The ‘new’ kidney allocation system (KAS) – what has it done?

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Disclosures
• No financial disclosure

Objectives
• Describe Guiding principles of organ allocation policy

Organ allocation and distribution – guiding general principles
• FAIRNESS/EQUITY
• UTILITY/EFFICACY
• EFFICIENCY
FINAL RULE – Organ allocation policy

(1) Shall be based on sound medical judgment;
(2) Shall seek to achieve the best use of donated organs;
(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with 121.7(b)(4)(i) and (ii);
(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;
(6) Shall be reviewed periodically and revised as appropriate;
(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program’s application of the policies to patients listed or proposed to be listed at the program; and
(8) Shall not be based on the candidate’s place of residence or place of listing, except to the extent required by paragraphs (a)(1) - (5) of this section.

‘NEW’ UNOS Kidney allocation system

- Implemented on Dec 4, 2014
- Attempts to match best kidneys with best candidates
- Prioritizes highly sensitized patients
- Unifies fragmented variances

Four Problems “KAS” Aimed to Solve

1. Longevity mismatches
2. Biological and ethnic inequities
3. Too many discarded kidneys
4. Fragmented, non-unified system

Problem #1: Longevity mismatches

Recipient

Donor

Longevity Mismatches

During the one year before KAS, 567 kidneys from 18-34 year old donors went to age 65+ recipients.

16.1% of age 18-34 donor kidneys

<table>
<thead>
<tr>
<th>KDRI DONOR FACTORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Age</td>
</tr>
<tr>
<td>• Height</td>
</tr>
<tr>
<td>• Weight</td>
</tr>
<tr>
<td>• Ethnicity (African American)</td>
</tr>
<tr>
<td>• Hypertension</td>
</tr>
<tr>
<td>• Diabetes</td>
</tr>
<tr>
<td>• Serum Creatinine</td>
</tr>
<tr>
<td>• HCV +</td>
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<tr>
<td>• DCD</td>
</tr>
</tbody>
</table>

KDPI and graft survival

Estimated post transplant survival score - EPTS

• Age
• Diabetes
• Duration of dialysis
• Previous transplant

• C-statistic = 0.69
### KDPI & EPTS in the New System

![Diagram showing KDPI and EPTS](image)

- **Kidney donor profile index (KDPI)**
- **Estimated post-transplant survival score (EPTS)**

### A Comprehensive Risk Quantification Score for Deceased Donor Kidneys: The Kidney Donor Risk Index

**Authors:**
- Pamela Y. Sun, 1, 3, 4
- Douglas L. Schuster, 1, 3
- Mary K. G_PK106
- Kenneth A. Andreyuk, 1
- Robert A. Wilf, 1, 4
- Robert H. Martin, 1
- Frederic K. Perk, 1
- and Rowland S. Sung 1, 4

**Background:**
The kidney donor risk index (KDRI) assesses the risk of death and non-function of a kidney donor.

**Methods:**
We used a logistic regression model to analyze the relationship between donor characteristics and mortality or kidney non-function. The KDRI was calculated using the model.

- **Donor Characteristics:**
  - Age
  - Sex (male/female)
  - Body mass index (BMI)
  - Blood pressure
  - Diabetes
  - History of hypertension

**Results:**
The KDRI was associated with a higher risk of death and non-function. A higher KDRI was associated with a greater risk of death or non-function.

**Conclusions:**
The KDRI is a useful tool for risk assessment in deceased donor kidney transplantation.

**Keywords:**
- Deceased donor kidneys
- Kidney transplant
- Risk assessment
- Donor characteristics

*(Transplantation 2008; 86: 370-376)*
Relationship between KDRI and KDPI

<table>
<thead>
<tr>
<th>KDRI</th>
<th>KDPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.65</td>
<td>1%</td>
</tr>
<tr>
<td>0.86</td>
<td>15%</td>
</tr>
<tr>
<td>0.91</td>
<td>20%</td>
</tr>
<tr>
<td>1.12</td>
<td>40%</td>
</tr>
<tr>
<td>1.25</td>
<td>50%</td>
</tr>
<tr>
<td>1.53</td>
<td>70%</td>
</tr>
<tr>
<td>1.85</td>
<td>85%</td>
</tr>
<tr>
<td>2.81</td>
<td>99%</td>
</tr>
</tbody>
</table>

Higher Quality, Longevity

Lower Quality, Longevity

Estimated Post Transplant Survival (EPTS) Score

- EPTS score range 0%-100%

**Estimated Post Transplant Survival Score**

- KDRI 0-20% / age 65+: pre-KAS 3.2%, post-KAS 1.1%

**Longevity-matching under KAS**

During the 1 year before after KAS, 562 382 kidneys from 18-34 year old donors went to age 65+ recipients.

**46.1% 10.1%** of age 18-34 donor kidneys
Did KAS Affect Equity by Recipient Age?

Deceased Donor Kidney Transplant Rates

<table>
<thead>
<tr>
<th>Age (in years)</th>
<th>Pre-KAS (2013-2014)</th>
<th>Post-KAS (2015-2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10</td>
<td>1.8%</td>
<td>1.1%</td>
</tr>
<tr>
<td>11-20</td>
<td>2.3%</td>
<td>1.8%</td>
</tr>
<tr>
<td>21-30</td>
<td>3.2%</td>
<td>3.0%</td>
</tr>
<tr>
<td>31-40</td>
<td>3.9%</td>
<td>4.2%</td>
</tr>
<tr>
<td>41-50</td>
<td>4.3%</td>
<td>4.5%</td>
</tr>
<tr>
<td>51-60</td>
<td>4.6%</td>
<td>4.8%</td>
</tr>
<tr>
<td>61-70</td>
<td>4.9%</td>
<td>5.1%</td>
</tr>
<tr>
<td>71-80</td>
<td>5.2%</td>
<td>5.3%</td>
</tr>
<tr>
<td>81+</td>
<td>5.5%</td>
<td>5.6%</td>
</tr>
</tbody>
</table>

Problem #2: Biological and ethnic inequity

Fun Facts

- The chances of you dying on the way to get your lottery tickets is greater than your chances of winning.

https://skeptics.stackexchange.com/

Transplants per patient-year by candidate CPRA

<table>
<thead>
<tr>
<th>CPRA Range</th>
<th>Transplants per Patient-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10%</td>
<td>1 transplant in 5 years</td>
</tr>
<tr>
<td>10-20%</td>
<td>1 transplant in 2 years</td>
</tr>
<tr>
<td>20-30%</td>
<td>1 transplant in 1 year</td>
</tr>
<tr>
<td>30-40%</td>
<td>1 transplant in 6 months</td>
</tr>
<tr>
<td>40-50%</td>
<td>1 transplant in 13 months</td>
</tr>
<tr>
<td>50-60%</td>
<td>1 transplant in 25 years</td>
</tr>
<tr>
<td>60-70%</td>
<td>1 transplant in 50 years</td>
</tr>
<tr>
<td>70-80%</td>
<td>1 transplant in 100 years</td>
</tr>
<tr>
<td>80-90%</td>
<td>1 transplant in 200 years</td>
</tr>
<tr>
<td>90-100%</td>
<td>1 transplant in 500 years</td>
</tr>
</tbody>
</table>

Transplant Rates by Fine CPRA Groups, post-KAS (20 mos)

- CPRA-80%
- CPRA-85-95%
- CPRA-95%
- CPRA-100%
CPRA 99-100% recipient “bolus effect”

- Transplants to CPRA 99-100% patients rose sharply after KAS but have tapered to around 10% nationally.

More Kidneys are Being Shipped under KAS

- “Local” Cold ischemic time 17 → 18 hours

KAS gives credit for pre-listing dialysis time

Patient started dialysis

Patient added to waiting list

“Waiting time” priority before KAS

“Waiting time” priority under KAS

Association of Race and Insurance Type with Delayed Assessment for Kidney Transplantation among Patients Initiating Dialysis in the United States

Young black patients much less likely to be presented option of transplantation around time of starting dialysis.
Kidney Transplants by Race/Ethnicity

- Under KAS, Blacks are now receiving transplants proportional to their representation on the waiting list.

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Pre-KAS (1 year)</th>
<th>Post-KAS (1 year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>34.3%</td>
<td>36.5%</td>
</tr>
<tr>
<td>White</td>
<td>31.5%</td>
<td>36.8%</td>
</tr>
<tr>
<td>Asian</td>
<td>6.2%</td>
<td>6.8%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>7.9%</td>
<td>7.3%</td>
</tr>
<tr>
<td>Pacific Island</td>
<td>2.3%</td>
<td>2.0%</td>
</tr>
<tr>
<td>American Indian</td>
<td>1.1%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Other</td>
<td>0.5%</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

High dialysis time recipient “bolus effect”

- After KAS, the % of transplants to recipients with 10+ years of dialysis rose sharply to nearly 19% but has tapered to about 6% nationally.

But what about post-transplant outcomes under KAS?

- More sensitized recipients
- More younger (EPTS 0-20%) recipients
- Improved longevity matching
- Higher cold ischemic times
- Fewer 0-ABDR mismatches
- More high dialysis time recipients

Delayed graft function (DGF) rates

- The percentage of recipients requiring dialysis within the first week after transplant increased from 24.3% pre-KAS to 29.5% after KAS.
- Increase driven by more high dialysis time recipients and other factors.
Graft survival at one year very similar, though slightly lower, post-KAS (93.6%) compared to pre-KAS (94.1%).

Patient survival at one year very similar, though slightly lower, post-KAS (96.2%) compared to pre-KAS (96.9%).

Problem #3: Too many discarded kidneys

Kidney Donor Trends

Long-run increasing trend in median age, BMI, and K/DR among recovered kidney donors.
Explaining the Kidney Discard Rate Trend (1999-2009)

- 5.7% rise


Kidney Discard Rate Trend

- Kidney Discard Rate: Pre (~5 years) vs. Post KAS (16 months)
  - Statistically significant rise in discard rates post KAS.
  - P-value=0.003
  - RR=1.08
  - OR=1.10

Kidney Discard Rate: Pre (~5 years) vs. Post KAS (16 months)

- Statistically significant rise for higher KDPI kidneys.
Did KAS Solve the 4 Problems?

1. Reduce longevity mismatches? Yes
2. Reduce biological (and other) inequity? Yes
3. Reduce kidney discard rate? No
4. Unified national system? Yes

What other problems remain?

- Long waiting times (not enough kidneys)
- Candidate blood type disparities
- **Geographic inequity**
- Long-term outcomes? Unknown
- Multi-organ inequity

The Final Rule – organ allocation

- Organ allocation policies and procedures shall be in accordance with sound medical judgment and shall be designed and implemented:
  - To allocate organs among transplant candidates in order of decreasing medical urgency status, with waiting time in status used to break ties within status groups.
  - Neither place of residence nor place of listing shall be a major determinant of access to a transplant.
  - Priority shall be given to reducing the waiting time variance in the most medically urgent status categories before reducing the waiting time variance in less urgent status categories, if equivalent reductions cannot be achieved in all status categories; and
  - To avoid futile transplantation, to avoid wasting organs, and to promote efficient management of organ placement.

The UNOS kidney committee has yet to tackle geographic inequity

- Huge variation in wait times, transplant rates for kidney recipients by geography

<table>
<thead>
<tr>
<th>Center</th>
<th>Volume</th>
<th>Volume</th>
<th>% txpat at 1 year</th>
<th>% txpat at 2 years</th>
<th>% txpat at 3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCSF</td>
<td>4,872</td>
<td>344</td>
<td>4.6</td>
<td>2.5%</td>
<td>4.4%</td>
</tr>
<tr>
<td>CPMC</td>
<td>1,867</td>
<td>183</td>
<td>7.4</td>
<td>6.0%</td>
<td>8.1%</td>
</tr>
<tr>
<td>UCLA</td>
<td>2,188</td>
<td>154</td>
<td>9.8</td>
<td>10.1%</td>
<td>15.1%</td>
</tr>
<tr>
<td>Ohio St.</td>
<td>627</td>
<td>265</td>
<td>24.9</td>
<td>6.5%</td>
<td>18.7%</td>
</tr>
<tr>
<td>U Wisconsin</td>
<td>950</td>
<td>297</td>
<td>18.9</td>
<td>22.0%</td>
<td>34.1%</td>
</tr>
<tr>
<td>U.S.</td>
<td>106,306</td>
<td>26,009</td>
<td>10.2%</td>
<td>16.8%</td>
<td>22.6%</td>
</tr>
</tbody>
</table>
Summary
• KAS has improved equity & longevity matching
• Impact on long term outcomes is unclear
• More work needed to improve kidney utilization
• Geographic disparities remain a significant challenge
• The UNOS kidney committee will have to work to eliminate DSA as a unit of distribution (as has the liver service in its proposals...stay tuned!!!!)

FINAL RULE – Organ allocation policy
(1) Shall be based on sound medical judgment;
(2) Shall seek to achieve the best use of donated organs;
(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with 121.7(b)(4)(d) and (e);
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(8) Shall not be based on the candidate’s place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

Recent letter from HRSA administrator

HRSA finds that geographic constraints may be appropriate if they can be justified in light of the regulatory requirements, but that DSAs and Regions have not and cannot be justified under said requirements. On this basis, the OPTN Board is directed to adopt a liver allocation policy that eliminates the use of DSAs and OPTN Regions and that is compliant with the OPTN final rule.

Given the imbalance between the livers available for transplantation and those in need of liver transplants, some transplant candidates will receive priority for organ offers and others will not, regardless of which organ allocation policy is in effect. We understand that liver allocation policy is complicated and that there is an absence of unanimity among transplant stakeholders and the public concerning the optimal methods of liver allocation. It appears that achieving consensus for a new liver allocation policy may not be possible. Such consensus is not required under the OPTN final rule and should not be a barrier to adopting a liver allocation policy that complies with the OPTN final rule.

Not just the liver.....
Geographic inequity in liver distribution

- Two competing new proposals are being modelled – SRTR will have modeling completed next week! (September 24)
- Both involve circles (distance) as the distribution areas
- One (favors local supremacy) put forward by those opposed to wider distribution
- One emphasizes sickest first, but given equal degrees of illness, favor more proximal candidates to the donor location (my proposal)
- Complex interplay between OPOs and transplant centers.

Thank you!