What’s New in Transplant?

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PRE-TRANSPLANT LEAD CLINICIAN
Learning objectives:

• Gain a surface understanding of UNOS, its history, and how it operates.
• Describe how the current allocation system works.
• Describe the major changes with the new allocation system and how they impact patients.
• Understand the KDPI and EPTS concepts.

I have no relevant financial relationships to disclose that could cause a conflict of interest.
By the Numbers…

- Nearly 3,000 new patients are added to the kidney waiting list each month.
- 12 people die each day while waiting for a life-saving kidney transplant.
- Every 14 minutes someone is added to the kidney transplant list.
- In 2013, 4,453 patients died while waiting for a kidney transplant.

As of September 8, 2014:

- There are currently 123,175 people waiting for lifesaving organ transplants in the U.S. Of these, 101,170 await kidney transplants.
- In 2013, 16,896 kidney transplants took place in the U.S. Of these, 11,163 kidney transplants came from deceased donors and 5,733 came from living donors.
Michigan residents waiting for organs

In 2013, the generosity of Michigan’s 284 organ donors resulted in 915 life-saving organ transplants.

Michigan patients waiting for a transplant as of August 1, 2014:

<table>
<thead>
<tr>
<th>Organ Type</th>
<th>Waitlist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>2,659</td>
</tr>
<tr>
<td>Liver</td>
<td>392</td>
</tr>
<tr>
<td>Lung</td>
<td>96</td>
</tr>
<tr>
<td>Heart</td>
<td>102</td>
</tr>
<tr>
<td>Kidney/Pancreas</td>
<td>45</td>
</tr>
<tr>
<td>Pancreas</td>
<td>16</td>
</tr>
<tr>
<td>Kidney/Liver</td>
<td>20</td>
</tr>
<tr>
<td>Intestine</td>
<td>1</td>
</tr>
<tr>
<td>TOTAL</td>
<td>3,341</td>
</tr>
</tbody>
</table>
United Network for Organ Sharing
Coordinates the nation’s organ transplanting system.

1977
SEOPF opens the “Kidney Center”: staffed around the clock; used a computerized system to house medical information and match organs regionally with potential recipients.

1982
1984
1986
“Kidney Center” evolves into UNOS to meet transplant needs nationwide.
Congress passes the National Organ Transplant Act.
UNOS is awarded the first Organ Procurement and Transplant Network (OPTN) contract by the Dept of Health and Human Services.

500,000 organs transplanted and counting
(20 million people in the US currently have some level of CKD)

1 UNOS Facts and Figures, 2013
2 Centers for Disease Control
The 42 board members are the policy makers, but all proposed policy changes, like that of the new Kidney Allocation System, are made available for public comment.

Once approved by the UNOS board, policies are then subject to review by the Department of Health and Human services.

UNOS has divided the country into regions, each of which has an administrative center and is represented by members of the board. The regions are also used in organ allocation.
What’s New?

The Kidney Allocation System (KAS)

The distribution of donor kidneys to recipients.
Waiting Time
- 1 point for every year of waiting, with fractions of a point given to each candidate in order.
- Longest wait = 1 additional point.

HLA Match
- Matches in the DR loci only are awarded points.
- 1 point per DR loci match (maximum of 2 points).

Sensitization (pre-formed antibodies)
- cPRAs > 80% = 4 points

Prior Donation
- 4 points
Current System

Kidney Becomes Available

Match run looks nationally for a perfect match.

Local candidates ordered according to number of points awarded.

Regional candidates ordered according to number of points awarded.

National candidates ordered according to number of points awarded.

Kidney cold time increasing.
2003: Began work to identify the limitations of the current system.
History of the New System:

2003: Began work to identify the limitations of the current system.

2007: First public forum to discuss limitations and seek public comment.
Limitations of Current System

- Waiting time has become the dominant factor in allocation.
- Higher than necessary discard rates of kidneys that could benefit patients on the waiting list.
- Variability of access to transplantation by candidate blood group and geographic location.
- Does not strive to improve post transplant outcomes or reduce mortality while on the waiting list.
- Kidney longevity and patient longevity are not considered resulting in unrealized graft years and causing the need for re-transplantation.

The Kidney Allocation System Friedewald et al. 2013
History of the New System:

2003: Began work to identify the limitations of the current system.

2007: First public forum to discuss limitations identified and seek public comment.

2009: Second public forum: discuss possible solutions to the problems with the current system, including using donor/recipient age matching as a possibility.
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2011: Age matching no longer considered.
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2011: Age matching no longer considered.

2013: OPTN Board of Directors approves the revised kidney allocation policy.

December 4, 2014: all aspects of the new allocation system go into effect.
Goals and Resulting Changes

Goals

1. Reduce differences in transplant access for racial/ethnic minority groups and sensitized candidates.
2. More accurately estimate graft and recipient longevity.
3. Promote post-transplant kidney function to reduce the need for re-transplantation.
4. Improve kidney offer system through the introduction of a new scale for kidney quality.

Change

1. Priority for sensitized candidates; eligible type B candidates can receive kidneys from eligible type A_{2} and A_{2}B donors.
2. Candidate classification using EPTS score which attempts to predict how long a candidate will survive post transplant.
3. Donor classification using KDPI score which attempts to predict how long a deceased donor kidney is expected to function.
Projected results

- >8000 additional life years annually
- Slight increase in transplants to African Americans, blood type B, and high PRA recipients
- Changes in age distribution
Let’s Dive Into the Details...
Major Changes

- Waiting time calculation from first day of dialysis.
Major Changes

- Waiting time calculation from first day of dialysis.
- Priority for sensitized candidates.
Candidates become sensitized when their immune system is exposed to, and mounts a response to, foreign tissue.

- Pregnancies
- Blood transfusions
- Prior transplants
• The immune response leaves behind antibodies that continue to circulate.

• When a corresponding antigen is introduced via a transplanted kidney, the pre-formed antibody binds to it and causes the immune cascade.

• This is what causes antibody mediated rejection.
• The antigens that a candidate is sensitized to are called “unacceptable antigens”.

• If the list of unacceptable antigens is long, it may be very difficult to find a kidney that the candidate will not reject.
Priority for Sensitized Candidates

• Every candidate is tested for preformed antibodies. Based on the number and commonality of the antibodies they possess, they are given a cPRA (calculated panel reactive antibody) score.

• Score is a percentage of donors in the general population that the candidate would reject immunologically.

• Candidates are given increasing points and, therefore, priority to donor kidneys as their cPRA score increases.
Current System = Point System

Waiting Time

- 1 point for every year of waiting, with fractions of a point given to each candidate in order.
- Longest wait = 1 additional point.

HLA Match

- Matches in the DR loci only are awarded points.
- 1 point per DR loci match (maximum of 2 points).

Sensitization (pre-formed antibodies)

- cPRAs > 80% = 4 points

Prior Donation

- 4 points

UNOS Policy 3.5
The previous allocation system assigned a maximum of 4 points for candidates with elevated cPRAs.

<table>
<thead>
<tr>
<th>If the candidate’s CPRA score is:</th>
<th>Then the candidate receives this many points:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>1-9</td>
<td>0.00</td>
</tr>
<tr>
<td>10-19</td>
<td>0.00</td>
</tr>
<tr>
<td>20-29</td>
<td>0.08</td>
</tr>
<tr>
<td>30-39</td>
<td>0.21</td>
</tr>
<tr>
<td>40-49</td>
<td>0.34</td>
</tr>
<tr>
<td>50-59</td>
<td>0.48</td>
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<tr>
<td>60-69</td>
<td>0.81</td>
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<tr>
<td>70-74</td>
<td>1.09</td>
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<td>75-79</td>
<td>1.58</td>
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<td>80-84</td>
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<tr>
<td>85-89</td>
<td>4.05</td>
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<td>90-94</td>
<td>6.71</td>
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<td>95</td>
<td>10.82</td>
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<td>96</td>
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<td>97</td>
<td>17.30</td>
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<td>98</td>
<td>24.40</td>
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<tr>
<td>99</td>
<td>50.09</td>
</tr>
<tr>
<td>100</td>
<td>202.10</td>
</tr>
</tbody>
</table>
Results: Kidney Transplants by Recipient CPRA

Percentages of wait-list candidates, actual recipients in 2010, and recipients in simulations of the current kidney allocation policy, and the new policy by cPRA.
Major Changes

- Waiting time calculation from first day of dialysis.
- Priority for sensitized candidates.
- Eligible type B candidates can receive kidneys from eligible type A\textsubscript{2} and A\textsubscript{2}B donors.
A\textsubscript{2} and A\textsubscript{2}B donate to B

- All blood type A and blood type AB donors will be typed to determine if they are part of the A\textsubscript{2} or A\textsubscript{2}B subgroup.

- The new system will give first priority for these donor kidneys for type B candidates.

- Transplant centers must have a protocol in place if they intend to perform cross blood group transplants.

- B blood group candidates must consent to taking on the higher risk that accompanies cross blood group transplants.
Major Changes

- Waiting time calculation from first day of dialysis.
- Priority for sensitized candidates.
- Eligible type B candidates can receive kidneys from eligible type A₂ and A₂B donors.
- Candidate classification using EPTS score. This score attempts to predict how long a candidate will survive post transplant.
All candidates will be given an EPTS score. “Low is good.” Scores are based on the following and are scaled 0-100%:

- Age.
- Diabetes status.
- Prior transplants.
- Time on dialysis.

EPTS calculator:
Date of birth: 10/23/1944   OR Age: 69.9055 years

On chronic maintenance dialysis?   ☑ Yes   ☐ No

Current diabetes status: ☑ Does Not Have Diabetes

Number of previous solid organ transplants: 0

Note: Number of previous solid organ transplants includes all transplants inside and outside the U.S. Solid organ transplants include kidney, pancreas, liver, heart, lung, and intestine.

Calculate EPTS as of this date: 09/19/2014

A future date can be entered to simulate a candidate's EPTS progression over time.
Diabetes Status

40 y/o (7%) with DM Type I or II EPTS increases to 23%

70 y/o (55%) with DM Type I or II EPTS increases to 70%
40 y/o (7%) with one or many prior transplants, EPTS increases to 15%

70 y/o (55%) with one or many prior transplants, EPTS increases to 79%
Time on Dialysis

40 y/o (7%) with one year on dialysis, EPTS increases to 8%

40 y/o (7%) with 5 years on dialysis, EPTS increases to 15%
70 y/o (55%) with one year on dialysis, EPTS increases to 60%

70 y/o (55%) with five years on dialysis, EPTS increases to 81%
Which Variable Can You Control?

AGE

Early referral is paramount.
Major Changes

- Waiting time calculation from first day of dialysis.
- Priority for sensitized candidates.
- Eligible type B candidates can receive kidneys from eligible type A\textsubscript{2} and A\textsubscript{2}B donors.
- Candidate classification using EPTS score. This score attempts to predict how long a candidate will survive post transplant.

- Donor classification using KDPI score. This score attempts to predict how long a deceased donor kidney is expected to function.
All donors will be given a KDPI score. Scores are based on the following criteria:

- Age
- Cause of Death
- Height
- Serum Creatinine
- Weight
- HCV Status
- Ethnicity
- DCD status
- History of diabetes
- History of Hypertension

KDPI calculator:
The KDPI is a score based on the quality of all kidneys recovered in the previous calendar year.

- Scale: 0-100%
- Low is good.

- A donated kidney with a KDPI of 80% has higher expected risk of graft failure than 80% of all kidneys recovered last year.

- A donated kidney with a KDPI of 80% would be expected to last longer than 20% of all kidneys recovered last year.
KDPIs are matched with candidates with a corresponding EPTS.

- **KDPI Score 0-20%**
  - EPTS: 0 - 20%

- **KDPI Score 21-85%**
  - EPTS: 21% and up

- **KDPI Score > 85%**
  - Opt in
Goal:

- Identify the top 20% of kidneys and offer them first to the top 20% of candidates.
50 y/o, on HD x 1 year, no diabetes, no prior transplant; EPTS = 19%

25 y/o, on HD x 1 year, Type II DM, no prior transplants; EPTS = 20%
KDPI Score: 0-20%

Young, previously healthy donor; normal - low creatinine; accidental/traumatic cause of death.

EPTS: 0 - 20%

Candidates < 50 y/o; maybe on dialysis for short time; maybe one other positive variable.
<table>
<thead>
<tr>
<th>Age</th>
<th>Dialysis Status</th>
<th>Diabetes Status</th>
<th>Previous Transplants</th>
<th>EPTS Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 y/o</td>
<td>No</td>
<td>Type I or II</td>
<td>No</td>
<td>23%</td>
</tr>
<tr>
<td>70 y/o</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>60%</td>
</tr>
</tbody>
</table>
KDPI Score 21-85%

EPTS: 21% and up

Middle age, maybe history of DM or HTN; normal – low creatinine; probably accidental/traumatic cause of death.

Young candidates with diabetes; on dialysis; maybe previous transplant.

Older candidates; with or without diabetes; maybe on dialysis; maybe previous transplant.
KDPI Score >85%

Opt in

Previous “ECD” designation:
- All donors age 60 and up.
- Donors age 50-59 to which 2 of 3 apply:
  1). Cause of death = stroke,
  2). History of HTN,
  3). Creatinine of 1.5 or greater at time of procurement.

Any candidate who consents to the higher risk.
Don’t Forget...

- Candidates with elevated cPRAs get sliding scale priority within their EPTS score group.

- Any type A₂ or A₂B donor is first offered to consented type B candidates within their EPTS score group.

- Donor location determines geographic allocation.
Let’s Put It All Together

Kidney Becomes Available

KDPI less than 20%
- Allocated to candidate whose EPTS is 20% or less in the following order:
  - 100% PRA local, regional, national
  - 99% PRA local, regional, national
  - 98% PRA local, regional, national
  - 0 MM
  - Previous organ donor
  - Candidates ordered using previous point system local, regional, national.

KDPI 21-85%
- Allocated to candidates whose EPTS is 21-85% in the following order:

KDPI greater than 85%
- Allocated to any candidate who has consented to receive from this subset of donors in the following order:
Let's Put It All Together

<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>Pediatric Patients Only</td>
<td>KDPI 21-85%</td>
<td>KDPI &gt;85%</td>
</tr>
<tr>
<td>Local CPRA 100</td>
<td></td>
<td>Local CPRA 100</td>
<td>Local CPRA 100</td>
</tr>
<tr>
<td>Regional CPRA 100</td>
<td></td>
<td>Regional CPRA 100</td>
<td>Regional CPRA 100</td>
</tr>
<tr>
<td>National CPRA 100</td>
<td></td>
<td>National CPRA 100</td>
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<tr>
<td>Local CPRA 99</td>
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<td>Local CPRA 99</td>
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<tr>
<td>Regional CPRA 99</td>
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<td>Regional CPRA 99</td>
<td>Regional CPRA 99</td>
</tr>
<tr>
<td>Local CPRA 98</td>
<td></td>
<td>Local CPRA 98</td>
<td>Local CPRA 98</td>
</tr>
<tr>
<td>Zero mismatch (top 20% EPTS)</td>
<td></td>
<td>Zero mismatch</td>
<td>Zero mismatch</td>
</tr>
<tr>
<td>Prior living organ donor</td>
<td></td>
<td>Prior living organ donor</td>
<td>Local</td>
</tr>
<tr>
<td>Local pediatrics</td>
<td></td>
<td>Local</td>
<td>Regional</td>
</tr>
<tr>
<td>Local top 20% EPTS</td>
<td></td>
<td>regional</td>
<td>National</td>
</tr>
<tr>
<td>Zero mismatch (all)</td>
<td></td>
<td>National pediatrics</td>
<td><em>all categories in Sequence D are limited to adult candidates</em></td>
</tr>
<tr>
<td>Local (all)</td>
<td></td>
<td>Regional (top 20%)</td>
<td></td>
</tr>
<tr>
<td>Regional pediatrics</td>
<td></td>
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<td></td>
</tr>
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<td></td>
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<td></td>
</tr>
<tr>
<td>National (all)</td>
<td></td>
<td>National (all)</td>
<td></td>
</tr>
</tbody>
</table>

New Kidney Allocation Policy and What it Means for Your Transplant Center and Your Patients, Wiseman, 2013
Case Scenario #1:

Donor A:

Candidate A: EPTS 15%; local candidate; cPRAs = 30%

Candidate B: EPTS 25%; local candidate; cPRAs = 30%

Candidate C: EPTS 8%; regional candidate; cPRAs = 100%

Candidate D: EPTS 30%; local candidate; cPRAs = 60%
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- EPTS 8%; regional candidate; cPRAs = 100%

Candidate D:
- EPTS 30%; local candidate; cPRAs = 60%
Case Scenario #1:

Donor A:

- **Age:** 25 years
- **Height:** 6 ft 0 in 182.88 cm
- **Weight:** 200 lbs 90.7185 kg
- **Ethnicity/race:** White
- **History of hypertension:** NO
- **History of diabetes:** NO
- **Cause of death:** HEAD TRAUMA
- **Serum Creatinine:** 0.9 mg/dl
- **Anti-HCV:** Negative
- **Donor meets DCD criteria:** NO

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- Candidate D: EPTS 30%; local candidate; cPRAs = 60%
Case Scenario #2:

Donor B:

Candidate A:
- EPTS 36%; cPRAs = 30%;
- local candidate

Candidate B:
- EPTS 25%; cPRAs = 0%;
- 0MM; national candidate

Candidate C:
- EPTS 75%; cPRAs = 60%;
- regional candidate

Candidate D:
- EPTS 30%; cPRAs = 100%;
- national candidate;
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Candidate A:
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Donor B:

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Candidate B: EPTS 25%; cPRAs = 0%; 0MM; national candidate

Candidate C: EPTS 75%; cPRAs = 60%; regional candidate

Candidate D: EPTS 30%; cPRAs = 100%; national candidate;
Case Scenario #3:

Donor C:

Candidate A:
EPTS 62%; cPRAs = 0%; local candidate; consented to KDPI > 85%

Candidate B:
EPTS 25%; cPRAs = 30%; local candidate; not consented to KDPI > 85%

Candidate C:
EPTS 8%; cPRAs = 100%; local candidate; not consented to KDPI > 85%

Candidate D:
EPTS 30%; cPRAs = 60%; regional candidate; consented to KDPI > 85%
Case Scenario #3:

Donor C:

Candidate A:
- EPTS 62%; cPRAs = 0%; local candidate; consented to KDPI > 85%

Candidate B:
- EPTS 25%; cPRAs = 30%; local candidate; not consented to KDPI > 85%

Candidate C:
- EPTS 8%; cPRAs = 100%; local candidate; not consented to KDPI > 85%

Candidate D:
- EPTS 30%; cPRAs = 60%; regional candidate; consented to KDPI > 85%