Updates in Kidney and Liver Allocation Algorithms

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The Revised Kidney Allocation System

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Allocation Component Changes

Waiting time calculation	• Pre-registration dialysis time added
Candidate classification	• Estimated Post Transplant Survival Score (EPTS)
Kidney donor classification	• Replace SCD/ECD with Kidney Donor Profile Index (KDPI)

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Allocation Component Changes

Priority for sensitized candidates	• Calculated panel reactive antibody (CPRA) sliding scale, regional/national sharing for CPRA greater than 98%
Blood type eligibility	• A_2 and A_2B to B compatible
Pediatric kidney allocation	• KDPI priority

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Sequence A KDPI <=20%	Sequence B KDPI >20% but <35%	Sequence C KDPI >=35% but <=85%	Sequence D KDPI>85%
Highly Sensitized 0-ABDRmm (top 20% EPTS) Prior living donor 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)	Highly Sensitized 0-ABDRmm Prior living donor Local pediatrics Local adults Regional pediatrics Regional adults National pediatrics National adults	Highly Sensitized 0-ABDRmm Prior living donor Local Regional National	Highly Sensitized 0-ABDRmm Local + Regional National

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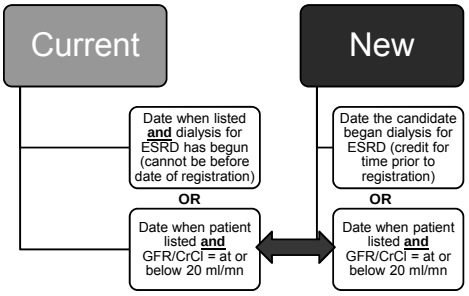
Waiting Time Points



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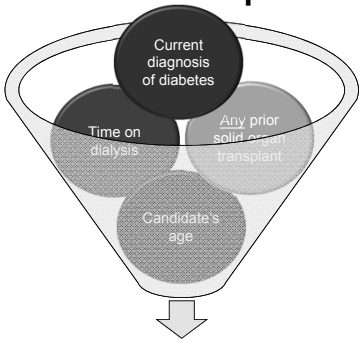
Estimated Post Transplant Survival



EPTS score range 0%-100%

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EPTS Groupings

EPTS score used to identify two groups of patients*
Those with scores of 0-20%
Those with scores of 21-100%

*The top 20% EPTS is calculated based on the national pool of candidates.

A missing EPTS score will be grouped with 21-100%

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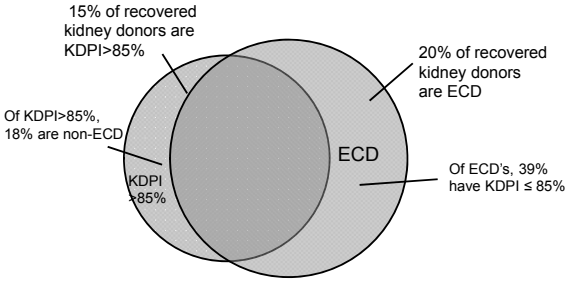

Based on deceased kidney donors recovered for tx in 2013

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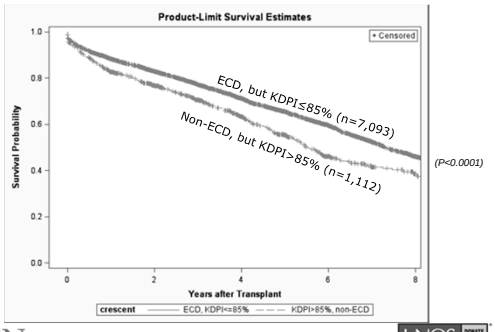
Kaplan-Meier Graft Survival Estimates for First-time, Adult, Solitary Kidney Transplants (Jan 2004 - Dec 2012)



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Kidney Donor Profile Index

Classified by KDPI based on:
Donor age
Height
Weight
Ethnicity
History of hypertension
History of diabetes
Cause of death
Serum creatinine
Hepatitis C virus status
Donation after circulatory death

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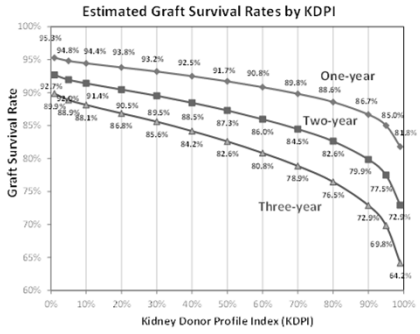

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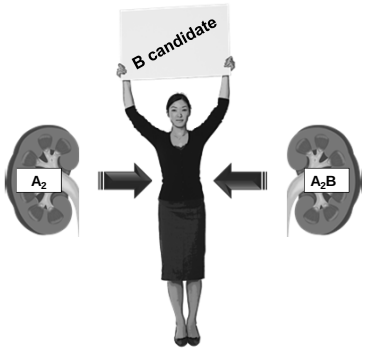
Blood Type B Eligibility



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Change– Paybacks eliminated

Current	New
Requires an OPO that receives a kidney from another OPO for 0-ABDR or combined organ transplant to payback the kidney.	All payback credits and debts are eliminated.

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Change– Variances eliminated

Current	New
Numerous variances exist in the system	All variances will be eliminated

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Prior Living Organ Donors

4 points with **every** registration

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Questions?

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Redesigning Liver Distribution to Decrease Variation in Access to Liver Transplantation

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OPTN/UNOS Liver & Intestinal Committee

Comprised of members of the transplant and donation community including but not limited to:

- Surgeons & Physicians
- Organ Procurement Organization Representatives

Charged with making **evidence-based**

proposals & policy

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Allocation & Distribution in Liver Transplantation

- **Allocation:** a ranking component for ordering candidates according to medical urgency, prioritizes candidates most in need
- **Distribution:** separate component for sub-setting the national list into geographic subunits within which candidates are ranked for each liver, how donor livers are offered to the prioritized list of candidates

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The Current System

Liver allocation has been based on the model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) scores since 2002.

The MELD/PELD score is calculated using laboratory values for INR, Bilirubin and Creatinine

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MELD/PELD

This system prioritizes candidates based on the risk of death while awaiting liver transplantation.

The HIGHER the MELD score the sicker the person and the higher the probability of death.

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Current Methods of Distribution

Livers are **allocated** to the sickest patients first and **distributed**:

- Locally
- Regionally
- Nationally

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Challenges Liver Candidates Face

- Despite improvements in liver allocation and distribution, waitlist mortality remains high for patients with higher MELD scores
- Significant disparity exists between OPOs and regions with regard to mean MELD at transplant and waitlist mortality
- **How can we direct livers to those people most in need?**

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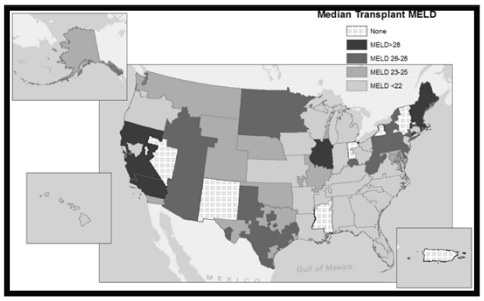
Existing Geographic Disparities



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Variation in Death Rates by DSA, 2011

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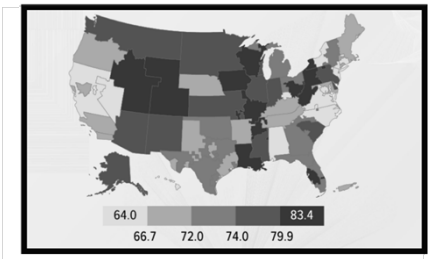
Variation in Donation Rates by DSA

Overall donation rates per 100 eligible deaths by DSA



SRTR,2011

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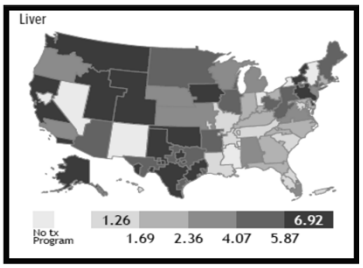
Variation in liver transplant wait time by DSA (months from listing)



SRTR, 2012

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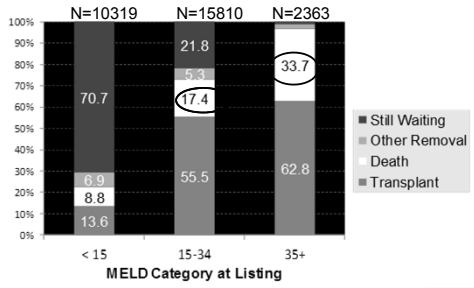
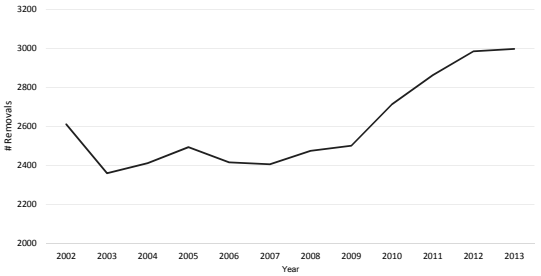
Liver Waiting List Outcome Probabilities at 1 Year: Candidates Added 2007-2010



OPTN *Status 1A/1B, and candidates with exceptions excluded

Removals From the Liver Waiting List for Died or Too Sick, 2002-2013



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Final Rule:

"Neither place of residence nor place of listing shall be a major determinant of access to a transplant."

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November 2012 OPTN Board Resolution

- The existing geographic disparity in allocation of organs for transplant is unacceptably high
- The Board directs the organ-specific committees to define the measurement of fairness and any constraints for each organ system.
- The Board requests that optimized systems utilizing overlapping v. non-overlapping geographic boundaries be compared

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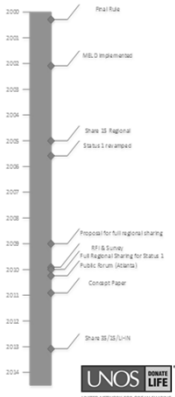
Previous Policy Change

•Status 1 Local/Regional Sharing, 1999
•MELD/PELD, 2002
•Share 15, 2005
•Status 1A/Status 1B better defined, 2005
•Status 1 Sharing Full Regional Sharing, 2010
•Share 35 Regional, Share 15 National, LI-IN National Share (June 2012)



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Alternate Concepts Considered Along the Way

- Full regional sharing (no local tier) using the current regions
- Concentric circles of 500 miles
- Full national sharing

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Redistricting as a Potential Solution

Full "district" sharing (no local tier) with DSAs grouped into optimized areas of 4, 5, 6, 7, 8 and 11 districts were modeled.

Statistical modeling strongly suggests that using **fewer** geographical allocation districts would likely result in reduced waitlist deaths and a reduced variation in the MELD or PELD scores at transplant.

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Redistricting as a Potential Solution

The Committee agreed upon the following parameters for these optimized maps:

- The number of districts should be at least 4 and no more than 8;
- The minimum number of transplant centers per district is 6;
- The maximum median travel time between DSAs placed in the same district is 3 hours; and
- The number of waitlist deaths under redistricting must not be statistically significantly higher than in the current system.
- The districts should be contiguous.

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Optimized Redistribution Plan Based on Statistical Evidence

Districts	*Standard deviation of tx MELD*	% MELD <15	% MELD >25	% Pediatric	Net total deaths	*Net waitlist deaths*
4	***1.87***	2.5%	64.3%	8.7%	-553.8	***-581.1***
8	***2.08***	3.7%	59.6%	8.1%	-332.4	***-342.1***
Local first	***3.01***	5.8%	50.1%	7.5%	0	***0***
Regional	***3.26***	5.5%	54.3%	7.7%	-164.6	***-122.4***
National	***1.66***	1.9%	83.3%	10.4%	-343.6	***-509.9***

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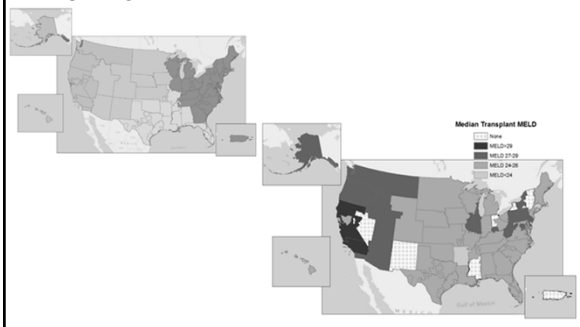
4 District Distribution Model & Reduction in Disparity



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8 District Distribution Model & Reduction in Disparity

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Our next steps

- Collect community responses today- July 11th, 2014
- Public Forum in Chicago September 16, 2014
- Proposal circulated for Public Comment Spring 2015

Alternative concepts that emerge from the community will be considered by the Committee

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Most Recent Policy Changes – Share 35/15/LI-IN

- On June 18, 2013, the OPTN implemented a number of changes to adult donor liver allocation:
  - Extend regional sharing of livers to MELD/PELD 15+ candidates on a national basis ("Share 15")
  - Regional sharing of livers to MELD/PELD 35+ candidates **("Share 35")**
  - National sharing of livers and intestines to liver-intestine candidates
- **Liver and Intestinal Organ Transplantation Committee** charged with monitoring the impact of allocation changes

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National Effects of Share 35*

- Regional sharing increased from 19.4% to 30.4% of deceased donor transplants
- MELD/PELD 35+ transplants increased from 19.9% to 25.2%
- Liver-intestine transplants increased from 12 to 44
- Liver discards decreased
- Waiting list mortality decreased 7%
- Import/export dynamics by DSA was similar between eras

= MORE LIVES SAVED

*6-months pre and post comparison

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QUESTIONS?

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UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING