Upcoming Change to Kidney Allocation Policy

In June 2013, the OPTN/UNOS Board of Directors approved a proposal to completely overhaul the national kidney allocation system. At that time, implementation of the new system was anticipated to occur by the end of 2014. The new system was designed to maintain access to kidney transplantation for all groups of candidates while seeking to improve outcomes for kidney transplant recipients, increase the years recipients may have a functioning transplant and increase utilization of available kidneys. The new system includes factors not used in the current policy. Their use is expected to enhance survival benefit and use of available kidneys. The new system will include a clinical formula to estimate the number of years each specific candidate on the waiting list would be likely to benefit from a kidney transplant. This score is referred to as Estimated Post-transplant Survival (EPTS).

The new system will also include new definitions for classifying donors. Existing policy definitions of "standard criteria" and "extended criteria" donors will be replaced with the Kidney Donor Profile Index (KDPI), a clinical formula that classifies donor kidneys based upon how long they are likely to function once transplanted.

Under the new policy, when a kidney donor is entered into the matching system, that individual donor's KDPI score will be considered along with the individual EPTS for compatible candidates. New categories will be incorporated into the allocation system for the 20% of candidates who are expected to have the longest potential survival. Candidates in these categories will receive priority for kidneys from the 20% of donors with the longest expected graft survival. This approach is expected to increase overall "life-years" (time that recipients retain kidney function after the transplant). It may also reduce recipients' future need for repeat transplants, thus allowing more transplants among candidates awaiting their first opportunity. The definition of waiting time will be expanded to include time a patient spent on dialysis prior to becoming a kidney transplant candidate.

Also under the new policy, kidney offers from donors estimated to have the shortest potential length of function based on KDPI score will be offered on a wider geographic basis. Transplant programs may be most likely to consider these offers for candidates who would have a better life expectancy with a timely transplant than they would remaining on dialysis. This approach is expected to increase utilization of donated kidneys currently available for transplant. It may also help minimize differences in local transplant waiting times across different regions of the country.

In the new system, points for sensitization will be scaled so that candidates with moderate levels of sensitization (CPRA > 20%) will receive points on a sliding scale. Additionally, as very highly sensitized candidates (CPRA >=98%) experience enormous barriers to finding a compatible donor, additional allocation categories were included in the new system to prioritize these candidates in wider distribution areas. Candidates with CPRA =100% will receive priority at the national level while those with CPRA = 99% will receive priority at the regional level. Candidates with CPRA =98% will receive priority at the local level. To address the matching difficulties that candidates with blood type B often face, the new system also includes a provision to allow kidney offers from donors with certain subtypes of blood type A.

The powerpoint slides below give a summary of the new allocation policy and additional information can be found at http://transplantpro.org/kidneypancreas/.
Changes in OPTN Kidney Transplant Allocation 2014

Kenneth Andreoni, MD, FACS
UNOS President
Associate Professor of Surgery
University of Florida
Gainesville, FL

Ciara J. Samana, MSPH
United Network for Organ Sharing
Richmond, VA
Proposed Policy Objectives

- Make the most of every donated kidney without diminishing access
- Promote graft survival for those at highest risk of retransplant
- Minimize loss of potential graft function through better longevity matching
- Improve efficiency and utilization by providing better information about kidney offers
## 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>
</tr>
<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>
</tr>
<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>
June 2013: OPTN Board of Directors approved revisions to the kidney allocation system

Two phased implementation

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Data updates required</td>
<td>• New allocation rules applied</td>
</tr>
<tr>
<td>• New reports released</td>
<td>• Variances turned off</td>
</tr>
<tr>
<td>• Calculators made available</td>
<td>• Payback system turned off</td>
</tr>
</tbody>
</table>

Anticipated mid 2014  Anticipated end 2014
UNOS Education and Communication Efforts

- Podcasts (begins in January 2014)
- Webinars (February-December 2014)
- E-learning modules (beginning in February 2014)
- System training (April-December 2014)
- In-person presentations (TMF, WTC, NATCO, etc.)
UNOS will release in April 2014

Will include:

- Fact sheet
- Template patient letters
- Patient brochures
- Information to dialysis patients re: early referral
- EPTS e-Learning Module
### ECD vs KDPI

**ECD**
- **Donor Age**
  - >60 alone
- **Donor Age**
  - >50 with two below:
    - Cr >1.5
    - HTN
    - CVA
- RR of graft failure >1.7 compared to the ‘ideal’ donor age 35 (16 – 17%)

**KDPI (donor variables)**
- Donor age
- Race/ethnicity
- Hypertension
- Diabetes
- Serum creatinine
- COD CVA
- Height
- Weight
- DCD
- HCV
Donor Age v. KDPI

2005-2007 Kidneys Removed for Transplant

KDPI overlaps substantially for donors from most age categories.
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

KDPI values now displayed with all organ offers in DonorNet®
Replace SCD/ECD with KDPI

- Consent requirement limited to kidneys with KDPI scores >85% - the new ECD
Overview of proposed policy

Current

Kidney becomes available

- SCD
- ECD
- DCD & ECD
- DCD & SCD

Proposed

Kidney becomes available

- KDPI \leq 20\%
- KDPI > 20\% \text{ but } \leq 35\%
- KDPI > 35\% \text{ but } < 85\%
- KDPI \geq 85\%

All allocation sequences to be based on KDPI
Sequences based on KDPI

Kidney becomes available

- KDPI <= 20%
  - Sequence A

- KDPI > 20% but < 35%
  - Sequence B

- KDPI >= 35% but <= 85%
  - Sequence C

- KDPI > 85%
  - Sequence D
<table>
<thead>
<tr>
<th>Sequence A</th>
<th>Sequence B</th>
<th>Sequence C</th>
<th>Sequence D</th>
</tr>
</thead>
<tbody>
<tr>
<td>KDPI (\leq 20%)</td>
<td>KDPI &gt;20% but &lt;35%</td>
<td>KDPI (\geq 35%) but (\leq 85%)</td>
<td>KDPI &gt;85%</td>
</tr>
<tr>
<td>Highly Sensitized 0-ABDRmm (top 20% EPTS)</td>
<td>Highly Sensitized 0-ABDRmm Prior living donor Local pediatrics Local top 20% EPTS 0-ABDRmm (all) Local (all) Regional pediatrics Regional (top 20%) Regional (all) National pediatrics National (top 20%) National (all)</td>
<td>Highly Sensitized 0-ABDRmm Prior living donor Local pediatrics Local adults Regional pediatrics Regional adults National pediatrics National adults</td>
<td>Highly Sensitized 0-ABDRmm Local + Regional National *all categories in Sequence D are limited to adult candidates</td>
</tr>
</tbody>
</table>

OPTN
Proposed Classification: *Longevity Matching*

- Estimated Post-Transplant Survival (EPTS)
  - Candidate age, time on dialysis, prior organ transplant, diabetes status
  - More predictive than age alone, uses only 4 variables to limit confusion

- Top 20% of candidates by EPTS to receive kidneys matched on longevity (KDPI<20%)
  - Candidates can have an EPTS score in the top 20% even at age 50

- Applies only to kidneys with KDPI scores <=20% not allocated for multi-organ, very highly sensitized, or pediatric candidates
### Relationship of EPTS and Age

#### EPTS “Vignettes”: Top 20%

<table>
<thead>
<tr>
<th>Age</th>
<th>Yrs on RRT</th>
<th>DM</th>
<th>Prior Txp</th>
<th>EPTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>0</td>
<td>No</td>
<td>No</td>
<td>1%</td>
</tr>
<tr>
<td>25</td>
<td>0</td>
<td>No</td>
<td>No</td>
<td>1%</td>
</tr>
<tr>
<td>18</td>
<td>2</td>
<td>No</td>
<td>No</td>
<td>2%</td>
</tr>
<tr>
<td>25</td>
<td>5</td>
<td>No</td>
<td>No</td>
<td>5%</td>
</tr>
<tr>
<td>25</td>
<td>2</td>
<td>No</td>
<td>Yes</td>
<td>7%</td>
</tr>
<tr>
<td>40</td>
<td>0</td>
<td>No</td>
<td>No</td>
<td>8%</td>
</tr>
<tr>
<td>18</td>
<td>0</td>
<td>Yes</td>
<td>No</td>
<td>12%</td>
</tr>
<tr>
<td>25</td>
<td>0</td>
<td>Yes</td>
<td>No</td>
<td>12%</td>
</tr>
<tr>
<td>40</td>
<td>5</td>
<td>No</td>
<td>No</td>
<td>17%</td>
</tr>
<tr>
<td>50</td>
<td>0</td>
<td>No</td>
<td>No</td>
<td>18%</td>
</tr>
</tbody>
</table>

#### EPTS Distribution by Candidate Age

<table>
<thead>
<tr>
<th>Age at Snapshot</th>
<th>N on WL (adults)</th>
<th>% on WL</th>
<th>% in EPTS Top 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-25</td>
<td>2,742</td>
<td>2.8</td>
<td>96.7%</td>
</tr>
<tr>
<td>26-35</td>
<td>8,256</td>
<td>8.4</td>
<td>80.6%</td>
</tr>
<tr>
<td>36-45</td>
<td>16,136</td>
<td>16.3</td>
<td>43.8%</td>
</tr>
<tr>
<td>46-55</td>
<td>25,094</td>
<td>25.4</td>
<td>10.1%</td>
</tr>
<tr>
<td>56-65</td>
<td>29,469</td>
<td>29.8</td>
<td>0.0%</td>
</tr>
<tr>
<td>66-75</td>
<td>14,762</td>
<td>14.9</td>
<td>0.0%</td>
</tr>
<tr>
<td>76+</td>
<td>1,516</td>
<td>1.5</td>
<td>0.0%</td>
</tr>
<tr>
<td>All</td>
<td>98,848</td>
<td>100.0</td>
<td>20.0%</td>
</tr>
</tbody>
</table>
KPSAM results by CPRA

Waitlist 2010 N1 N4

Percent

0 10 20 30 40 50 60

0 1 2 3 4 5 6

OPTN
Offers per Patient-Year

- Offer rate
- Offer rate (excluding 0-MM's)
Proposed Point Change: Sensitization

- Current policy: 4 points for CPRA≥80%. No points for moderately sensitized candidates.
- Proposed policy: sliding scale starting at CPRA≥20%

Current policy:

- CPRA=98, 99, 100 receive 24.4, 50.09, and 202.10 points, respectively.

Proposed policy:

- Sliding scale starting at CPRA≥20%

Graph showing CPRA sliding scale (allocation points) for CPRA<98%. The graph illustrates the proposed policy and current policy with points assigned based on CPRA values.
Point Changes: *Waiting Time*

- Current policy begins waiting time points for adults at registration with:
  - GFR\(\leq20 \, \text{ml/min}\)
  - Already on dialysis

- Proposed policy would also award waiting time points for dialysis time prior to registration
  - Applies to both pediatric and adult candidates
  - Better recognizes time spent with ESRD as the basis for priority

- Pre-emptive listing would still be advantageous for 0-ABDR mismatch offers
Candidates with blood type B who meet defined clinical criteria will be eligible to accept kidneys from donors with blood type A₂ or A₂B.

Transplant programs must establish written policies and recertify candidate eligibility every 90 days (+/- 20 days) in place of prior suggested titer policy.

Modified Classification: B Candidates receiving A₂/A₂B Kidneys
BASE PEDIATRIC ALLOCATION ON KDPI INSTEAD OF DONOR AGE
Modified Classification: Pediatric

- Current policy prioritizes donors younger than 35 to candidates listed prior to 18th birthday

- Proposed policy would
  - Prioritize donors with KDPI scores <35%
  - Eliminate pediatric categories for non 0-ABDR KPDI >85%

- Provides comparable level of access while streamlining allocation system
<table>
<thead>
<tr>
<th>Sequence A</th>
<th>Sequence B</th>
<th>Sequence C</th>
<th>Sequence D</th>
</tr>
</thead>
<tbody>
<tr>
<td>KDPI &lt;=20%</td>
<td>KDPI &gt;20% but &lt;35%</td>
<td>KDPI &gt;=35% but &lt;=85%</td>
<td>KDPI&gt;85%</td>
</tr>
<tr>
<td>Highly Sensitized 0-ABDRmm (top 20% EPTS) Prior living donor Local pediatrics Local top 20% EPTS 0-ABDRmm (all) Local (all) Regional pediatrics Regional (top 20%) Regional (all) National pediatrics National (top 20%) National (all)</td>
<td>Highly Sensitized 0-ABDRmm Prior living donor Local pediatrics Local adults Regional pediatrics Regional adults National pediatrics National adults</td>
<td>Highly Sensitized 0-ABDRmm Prior living organ donor Local Regional National</td>
<td>Highly Sensitized 0-ABDRmm Local + Regional National</td>
</tr>
</tbody>
</table>

**Continued priority pediatric candidates** (now based on KDPI)
ELIMINATE KIDNEY PAYBACKS

OPTN
Removed Classification: *Kidney Paybacks*

- Current payback policy was evaluated and found to be
  - Administratively challenging
  - Unfair in that it affected all candidates in an OPO even if only one center was responsible for accruing debt
  - Ineffective in improving outcomes of recipients
- Kidney paybacks would no longer be permitted.
- All payback credits and debts would be eliminated upon the implementation of the revised kidney allocation system.
ALLOCATE HIGH KDPI KIDNEYS TO COMBINED LOCAL/REGIONAL
Modified Classification: 
*Local + Regional for High KDPI Kidneys*

- KDPI >85% kidneys would be allocated to a combined local and regional list
- Would promote broader sharing of kidneys at higher risk of discard
- DSAs with longer waiting times are more likely to utilize these kidneys than DSAs with shorter waiting times
<table>
<thead>
<tr>
<th>Sequence A</th>
<th>Sequence B</th>
<th>Sequence C</th>
<th>Sequence D</th>
</tr>
</thead>
<tbody>
<tr>
<td>KDPI (\leq 20%)</td>
<td>KDPI (&gt;20%) but (&lt;35%)</td>
<td>KDPI (\geq 35%) but (\leq 85%)</td>
<td>KDPI(&gt;85%)</td>
</tr>
<tr>
<td>Highly Sensitized 0-ABDRmm (top 20% EPTS)</td>
<td>Highly Sensitized 0-ABDRmm Prior living organ donor Local pediatrics Local top 20% EPTS 0-ABDRmm (all) Local (all) Regional pediatrics Regional (top 20%) Regional (all) National pediatrics National (top 20%) National (all)</td>
<td>Highly Sensitized 0-ABDRmm Prior living organ donor Local pediatrics Local adults Regional pediatrics Regional adults National pediatrics National adults</td>
<td>Highly Sensitized 0-ABDRmm Prior living organ donor Local pediatrics Local adults Regional pediatrics Regional adults National pediatrics National adults</td>
</tr>
</tbody>
</table>

**Proposed Regional Sharing**

Local + Regional National