Kidney Allocation Policy Proposal

November 7, 2012 2:00 p.m. – 3:15 p.m. (EDT)

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Objectives

- State the importance of making the most of every donated kidney while maintaining access for all groups of candidates
- Describe the use of the Kidney Donor Profile Index (KDPI) and the Estimated Post-Transplant Survival Formula (EPTS)
- Identify ways to help increase access for type B transplant candidates, many of whom are minorities, through blood type subgroup matching

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Objectives

- Describe how highly sensitized candidates will be given more equitable access based on a sliding scale and increased priority for those that are hardest to match
- Relate waiting time priority to a defined stage of kidney function
- Explain the rationale for eliminating the payback system
- State the need for a single national kidney allocation system that is modifiable over time



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John J. Friedewald, M.D.
Chair, OPTN/UNOS Kidney Transplantation
Committee
Associate Professor of Medicine and Surgery
Northwestern University Feinberg School of
Medicine



Bertram L. Kasiske, MD
Project Director, Scientific Registry of Transplant
Recipients
Professor of Medicine, University of Minnesota
Medical School
Transplant Nephrologist University of Minnesota

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Medical Center/ Hennepin County Medical Center

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OVERVIEW OF THE PROPOSAL

John J. Friedewald, MD Chair, OPTN/UNOS Kidney Transplantation Committee

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Proposal Summary

- Existing kidney allocation system needs to be improved
- Proposed improvements expected to:
- enhance the long-term benefit of kidney transplantation,
- make better use of available kidneys,
- increase transplant opportunities for hard-tomatch candidates.



Pro	posal	I Sum	mary
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- Candidates should see benefits of better long-term kidney function or a possible reduction in waiting time for a transplant.
- Proposed system would continue to provide transplants for people of all ages.

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Current Allocation System Limitations

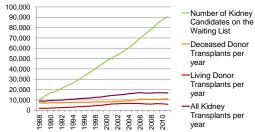
- High discard rates of kidneys that could help individuals on dialysis
- Mismatch in patient/graft survival
- Access variability due to geography and biology

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The Growing Waiting List

Kidney Waiting List and Transplants



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OPTN data as of September 1, 2012



Goals of Proposed Changes

- Improve the length of time kidney recipients may have a functioning transplant
- Make better use of available kidneys through improved and fair distribution
- Improve the chance of receiving a transplant for people who are hard to match with most donors

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Overview of Proposed Changes

- Revised kidney classifications
- Inclusion of longevity matching for some candidates
- Modifications to blood type subgroup matching
- Revisions to immune sensitivity matching
- Revisions to waiting time definition
- Elimination of kidney paybacks and variances

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The Course of Policy Development

Date	Sentinel Event
2003	Board requests review of kidney allocation system; public hearings held
2004	Board directs investigation of benefit use in a kidney allocation system
2007	Public Forum held in Dallas; main topic LYFT
2008	RFI released: main topics KDPI/LYFT
2009	Public Forum held in St. Louis; main topics LYFT/KDPI
2009	Donor/recipient age matching reviewed as possibility
2011	Concept document released: main topics EPTS/age matching/ KDPI
2011	Age matching no longer under consideration
2012	Public comment proposal

Determining a Balance: Equity and Utility								
Equity a	na oti	illey						
Life Years	Gained							
				Tx in Old	er Pts			
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Evolutio	n of B	rono	eal					
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	National Sharing		Age Matching+ Longevity	Age	Longevity			
Gain in life years	+LYFT 34,026	25,794	Matching 15,223	Matching 14,044	Matching 8,380			
Proportion of kidneys transplanted into								
recipients >50 years old	10	29	46	45	52			
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Revised	Kidne	ey Cla	assific	ation	S			
Current kidney donor classification: Standard criteria donor (SCD)								
 Expande 								
Kidney D	Proposed system includes the Kidney Donor Profile Index (KDPI)							
 Continuo function 	ous mea	asure o	of expec	ted kidr	ney			

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		Estimated Graft Survival Rates by KDPI
KDPI Variables -Donor age +Height -Weight -Ethnicity -History of Hypertension -History of Diabetes -Cause of Death -Serum Creatinine -HCV Status -DCD Status	Graft Survival Rate	95% 93.5% 93.1% 92.4% 92.6% 90.7% 93.2% 82.5% 82.5% 82.5% 92.5% 82
OPTN	H	KDPI values now displayed with all organ offers in DonorNet®

Inclusion of Longevity Matching

- Current system does not include measure of potential longevity with transplant
- Longevity matching for some candidates could reduce the need for repeat transplants

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Inclusion of Longevity Matching

- Four medical factors used to calculate Estimated Post Transplant Survival (EPTS)
- Age
- History of diabetes
- Length of time on dialysis
- History of a prior transplant



Modifications to Blood Type Subgroup Matching

- Blood type B candidates face biological challenges
- Many of these candidates are ethnic minorities
- Allow access for blood type B candidates to additional kidneys from donors with specific subtypes of blood type A

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Changes to Immune Sensitivity Matching

- Sensitized candidates wait substantially longer due to biological challenges
- Some candidates are so sensitized, they require access to a larger pool of kidneys to find a match
- Proposed system priority

CPRA=100%	National
CPRA=99%	Regional
CPRA=98%	Local

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Proposed Point Changes: Sensitization

 Current policy: 4 points for CPRA>=80% No points for moderately sensitized candidates.

 Proposed policy: sliding scale starting at CPRA>=20%

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D	ovica	d W	aiting	Time	Dofin	ition
К	evise	a vv	aiting	Hime	Denn	ition

- Current policy: waiting time points for adults at registration with:
- GFR<=20 ml/min
- On Dialysis
- Proposed policy: waiting time points for dialysis time prior to registration
- Pediatric and adult candidates
- Better recognizes time spent with ESRD as the basis for priority
- Pre-emptive listing still advantageous for 0-ABDR mismatch offers

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Elimination of Kidney Paybacks and Variances

- Current payback policy evaluated and found to be
- · Administratively challenging
- Ineffective in improving outcomes of recipients
- Kidney paybacks would no longer be permitted
- Proposal also recommends eliminating a number of local allocation variances

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Evaluating Potential Policy Changes

- Scientific Registry of Transplant Recipients (SRTR) simulates proposed policy changes
- Kidney-Pancreas Simulated Allocation Model (KPSAM)
- 50+ KPSAM runs conducted throughout policy development



Summary of Findings

- New system forecasted to result in:
- 8,380 additional life years gained annually
- Improved access for moderately and very highly sensitized candidates
- Improved access for ethnic minority candidates
- Comparable levels of kidney transplants at regional/national levels

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Simulation Modeling Results Key

WL

Actual proportion of candidates on waitlist

2010

Actual proportion of transplants in 2010



Simulated proportion of transplants in 2010

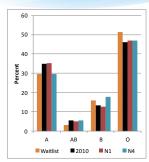
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Simulated proportion of transplants with proposed rules

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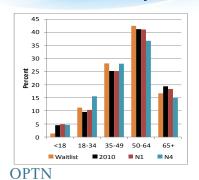
KPSAM Results by Blood Type



The simulation results show an increase in the number of transplants for candidates with blood type B, many of whom are minorities.



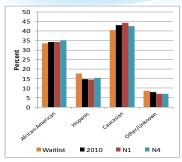
KPSAM Results by Candidate Age



Broad access for candidates of all ages

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KPSAM Results by Ethnicity

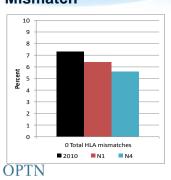


Better alignment of transplants with the distribution of candidates on the waiting list

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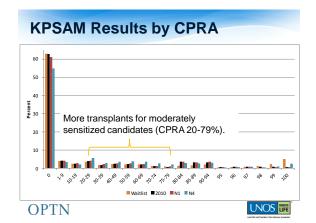
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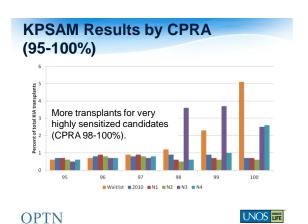
KPSAM Results by 0-ABDR Mismatch

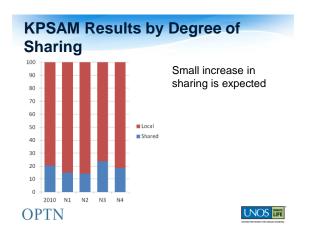


Somewhat fewer zero ABDR mismatched transplants expected

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Summary

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Participate in Policy Development

Submit comments online:

optn.transplant.hrsa.gov

 Access webinar schedules

 Download educational materials

