

Progress Toward a New Kidney Allocation System

**Excerpted from the Presentation by
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Kidney Transplantation Committee at the
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Important Caveats

- This is not a final proposal
- Even after a final proposal is implemented, there will be ongoing changes

Outline

- Why are is the OPTN/UNOS Kidney Transplantation Committee reviewing kidney allocation?
- What has been the process?
- What are likely changes?
- When will changes be implemented?

Why are we reviewing kidney allocation?

- Required by Final Rule
- 2004 UNOS Board charges Kidney Committee to conduct comprehensive review of allocation
- 2005 UNOS Board charges Kidney Committee to consider net survival benefit

OPTN Final Rule

Policy development should:

- “seek to achieve the best use of donated organs”
- Be “designed to avoid wasting organs”
- Set “priority rankings through objective and measurable medical criteria”
- De-emphasize the use of waiting time in rank ordering candidates

HRSA Program Goals for the OPTN

- **By 2013, ... Increase the average number of life-years gained in the first 5 years after transplantation for deceased kidney/kidney-pancreas transplants by 0.003 life-years until the goal of 0.436 life-years gained per transplant is achieved in 2013.**

***<http://www.hrsa.gov/about/budgetjustification07/HealthCareSystemsPerformanceAnalysis.htm>**

What has been the process?

1. KARS Process

(comprehensive review, define general direction)



2. Benefit

(create the model, simulate the impact of benefit)



3. Develop the Proposal

(modifying benefit, eliciting feedback)

Started

4. Finalizing the Proposal

Fall 2007

Deceased Donor Kidney Waiting List

- 68,902 candidates for kidneys
 - 66,402 solitary kidney
 - 2500 simultaneous pancreas-kidney
- 2005 Kidney Transplants
 - 17,379 total
 - 10,816 deceased donors
 - 9914 solitary kidneys
 - 902 SPK
 - 6663 living donor (doubled over 15 years)

OPTN

New Allocation Systems

- Liver → MELD/PELD
- Heart
- Lung
- For liver, heart and lung, there is no other life-saving therapy except transplant
- All primarily focused on preventing death on the waiting list and maximizing early post-transplant survival (1 month to 1 year)

End-Stage Renal Disease

- Dialysis = 300,000 people
- Living donor kidney transplant = 6600/yr
- Deceased donor kidney transplant = 10,000/yr
- Mortality not directly related to lack of an organ
- Mortality related to co-morbidities and dialysis-related deterioration
- Candidates with highest wait-list mortality generally have poorest long-term survival

What is the goal of a kidney transplant?

- Freedom from dialysis
- Better quality of life
- Prolongs life compared to dialysis
- To maximize survival

Standard Criteria Donor (SCD) Kidneys

- Objective:

Maximize the total life-years
for wait-listed candidates

- Survival Benefit:

Candidate survival with SCD transplant
minus

Candidate survival without a kidney transplant
on the waiting list

Developing the Survival Benefit Model

- Time 1/1/92-12/31/04
- 110,777 adult Kidney and SPK candidates
- 96,275 transplants
- Extrapolated survival — Post Transplant and Wait List

Survival Benefit: Candidate Variables in Equation

- Age
- Time on dialysis
- Albumin
- BMI
- Diagnosis:
 - HTN
 - Polycystic
 - Diabetic
 - Other
- Previous Transplant
- Peak PRA*

Candidate Variables Excluded:

(gameable, poor data, or not a major factor)

- Ethnicity/Race
- Angina
- Peripheral Vascular Disease
- Calendar Year of Listing
- Gender
- NYHA Functional Class
- Primary Insurance Status
- Drug Treated Hypertension
- Type of Dialysis
- DSA (Surrogate for Geography)

Other Included Variables

■ Donor Variables:

- Weight
- Cause of death
- Age
- DCD
- CMV status
- Hypertension

■ Other Variables:

- HLA Mismatch
- Shared vs. Local organ
- Year of offer

Goal: To transplant the patient who will derive the greatest benefit from receiving an SCD kidney

Survival Benefit is two-fold

- Limits the wait-list associated mortality (such as that experienced by young diabetics)
- Realizes the maximum survival of the SCD kidney (that is possible in relatively healthy young-to-middle age candidates)

HLA Matching

Incorporated into Benefit Score

- No absolute priority for 0-ABDR matching
- No separate points for DR matching
- No paybacks
- Allow HLA to have its appropriate impact on candidate survival benefit

Increasing Waiting Time* by blood type

	<u>1999-2000</u>	<u>2001-2002</u>
AB	484	732
A	1084	1141
O	1767	1840 (5.04 yrs)
B	1981	>2000 (estimated)

*Median #days to 50% of wait-listed patients transplanted
OPTN

A₂/A₂B Component

- Goals:
 - Minimize waiting time disparities between blood groups
 - Improve access for Blood Type B candidates (often minorities)
- Proposal would be very similar to current Committee sponsored alternative system

Sensitized Patients

- Old methods outdated
 - Now can identify “unacceptable” antigens in sensitized patients
 - Larger geographic sharing for high benefit sensitized candidates
 - Place highest combine score on national list: QENSLB+Sensitized
 - Allocate if “virtual crossmatch” negative
- Ex. Bray AJT 2006; 6: 2307-2315.**

Simultaneous Pancreas Kidney (SPK) Transplant Candidates

- Most SPK Candidates have high benefit scores
- Simulated direct competition with other kidney candidates

Phase II

Simulations → Stepwise Changes

- Current system
- No paybacks
- No mandatory sharing for 0-ABDR
- Points by benefit alone (remove points for DR matching, waiting time)
- $A_2/A_2B \rightarrow B$
- National sharing for highly sensitized candidates

Phase III

Modifying Benefit

- **Candidates do not move up the list over time**
- **Simulations currently only span 1 year, will the list change over time?**
- **Benefit does not clearly address differences in wait-list mortality**
- **Impact on living donation**

Waiting Time/Time on Dialysis adjustment

- Allows patients to move up the list
- The impact of this modifier can be simulated using different weights for time on dialysis

SCD Kidneys

Proposed Modifiers to Benefit

- Prior living donors
- Sensitization
- A_2/A_2B
- Time on dialysis
- Medical urgency

Overall

- **Prior living donor**
- **Pediatric priority for donors <35**
- **SCD kidneys using benefit modified by time, sensitization and urgency**
- **SPK and Kidney alone intermixed**
- **ECD kidneys by waiting time**

The Proposed Timeline

2007

- **Public Forum, Feb 8th Dallas**
- **Kidney Committee Approval**
- **Public Comment x2**
- **Regional Meetings in the Fall**
- **Second Public Forum**