Kidney Allocation Policy Proposal

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

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

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
Today’s Speaker and Panelist

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

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Project Director, Scientific Registry of Transplant Recipients
Professor of Medicine, University of Minnesota Medical School
Transplant Nephrologist University of Minnesota Medical Center/
Hennepin County Medical Center

OVERVIEW OF THE PROPOSAL

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

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-to-match candidates.
Proposal Summary

- 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.

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

The Growing Waiting List

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Kidney Candidates on the Waiting List</th>
<th>Deceased Donor Transplants per year</th>
<th>Living Donor Transplants per year</th>
<th>All Kidney Transplants per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1988</td>
<td>10,000</td>
<td>0</td>
<td>0</td>
<td>10,000</td>
</tr>
<tr>
<td>1990</td>
<td>20,000</td>
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<tr>
<td>1992</td>
<td>30,000</td>
<td>0</td>
<td>0</td>
<td>30,000</td>
</tr>
<tr>
<td>1994</td>
<td>40,000</td>
<td>0</td>
<td>0</td>
<td>40,000</td>
</tr>
<tr>
<td>1996</td>
<td>50,000</td>
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<td>1998</td>
<td>60,000</td>
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</tr>
<tr>
<td>2000</td>
<td>70,000</td>
<td>0</td>
<td>0</td>
<td>70,000</td>
</tr>
<tr>
<td>2002</td>
<td>80,000</td>
<td>0</td>
<td>0</td>
<td>80,000</td>
</tr>
<tr>
<td>2004</td>
<td>90,000</td>
<td>0</td>
<td>0</td>
<td>90,000</td>
</tr>
<tr>
<td>2006</td>
<td>100,000</td>
<td>0</td>
<td>0</td>
<td>100,000</td>
</tr>
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</table>

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

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

Evolution of Proposal

<table>
<thead>
<tr>
<th>Gain in life years</th>
<th>National Sharing +LYFT</th>
<th>LYFT</th>
<th>Age Matching + Longevity Matching</th>
<th>Age Matching</th>
<th>Longevity Matching</th>
</tr>
</thead>
<tbody>
<tr>
<td>34,026</td>
<td>25,794</td>
<td>15,223</td>
<td>14,044</td>
<td>8,380</td>
<td></td>
</tr>
</tbody>
</table>

Proportion of kidneys transplanted into recipients >50 years old

Revised Kidney Classifications

- **Current** kidney donor classification:
  - Standard criteria donor (SCD)
  - Expanded criteria donor (ECD)

- **Proposed** system includes the Kidney Donor Profile Index (KDPI)
  - Continuous measure of expected kidney function
Kidney Donor Profile Index (KDPI)

KDPI Variables
- Donor age
- Height
- Weight
- Ethnicity
- History of Hypertension
- History of Diabetes
- Cause of Death
- Serum Creatinine
- HCV Status
- DCD Status

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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

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**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

<table>
<thead>
<tr>
<th>CPRA (%)</th>
<th>National</th>
<th>Regional</th>
<th>Local</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>99%</td>
<td></td>
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<td></td>
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<tr>
<td>98%</td>
<td></td>
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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%

![Proposed CPRA Sliding Scale (Allocation Points)](chart)
Revised Waiting Time Definition

- **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

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

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

Simulation Modeling Results Key

<table>
<thead>
<tr>
<th>WL</th>
<th>Actual proportion of candidates on waitlist</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>Actual proportion of transplants in 2010</td>
</tr>
<tr>
<td>N1</td>
<td>Simulated proportion of transplants in 2010</td>
</tr>
<tr>
<td>N4</td>
<td>Simulated proportion of transplants with proposed rules</td>
</tr>
</tbody>
</table>

KPSAM Results by Blood Type

<table>
<thead>
<tr>
<th>Blood Type</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
</tr>
<tr>
<td>AB</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td></td>
</tr>
<tr>
<td>O</td>
<td></td>
</tr>
</tbody>
</table>

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

KPSAM Results by Ethnicity

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

KPSAM Results by 0-ABDR Mismatch

Somewhat fewer zero ABDR mismatched transplants expected
More transplants for moderately sensitized candidates (CPRA 20-79%).

More transplants for very highly sensitized candidates (CPRA 98-100%).

Small increase in sharing is expected.
Summary

- 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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Participate in Policy Development

- Submit comments online:
  optn.transplant.hrsa.gov
- Access webinar schedules
- Download educational materials

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Public comment period ends December 14