New Kidney Allocation System

An update on new UNOS kidney program
Fresenius Medical Care Regional Office
August 7, 2014
- Jim Gleason, UNOS Board Member
  & Alden Doyle, M.D., M.S., M.P.H
An 11-year-old's wish to give the gift of life to others came true on the last day of his life. The photograph above shows doctors bowing to Liang Yaoyi, a gifted student from Shenzhen, China, who died from a brain tumor in June. His mother can be seen crying in the background.
United Network for Organ Sharing (UNOS) is the private, non-profit organization that manages the nation's organ transplant system under contract with the federal government.

UNOS is involved in:

- Managing the national transplant waiting list, matching donors to recipients 24 hours a day, 365 days a year.
- Maintaining the database that contains all organ transplant data for every transplant event that occurs in the U.S.
- Bringing together members to develop policies that make the best use of the limited supply of organs and give all patients a fair chance at receiving the organ they need, regardless of age, sex, ethnicity, religion, lifestyle or financial/social status.
- Monitoring every organ match to ensure organ allocation policies are followed.
- Providing assistance to patients, family members and friends.
- Educating transplant professionals about their important role in the donation and transplant processes.
- Educating the public about the importance of organ donation.
UNOS.ORG
KAS UNOS Introduction Video

- Why are changes to the kidney allocation system needed?
- What are the goals of the new system?
- What should providers expect from UNOS with regard to preparing for the new system?
- What is the biggest change the average patient will experience?
- What is the biggest change that will be experienced by a transplant program?

Overall Goals of the New Kidney Allocation System (KAS)

- Primary goal: to make the system better without making major changes to the parts of the current system that work well.

- To help more people have longer function with their transplanted kidney.
  - Result: fewer need repeat transplants = more get transplants who need them.

- To shorten the waiting time for some groups who often wait a very long time because they are hard to match with most kidneys (due to blood type or immune response).
“What will change? What stays the same?”

- Many will not see any major change . . .
  - Time spent waiting is still a major factor in matching
  - No lost credit for any time already spent waiting
- What some may see . . .
  - If dialysis began before being listed for transplant, transplant waiting time will be backdated to their first dialysis date
  - Those expected to need a kidney for the longest time will be matched more often with kidneys that have the longest expected function
- SCD and ECD donor kidney classifications go away
- KDPI donor score and EPTS patient score are new factors that become integral to the new allocation process
Classification of Deceased Donor Kidneys:

**Kidney Donor Profile Index (KDPI)**

- The Kidney Donor Profile Index (KDPI) is an integral component of the new kidney allocation system scheduled to be implemented in December 2014.
- The Kidney Donor Profile Index (KDPI) is a single number that summarizes the likelihood of graft failure after deceased donor kidney transplant.
- KDPI scores range from 0% to 100% with lower scores describing a kidney with longer projected longevity relative to other donor kidneys.
Kidney Donor Profile Index (KDPI)

- Lower KDPI scores are associated with longer estimated function, while higher KDPI scores are associated with shorter estimated function.
- For example, a kidney with a KDPI of 20% is expected to have shorter longevity than 20% of recovered kidneys (i.e., longer function than 80% of recovered kidneys).
- A donor with a KDPI of 80% has higher expected risk of *graft failure* than 80% of all kidney donors recovered last year.
- A kidney with a KDPI greater than 85% will be offered first to a wider area of the country than other kidneys (thus encouraging use of these kidneys by finding a suitable patient as quickly as possible).
Kidney Donor Profile Index (KDPI)

• The Kidney Donor Profile Index (KDPI) calculator summarizes the risk of graft failure after kidney transplant.

• KDPI is a % score that ranges from 0% to 100%

• KDPI combines 10 factors (next slide) about the donor’s medical history and lab values to determine how long a kidney is likely to function once transplanted.
“What goes into a KDPI score?”

- KDPI is calculated based on facts about the donor that affect how long the kidney is likely to function . . .
  - Age
  - Height
  - Weight
  - Ethnicity
  - Cause of death: loss of heart function or brain function
  - Stroke as cause of death
  - History of high blood pressure
  - History of diabetes
  - Exposure to the hepatitis C virus (HCV)
  - Serum creatinine (a measure of kidney function)

PGA TOUR golfer and two-time heart transplant recipient Erik Compton
KDPI Calculator Factors
(...taken from the donor)

Age: [ ] years
DOB: [ ]

Height: [ ] ft [ ] in

Weight: [ ] lbs [ ] kg

DOB: [ ] cm

Ethnicity/race:

History of hypertension:

History of diabetes:

Cause of death:

Serum Creatinine: [ ] mg/dl

Anti-HCV:

Donor meets DCD criteria:

Note: Click above to link to on-line KDPI calculator
Difference in expected longevity between low, medium, and high KDPI

[Diagram showing estimated graft half lives (years) for different KDPI ranges]

i.e. a deceased donor kidney with KDPI of 0-20% is expected to function, on average, nearly 11 and a half years after transplant, compared to over 12 years for a living donor kidney. The majority (65%) of deceased donor kidneys have KDPI between 21 and 85% and are expected to function for about 9 years. Kidneys with KDPI exceeding 85% are expected to function for more than five and a half years.
Kidney Donor Profile Index (KDPI)

- Historically, the kidney allocation system has used two designations to describe kidneys...
  - Kidney from a standard criteria donor (SCD) or
  - Kidney from an expanded criteria donor (ECD) (higher risk)

  ...It turns out there are wide variations of expected kidney function within these two broad categories. SCD and ECD as categories will go away under the new allocation system.

- KDPI provides more granularity in how each kidney is expected to function relative to other available kidneys.

- KDPI is intended to be used as one element in evaluation of the kidney along with other donor characteristics (not as the only metric for determining donor suitability)

- Candidates need to consent to receive kidneys with KDPI over 85% (i.e. Lower expected longevity, expanding opportunities = shorter wait time)
Classification of Candidates: Estimated Post-Transplant Survival (EPTS)

- The individual Estimated Post-Transplant Survival (EPTS) score is associated with how long the candidate will need a functioning kidney transplant compared with other candidates.

- An Estimated Post-Transplant Survival (EPTS) score is assigned to all wait listed adult candidates.

- The Estimated Post-Transplant Survival (EPTS) score is a single number that ranges from 0% to 100% with lower scores describing a patient needing a kidney the longest.
Classification of Candidates: Estimated Post-Transplant Survival (EPTS)

- Candidates with longer estimated post-transplant longevity (EPTS of 20% or less) will receive priority for kidneys from donors expected to last the longest (KDPI of 20% or less).
- If a kidney with a KDPI of 20% or less is not accepted above, it will then be offered to any other person who will match regardless of their EPTS score.
- The EPTS score is not used in allocation of kidneys from donors with KDPI scores greater than 20%.
- Other candidates follow the non-prioritized allocation process (time waiting, geography, etc.)
Estimated Post-Transplant Survival (EPTS)

- Factors included in the EPTS formula are . . .
  - the candidate’s age in years
  - duration on dialysis in years
  - current diagnosis of diabetes
  - whether the candidate has had a prior solid organ transplant
Estimated Post-Transplant Survival (EPTS)

Date of birth: [ ] OR Age: [ ] years

On chronic maintenance dialysis? [ ] Yes [ ] No

Current diabetes status: [ ]

Number of previous solid organ transplants: [ ]

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: [ ]

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

EPTS calculator:
Estimated Post-Transplant Survival (EPTS)

(EPTS calculation for Jim)

**Attention:** The EPTS % may change on a daily basis due to age and time on dialysis.

<table>
<thead>
<tr>
<th>Date of birth:</th>
<th>OR Age: 71 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>On chronic maintenance dialysis?</td>
<td>Yes</td>
</tr>
<tr>
<td>Current diabetes status:</td>
<td>Type II Diabetes</td>
</tr>
<tr>
<td>Number of previous solid organ transplants:</td>
<td>1</td>
</tr>
</tbody>
</table>

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: 08/05/2014

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

Result: Jim's EPTS calculates as 81%
Other considerations

- **Children & teen matching** (younger than 18)
  - Will have priority for the 35% of kidneys that are likely to function the longest (KDPI scores of 35% or lower)

- **Hard to match patients** (uncommon blood types or “highly sensitized” immune systems that would reject most kidneys)
  - First priority for blood type B patients (rarest type)
  - First priority to very highly sensitized (98% or above)
“Will my waiting time calculation change?”

- If listed for a transplant at the time the patient...
  - Began dialysis, or
  - Met a medical definition of kidney failure (creatinine clearance below 20 ml/min)
  
  ... waiting time will not change under the revised policy

- If began dialysis before listing for transplant, waiting time will now be calculated from dialysis start date

- If listed for transplant before starting dialysis, can be matched for deceased donor kidneys based on medical matching criteria (no added priority for waiting time until either starting dialysis or have kidney failure)
In summary . . .

- New KAS is carefully designed to help those who need more access to kidney offers without significantly affecting the needs of others.
- Those with longest potential need for a transplant, and those who have been hard to match under current system, will get priority in the new system.
- Since these make up a fairly small proportion of everyone needing a kidney, the effect on the majority should not be very large.
- New system should provide more transplant opportunities, so everyone has a better chance to be transplanted.
- These changes are expected to result in more than 8,000 total extra years of life, among all patients receiving a kidney in a given year.
- UNOS will continue to study the system closely to make sure it performs as expected, addressing any issues where the policy is not meeting needs, or if other issues arise.
Living kidney donation

- Types of living kidney donation . . .
  - **Directed donation**: the donor names the specific person to receive the transplant, typically . . .
    - A biological relative (parent, brother, sister or adult child)
    - A biologically unrelated person with a person or social connection with the transplant candidate (spouse, significant other, friend, co-worker)
    - A biologically unrelated person who has heard about the transplant candidate’s need
  - **Non-directed or altruistic donation**: the donor does not name the specific person to get the transplant (whom they may or may not ever meet)
Living kidney donation

Transplants by Donor Type - All Organs
January 1, 1988 - October 31, 2012
Based on OPTN data as of January 25, 2013

<table>
<thead>
<tr>
<th>Year</th>
<th>Deceased Donor Transplants</th>
<th>Living Donor Transplants</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>21,850</td>
<td>6,609</td>
</tr>
<tr>
<td>2010</td>
<td>22,101</td>
<td>6,560</td>
</tr>
<tr>
<td>2011</td>
<td>22,518</td>
<td>6,019</td>
</tr>
<tr>
<td>2012</td>
<td>20,419</td>
<td>5,366</td>
</tr>
<tr>
<td>Totals</td>
<td>86,888</td>
<td>24,554</td>
</tr>
</tbody>
</table>

Bar chart showing the comparison between deceased and living donor transplants from 2009 to 2012.
KPD: Kidney Paired Donation

A paired kidney exchange, also known as a “kidney swap” occurs when a living kidney donor is incompatible with the recipient, and so exchanges kidneys with another donor/recipient pair.

Experts anticipate that, each year, an additional 1,000 – 2,000 donations can be performed through this national KPD program.

This kidney paired donation transplant enables two incompatible recipients to receive healthy, more compatible kidneys. All medically eligible donor/recipient pairs may participate in the paired kidney exchange program.
Kidney Paired Donation (KPD) is a transplant option for candidates who have a living donor who is medically able, but cannot donate a kidney to their intended candidate because they are incompatible (i.e., poorly matched).

The Kidney Paired Donation Pilot Program

The KPD Pilot Program is part of the Organ Procurement and Transplantation Network (OPTN). The OPTN is managed by the United Network for Organ Sharing (UNOS) through a contract with the Health Resources and Services Administration (HRSA).

Vision: Every kidney transplant candidate with an incompatible but willing and approved living donor receives a living donor kidney.
Local KPD Participating Programs

<table>
<thead>
<tr>
<th>Transplant Centers Participating in the OPTN Kidney Paired Donation Pilot Program (KPDPP) as of June 19, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PENNSYLVANIA</strong></td>
</tr>
<tr>
<td>Allentown, PA</td>
</tr>
<tr>
<td>Harrisburg, PA</td>
</tr>
<tr>
<td>Philadelphia, PA</td>
</tr>
<tr>
<td>Children's Hospital of Philadelphia</td>
</tr>
<tr>
<td>Hahnemann University Hospital</td>
</tr>
<tr>
<td>Hospital of the University of Pennsylvania</td>
</tr>
<tr>
<td>Temple University Hospital</td>
</tr>
<tr>
<td>Thomas Jefferson University Hospital</td>
</tr>
<tr>
<td>Pittsburgh, PA</td>
</tr>
<tr>
<td>Wynnewood, PA</td>
</tr>
</tbody>
</table>

...And in NJ, Lourdes in Camden; in DE, DuPont for Children
Transplant history

Transplants By Organ - January 1, 1988 - October 31, 2012
Based on OPTN data as of January 25, 2013

<table>
<thead>
<tr>
<th>Organ</th>
<th>Transplants</th>
</tr>
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<tbody>
<tr>
<td>Heart</td>
<td>54,309</td>
</tr>
<tr>
<td>Heart / Lung</td>
<td>1,119</td>
</tr>
<tr>
<td>Intestine</td>
<td>2,260</td>
</tr>
<tr>
<td>Kidney</td>
<td>333,046</td>
</tr>
<tr>
<td>Kidney / Pancreas</td>
<td>19,069</td>
</tr>
<tr>
<td>Liver</td>
<td>119,189</td>
</tr>
<tr>
<td>Lung</td>
<td>24,988</td>
</tr>
<tr>
<td>Pancreas</td>
<td>7,385</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>561,365</strong></td>
</tr>
</tbody>
</table>

- Heart: 59.3%
- Heart / Lung: 2.1%
- Intestine: 0.4%
- Kidney: 59.3%
- Kidney / Pancreas: 3.5%
- Liver: 21.2%
- Lung: 4.7%
- Pancreas: 1.3%
The waiting list today:

Waiting for a kidney: 101,076 (82%)
Waiting list candidates by age - Kidney

<table>
<thead>
<tr>
<th>Age</th>
<th>Candidates</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 Year</td>
<td>2</td>
</tr>
<tr>
<td>1-5 Years</td>
<td>178</td>
</tr>
<tr>
<td>6-10 Years</td>
<td>157</td>
</tr>
<tr>
<td>11-17 Years</td>
<td>495</td>
</tr>
<tr>
<td>18-34 Years</td>
<td>9,223</td>
</tr>
<tr>
<td>35-49 Years</td>
<td>24,690</td>
</tr>
<tr>
<td>50-64 Years</td>
<td>41,178</td>
</tr>
<tr>
<td>65 +</td>
<td>19,322</td>
</tr>
<tr>
<td>Total</td>
<td>95,240</td>
</tr>
</tbody>
</table>

Waiting List Candidates by Age - Kidney
Based on OPTN data as of January 25, 2013

- 1-5 Years: 20.3%
- 6-10 Years: 9.7%
- 11-17 Years: 25.9%
- 18-34 Years: 43.2%
- 35-49 Years: 43.2%
- 50-64 Years: 43.2%
- 65 +: 43.2%
- Other: 43.2%
On the phone: Dr. Alden Doyle

- Medical Director, Kidney and Pancreas Transplant Program, Hahnemann University Hospital
- Associate Professor of Medicine, Drexel University College of Medicine
- Member, OPTN/UNOS Operations and Safety Committee
For your questions later . . .

For more information:

OPTN web site - http://optn.transplant.hrsa.gov/

Transplant Pro* - http://transplantpro.org/

Transplant Pro is a service of United Network for Organ Sharing and is not produced under the OPTN contract.

my free book: A Gift from the Heart is available on-line at . . .
http://GleasonJim.wordpress.com

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“Are you a registered organ donor?”