<table>
<thead>
<tr>
<th><strong>Sequence A</strong></th>
<th><strong>Sequence B</strong></th>
<th><strong>Sequence C</strong></th>
<th><strong>Sequence D</strong></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)</td>
<td>Highly Sensitized 0-ABDRmm Prior living organ donor Local pediatric</td>
<td>Highly Sensitized 0-ABDRmm Prior living organ donor Local</td>
<td>Highly Sensitized 0-ABDRmm Prior living organ donor Local + Regional National</td>
</tr>
<tr>
<td>Prior living organ donor</td>
<td>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>Regional pediatrics Regional adults National pediatrics National adults</td>
<td>Local + Regional National</td>
</tr>
</tbody>
</table>

**Proposed Regional Sharing**
KPSAM results by degree of sharing

- Local
- Shared

OPTN
Comments Received

- May lead to inefficiency in placement, increased CIT and discards

- Candidates in regions with extreme variations in waiting times may be shut out of receiving high KDPI kidneys

- No changes made to proposal
ELIMINATE VARIANCES
Eliminate Variances

- Numerous variances to existing kidney allocation system
- Many instituted prior to OPTN Final Rule
- Designed to address limitations of current system
- Necessary to eliminate variances
  - To establish a baseline from which to evaluate new variances
  - To bring new variances into alignment with OPTN Final Rule requirements
- Two requests for transition circulated for public comment
  - Region 1 (Ex Com approved 2/2013)
  - Southwest Transplant Alliance (TXSB) request not forwarded
Eliminate Variances

- Requests to retain ALUs
  - TXSB, PATF, PADV, TXGC, OKOP
- Request to retain intended candidate variance (VATB)
- Concerns cited regarding
  - patient access
  - effects on smaller transplant programs in non-metropolitan areas
- Increased waiting time in subunits
Eliminate Variances

- Proposal makes DSA first level of allocation
- Need a geographic metric to better assess disparity before variances can effectively address
- Variances add significant cost/time to national policy revisions

- No changes made to proposal—recommendation to eliminate variances
OVERVIEW OF OUTREACH AND FEEDBACK
Public Comment Overview

- **Individuals**
  - 225 responses (54% in favor, 43% opposed, 4% no opinion)

- **Regions**
  - 9 in favor, 1 in favor as amended, 1 opposed

- **Committees**
  - 6 in favor, 2 in favor as amended, 1 opposed

- **Comments from:**
  - AST, ASTS, NATCO, AAKP, PKD Foundation
Media outlets

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

OPTN
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 came 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 25 years. The existing policy has facilitated more than 360,000 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 non-profit United Network for Organ Sharing (UNOS), matches deceased donor kidneys with transplant candidates nationwide. The OPTN is seeking public comment on a proposal to make needed improvements in 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 20 percent of kidneys likely to have the longest function would be offered first (but not exclusively) to the 20 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 time on the kidney waiting list. Critics object to the inefficiencies of the current system because a candidate who has a short life expectancy may be allocated a healthy deceased donor kidney that can be expected to outlive the recipient by years, maybe decades. The Kidney Committee has proposed a 20/60 allocation method. The “20” stands for the top 20 percent of kidneys (based on 10 donor traits that estimate expected graft survival) that are to be allocated to the top 20 percent of candidates (defined by four recipient traits—age, diabetes, diabetes time, and prior transplant status—that help determine post-transplant survival). The remaining 60 percent of kidneys will be allocated mainly on dialysis time, a matter of waiting time.

While the 20 percent rule will improve efficiency, it is unjust for three distinct reasons. First, it is
“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.”
“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.”
IMPLEMENTATION PLAN
Scope of Project

- Enterprise level project (~10,500 hours)
- Significant resources required to program system and to educate/assist transplant community
- Expected to *reduce* resources required to program future policy modifications
Two Phase Approach

- Phase I (estimated time period 6 months)
  - Educate and assist transplant programs with data updates
  - New reports made available
  - Training and tools for data uploads made available
  - EPTS calculator made available

- Phase II
  - Begin allocating according to new rules
  - Variances removed
  - Payback system removed
Communication/Education Vehicles

- UNOS Update
- Transplant Pro
- Distribution Lists
- Policy and System notices
- Updated kidney allocation brochure
- Webinars
- Educational sessions at professional meetings
IN RECOGNITION
Countless individuals gave time and talent to this proposal

- Over 250 Committee members, HRSA representatives, SRTR and UNOS staff

- All who participated in forums, regional meetings, and public comment

- Prior Committee Chairs

Mark Stegall, MD

Peter Stock, MD, PhD

Ken Andreoni, MD
RESOLVED, that Policy 3.5 (Allocation of Deceased Kidneys) is struck in its entirety and replaced with Policy 3.5 (Allocation of Kidneys), and modifications to Policies 3.1.13 (Definition of Directed Donation), 3.2.4.2 (Waiting Time Reinstatement for Kidney Recipients), 3.3.5 (Transplant Recipient Backups for Organ Offers), 3.4.2 (Time Limit for Acceptance), 3.8.1.4 (Criteria to Accrue Kidney-Pancreas Waiting Time), 3.8.3.2 (Blood Type O Kidney-Pancreas Allocation), 3.8.3.5 (Organ Offer Limits), 3.8.4.1 (CPRA), 3.8.4.2 (Waiting Time), 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates), 6.4.1.1 (Requirements for Importing Deceased Donor Organs through a Formal Agreement), 9.6.8, 12.5.6 (Placement of Non-directed Living Donor Organs), and 12.9.4 (Exception for Prior Living Donor Organs), as set forth in Resolution 14, are hereby approved, effective pending programming and notice to OPTN membership.

* Page 24 of Board Book
FURTHER RESOLVED, the variances, as set forth in Resolution 14, are terminated, effective pending programming and notice to OPTN membership.
Committee Leadership and Support

- **John J. Friedewald, MD**
  Committee Chair

- **Richard N. Formica, Jr, MD**
  Committee Vice Chair

- **Ciara J. Samana, MSPH**
  UNOS Committee Liaison
  ciara.samana@unos.org
  804-782-4073

- **Wida Cherikh, PhD and Darren Stewart, MS**
  UNOS Biostatisticians
BACKUP SLIDES
Percent of candidates in national top 20%, by Donor Service Area of candidate’s listing center
Percent of kidney donors in national top 20%, by DSA of donor
DEEPDIVE INTO POSITIVE CROSSMATCH REFUSAL RATES BY CPRA

DERIVED FROM CPRA ANALYSIS PRESENTED AT SEP 19, 2011 KIDNEY COMMITTEE MEETING ("TABLE 18")

Darren Stewart, Anna Kucheryavaya, Wida Cherikh
UNOS Research Department

Prepared for
Kidney Transplantation Committee
February 6, 2012
(Super Bowl Monday)
DATA REQUESTS FROM MARCH 21, 2011

5. Offers refused for “positive crossmatch” by CPRA
   • 0-mismatches and non-0-mismatches
   • **Purpose**: are positive crossmatch results occurring too often for very highly sensitized (95%+) candidates to give them national priority?
DATA/METHODS

- All analyses are for adult, kidney-alone registrations.
- Considered adult if listed when age 18 or greater.
- Based on year 2010 data.
- Refusals due to “positive crossmatch” that occurred after a “final acceptance” are identifiable if on a subsequent match to reallocate the kidneys, the accepting candidate is refused for this reason.
- Results are based on the OPTN database as of August 5, 2011.

➤ See formal reports (.pdfs) for more detailed information about data and methodology.
REQUEST #5: POSITIVE CROSSMATCH REFUSALS BY CPRA RESULTS

- Overall, 0.7% of offers were refused due to +XM.
  - N=5,106 positive crossmatch refusals.
- However, for very highly sensitized candidates (CPRA>=95%), over 10% of offers were refused due to +XM.
- Though zero-mismatch offers had a higher rate of refusal due to +XM (3.6%), they only accounted for 73 (1.6%) of the 5,106 +XM refusals.
- The rate of refusal due to positive crossmatch was higher for local offers (1.5%) then non-local offers (0.2%).
POSITIVE CROSSMATCH REFUSALS BY CPRA (LOCAL OFFERS)

None of these refusals came after final acceptance.

<table>
<thead>
<tr>
<th>CPRA</th>
<th>0</th>
<th>1-69</th>
<th>70-94</th>
<th>95</th>
<th>96</th>
<th>97</th>
<th>98</th>
<th>99</th>
<th>100</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>+XM refusals</td>
<td>2,071</td>
<td>992</td>
<td>1,107</td>
<td>53</td>
<td>57</td>
<td>68</td>
<td>65</td>
<td>44</td>
<td>20</td>
<td>4,477</td>
</tr>
<tr>
<td>Offers</td>
<td>234,814</td>
<td>45,437</td>
<td>7,367</td>
<td>248</td>
<td>306</td>
<td>275</td>
<td>286</td>
<td>235</td>
<td>98</td>
<td>288,973</td>
</tr>
<tr>
<td>Rate</td>
<td>0.9%</td>
<td>2.2%</td>
<td>15.0%</td>
<td>21.4%</td>
<td>18.6%</td>
<td>24.7%</td>
<td>22.7%</td>
<td>18.7%</td>
<td>20.4%</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

Rate of Offer Refusal Due to Positive Crossmatch
(Local offers in 2010)
### POSITIVE CROSSMATCH REFUSALS BY CPRA (NON-LOCAL OFFERS)

<table>
<thead>
<tr>
<th>CPRA</th>
<th>0</th>
<th>1-69</th>
<th>70-94</th>
<th>95</th>
<th>96</th>
<th>97</th>
<th>98</th>
<th>99</th>
<th>100</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offers</td>
<td>332,058</td>
<td>69,515</td>
<td>9814</td>
<td>317</td>
<td>371</td>
<td>325</td>
<td>384</td>
<td>314</td>
<td>196</td>
<td>412,279</td>
</tr>
<tr>
<td>+XM refusals</td>
<td>331</td>
<td>124</td>
<td>116</td>
<td>4</td>
<td>9</td>
<td>8</td>
<td>13</td>
<td>15</td>
<td>10</td>
<td>629</td>
</tr>
<tr>
<td>Rate</td>
<td>0.1%</td>
<td>0.2%</td>
<td>1.2%</td>
<td>1.3%</td>
<td>2.4%</td>
<td>2.5%</td>
<td>3.4%</td>
<td>4.8%</td>
<td>5.1%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

- **59** +XM refusals for CPRA of 95+
- (About half were 0MM)
- **38** +XM refusals for CPRA of 98+

• For CPRA=98+, 22/38 (58%) of refusals came after final acceptance.
POSITIVE CROSSMATCH REFUSALS – SUMMARY

✓ Rate of offer refusal due to + XM in 2010...
  ✓ Increased as CPRA increased
  ✓ Was much higher for local offers (1.5%) than non-local offers (0.2%).

✓ However, none of the local refusals came after a final acceptance.

✓ Of 894 non-local offers to CPRA=98+, 38 were refused due to positive crossmatch. Many were after final acceptance.

➢ For more details on these results, see associated formal (.pdf) version of this report from September 19, 2011 meeting.
CPRA Update: 30 Month Follow Up
Center Specific Variable Use of Listing UAs

Kidney Committee,
August 27, 2012
Nancy L. Reinsmoen, PhD
Anna Y. Kucheryavaya, MS
PRA/CPRA distribution for primary vs. repeat transplant*

*Based on adult kidney alone registrations on the waiting list
CPRA distribution for primary vs. repeat transplant on 03/31/2012*

*Based on adult kidney alone registrations on the waiting list

Total N= 94,309
During 15 months prior to policy implementation, the number of offers refused due to a positive crossmatch decreased by 28%. It further decreased in the first and second 15 months after the change (by 65% and 9%, respectively).

Overall percentage of offers refused due to a positive crossmatch significantly decreased in each era.

**Based on percentage of positive crossmatches reported as a reason for organ refusal. Analysis was limited to adult kidney alone registrations**

**N** is the total number of offers refused due to a positive crossmatch
The number of 0ABDR mismatch offers refused due to a positive crossmatch remained similar through the recent years. Mandatory non local sharing of 0ABDR mismatched kidneys was eliminated for 0-20% PRA adults on January 21, 2009.

For moderately and broadly sensitized registrations, percentage of 0ABDR mismatch offers refused due to a positive crossmatch didn’t change significantly after CPRA implementation.

*Based on percentage of positive crossmatches reported as a reason for organ refusal. Analysis was limited to adult kidney alone registrations.
Mandatory non local sharing of 0ABDR mismatched kidneys was eliminated for 0-20% PRA adults on January 21, 2009.

Total number of 0ABDR mismatch transplants: era 1 = 1,671; era 2 = 1,179; era 3 = 928; era 4 = 1,013

era 1 = 04/01/2007 – 06/30/2008; era 2 = 07/01/2008 – 09/30/2009;
era 3 = 10/01/2009 – 12/31/2010; era 4 = 01/01/2011 – 03/31/2012

* Based on adult kidney alone transplants
Transplant rates per 1,000 active patient years

Data and Methods

- Transplant rates (expressed by transplants per 1,000 active patient-years) were calculated by dividing the number of all deceased donor kidney transplants within an interval by the number of active years patients spent waiting, and then multiplying by 1,000.

- Transplant rates were calculated taking into account CPRA changes on the waiting list.
Transplant rate per 1,000 active patient-years

*Based on adult kidney alone patients on the waiting list
Accumulated waiting time for registrations waiting on 07/13/2012*

* Based on adult kidney alone registrations
## Kaplan-Meier 6, 12, 18 month Graft Survival Rates by PRA/CPRA Groups: No Significant Change

<table>
<thead>
<tr>
<th>Months</th>
<th>PRA/CPRA Group (%)</th>
<th>0/Not Reported</th>
<th>1 - 20</th>
<th>21 - 79</th>
<th>80+</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td></td>
<td>94.2</td>
<td>94.2</td>
<td>94.2</td>
<td>95.0</td>
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<tr>
<td>12</td>
<td></td>
<td>91.8</td>
<td>91.3</td>
<td>91.6</td>
<td>92.0</td>
</tr>
<tr>
<td>18</td>
<td></td>
<td>89.6</td>
<td>88.1</td>
<td>89.6</td>
<td>88.3</td>
</tr>
</tbody>
</table>