Kidney Transplantation Committee Update
Board of Directors Meeting
June 27-28, 2011
Ken Andreoni, MD, Chair
Major Progress

- Kidney Allocation Policy
  - Comments received on concept document

- Kidney Paired Donation Pilot Program
  - Matches run
  - Chains incorporated
KIDNEY ALLOCATION POLICY

OPTN
Process to date

- KARS formed in 2004
- Investigation of additional concepts
- Public Forum #2 Jan 2009
- 360° review of allocation
- Public Forum #1 Feb 2007
- Consideration of feedback
- Models proposed
- KARS merged with Kidney Committee
- KPSAM modeling
- Review and discussion
- Common Sense Clinical Sense Flexibility
- Part 1 of New Allocation Proposal

OPTN
Addressing Current System Limitations

- mismatch between potential survival of the kidney and the recipient which increases the need for retransplant and results in hundreds of potential life years not being realized
- variability in access to transplantation by blood group and geographic location
- high discard rates of kidneys (especially ECD) that could benefit candidates on the waiting list
Major Goals for Kidney Allocation

- Better match graft longevity and recipient longevity within biological reason and acceptable levels of accessibility
  - Decrease return to wait list
  - Minimize loss of potential graft function
- Improve system efficiency and organ utilization
- Make comprehensive data better available to patients and transplant programs
- Address differences in accessibility for populations described in the National Organ Transplant Act
A plan for reaching these goals

- Utilize a kidney donor profile index (KDPI) to better characterize donor kidneys and to provide additional clinical information for patients and providers to consider during the transplant evaluation process and organ offer process.

- Allocate the majority of organs (80%) by age matching so that candidates within 15 years (older and younger) of the donor are prioritized.

- Allocate some kidneys (20%) by a kidney donor profile index (KDPI) and estimated recipient post-transplant survival.
  - Longest lived recipients receiving kidney with longest potential function

OPTN
Concepts for Kidney Allocation

The Organ Procurement and Transplantation Network (OPTN) is seeking feedback regarding the use of two concepts in the allocation of deceased donor kidneys. Any feedback received will be reviewed by the OPTN Deceased Donor Committee in its work to develop a new deceased donor allocation system.
In three steps: How does this system work?

1. Estimate longevity of donor kidney (KDPI)
2. Divide candidates into broad groups (by age or EPTS)
3. Rank order candidates within each group (Points)

The concept document covered Steps 1 and 2. Step 3 (rank ordering) will be addressed in the future.
Comments Received

- Opposed: 59%
- In favor: 34%
- Mixed opinion: 6%
- Unknown: 1%

n=264 comments
Transplant professionals were more likely to be in favor of the concepts than the general public or transplant patients, recipients, family members.
Plausible New Suggestions

N= 0 comments
Professional organizations were more likely to support the concepts than organizations representing patients. This is an opportunity for future engagement.
Major Concerns

- Inadequate data
- Considerations for special...
- Social factors
- Living Donation
- Other
- Geography
- Age Discrimination
Concerns about Age Discrimination

- Comments seemed to be focused not on use of age in an allocation system, but on access for candidates of all ages.
- Confusion still exists over types of kidneys that older candidates would receive.
Donor Age v. KDPI

2005-2007 Kidneys Removed for Transplant

KDPI overlaps substantially for donors from most age categories
VARIANCE REVIEW
Variance Review: Phase 1

- Committee intends to incorporate
  - A2/A2B
  - Dialysis waiting time
- OPOs with other variances will have opportunity to propose that their variance be incorporated into national policy.
Variance Review: Phase 2

- ALUs and sharing arrangements
- OPOs wishing to maintain variances due to unique geographical constraints will be asked to submit a rationale.
Variance Review: Recommendations

- Committee will recommend to BOD for each variance:
  - incorporate into national kidney allocation policy
  - acknowledge that the OPO has a permanent need for an alternative arrangement and codify in policy
  - discontinue the variance
Path Forward

- Committee moving forward with policy development
  - Next phase will address rank-ordering
- Increased effort to work with patient organizations
  - Plans for webinars prior to any public comment release
Offer Rate per 1,000 Active Patient Years for Adult Kidney Alone Registrations on the Waiting List by CPRA, 10/01/2009-07/31/2010

Reversed offer ratio: CPRA=60-69 to CPRA group

CPRA=60-69 to CPRA group
Kidney Paired Donation Pilot Program Update

Board of Directors Meeting
June 28-29, 2011
Major Updates since the November 2010 Board Meeting

- Implementation of donor chains in May 2011
- Hiring of a KPD Program Manager
  - Ruthanne Hanto, RN, MPH
- Development of KPD screens in UNet has begun
  - Some screens will be released by the end of the year.
List of Coordinating Centers

- Alliance for Paired Donation
- Johns Hopkins Hospital
- New England Program for Kidney Exchange (NEPKE)
- UCLA Medical Center/ California Pacific Medical Center

*Represent 82 participating centers from all 11 regions

OPTN
## June 2011 Match Run Results

### Participants included in the match

<table>
<thead>
<tr>
<th>Count</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>132</td>
<td>candidates</td>
</tr>
<tr>
<td>142</td>
<td>total donors</td>
</tr>
<tr>
<td>5</td>
<td>NDDs (1 blood type O, 2 blood type A, 2 blood type B)</td>
</tr>
<tr>
<td>41</td>
<td>centers from 11 regions had at least one eligible pair.</td>
</tr>
</tbody>
</table>

### Results

<table>
<thead>
<tr>
<th>Count</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>pairs from 7 regions matched</td>
</tr>
<tr>
<td></td>
<td>Chain with 16 links (1 NDD, 15 pairs, 1 waiting list candidate)</td>
</tr>
<tr>
<td>1</td>
<td>three-way match</td>
</tr>
<tr>
<td>8</td>
<td>highly sensitized candidates matched</td>
</tr>
</tbody>
</table>
*Blue circles indicate a highly sensitized (CPRA ≥ 80) candidate.
OPTN

*Blue circles indicate a highly sensitized (CPRA ≥ 80) candidate
Waiting List Candidate
Region 1
Center A
## Previous Match Run Results

<table>
<thead>
<tr>
<th>Match Run Date</th>
<th>Candidates</th>
<th>Donors</th>
<th>Pairs Matched</th>
<th>Pairs Transplanted</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 27, 2010</td>
<td>43</td>
<td>45</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>December 8, 2010</td>
<td>60</td>
<td>62</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>January 19, 2011</td>
<td>66</td>
<td>69</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>February 23, 2011</td>
<td>76</td>
<td>78</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>March 23, 2011</td>
<td>88</td>
<td>90</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>April 28, 2011</td>
<td>106</td>
<td>109</td>
<td>6</td>
<td>3 scheduled for 07/19/2011</td>
</tr>
<tr>
<td>May 26, 2011</td>
<td>117</td>
<td>124</td>
<td>7</td>
<td>3 under consideration</td>
</tr>
</tbody>
</table>
Why did matches fall apart?

- Most matches fell apart because there was a positive crossmatch between one matched pair in a 3-way match.
  - Large number of sensitized candidates in the KPDPP.
<table>
<thead>
<tr>
<th></th>
<th>Candidate 1 CPRA</th>
<th>Candidate 2 CPRA</th>
<th>Candidate 3 CPRA</th>
<th>Refusal Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>October</td>
<td>73</td>
<td>95</td>
<td>99</td>
<td>Expected positive crossmatches</td>
</tr>
<tr>
<td>December</td>
<td>0</td>
<td>92</td>
<td>99</td>
<td>Positive crossmatch</td>
</tr>
<tr>
<td>December</td>
<td>0</td>
<td>94</td>
<td>96</td>
<td>Candidate and Donor cannot be contacted</td>
</tr>
<tr>
<td>December</td>
<td>0</td>
<td>58</td>
<td>86</td>
<td>Number of mismatches unacceptable</td>
</tr>
<tr>
<td>December</td>
<td>83</td>
<td>84</td>
<td>94</td>
<td>Positive Crossmatch</td>
</tr>
<tr>
<td>January</td>
<td>70</td>
<td>81</td>
<td>94</td>
<td>Positive Crossmatch</td>
</tr>
<tr>
<td>January</td>
<td>58</td>
<td>88</td>
<td>99</td>
<td>Positive Crossmatch</td>
</tr>
<tr>
<td>January</td>
<td>73</td>
<td>88</td>
<td>98</td>
<td>Positive Crossmatch</td>
</tr>
<tr>
<td>March</td>
<td>29</td>
<td>85</td>
<td>99</td>
<td>Unacceptable BMI and BP</td>
</tr>
<tr>
<td>April</td>
<td>0</td>
<td>85</td>
<td>86</td>
<td>New unacceptables identified</td>
</tr>
</tbody>
</table>

Highlighted boxes indicate which candidate refused the match.
# Candidate Characteristics

Candidates entered in May Match Run

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Candidates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>117</td>
</tr>
<tr>
<td>Blood Type O</td>
<td>65.8% (77)</td>
</tr>
<tr>
<td>CPRA ≥ 80%</td>
<td>66.7% (78)</td>
</tr>
<tr>
<td>Ethnicity- Black</td>
<td>16.2% (19)</td>
</tr>
<tr>
<td>Ethnicity- Hispanic</td>
<td>7.7% (9)</td>
</tr>
<tr>
<td>Age over 50</td>
<td>34.2% (40)</td>
</tr>
<tr>
<td>DD Waiting Time &gt; 1 year</td>
<td>27.4% (32)</td>
</tr>
<tr>
<td>Previous Kidney Transplant</td>
<td>62.4% (73)</td>
</tr>
<tr>
<td>Willing to accept a shipped kidney from any center</td>
<td>92.3 (108)</td>
</tr>
</tbody>
</table>
**Donor Characteristics**

*Donors entered in May Match Run*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>124</td>
</tr>
<tr>
<td>Blood Type O</td>
<td>39.5% (40)</td>
</tr>
<tr>
<td>Age over 50</td>
<td>24.2% (30)</td>
</tr>
<tr>
<td>BMI over 30</td>
<td>21.0% (26)</td>
</tr>
<tr>
<td>Willing to ship a kidney</td>
<td>98.4% (122)</td>
</tr>
<tr>
<td>Willing to travel to any center</td>
<td>37.1% (46)</td>
</tr>
<tr>
<td>Non-directed donor</td>
<td>1.6% (2)</td>
</tr>
</tbody>
</table>
Why weren’t there more matches?*

- Lack of inclusions of non-directed donors and chains
- Many pairs are hard to match
- Not enough pairs being added in between match runs to yield more matches

*Based on feedback from coordinating centers
Potential Impact of NDDs

OPTN Uses data from candidates and donors entered in February 2011 match run
Potential Impact of A Candidates with O Donors

OPTN Uses data from candidates and donors entered in February 2011 match run
Ways to Improve the KPDPP

- Implement chains - May 2011
- Encourage entry of more pairs
  - Kidney Committee suspended the requirement for DP typing for 6 months
- Hire a dedicated KPD Program Manager
- Automate the KPDPP
  - Data entry screens will be released this year.
KPD Automated Solution Project

- Converting the KPD Manual Solution into a KPD system integrated with UNet℠
- Functionality will be released in batches
First Release of Screens

- Candidate and Donor record data entry screens
- Print functionality
- Eliminates need for Access databases for data entry
External User Demos

- UNOS Staff held demonstrations of these screens for Pilot participants to gather feedback on the data entry screens.
- The design of the screens has been modified based on feedback from these end users.
Announcements

5/17/2011  KPD Match Run Schedule
Pair eligibility report post date: 06/13/2011
Last day for pair data entry: 06/15/2011
Match run date: 06/22/2011
Match results post date: 06/24/2011
Preliminary match response deadline: 06/29/2011
Final match response deadline: 07/21/2011

4/1/2011  Donor Chains functionality is now available.

ABO Pending Candidates
To verify the ABO, select the candidate's KPD ID below. The ABO must be verified by a second user before the candidate can be eligible for KPD match runs.

<table>
<thead>
<tr>
<th>KPD candidate ID</th>
<th>Name</th>
<th>SSN</th>
<th>Center</th>
<th>Add date</th>
</tr>
</thead>
<tbody>
<tr>
<td>123456</td>
<td>Brown, Tom</td>
<td>123-45-6789</td>
<td>ALUA-TX1</td>
<td>5/17/2011</td>
</tr>
<tr>
<td>765432</td>
<td>Smith, Scott</td>
<td>222-33-4444</td>
<td>ALUA-TX1</td>
<td>5/17/2011</td>
</tr>
</tbody>
</table>

ABO Pending Donors
To verify the ABO, select the donor's KPD ID below. The ABO must be verified by a second user before the donor can be eligible for KPD match runs.

<table>
<thead>
<tr>
<th>KPD donor ID</th>
<th>Name</th>
<th>SSN</th>
<th>Center</th>
<th>Add date</th>
</tr>
</thead>
<tbody>
<tr>
<td>76584</td>
<td>Jones, Anne</td>
<td>998-88-8888</td>
<td>ALUA-TX1</td>
<td>5/18/2011</td>
</tr>
<tr>
<td>44356</td>
<td>Steet, Pete</td>
<td>987-65-4321</td>
<td>ALUA-TX1</td>
<td>5/15/2011</td>
</tr>
</tbody>
</table>
Donor name: Simpson, Marge B  
KPD donor ID: 654321  
KPD candidate ID: 778899  
Candidate name: Simpson, Homer J

**INSTITUTION**

Home transplant center: ALUA-TX1

**DEMOGRAPHIC INFORMATION**

Last name: **Simpson**  
First name: **Marge**  
Middle initial: **B**

SSN: **444-55-6666**

Date of birth: **10/01/1956** (MM/DD/YYYY)  
Current age: 54 years  
Gender: **Female**

Center’s patient ID:

Ethnicity/race:
- American Indian or Alaska Native
  - American Indian
  - Eskimo
  - Aleutian
  - Alaska Indian
  - American Indian or Alaska Native: Other
  - American Indian or Alaska Native: Not Specified/Unknown

American Indian or Alaska Native
- American Indian
- Eskimo
- Aleutian
- Alaska Indian
- American Indian or Alaska Native: Other
- American Indian or Alaska Native: Not Specified/Unknown

Asian
- Asian Indian/Indian Sub-continent
- Chinese
- Filipino
- Japanese
- Korean
- Vietnamese
### INSTITUTION

Home transplant center: ALUA-TX1

### KPD CANDIDATE CHOICES

<table>
<thead>
<tr>
<th>Candidate willing to travel? R</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

If yes, to which center(s) is the candidate willing to travel? R

Available options:
- All centers
- Any center within 50 miles
- Any center within 100 miles
- Any center within 250 miles
- Any center within 500 miles
- AZMC-Mayo Clinic Hospital
- CAGH-Scripps Green Hospital
- CAPM-California Pacific Medical Center

Your selections:
- ALUA-University of Alabama Hospital
- CTHH-Hartford Hospital
- MABU-Boston Medical Center

Would candidate be willing to travel further if funding were provided?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

Candidate will accept a shipped kidney? R

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>
Ongoing Work

- Working with the Living Donor Committee to address issues around transportation, psychosocial outcomes, and informed consent
- Continuing discussion on the potential use of bridge donors
- Addressing questions that arise from what we are learning through the Pilot
- Converting the Operational Guidelines to interim policy
KPD Financial Subcommittee

- In the short term, the subcommittee is developing KPD financial best practices and templates.
- The subcommittee is also discussing recommendations for the overall structure of financing for KPD.
Backup Slides

OPTN
<table>
<thead>
<tr>
<th>Current Allocation Sequence</th>
<th>Proposed Allocation Sequence</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Zero-antigen mismatches</td>
<td>• Group A zero-antigen mismatches (peds then adults)</td>
</tr>
<tr>
<td>• Local prior living organ donor</td>
<td>• Local prior living organ donor</td>
</tr>
<tr>
<td>• Highly sensitized candidates</td>
<td>• Local pediatric (for certain range of KPDI kidneys)</td>
</tr>
<tr>
<td>• Payback debts</td>
<td>• Local Group A</td>
</tr>
<tr>
<td>• Local pediatric (donor age &lt;35)</td>
<td>• Local Group B (all remaining Group A Candidates)</td>
</tr>
<tr>
<td>• Local all candidates</td>
<td>• Group B zero antigen mismatches</td>
</tr>
<tr>
<td>• Regional pediatric (donor age &lt;35)</td>
<td>• Regional pediatric (KPDP range)</td>
</tr>
<tr>
<td>• Regional all candidates</td>
<td>• Regional Group A</td>
</tr>
<tr>
<td>• National pediatric (donor age &lt;35)</td>
<td>• Regional Group B (All remaining Regional Candidates)</td>
</tr>
<tr>
<td>• National</td>
<td>• National pediatric (KPDP range)</td>
</tr>
<tr>
<td></td>
<td>• National Group A</td>
</tr>
<tr>
<td></td>
<td>• National Group B (All remaining Candidates)</td>
</tr>
</tbody>
</table>
Example 1: KDPI >20%

Candidates within 15 years of the donor’s age are GROUP A.

If a kidney is not accepted by a candidate in Group A, it is then allocated to all other candidates (Group B).

OPTN
Example 2: KDPI $\leq 20\%$

Candidates with post-tx survival in Longest 20% are GROUP A

If a kidney is not accepted by a candidate in Group A, it is then allocated to all other candidates (Group B).
### Who gets priority for which kidneys?

<table>
<thead>
<tr>
<th>Kidney</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>KDPI &lt;=20%</td>
<td>Candidates with longest 20% estimated post-transplant survival</td>
<td>Candidates with 21%-100% estimated post-transplant survival</td>
</tr>
<tr>
<td>KDPI &gt;20%</td>
<td>Candidates within +/- 15 years of donor’s age</td>
<td>Candidates more than 15 years older/younger than the donor</td>
</tr>
</tbody>
</table>
Recipient Age Distribution for U.S. Kidney Transplants
1990, 2000, and 2009

Based on OPTN data as of November 6, 2009
How were the 20% thresholds for KDPI and post-tx survival chosen?

- Median life span for recipients is markedly different at 80%-100%
- Relative Risk for graft failure is not markedly different for top 20% of kidneys

Median life span for recipients is markedly different at 80%-100%.

OPTN Uses patient factors only

Relative Risk for graft failure is not markedly different for top 20% of kidneys.
Example: Who gets priority?
Kidney with a KDPI of 30%

<table>
<thead>
<tr>
<th>Candidates</th>
<th>Donor A Age: 34</th>
<th>Donor B Age: 15</th>
<th>Donor C Age: 55</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A Age</td>
<td>19 to 49</td>
<td>0 to 30</td>
<td>40 to 70</td>
</tr>
<tr>
<td>Group B Age</td>
<td>&lt;19 or &gt;49</td>
<td>&gt;30</td>
<td>&lt;40 or &gt;70</td>
</tr>
<tr>
<td>Mary</td>
<td>A</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>David</td>
<td>B</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>Manuel</td>
<td>A</td>
<td>B</td>
<td>B</td>
</tr>
<tr>
<td>Sophia</td>
<td>A</td>
<td>A</td>
<td>B</td>
</tr>
</tbody>
</table>

OPTN If a kidney is not accepted by a candidate in Group A, it is then allocated to all other candidates (Group B).
Example: Who gets priority?
Kidney with a KDPI of 10%

<table>
<thead>
<tr>
<th>Candidates</th>
<th>Post-transplant survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mary</td>
<td>19%</td>
</tr>
<tr>
<td>David</td>
<td>35%</td>
</tr>
<tr>
<td>Manuel</td>
<td>27%</td>
</tr>
<tr>
<td>Sophia</td>
<td>12%</td>
</tr>
</tbody>
</table>

If a kidney is not accepted by a candidate in Group A, it is then allocated to all other candidates (Group B).
Policy Language Correction to 3.5.5.3 (Kidney Payback Debt Limit)

Board of Directors Meeting
June 27-28, 2011
Problem Description

- Policy 3.5.5.3 (Kidney Payback Debt Limit) was not changed to reflect the removal of regional and national allocation categories for adult, unsensitized, zero-mismatched candidates in 2008.

- The language continues to state the candidates in these categories will be reprioritized if an OPO exceeds the kidney payback debt limit.

OPTN
Proposed Solution

- Remove the out-of-date reference to the reprioritization
**RESOLVED, that effective pending notice to the membership, the language in Policy 3.5.5.3 (Kidney Payback Debt Limit) be amended as set forth below.**

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered longterm debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO’s short-term (i.e., incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3.