Kidney Transplantation Committee Update

John J. Friedewald, MD, Committee Chair

OPTN/UNOS Board of Directors
November 13, 2012
Saint Louis, Missouri
Review of Major Proposal Concepts

- Inclusion of Kidney Donor Profile Index (KDPI)
- Longevity matching
- New classifications for very highly sensitized candidates
- Sliding point scale for sensitized candidates
- Local/Regional sharing for high KDPI kidneys
- A₂/A₂B kidneys allocated to B candidates
- Elimination of kidney paybacks
- Elimination of variances
- Inclusion of prior dialysis time in waiting time calculation
Overview of Expected Outcomes

- 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
Kidney Allocation Proposal

- Released on September 21, 2012
- Extensive communications plan activated prior to release
- Favorable coverage in national media
- Coordinated effort to reach Regions and Committees
- Outreach to members and public
- Expected Board review in June 2013
Individual Feedback Received

- Each comment will receive a response
- Concerns appear to be localized, general themes not apparent at this time

*Information as of 11/5/2012
Committee Reviews

**Completed**
- Living Donor
- Transplant Coordinators
- Ethics
- OPO
- Pancreas
- Transplant Administrators
- Patient Affairs

**Scheduled**
- Minority Affairs
- Histocompatibility
- Pediatric
Media Coverage To Date

- NBCNews.com
- U.S. News & World Report
- Denver Post
- The New York Times
- NPR
- Chicago Tribune
- Detroit Free Press

OPTN
“We understand why some people are nervous about these changes. In a fairer world, there would be enough kidneys to go around. But there aren't. This is about maximizing the years that a kidney will work inside someone's body, not rendering a judgment about how any recipient uses that time. Officials have spent the last nine years seeking to make the system more efficient. Let's not wait another nine. The board that oversees transplants in the U.S. can — and should — make these changes next summer. Thousands of people are on kidney transplant waiting lists. Every day, every week, that officials delay, people die waiting.”

Chicago Tribune Editorial. 2 October 2012
“A previous proposal to increase survival rates was abandoned after federal officials warned that it violated age discrimination laws because most of the kidneys were to be distributed based on age, to patients no more than 15 years older or younger than the donor. The new proposal avoids that problem by making age only one of many factors considered. If this proposal, too, doesn’t pass muster, Congress ought to pass a law exempting this sensible approach from age discrimination laws.”
Member and Public Outreach

- Educational webinar held November 7
  - 400+ dedicated ports

- Additional presentations to:
  - Dialysis Patient Citizens
  - Polycystic Kidney Disease Foundation

- Continuing to schedule presentations for interested organizations
Balancing Equity and Utility

TWO TAKES

Is the New Kidney Allocation Proposal Fair?

An organization that manages organ donation in the United States has proposed changes to how donated kidneys are allocated. Proponents say the proposal to match donors to patients based on certain attributes will make the system more efficient. Opponents say it’s unfair. Edited by Kira Zalan

YES

For most of human history, kidney failure was a death sentence for those who encountered it. Today, dialysis is effective in supporting people with kidney failure, but it too comes with limitations and potential complications. Kidney transplantation offers many of the most effective long-term improvements in length and quality of life.

The way kidneys from deceased donors are matched to patients in the United States has not changed fundamentally in the last 35 years. The existing policy has facilitated more than 200,000 transplants over the years and has many well-designed features. Yet there are specific opportunities for improvement.

The Organ Procurement and Transplantation Network (OPTN), managed under federal contract by the nonprofit United Network for Organ Sharing (UNOS), matches deceased donor kidneys with transplant candidates nationwide. The OPTN is seeking public comments on a proposal to make several improvements to kidney allocation policy.

The proposal is the result of eight years of study and discussion among transplant professionals and patient advocates. Under the proposal, the 50 percent of kidneys likely to have the longest function would be offered first, but are exclusively to the top 10 percent of candidates.

NO

Three facts about end-stage renal disease (ESRD) shape the kidney allocation debate. First, individuals with ESRD have two therapeutic options: dialysis or kidney transplantation. Second, virtually all individuals with ESRD, regardless of age, have a better quality of life and lower mortality and morbidity with kidney transplantation. Third, demand for kidney transplantation far exceeds supply.

The current allocation system is based mainly on survival on the kidney waiting list. Critics object to the indefensibility of the current system because a candidate who had a short life expectancy may be favored at the expense of the patient who has a longer predicted survival. The Kidney Committee has proposed a 20/80 allocation method. The "20" means that the top 20 percent of kidneys (based on 10 donor traits that estimate expected graft survival) that are to be allocated to the top 50 percent of candidates (defined by recipient traits: age, diabetes, diabetes time, and prior transplant status--that help determine post-transplant survival). The remaining 80 percent of kidneys will be allocated mainly on dialysis time, a variant of waiting time.

While the 20/80 proposal will improve efficiency, it is unfair for these obvious reasons. First, it is UNFAIR.
Addressing Comments Received:

Balancing Equity and Utility

- Life Years Gained
- Tx in Older Pts
## Balancing Equity and Utility: Evolution of Proposal

<table>
<thead>
<tr>
<th></th>
<th>National Sharing +LYFT</th>
<th>LYFT</th>
<th>Age Matching+ Longevity Matching</th>
<th>Age Matching</th>
<th>Longevity Matching</th>
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<tbody>
<tr>
<td>Gain in life years over the current allocation system</td>
<td>34,026</td>
<td>25,794</td>
<td>15,223</td>
<td>14,044</td>
<td>8,380</td>
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<tr>
<td>Proportion of kidneys transplanted into recipients &gt;50 years old</td>
<td>10</td>
<td>29</td>
<td>46</td>
<td>45</td>
<td>52</td>
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</table>

OPTN

[UNOS Donate Life Logo]
Path Forward

- Public Comment period closes December 14, 2012
- Committee will review and respond to feedback in January and March 2013
- Earliest Board consideration in June 2013
OPTN/UNOS Kidney Paired Donation Pilot Program
Centers participating in OPTN KPDPP

- 127 Transplant centers (55% of 230 living donor kidney programs)
- All 11 Regions
## Data

### Increase in donors and candidates per match run

<table>
<thead>
<tr>
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<th>October 2010</th>
<th>October 2012</th>
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<tbody>
<tr>
<td>Donors</td>
<td>45</td>
<td>202</td>
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<tr>
<td>Candidates</td>
<td>43</td>
<td>182</td>
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</table>

### ABO/CPRA (As of May 2012)

- 66% candidates ABO – O
- 61% candidate CPRA ≥ 80%
- 35% both
## Matches October – November 2012

<table>
<thead>
<tr>
<th>Match #</th>
<th>35</th>
<th>36</th>
<th>37</th>
<th>38</th>
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<tr>
<td>Donors</td>
<td>202</td>
<td>199</td>
<td>197</td>
<td>194</td>
<td>181</td>
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<td>182</td>
<td>177</td>
<td>181</td>
<td>179</td>
<td>178</td>
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<tr>
<td>&gt;= 80% CPRA</td>
<td>63%</td>
<td>64%</td>
<td>64%</td>
<td>64%</td>
<td>63%</td>
<td>63%</td>
</tr>
<tr>
<td>Centers</td>
<td>56</td>
<td>55</td>
<td>54</td>
<td>54</td>
<td>54</td>
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<tr>
<td>Exchanges/Matches</td>
<td>4/10</td>
<td>1/2</td>
<td>1/2</td>
<td>7/21</td>
<td>6/16</td>
<td>9/27</td>
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<tr>
<td>&gt;=80% matched</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>8</td>
<td>6</td>
<td>12</td>
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<tr>
<td>NDD entered/matched</td>
<td>6/3</td>
<td>3/0</td>
<td>2/1</td>
<td>2/0</td>
<td>2/0</td>
<td>3/2</td>
</tr>
<tr>
<td>Matches pending</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>8</td>
<td>27</td>
</tr>
</tbody>
</table>
Total and Pending Transplants to Date

- Total 27 transplants to date
- Data as of Nov 11, 2012
- 27 additional matches offered Nov 12, 2012

OPTN

UNOS DONATE LIFE
65.7% of KPD candidates were blood group O, 61.3% of candidate had a CPRA≥80% and 34.9% were both O and PRA=80+

OPTN (Includes Match Runs from Oct 27, 2010 – May 2, 2012)
Results by Exchange Type

Matches and Transplants by Exchange Type

241 matches offered; 222 declined; 19 transplants, 2 pending

Offer: Decline rate consistent with other KPD programs

Includes Match Runs from Oct 27, 2010 – May 2, 2012
Match Offer Refusal Reasons

- Data are incomplete: 20% of matches have unreported refusal reason
- 40% might have accepted the match, but could not because other matches in the exchange fell through

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- Of the remaining (40%) of refused matches:
  - 33% refused due to positive crossmatch or unacceptable antigens
  - 7% due to “candidate involved in a pending exchange”
  - 60% due to a variety of other reasons, including
    - Donor unacceptable due to age, weight, med. history
    - Donor refused candidate
    - Candidate ill or could not be contacted
    - Candidate already received a transplant
Early Post-Transplant Outcomes

- Shipped kidneys (16 of the 19)
  - Most (69%) had cold ischemic times between 7 and 11 hours; one was 12.8 hours
  - None experienced delayed graft function

- Same center transplants (3 of the 19)
  - Cold times were 90 minutes or less (1 not reported)
  - None experienced delayed graft function (1 not reported)
What’s new?

- May 2011 began entering NDD’s – closed chains
- Centers now join individually – instead of through a coordinating centers
- Match runs frequency increased 1x/week versus 1x/month
- Donor pre-select tool developed
- Policy proposals – KPD policy and Bridge donors
- Transplant Pro – Everything KPD in one place
Committee Leadership and Support

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