20\%$ for those recipients with the estimated post-transplant survival in the top 20%.
- ▶ It increases priority for sensitized individuals, by taking into account the percent calculated panel reactive antibodies (CPRA), with additional weighting for those with the most highly sensitized CPRA greater than 98%.
- ▶ It begins accrual of waiting time for kidney transplant candidates at the earlier of the following: i) the date of dialysis initiation for those patients who were on dialysis prior to being added to the wait list, or ii) the date when the (measured or calculated clearance or GFR) is documented to be less than or equal to 20mL/min for those who are wait-listed prior to initiating dialysis.
- ▶ Allows allocation of A2/A2B blood group kidneys to blood type B recipients to increase their access to deceased donor kidneys.
- ▶ Maintains priority of pediatric kidney transplant candidates for deceased donor kidneys with KDPI $< 35\%$.
- ▶ Eliminates the payback system.
- ▶ Eliminates regional variances in organ allocation. Currently, some regions of the country have organ allocation rules that apply only to potential recipients listed in that area.



IMPROVEMENTS TO THE KIDNEY ALLOCATION SYSTEM—COMING 2014 CONTINUED

Potential questions about the new system:

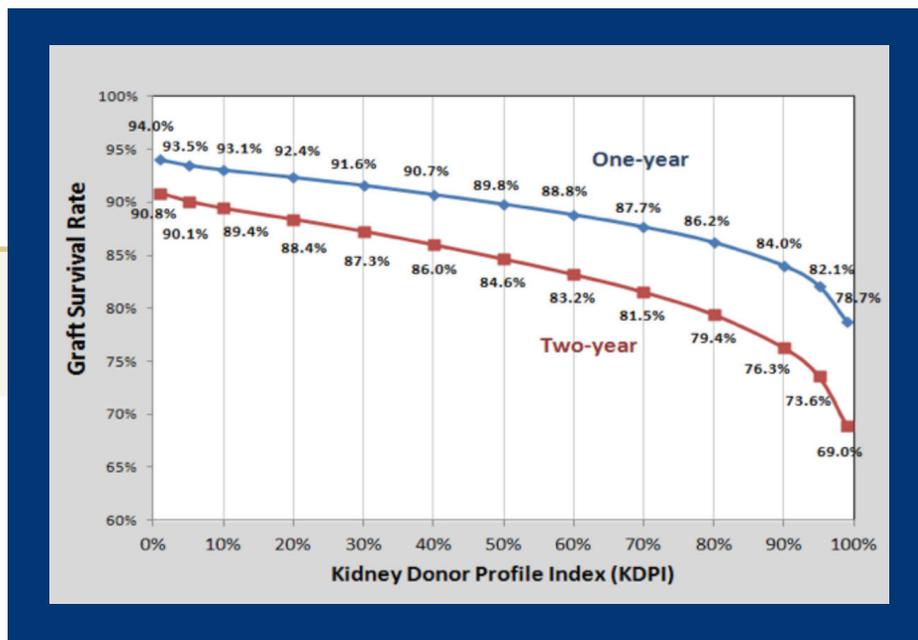
Q What is KDPI?

A KDPI is a score that was developed as a measure of deceased donor kidney quality. It incorporates the following factors about the potential donor:

1. Donor age
2. Height
3. Weight
4. Ethnicity
5. History of Hypertension
6. History of Diabetes
7. Cause of Death
8. Serum creatinine
9. HCV Status
10. DCD Status

KDPI is a percentage score that compares the expected survival of each donated deceased donor kidney to all other deceased donor kidneys donated in the prior year. A low KDPI indicates longer expected function and a high KDPI indicates shorter expected graft survival. A KDPI of 20%, for example suggests the kidney offer will likely function longer than 80% of available kidneys. Prior informed consent will be required for candidates to be offered kidneys with KDPI scores >85%. Based on the KDPI score the following graft survival is predicted:

Estimated Graft Survival Rates by KDPI



page 3 of 5

UNOS Research Department, based on OPTN database as of November 16, 2012.¹



IMPROVEMENTS TO THE KIDNEY ALLOCATION SYSTEM—COMING 2014

CONTINUED

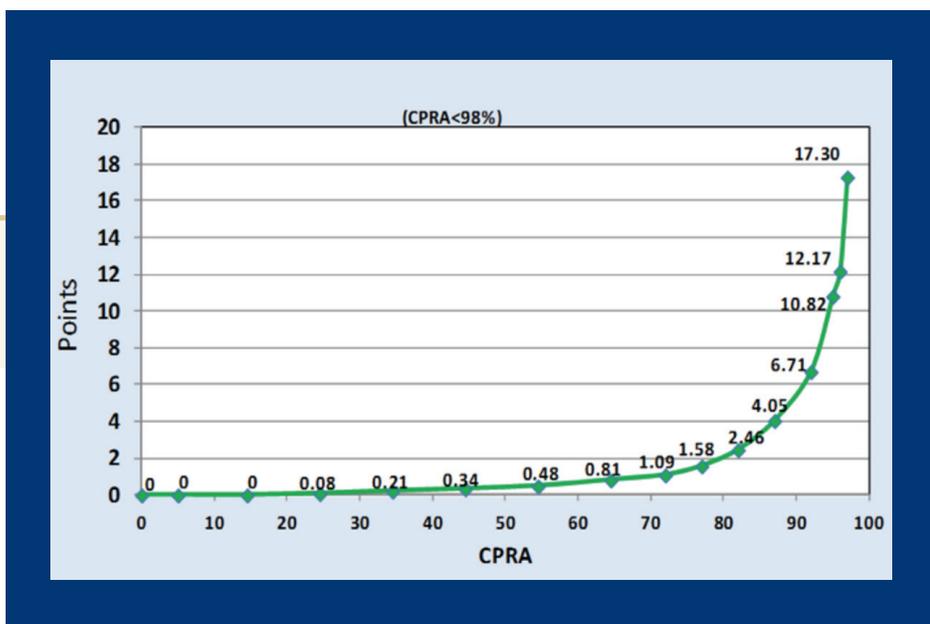
Q How will longevity matching be achieved in this new system?

A Analogous to KDPI as a reflection of donor quality, a measure of the likelihood of post-transplant survival will be calculated for kidney transplant candidates. This measure is the Estimated Post-Transplant Survival (EPTS). The EPTS takes into account four factors: i) candidate age, ii) time on dialysis, iii) prior organ transplant and iv) diabetes status. An EPTS score of 20% suggests that if the candidate is transplanted, he or she would likely survive longer than 80% of other recipients nationally. The candidates with an EPTS in the top 20% will be eligible for kidneys with a KDPI of < 20%. A potential recipient may have an EPTS in the top 20% even at the age of 50 yo. Exceptions to this consideration include candidates who are receiving multi-organ transplants, the highly sensitized and pediatric transplant recipients.

Q How will increased priority for sensitized individuals using the CPRA scale be done?

A Due to the recognition that access to transplantation is impaired even at relatively low cPRA, a sliding-scale was created to give increased priority to individuals with CPRA > 20%. In addition local priority will be given to individuals with a PRA of 98%, regional priority to those with a PRA of 99% and national priority to individuals with a PRA of 100%.

CPRA Sliding Scale (Allocation Points)



page 4 of 5

UNOS Research Department, derived from an analysis of the OPTN database as of August 5, 2011



IMPROVEMENTS TO THE KIDNEY ALLOCATION SYSTEM—COMING 2014

CONTINUED

Q What does it mean to incorporate A2/A2B to B kidneys?

A Blood group B is the most common blood type amongst minorities yet it is less common amongst donors. Currently, in most parts of the country, blood type B candidates face longer waiting times compared with other blood group recipients. The A blood group has many subtypes: A1 and A2 are most common. The ABO subgroup A2 has been found to be less reactive and thus low anti-A titer non-A recipients can often have successful kidney transplants from A2 donors. In order to proceed with this type of transplant, the candidates will have to demonstrate an anti-A antibody titer that is below an acceptable cutoff.

Q What does it mean to eliminate the payback system?

A The previous kidney allocation system has required an organ procurement organization (OPO) that receives a kidney from another OPO for a zero-antigen mismatch or for a combined organ transplant to payback a kidney of the same blood type to the national pool. For a variety of reasons including that payback kidneys tend to have more cold ischemic time and a higher risk of delayed graft function than kidneys transplanted locally, the payback system has been eliminated. Nevertheless, the new allocation system continues to prioritize transplantation with zero-antigen mismatched kidneys.

Q Does the new allocation policy affect when you should refer your patient for transplant evaluation?

A In order to mitigate disadvantage to patients with diminished access, and to maximize life-years gained from transplanted kidneys, the new policy places importance on other factors in addition to duration on the waiting list to determine kidney allocation. However, despite more emphasis on these additional factors, waiting time will remain a major determinant of when a patient will be transplanted. Potential transplant recipients can still accrue waiting time points when their measured or calculated clearance or GFR is < 20 ml/min and access zero mismatch offers regardless of the amount of waiting time. For this reason, potential transplant recipients should be referred for transplant evaluation as soon as they approach this level of function. This will provide patients their best opportunity to get a pre-emptive transplant, either by seeking out a living donor in a timely manner, or by starting to accumulate time on the waiting list as soon as possible for a future deceased donor transplant.

i Based on OPTN data as of Nov 16, 2012 including primary, solitary, adult kidney transplants from 2000-2007. These survival rates are for SINGLE kidney-alone transplants; survival rates are generally higher for en bloc or double kidney transplants. These rates were not adjusted for recipient characteristics, but instead reflect the expected survival averaged across the broad spectrum of adult recipients. The survival rates for any particular recipient will depend on specific characteristics of that recipient. Survival rates were estimated using a Cox regression model with log(KDRI) as the sole independent variable and graft failure defined as loss of graft or patient death. Donor reference population: all kidney donors recovered in 2011.

