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Dec. 18, 2008

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Statement of the Renal Support Network Regarding Kidney Allocation Policy

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The Renal Support Network (RSN) is a patient-run, patient-centered advocacy and education organization that strives to help patients with chronic kidney disease (CKD) improve their employability and develop their personal coping skills and special talents by educating and empowering them as well as their family members to take control of the course and management of the disease.

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We who have CKD are grateful for the oversight, guidance and regulation that the Organ Procurement and Transplant Network and the United Network for Organ Sharing (OPTN/UNOS) provides the organ donation and transplantation programs across this country. It helps both prolong and improve the quality of our lives.

The new formula for calculating the Kidney Allocation System (KAS) incorporates three significant components: Life Years from Transplant, Donor Profile Index and Dialysis Time. These are incorporated so that kidneys are matched to candidates based on the expected survival of both the kidney and the recipient.

Life Years from Transplant (LYFT) is primarily a measure of utility, and allows for the determination of the estimated survival that a recipient of a specific donor kidney may expect to receive versus remaining on dialysis. The objective of this component then is to prolong life. There are more than 15 variables imbedded in the LYFT formula, each with a calculated weight.

Candidate-related variables include: Age, Years on dialysis, Body mass index, Diabetes status, Previous transplant, Histo-compatibility factors, Calculated panel reactive antibody, and Diagnosis of polycystic kidney disease

Donor-related variables that affect LYFT include: Age, Cause of death, CMV serology, Hypertension and Weight

The kidney allocation system now being suggested would require that a Kidney Allocation Score (KAS) be calculated for each transplant candidate whenever a deceased donor kidney is available. This scoring process differs significantly from the allocation process used today.

We understand the intent of the new policy is to bring a more balanced approach to the organ allocation process, but there are areas of concern about the policy that we find may unintentionally harm people who are awaiting a life saving organ and need to be reconsidered.

An illness is too demanding when you don't have hope!

Areas of concern:

1. Eliminating Six Antigen Match Allocation

Many of our members have received a kidney because of the six antigen match allocation policy and have heard the reason this policy is being discontinued is because of administration costs and not because it is in the best interest of patients.

2. Life Years From Transplants

Given the length of time that some potential recipients are on the wait list, there needs to be an adjustment available in the scoring to reflect changes, for better or worse, in the health status of that candidate, and not just the advancement of age criteria annually. Many dialysis patients are receiving more dialysis which is showing to dramatically improve their well being. This policy will impede their chances of getting a transplant.

Age in and of itself is not an equitable measure; chronological age does not always reflect real age factoring in health, wellness and functionality, as there can be a relatively fit 50 year old vs. a less well, fragile 30 year old with unmanaged co-morbidities.

3. Previous Transplant Measure

Prior transplant in and of itself is not a measurable criteria. It depends upon the success and longevity of the transplants and the eventual outcomes' impact on the overall health of the patient. While statistically speaking, recipients of 2 or more kidneys do less well than with the first kidney, the reason why remains undetermined. And of course this is not true for all recipients, it's only a statistic, and could negatively impact those who have done well with prior transplants, but have simply received more of them. In addition, immunosuppressant medication has improved dramatically over the years. It would be inequitable to punish recipients who were on early drug regimes.

4. Transparency In New Measuring System

It would be critical that the process be transparent as to the weight of each variable, so that both potential donors and recipients are aware of the relative importance of each of the criteria.

5. Grandfathering Existing People Who Are On The Waiting List

We also suggest to Grandfather existing people who are on the list. People who have been on the list for years and told they have two years to wait will be devastated to learn that they will be pushed back.

6. Patients Can List At A GFR Of 20 For Preemptive Transplant

Many people do not go on dialysis until their GFR is under 15. Many CKD patients have remained at a GFR between 15 and 20 for some time. The policy is confusing as to why have a patient list if it is meaningless until they go on dialysis.

7. Impact And Implementation Plan For Transplant Centers And Patients

Has it been discussed how this new system will be implemented so as not to create a chaotic environment? Will there be materials and educational seminars to inform the transplant facilities, healthcare professionals and patients? Have the resources to educate patients and health care professionals been considered?

Renal Support Network

We find that the Kidney Allocation Score, which looks like this $KAS = LYFT \times 0.8 \times (1 - DPI) + DT \times (0.8 \times DPI + 0.2) + (CPRA \times 4/100)$ for many patients will be a difficult and overly complicated calculation that makes the understanding of how the transplant waiting list works even more difficult than it already is. Simplifying this and developing and providing good, clear educational materials for health care professionals and patients alike, especially patients already burdened with understanding the complicated nature of their disease and its frequent co-morbidities, will be needed so all can readily comprehend the rationale behind this new system.

We understand that current policy variations have created a patchwork of protocols that render a national system serving 78,000 recipients less meaningful, and that organs are not necessarily given to those who will benefit the most.

We acknowledge that ultimately a comprehensive philosophical shift is necessary, so perhaps we could model the US organ donation system after one of those in European countries, where “opt-out” and presumed consent is the rule. But until that shift can be realized, the current allocation system needs to be effectively and sensitively modified to best serve those on that waiting list. Also, we know you are well aware of the kidneys that are lost due to the inability to afford medications. There needs to be continued access to immunosuppressive drugs which are critical to the viability of the transplanted organ.

Thousands of lives will be affected. So we ask that OPTN/UNOS allow ongoing conversation and input prior to a decision, that a final process be more simplified and readily comprehensible than that which is currently proposed and that a pilot program be considered. This will help understand the impact and allow for changes if the new system needs adjusting.

We appreciate the time and effort that the OPTN/UNOS Kidney Transplantation Committee has put into examining the best way to re-evaluate the allocation process, as well as the opportunity we have to impact that process with our comments. With the best interests of the patient in mind, and considering the fact that there are not enough kidneys for the number of candidates waiting on the list, we recognize that it is extremely difficult to determine the wisest allocation policy and thank you for the opportunity to comment.