OPTN The Organ Procurement and Transplantation Network

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Answers to Frequently Asked Questions
Regarding Kidney Allocation Public Comment Proposal

What issues does this proposal intend to address?
No organ allocation policy can resolve the existing gap between donated organs and candidates listed for a deceased donor transplant. That gap is greatest in kidney transplantation, as the kidney is by far the most commonly needed organ. A shared personal commitment to save lives through organ donation is the best way to help all candidates have an opportunity for a transplant.

This proposal is intended to maintain access for kidney transplantation for all candidates while making sure more recipients have the longest possible function from a kidney transplant, thus reducing need for repeat transplants. The proposed policy also would offer harder-to-place kidneys over a wider geographic area to increase use these kidneys. Finally, the proposal seeks to give an appropriate level of access for candidates who are hard to match for most kidneys and thus face a wait much longer than average.

Is this a policy that will go into effect soon?

No. This is a proposed policy. You are welcome to review it and offer any comment you may have. The OPTN/UNOS Kidney Transplantation Committee will review all comments. It may make changes to the proposal to address questions or suggestions raised by the public. The committee would then make a final proposal to the OPTN/UNOS Board of Directors for a public discussion and vote. The earliest time the OPTN/UNOS Board may consider a final proposal would be at its June 2013 meeting.

Would this proposal deny older kidney transplant candidates a chance to have a transplant?

No. The proposed policy continues to allow broad access for candidates who are age 50 and older. Candidates who are 50 or older make up more than 60 percent of the kidney transplant waiting list and currently receive more than 60 percent of deceased donor kidney transplants.

Under the proposed policy, some kidneys with the longest estimated function would be offered first to candidates who are expected to need a transplant for the longest time. While the formula to assess long-term benefit includes a candidate's age, it also includes other factors (see below for the list of factors considered). This formula would only be used for the 20 percent of candidates expected to have the longest need for a transplant. Age will not be a factor in determining transplant priority for most candidates.

Will the proposed policy increase transplant opportunities for minority candidates?

Yes, for minority candidates who have potential disadvantages under the current system. Blood type B is more common among minority populations, but only about 12 percent of deceased donors have this blood type. As a result, many type B candidates face a longer wait for a transplant than those with more

common blood types. The proposed matching of donors with compatible subgroups of blood type A is expected to reduce waiting time for type B candidates, many of whom are minorities. The additional priority for candidates with high immune system sensitivity should also provide additional transplant access for minority candidates who are highly sensitized.

In addition, studies have shown that some minority candidates are less likely than Caucasians to be listed for a kidney transplant either at or before the time they start dialysis. Thus by the time they are listed and start earning waiting time priority for a transplant, their kidney disease is more advanced and they are more likely to experience additional health complications. In some cases, this time gap between dialysis and transplant listing may happen because the potential candidate hasn't received reliable information about the option of getting a transplant. Under the proposed policy, waiting time priority for all candidates would begin from the time they begin dialysis or meet a medical definition of end-stage kidney failure. This should make transplant waiting times more equivalent in terms of medical need and benefit among all candidates.

Who are "expanded criteria donors" under current policy? Why is a change proposed?

Donor age and certain medical facts about the donor are known to affect how long a donated kidney is likely to function. Under current policy definitions, any deceased kidney donor age 60 or older is considered an "expanded criteria donor," as are those between age 50 and 59 who have certain medical history profiles. All other kidney donors are defined as "standard" criteria donors.

Currently, kidneys from expanded criteria donors are used in patients who are expected not to do well on dialysis over a long period of time. By undergoing transplantation with a kidney from an expanded criteria donor, they can be transplanted more rapidly than if they waited a standard criteria donor kidney.

Research has shown that the current definitions do not always precisely estimate the length of donor kidney function. Kidneys from some donors currently considered "expanded criteria" may function longer than kidneys from some "standard criteria" donors. The Kidney Donor Profile Index (described below) provides a more detailed and accurate estimate of kidney longevity from each donor than the current criteria.

What factors are used in KDPI and EPTS? Do they predict a specific, individual outcome?

Ten medical factors about the potential donor are used to calculate the Kidney Donor Profile Index (KDPI) score:

- Age
- Height
- History of diabetes
- Cause of death

- Weight
- Ethnicity
- History of hypertension
- Serum creatinine (a measure of kidney function)
- Hepatitis C virus status
- Whether the donation occurred after circulatory death

These factors are used in a clinical formula. A percentage score estimates how long a kidney offer is likely to function when compared with all other offers. A *low* KDPI percentage indicates likely longer function, and a *high* percentage indicates likely shorter function. A KDPI of 20 percent, for example, suggests the kidney will likely function longer than 80 percent of available kidneys.

Four medical factors about the transplant candidate are used to calculate the Estimated Post-Transplant Survival (EPTS) score:

- Age
- Length of time on dialysis
- History of diabetes
- History of a prior organ transplant

These factors are also used in a clinical formula. A percentage score estimates how long a candidate is expected to benefit from a functioning kidney when compared to the experience of other recipients over a recent time. A low EPTS percentage indicates likely longer-term survival, and a high percentage indicates shorter likely benefit. An EPTS of 20 percent, for example, suggests that if the candidate is transplanted, he or she would likely survive longer than 80 percent of other recipients.

Neither the KDPI score nor the EPTS score can precisely predict the outcome for a specific donated kidney or a specific patient's survival. However, when viewed over a large sample of donor offers or recipient outcomes, these formulas accurately estimate general trends and tendencies. The use of KDPI would *not* change the majority of kidney offers based on an average length of function – only those expected to have the longest and shortest function. Similarly, the use of EPTS would *not* change how the majority of kidney candidates get priority for kidneys – only those expected to need and benefit from a transplant the very longest.

Does the proposal include any sort of "grandfather clause" or transition if the policy is approved?

No, because transplant candidates will keep any allocation priority already earned if the policy goes into effect. The organ offer process would not change for most transplant candidates. The revised policy would only provide additional priority for certain candidates who are likely to receive greater long-term benefit or who face a longer-than-average wait under the current system.

Will this policy affect living kidney donation?

The proposed policy is not intended to change living donation. Often a living donor is a family member or friend of the recipient and donates to end a potentially long wait for a deceased donor kidney. If the

policy results in shorter waiting times for some candidates, some general trends in living donation may change over time. But living donation is and will remain an individual, voluntary decision made by someone motivated to help an individual candidate.

How can I learn more and comment about the proposal?

This and other current public comment proposals are available online on the OPTN website: http://optn.transplant.hrsa.gov/policiesAndBylaws/publicComment/ Before commenting, please read the proposal. It explains in detail the intended goals, alternative approaches that have been considered, and statistical modeling of possible effects of the policy. You may then submit a comment online through the website. Comments will be accepted through Friday, December 14, 2012.

If you do not have Internet access, please call United Network for Organ Sharing (UNOS) at 804-782-4800 for additional information or assistance in getting a copy of the proposal and submitting a comment.