## Public Forum to Discuss Kidney Allocation Policy Development

### Airport Marriott South
### Dallas, Texas
### February 8, 2007

### AGENDA

| | | |
|---|---|---|
| **8:00 - 9:00** | Open Registration | |
| **9:00** | Welcoming Remarks | Kevin O'Connor, MS, PA |
| | Charge of the OPTN/UNOS Kidney Transplantation Committee | Mark Stegall, MD |
| | Overview of the Current National Kidney Allocation System<br>Work of the Kidney Transplantation Committee to Date | Dale Distant, MD |
| | Methodology of Benefit Modeling | Robert Wolfe, PhD |
| | Results of Simulations | Alan Leichtman, MD |
| | Ethical Considerations in Organ Allocation | Michael Shapiro, MD |
| | Benefit as a Component of Kidney Allocation | Mark Stegall, MD |
| **12:00** | Lunch | |

Public Testimony

- Chris Bryan, PhD
- Stefanos Zenios, PhD
- Clive Grawe
- John Friedewald, MD
- Burl Osborne
- Glenda Rosenbloom
- Rich Freeman, MD

Table Discussions

Participant Reports from Breakout Session

| | | |
|---|---|---|
| **4:00** | Closing Comments and Summary Remarks | Mark Stegall, MD |

## Venue Information

To register to attend the forum *in person*, please visit the following site:

http://www.optn.org/news/newsDetail.asp?id=777

Registration is free for all participants. The forum will be held at the Dallas/Ft. Worth Airport Marriott South, 4151 Centreport Boulevard Fort Worth, Texas 76155 (Phone: 1-817-358-1700; Fax: 1-817-358-1800).

## Remote Participation Options

For those who are unable to attend the forum in person, a phone and internet simulcast will be available.

**Phone Participants**

To participate by phone, please dial toll-free **1-877-322-9654** and enter participant code **836175**. You will be asked to provide your name and any institutional affiliation. Submit questions and comments to kidneypolicy@unos.org during the forum. Your questions will be viewed by the forum's moderator. Due to time constraints, all questions may not be answered during the forum but will be considered by the Committee as a part of the public comment process.

**Internet Participants**

To participate on-line through Microsoft Live Meeting, you will need a computer with an internet connection. Follow the link provided below and enter the meeting ID if prompted.

https://www.livemeeting.com/cc/unos/join?id=PublicForum&role=attend
**Meeting ID: PublicForum**

With Live Meeting, remote participants will be able to view the presentations as they are being given. Live Meeting participants will also be able to hear the presentations through their own computer speakers. Therefore, Live Meeting participants will not need to dial-in by phone.

Please note that support for Microsoft Live Meeting will not be available during the forum. Please check your system to ensure that it is compatible with Live Meeting prior to the forum. If you are unable to connect to the Live Meeting, the presenters' slide sets will be available at www.unos.org.

## Questions

Please direct any questions regarding the forum to kidneypolicy@unos.org.

## OPTN/UNOS Kidney Transplantation Committee

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| Daniel H. Hayes MD | At Large |
| Mary S. Leffell PhD | At Large |
| Alan B. Leichtman MD | At Large |
| Ruth A. McDonald MD | At Large |
| Kevin J. O'Connor MS, PA | At Large |
| Janis M. Orlowski MD | At Large |
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| Milton (Sandy) Sander III, RN, CCTC | At Large |
| Velma P. Scantlebury MD | At Large |
| Mark A. Schnitzler PhD | At Large |
| Rodney Spangler | At Large |
| Henkie P. Tan MD, PhD, FACS | At Large |
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| Winfred W. Williams MD | At Large |
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| Gregory Fant Ph.D. | Ex. Officio |
| James F. Burdick MD | Ex Officio |
| Ginny McBride RN,MPH,CPTC | Ex Officio |
| Elizabeth Ortiz-Rios MD, MPH | Ex Officio |

## Public Forum to Discuss Kidney Allocation Policy Development

## Selected Glossary of Acronyms and Terms Used in Public Forum Presentations

| | |
|---|---|
| 0 HLA MM | zero antigen mismatch |
| 0-ABDR | zero antigen mismatch |
| 0MM | zero antigen mismatch |
| $A_2$ | blood type |
| $A_2$/$A_2$B to B | A and AB blood types compatible with B blood type |
| $A_2$B | blood type |
| ABDR Match | antigens identified to determine match quality |
| ALU | alternative local unit |
| BDR Match | antigens identified to determine match quality, less A matching |
| BMI | body mass index |
| CMV | Cytomegalovirus |
| DM | Diabetes Mellitus |
| DR | antigen used in matching |
| DSA | donation service area |
| ECD | expanded criteria donor |
| Equity | just, impartial and fair |
| ESRD | End-stage Renal Disease |
| Final Rule | A regulatory framework for the structure and operations of the OPTN. Under the terms of the Final Rule, policies intended to be binding upon OPTN members are developed through the OPTN committees and Board of Directors and then submitted to the Secretary of HHS for final approval. |
| HHS | Department of Health and Human Services |
| HLA | human leukocyte antigen |
| HLA MM | human leukocyte antigen - mismatch |
| HLA-DR | specific human leukocyte antigen - DR |
| HRSA | Health Resources and Services Administration, an agency of the Department of Health and Human Services |
| HTN | hypertension or high blood pressure |
| KARS | Kidney Allocation Review Subcommittee of the OPTN/UNOS Kidney Transplantation Committee |
| KI | isolated kidney |
| KP | kidney pancreas |
| KPSAM | Kidney-Pancreas Simulated Allocation Model |
| LYFT | life years from transplant |
| MELD | model for End-stage Liver Disease |
| Net Benefit | life years with a transplant less life years without a transplant |
| NLSB | net lifetime survival benefit |
| OPO | organ procurement organization |
| OPTN | Organ Procurement and Transplantation Network |
| PRA | panel reactive antibody |
| QENLSB | quality of life adjusted, estimated net lifetime survival benefit |
| QOL | quality of life |
| SAM | simulated allocation model |
| SCD | standard criteria donor |

| | |
|---|---|
| Sensitized patients | candidates with high levels of antibodies as measured by panel reactive antibody (PRA) test |
| SPK | simultaneous pancreas-kidney transplant |
| Spline | A series of connected straight lines, used in these analyses when a relationship (e.g. between BMI and survival) is not well modeled by a single straight line. |
| SRTR | Scientific Registry of Transplant Recipients |
| Tx | transplant |
| UNOS | United Network for Organ Sharing |
| Utility | provide benefit, be useful |
| WL | wait list |

## Charge of the OPTN/UNOS Kidney Transplantation Committee

Mark Stegall, MD
Committee Chair

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## Outline

- Why are we reviewing kidney allocation?
- What has been the process?
- What are likely changes?
- When will changes be implemented?

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## Possible Schema

- Prior living donor
- Pediatric priority for donors <35
- SCD kidneys using benefit modified by time, sensitization and urgency
- SPK and Kidney alone intermixed
- ECD kidneys by waiting time

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## Why are we reviewing kidney allocation?

- Required by Final Rule
- 2004 UNOS Board charges Kidney Committee to conduct comprehensive review of allocation
- 2005 UNOS Board charges Kidney Committee to consider net survival benefit

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## OPTN Final Rule

Policy development should:

- "seek to achieve the best use of donated organs"
- Be "designed to avoid wasting organs"
- Set "priority rankings through objective and measurable medical criteria"
- De-emphasize the use of waiting time in rank ordering candidates

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## HRSA Fiscal Year 2007 Justification of Estimates for Appropriations*

- By 2013, ... Increase the average number of life-years gained in the first 5 years after transplantation for deceased kidney/kidney-pancreas transplants by 0.003 life-years until the goal of 0.436 life-years gained per transplant is achieved in 2013.

*http://www.hrsa.gov/about/budgetjustification07/HealthCareSystemsPerformanceAnalysis.htm

## What has been the process?

I. KARS Process—comprehensive review, define general direction Finished

II. Benefit—create the model, simulate the impact of benefit Finished

III. Refining the Proposal—modifying benefit, eliciting feedback Started

IV. Finalizing the Proposal Fall 2007

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## Modeled and Simulated "Pure Benefit"

Where do we go from here?

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## How much should allocation depend on benefit?

- 100%--unlikely
- 75%?
- 50%?

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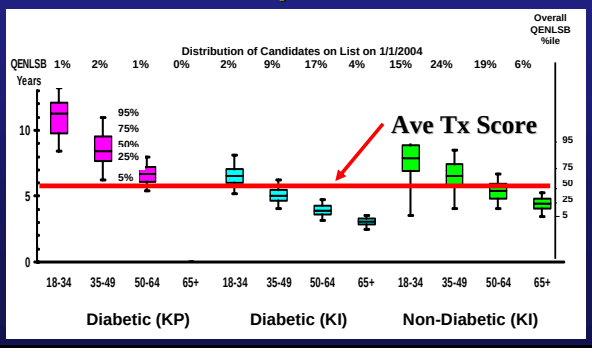
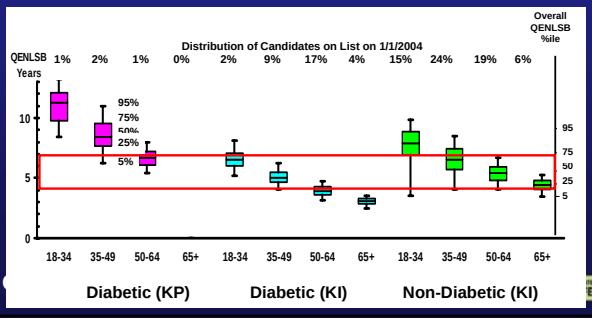
## QENLB—Mean Score that is Transplanted




## Phase III—Modifying Benefit

- Candidates do not move up the list over time
- Simulations currently only span 1 year, will the list change over time?
- Benefit does not clearly address differences in wait-list mortality
- Impact on living donation

## QENLB—Overlapping Scores



## Waiting Time/Time on Dialysis adjustment

- Allows patients to move up the list
- The impact of this modifier can be simulated using different weights for time on dialysis

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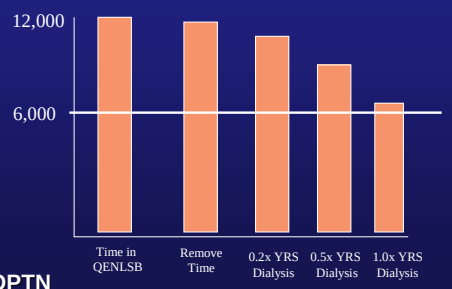
## Possible Approach to Time on Dialysis as a Modifier

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## SCD Kidneys

<u>Proposed Changes:</u>

- Prior living donor
- Survival Benefit
- Sensitization
- A2/A2B
- Time on Dialysis
- Urgency

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## Overall

- Prior living donor
- Pediatric priority for donors <35
- SCD kidneys using benefit modified by time, sensitization and urgency
- SPK and Kidney alone intermixed
- ECD kidneys by waiting time

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## What do I tell patients?

- Clearly delineates a candidates transplant benefit (Website will be developed for SCD, ECD, living donor)
- Different impact on different programs
- More predictable waiting list
- Maintain workups for top candidates

## Important Caveats

- This is not a final proposal
- Even after a final proposal is implemented, there will be ongoing changes

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## The Proposed Timeline

2007

- Public Forum, Feb 8th Dallas
- Kidney Committee Approval
- Public Comment x2
- Regional Meetings in the Fall
- Second Public Forum
- ?Board approval December 2007

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# Predicting
# Life Years From Transplant
# (LYFT)

## Focus Upon Methods

Robert Wolfe, SRTR

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Slide 1

## Acronyms

- Transplant Benefit: (Value-laden)
- QENLSB: Quality Adjusted Estimated Net Lifetime Survival Benefit (Too Long)
- LYFT: Life Years From Transplant (Descriptive)

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## Background

- Nearly all types of chronic renal failure patients are predicted to live longer with transplant than without (dialysis alone).
- Some types of patients are predicted to gain more Life Years From Transplant (LYFT) than others.
- Reference: Wolfe et al NEJM 1999
- Transplantation gives:
  - Longer life
  - Better quality of life

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## Life Years From Transplantation From A Donated Organ

- LYFT is the number of extra years of life that a candidate could expect to live with that donated organ compared to without a transplant.
- Example: Based on patient and donor characteristics the remaining lifetime might be estimated as:
  - 15 years with this transplant and
  - 5 years without transplant.
  - LYFT = 10 = 15 – 5 = Ten extra years of life

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## LYFT Combines Two Major Approaches to Organ Allocation

- Prioritize medical urgency
  - Higher priority if waitlist lifetime is shorter
- Prioritize graft survival
  - HLA matching
  - Avoid futile transplantation
  - Higher priority if post-transplant lifetimes are longer
- Prioritize both: LYFT
  - Uses common metric of years of life

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## Why Allocate Organs to Candidates With Large LYFT?

- Achieving the greatest total LYFT among all the recipients, given the available organ pool, would yield the greatest total years of life among all the candidates.
- Allocation of each organ to the candidate with the greatest LYFT for that organ is a way to approach this goal.
- Simulation results show that such an allocation system achieves many more total years of life

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## Choices For Calculating LYFT

- How to measure lifetimes?
  - Median survival (stable to estimate)
  - Truncated lifetime (stable but incomplete)
  - Average Survival (area under the curve, less stable)
- Different weights for lifetimes
  - Urgency emphasis?
  - Quality of life considerations (dialysis vs. transplant)?
- Discounting future years compared to near years

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## A Hard Problem: Waiting List Lifetimes?

- Waiting list lifetimes are not completely observed for transplant recipients.
- Cox models have been developed to analyze such data and relate patient characteristics to survival rates.

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# Variables Used In LYFT Model

- Age
- Time exposed to ESRD
- Albumin
- BMI
- Diagnosis:
  - HTN
  - Polycystic
  - Diabetic
  - Other
- Previous Transplant
- HLA
- ~~Shared/local~~
- ~~Donor Factors~~
- ~~Peak PRA~~

- ~~Ethnicity/Race~~
- ~~Angina~~
- ~~Peripheral Vascular Disease~~
- ~~Calendar Year of Listing~~
- ~~Gender~~
- ~~NYHA Functional Class~~
- ~~Primary Insurance Status~~
- ~~Drug Treated Hypertension~~
- ~~Type of Dialysis~~
- ~~DSA (Surrogate for Geography)~~
- ~~Dialysis modality~~
- ~~Previous malignancy~~

**Variables excluded:**
**gameable, poor data or not a major factor**

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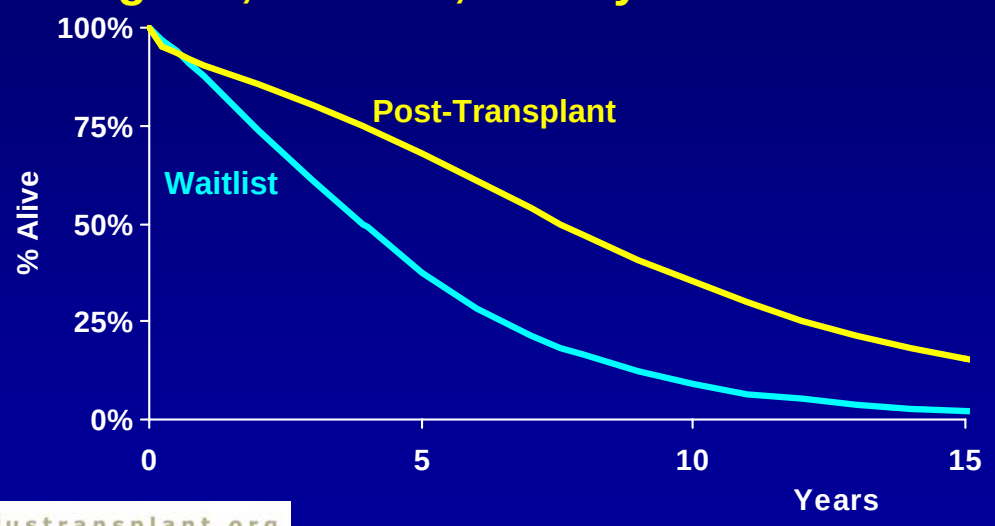
# Survival With / Without Transplant
## Age 55, Diabetic, Kidney Candidate

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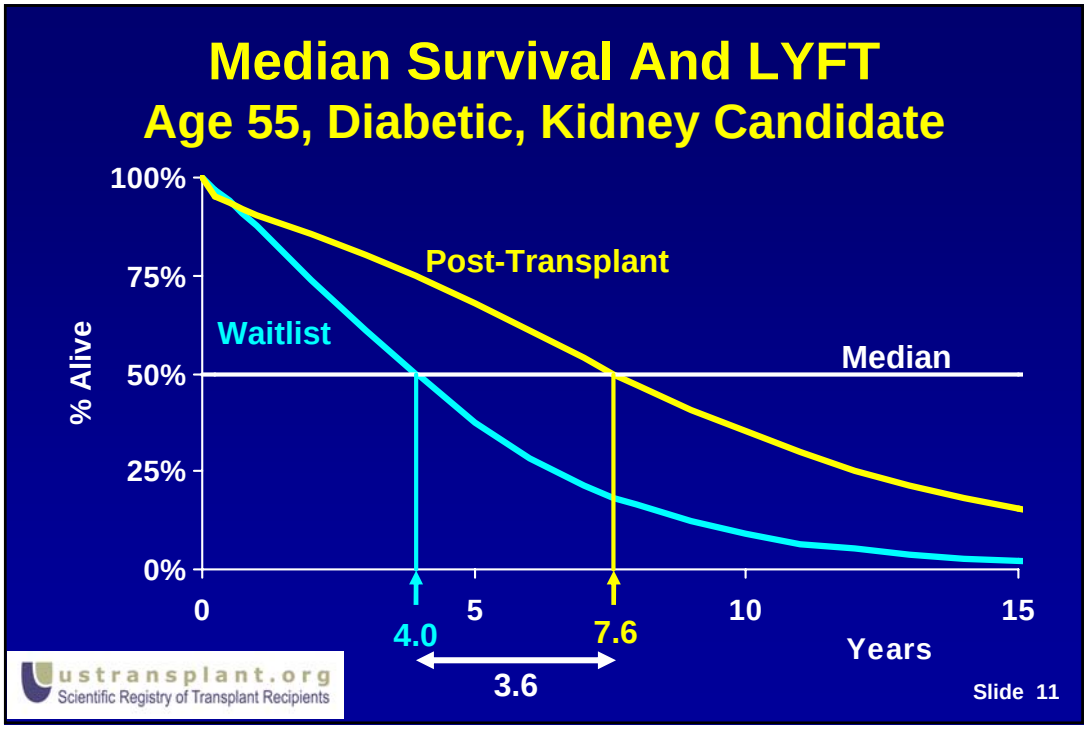
Median Survival And LYFT
Age 55, Diabetic, Kidney Candidate
100%
75%
50%
25%
0%
% Alive
Post-Transplant
Waitlist
Median
0
5
10
15
4.0
7.6
3.6
Years
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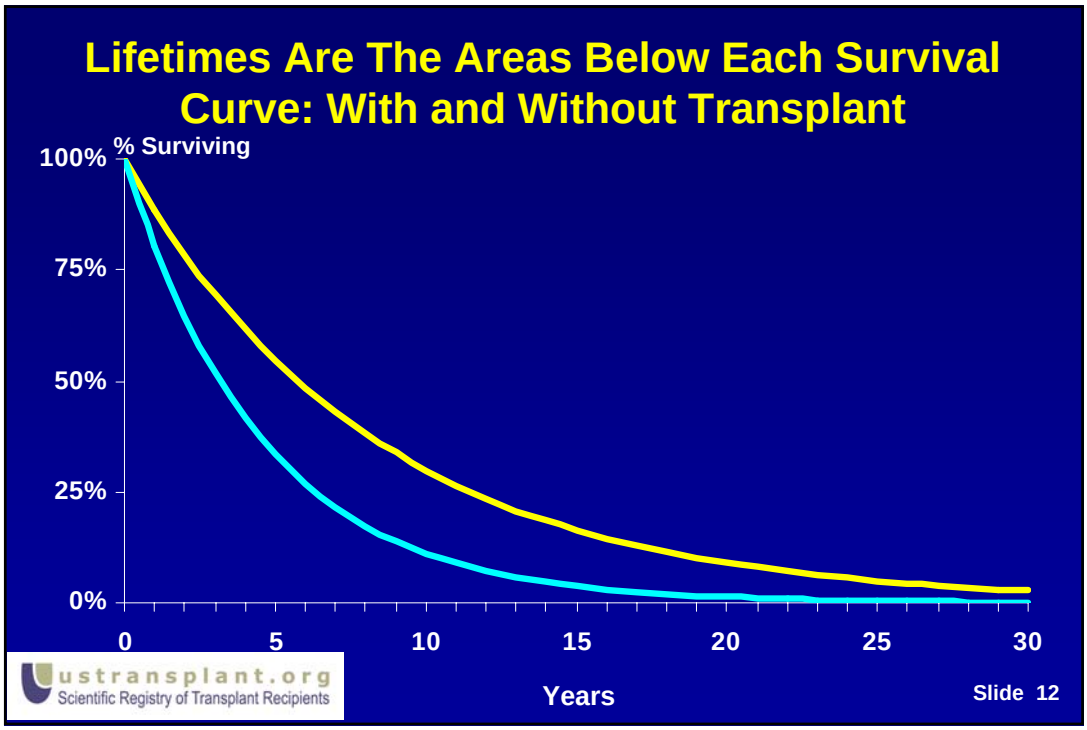
Lifetimes Are The Areas Below Each Survival Curve: With and Without Transplant
% Surviving
100%
75%
50%
25%
0%
0
5
10
15
20
25
30
Years
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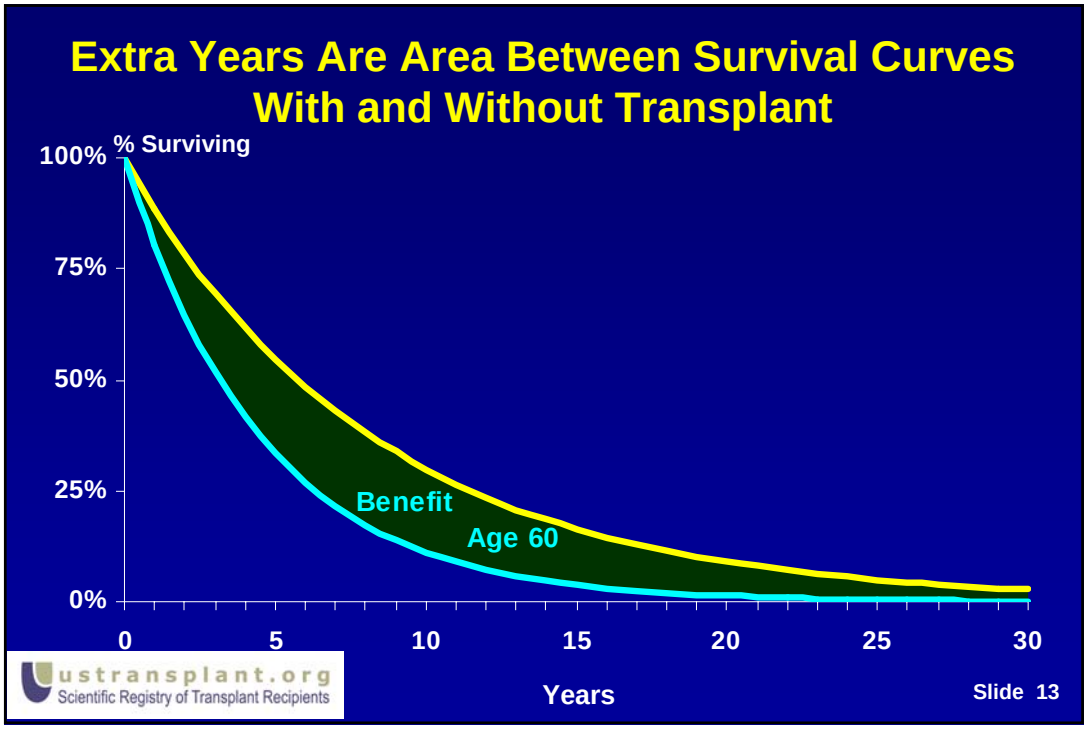
Extra Years Are Area Between Survival Curves With and Without Transplant
% Surviving
100%
75%
50%
25%
0%
Benefit
Age 60
0
5
10
15
20
25
30
Years
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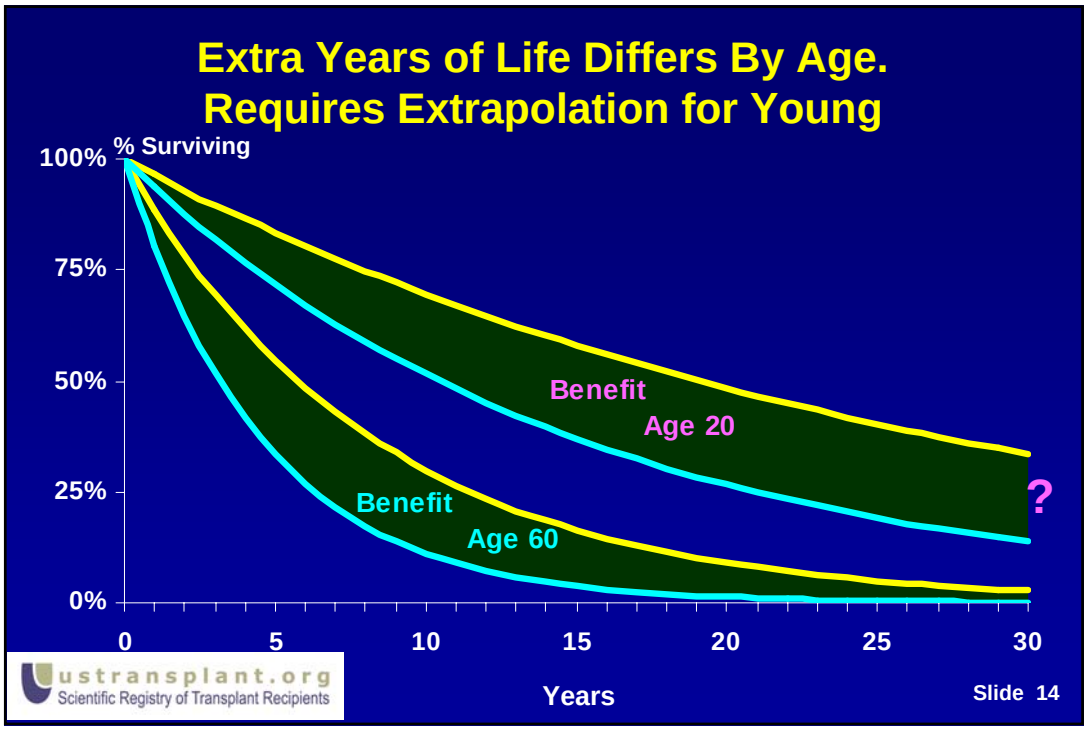
Extra Years of Life Differs By Age. Requires Extrapolation for Young
% Surviving
100%
75%
50%
25%
0%
Benefit
Age 20
Benefit
Age 60
?
0
5
10
15
20
25
30
Years
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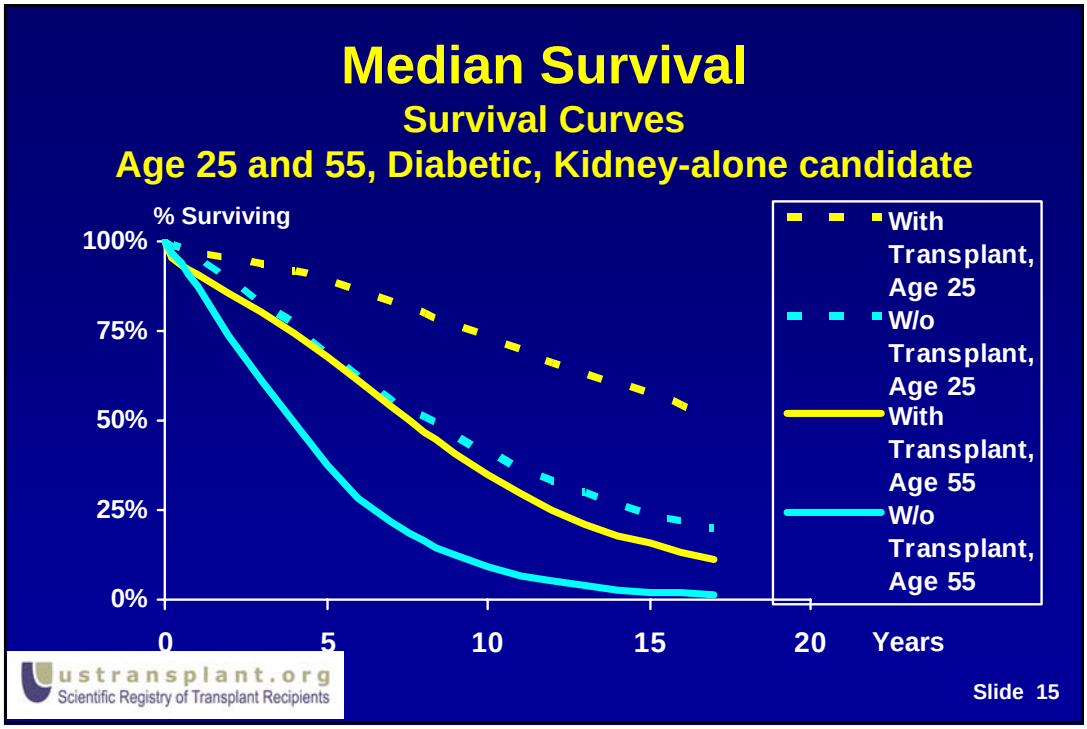
Median Survival
Survival Curves
Age 25 and 55, Diabetic, Kidney-alone candidate
% Surviving
100%
75%
50%
25%
0%
0
5
10
15
20
Years
With Transplant, Age 25
W/o Transplant, Age 25
With Transplant, Age 55
W/o Transplant, Age 55
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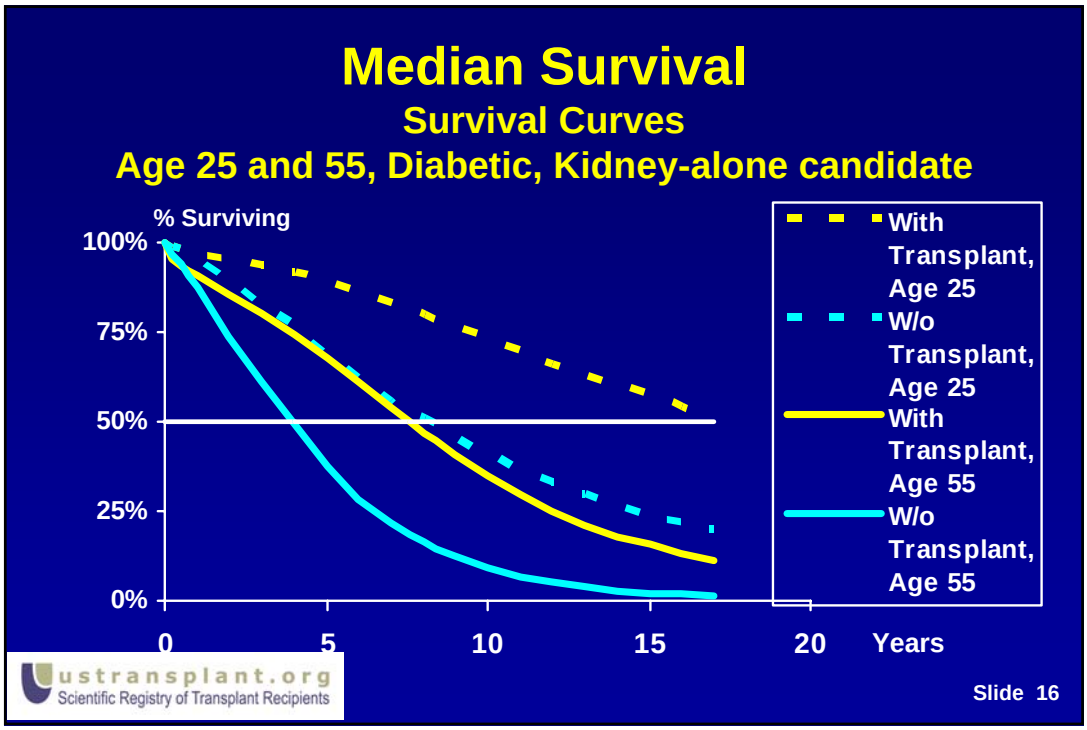
Median Survival
Survival Curves
Age 25 and 55, Diabetic, Kidney-alone candidate
% Surviving
100%
75%
50%
25%
0%
0
5
10
15
20
Years
With Transplant, Age 25
W/o Transplant, Age 25
With Transplant, Age 55
W/o Transplant, Age 55
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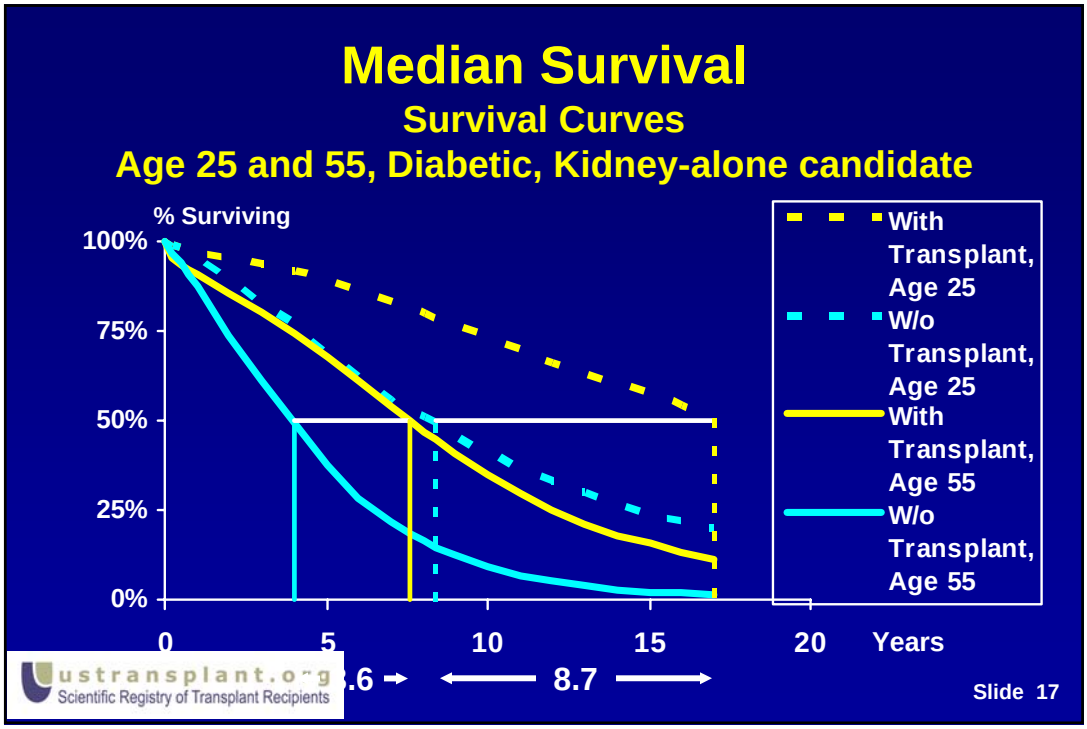
Median Survival
Survival Curves
Age 25 and 55, Diabetic, Kidney-alone candidate
% Surviving
100%
75%
50%
25%
0%
0
5
10
15
20
Years
With Transplant, Age 25
W/o Transplant, Age 25
With Transplant, Age 55
W/o Transplant, Age 55
8.7
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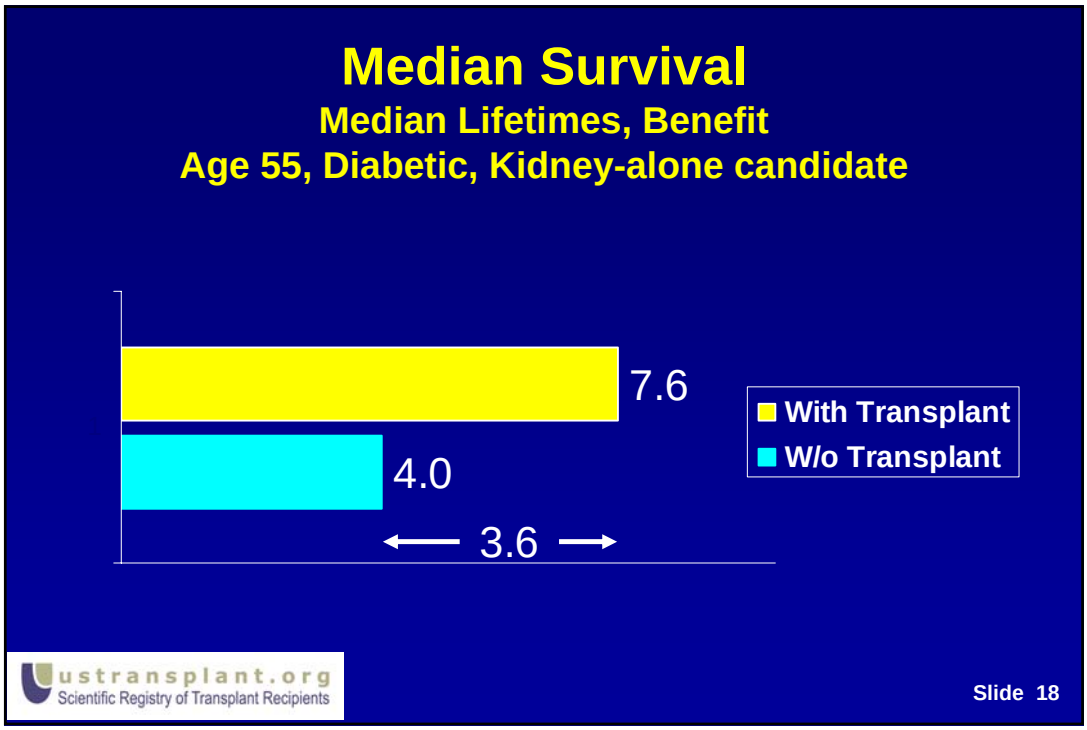
Median Survival
Median Lifetimes, Benefit
Age 55, Diabetic, Kidney-alone candidate
7.6
4.0
3.6
With Transplant
W/o Transplant
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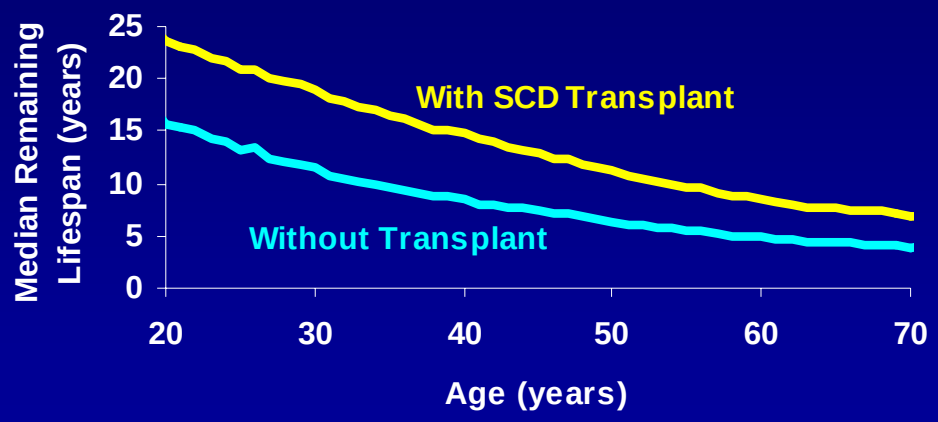
# Median Survival by Age




Median lifespans with average SCD kidney and without any transplant are based on average of median survival estimated for candidates active on the waitlist on 1/1/2004. General population data from 1996 Interpolated Abridged Life Table from Public Health Service, DHHS

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# Quality of Life (QoL) for Candidates and Recipients

- LYFT could value post-transplant years and waitlist years equally
- However, several published studies indicate that QoL is lower on dialysis than with a functioning transplant
- Appropriate emphasis to post-transplant survival with a functioning graft can be incorporated into transplant benefit calculation in order to account for this difference:
  - Adjustment factor of 0.8 obtained from published literature
  - All candidates receive the same QoL adjustment

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## QoL Sources

**What is the relative value of dialysis years v. years with functioning graft?**

- Laupacis et al. (1996, Kidney International).
  - Time trade-off analysis
  - 168 Canadian patients
  - Ratio varies by time since transplant from 0.76 – 0.84
  - 0.80 seems a reasonable overall value
- Hornberger et al. (1997, Med. Decis. Making)
  - Health state value
  - 878 patients
  - Ratio = 0.81

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## Quality of Life (QoL) - Adjusted LYFT

- QoL adjustment weights dialysis years by 80%:
  - Transplant Lifetime (QoL) = Years with functioning graft + 0.8 * Dialysis Years after graft failure
  - Non-Transplant Lifetime (QoL) = 0.8 * Dialysis Years
- QoL adjusted LYFT is the difference between the adjusted lifetimes.
- Simulations use QoL adjusted LYFT

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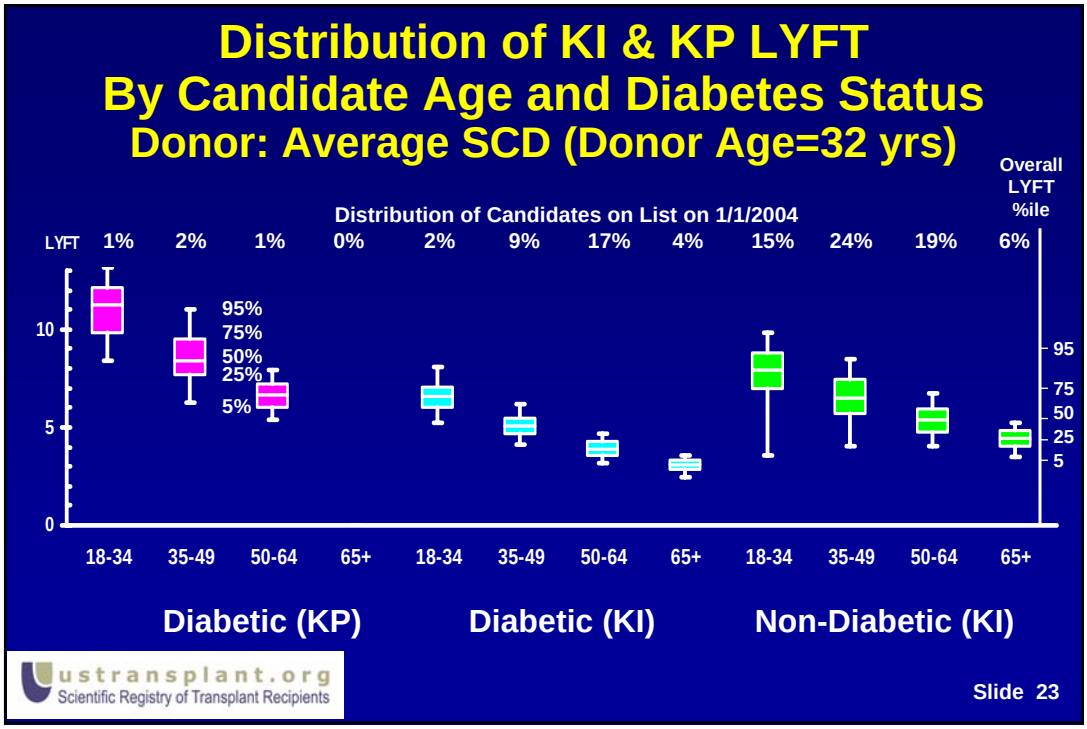
Distribution of KI & KP LYFT
By Candidate Age and Diabetes Status
Donor: Average SCD (Donor Age=32 yrs)
Overall LYFT %ile
Distribution of Candidates on List on 1/1/2004
LYFT 1% 2% 1% 0% 2% 9% 17% 4% 15% 24% 19% 6%
95%
75%
50%
25%
5%
10
5
0
95
75
50
25
5
18-34 35-49 50-64 65+ 18-34 35-49 50-64 65+ 18-34 35-49 50-64 65+
Diabetic (KP)
Diabetic (KI)
Non-Diabetic (KI)
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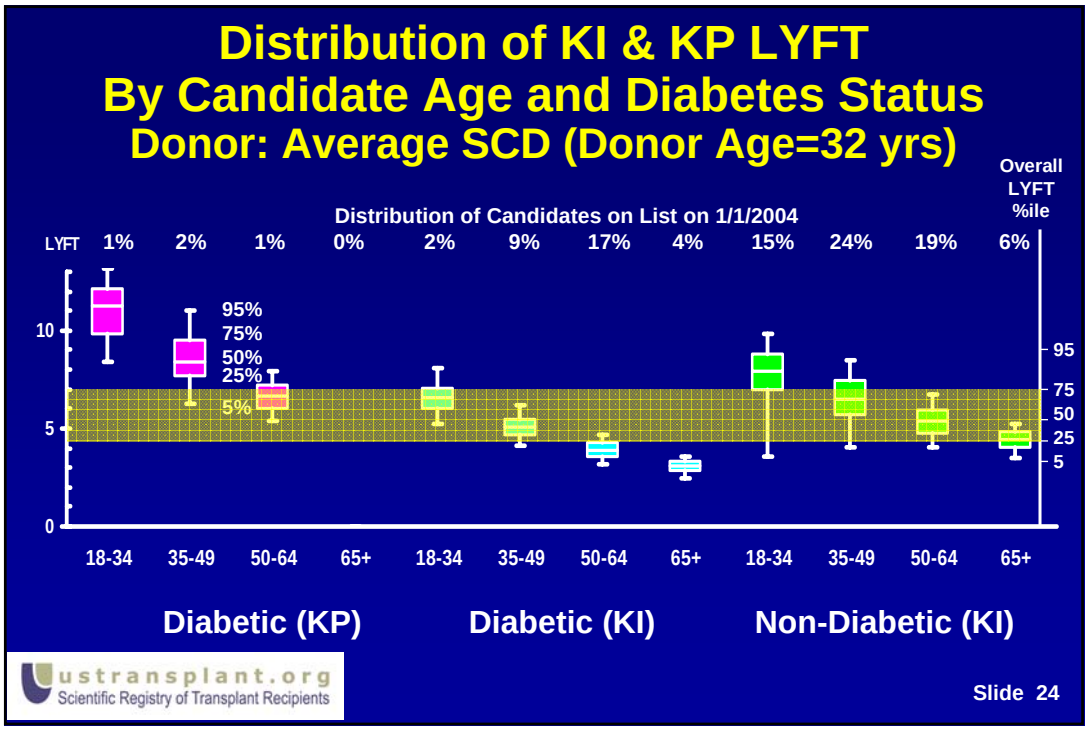
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Donor: Average SCD (Donor Age=32 yrs)
Overall LYFT %ile
Distribution of Candidates on List on 1/1/2004
LYFT 1% 2% 1% 0% 2% 9% 17% 4% 15% 24% 19% 6%
95%
75%
50%
25%
5%
10
5
0
95
75
50
25
5
18-34 35-49 50-64 65+ 18-34 35-49 50-64 65+ 18-34 35-49 50-64 65+
Diabetic (KP)
Diabetic (KI)
Non-Diabetic (KI)
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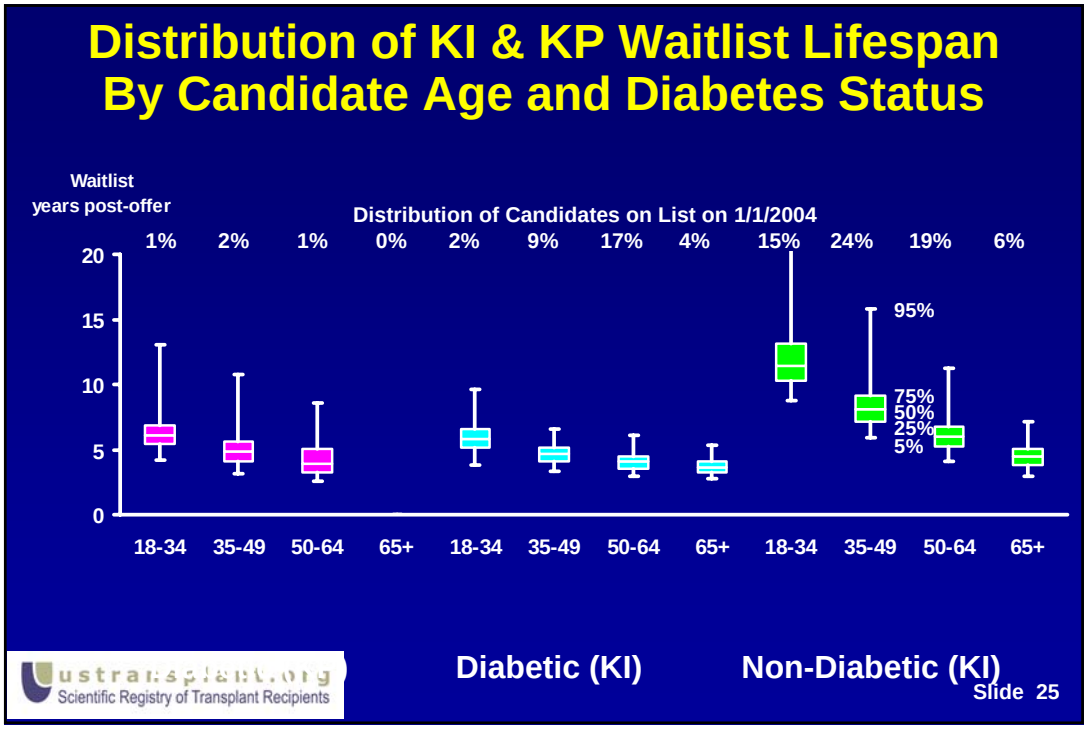
Distribution of KI & KP Waitlist Lifespan
By Candidate Age and Diabetes Status
Waitlist
years post-offer
Distribution of Candidates on List on 1/1/2004
1% 2% 1% 0% 2% 9% 17% 4% 15% 24% 19% 6%
20
15
10
5
0
95%
75%
50%
25%
5%
18-34 35-49 50-64 65+ 18-34 35-49 50-64 65+ 18-34 35-49 50-64 65+
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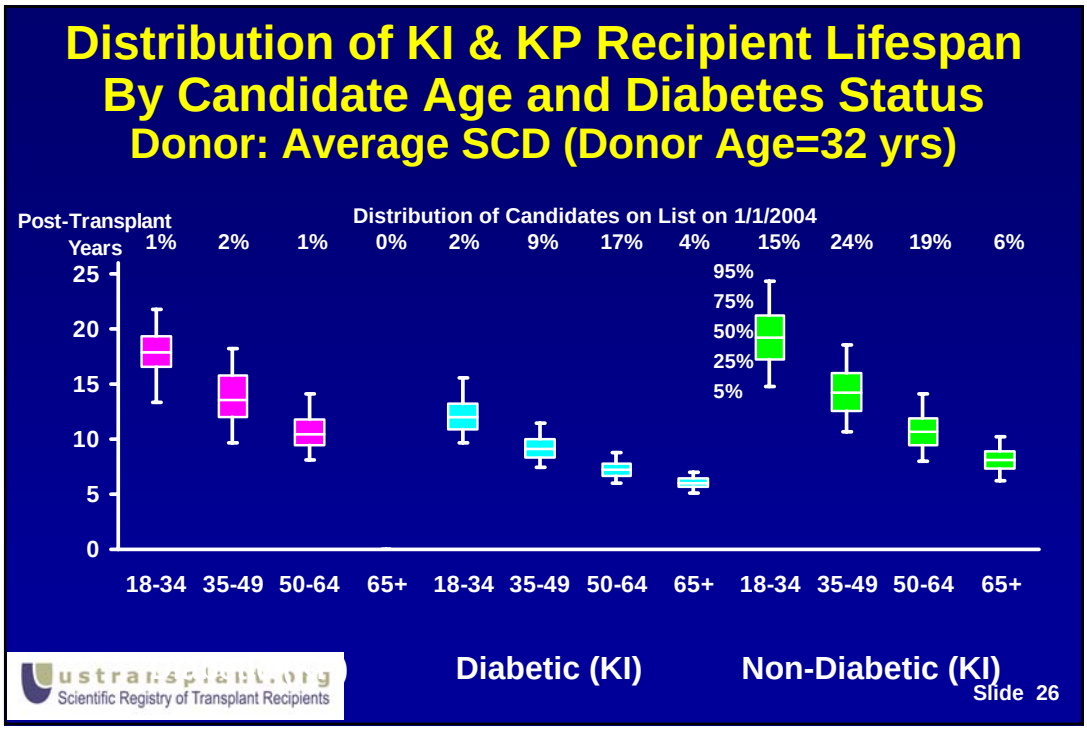
Diabetic (KI)
Non-Diabetic (KI)
Slide 25


Distribution of KI & KP Recipient Lifespan
By Candidate Age and Diabetes Status
Donor: Average SCD (Donor Age=32 yrs)
Post-Transplant
Years
Distribution of Candidates on List on 1/1/2004
1% 2% 1% 0% 2% 9% 17% 4% 15% 24% 19% 6%
25
20
15
10
5
0
95%
75%
50%
25%
5%
18-34 35-49 50-64 65+ 18-34 35-49 50-64 65+ 18-34 35-49 50-64 65+
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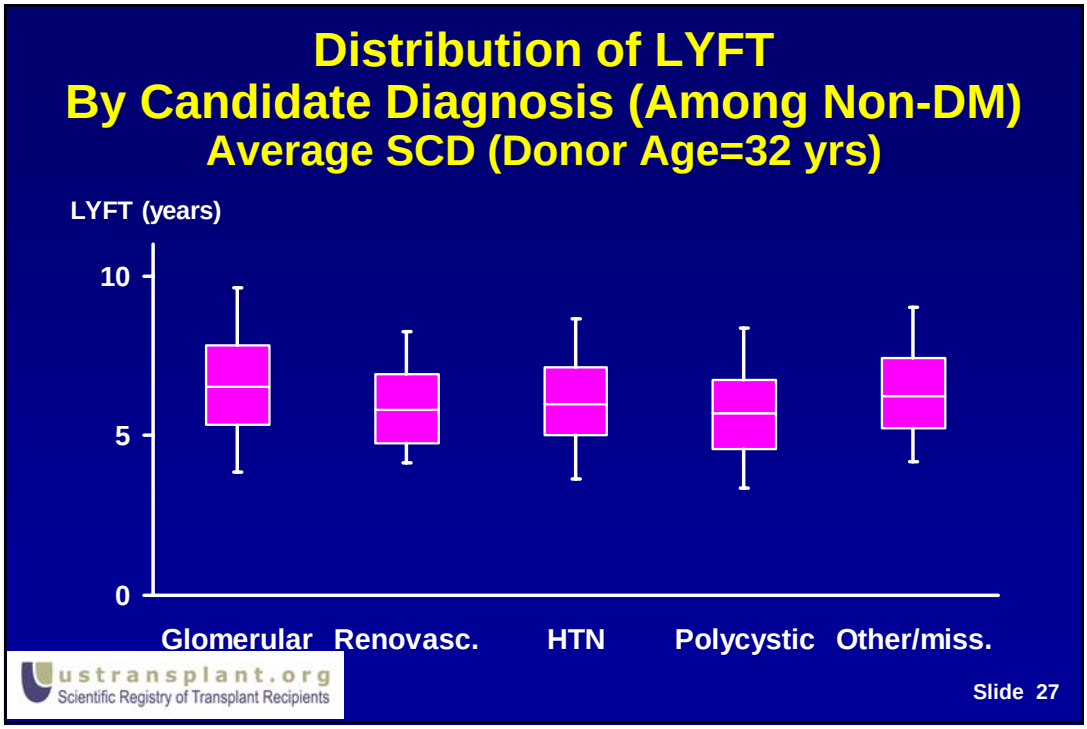
Diabetic (KI)
Non-Diabetic (KI)
Slide 26


Distribution of LYFT
By Candidate Diagnosis (Among Non-DM)
Average SCD (Donor Age=32 yrs)
LYFT (years)
10
5
0
Glomerular
Renovasc.
HTN
Polycystic
Other/miss.
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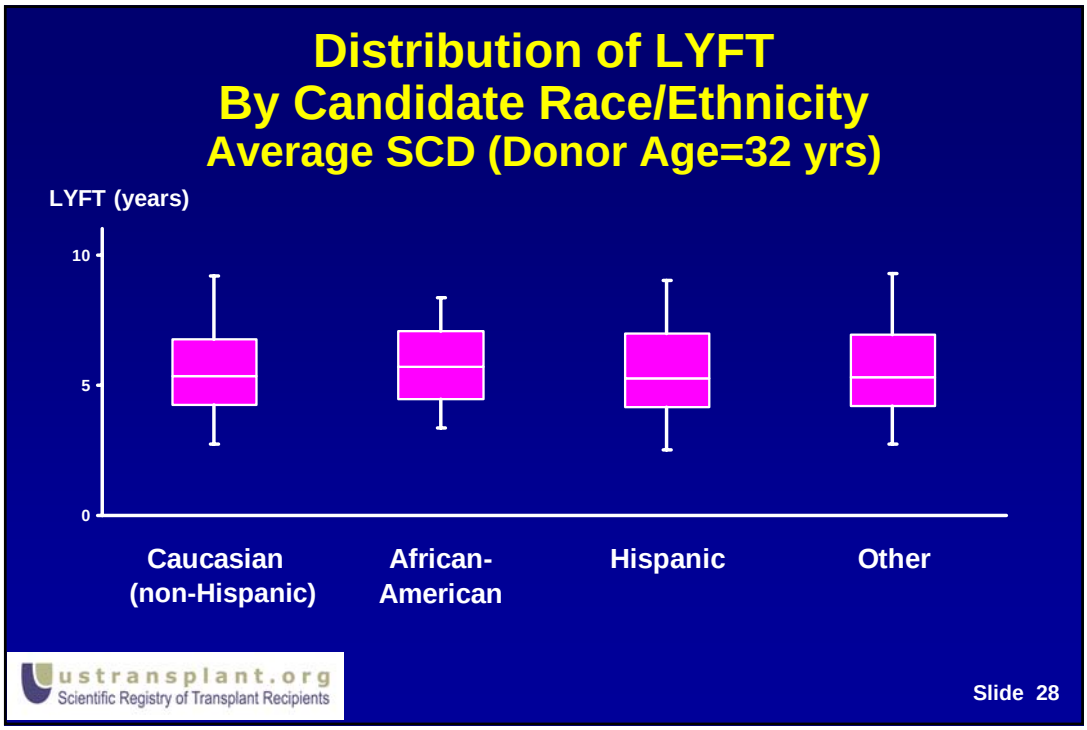
Distribution of LYFT
By Candidate Race/Ethnicity
Average SCD (Donor Age=32 yrs)
LYFT (years)
10
5
0
Caucasian (non-Hispanic)
African-American
Hispanic
Other
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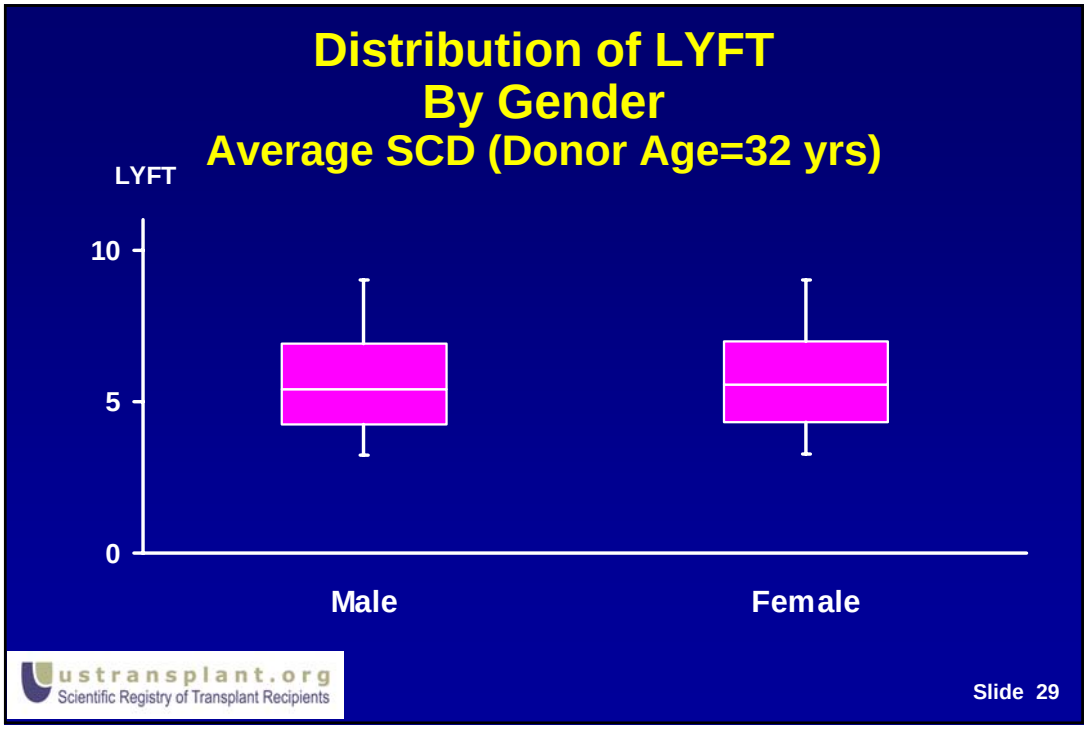
Distribution of LYFT
By Gender
Average SCD (Donor Age=32 yrs)
LYFT
10
5
0
Male
Female
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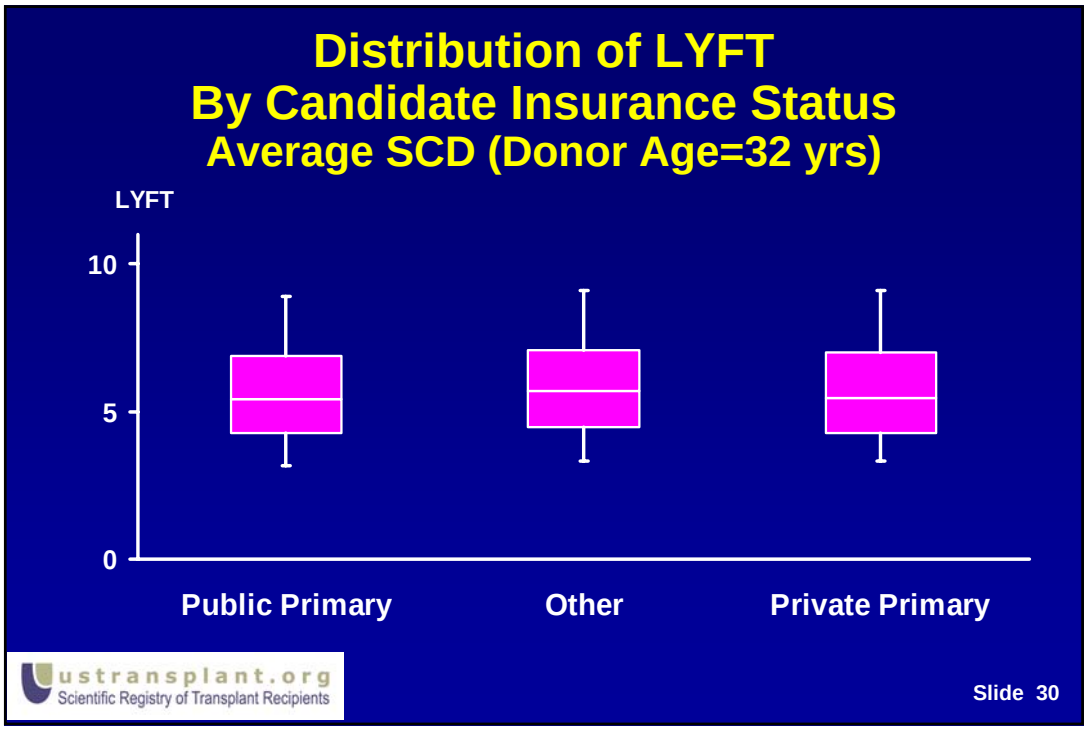
Distribution of LYFT
By Candidate Insurance Status
Average SCD (Donor Age=32 yrs)
LYFT
10
5
0
Public Primary
Other
Private Primary
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Slide 30

# Summary – Methods

- LYFT due to a kidney transplant can be estimated using information known about the potential recipients and the donor
  - Based on median lifetimes
  - Modest extrapolation beyond 15 years required for Dialysis lifetimes
  - Moderate extrapolation required for Transplant lifetimes
  - Predictors based on predictive value, data quality, objectivity
  - Dialysis years weighted to 80% of Functioning transplant years
- LYFT varies greatly among candidates primarily by age, diabetes (Range 1 to 15 years)
- LYFT is similarly distributed by race, blood type, gender, and insurance type.

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# Simulations Integrating a Measure of Life Years From Transplant (LYFT) into Deceased Donor Kidney Allocation

Kidney Allocation Review Subcommittee
Public Forum
February 8, 2007

Alan Leichtman, M.D.
Scientific Registry of Transplant Recipients

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Slide 1

# Scientific Registry of Transplant Recipients (SRTR) Collaborators

- Robert Wolfe
- Keith McCullough
- Ann Rodgers
- Mary Guidinger
- Laura Christensen

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Slide 2

# What is the Kidney and Pancreas Simulation Allocation Model (KPSAM)?

- KPSAM is a sophisticated computer program that can
  - replicate the results of the current kidney allocation system
  - predict the consequences of proposed policy changes before they are instituted
  - allow comparisons between alternative allocation rules or algorithms
- KPSAM uses specified allocation rules and the characteristics of actual candidates and donors
  - The order of offers of organs to candidates is based on the specified allocation rules being considered
  - Data from actual candidates and donors are used to predict
    - candidate, recipient and allograft outcomes
    - probability of accepting an offer
  - Outputs include demographic and survival outcomes resulting from application of the rules under consideration

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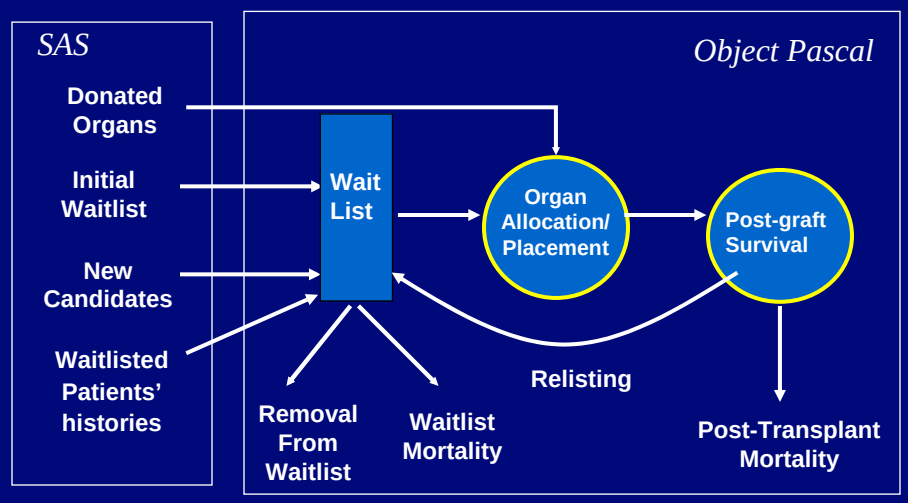
# SAM Event-Sequenced Modeling Processes Events in Time Order

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## Status of KPSAM Models Incorporating a Measure of LYFT into Deceased Donor Kidney Allocation

**KPSAM LYFT runs fall into three broad categories:**

1. determine a baseline for comparison to the current allocation system
2. model rules intended to incorporate and maximize attainable LYFT
3. model rules that provide allocation priority based on considerations other than maximizing LYFT
   - in progress: time on dialysis, PRA
   - pending: medical urgency, quotas, discounting future years

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## KPSAM Baseline Run

- Uses the rules of the current national allocation system applied to the 2003 cohorts of candidates and donors
- Assumes a single national allocation system, i.e. no alternative local allocation units (ALUs) or alternative local allocation systems (variances)
- Assumes that every center and OPO follows the allocation rules
- Replicates the results seen nationally, but not by DSA

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## KPSAM Runs to Incorporate LYFT

- LYFT used in place of current allocation points (wait time, PRA, HLA-DR match) for ordering offers of SCD kidneys to adult candidates
- For allocation of SCD kidneys, candidates that are to be ranked by LYFT are separated from candidates to be ranked by waiting time or by "allocation points"
  - pediatric v. adult
  - SPK v. pancreas alone
- Preserve current
  - absolute priority for zero mismatch
  - pediatric priority for donors under the age of 35 years
  - ECD allocation system

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## KPSAM Runs Removing Barriers to Improving Attainable LYFT

- Eliminate the existing payback system
- Eliminate 0 HLA MM priority
- Nationalize Blood Type A2->B and A2B->B
- Eliminate local allocation boundaries, i.e. national allocation of SCD kidneys to adults (in progress)

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# Years of Life Expected With LYFT-Based Allocation of Kidneys

| | Current System | LYFT | No Pay-Back | No 0MM Priority | A2->B |
|---|---|---|---|---|---|
| Years after transplant | 113,541 | 139,334 | 140,556 | 145,174 | 145,879 |
| Total graft years | 75,940 | 85,388 | 86,019 | 86,221 | 86,525 |
| Total extra life years | 43,940 | 55,397 | 56,371 | 58,030 | 58,363 |
| Δ years after transplant | | 25,793 | 1,222 | 4,618 | 705 |
| Δ graft years | | 9,448 | 631 | 202 | 304 |
| Δ extra life years | | 11,457 | 974 | 1,659 | 333 |

Each Δ (change) is relative to the prior run in this cumulative series

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Slide 9

# Average LYFT from Each Kidney Transplant

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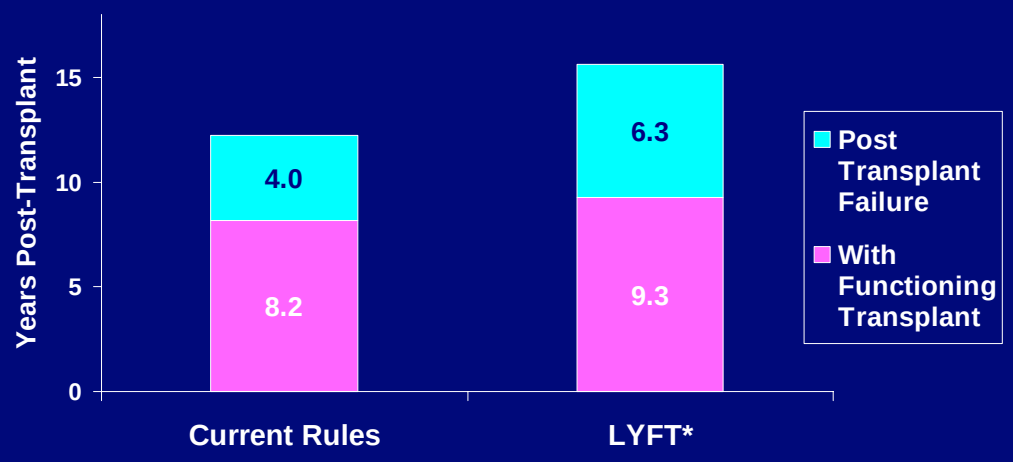
Slide 10

## Survival Among All Kidney Recipients

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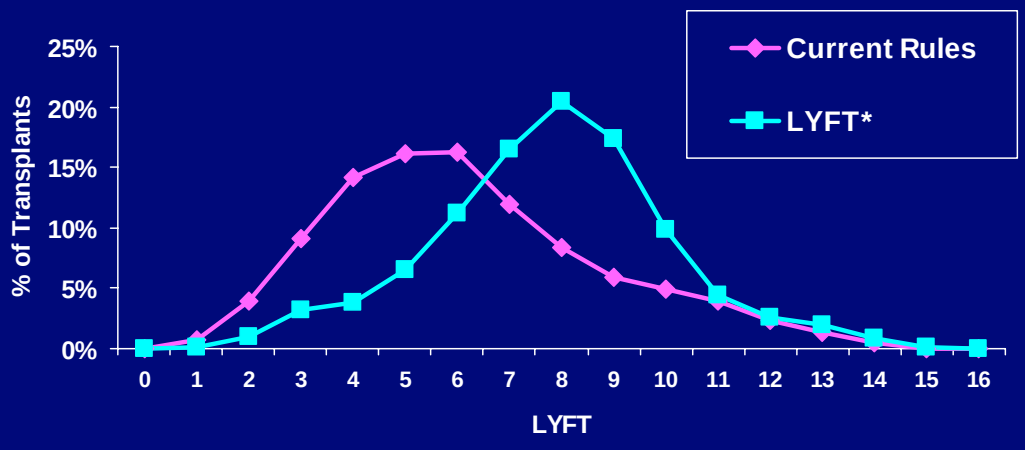
*LYFT also includes runs that eliminate paybacks and 0MM priority, and incorporate A2->B.

Slide 11

## When Allocation Incorporates LYFT, Distribution of SCD Kidney Recipients Changes

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*LYFT also includes runs that eliminate paybacks and 0MM priority, and incorporate A2->B.

Slide 12

## Summary of KPSAM Life Year Results

- LYFT is the estimated extra years of life obtained by recipients compared to the number of expected years of life had they remained on dialysis
- Under the current allocation system, transplantation added 43,900 years of life to the lifetimes of approximately 9,000 recipients of deceased donor transplants in 2003
- Substituting LYFT for "allocation points" would have added an estimated 11,500 extra years of life, increasing this total to 55,400 years
- Eliminating rules that allocate organs away from high LYFT candidates would have added an incremental 14,500 years over the current system, bringing the added years of life due to transplant to 58,500 years
- Additional increases in life years gained from transplant would be obtained from wider sharing of donated kidneys
- The consequences in terms of life years gained from transplant from accommodating other considerations (PRA, ESRD time, etc.) can be estimated

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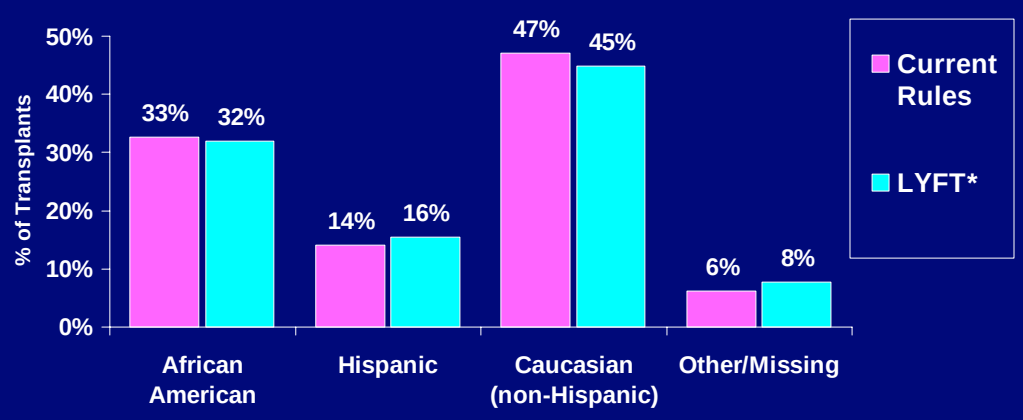
Slide 13

## Racial Distributions of SCD Kidney Recipients Are Similar

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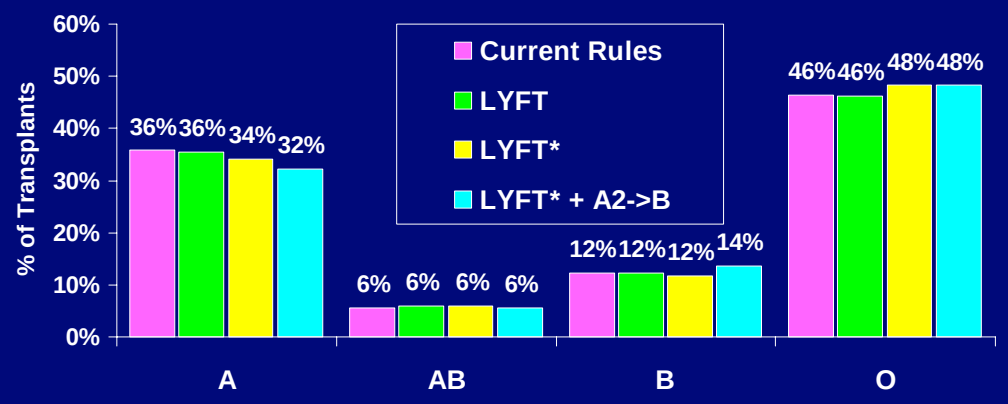
*LYFT also includes runs that eliminate paybacks and 0MM priority, and incorporate A2->B.

Slide 14

## Blood Type Distributions of SCD Kidney Recipients Are Similar

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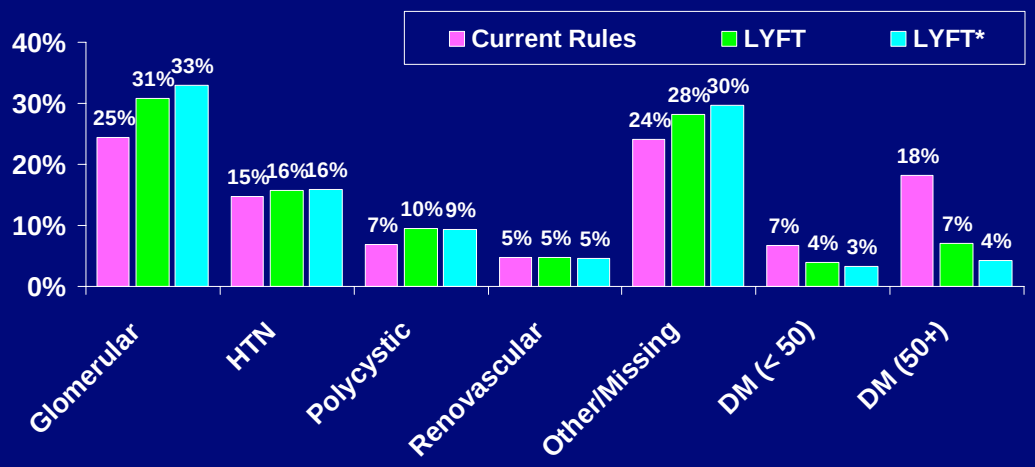
*This LYFT run also includes runs that eliminate paybacks and 0MM priority.

Slide 15

## Distribution of Diagnoses of SCD Kidney Recipients Changes When LYFT Is Used

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*LYFT also includes runs that eliminate paybacks and 0MM priority, and incorporate A2->B.

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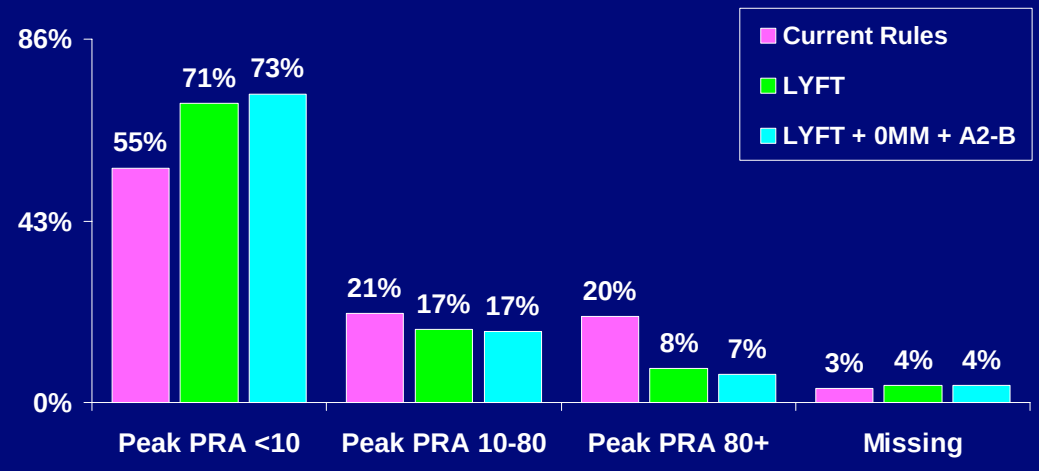
## PRA Distribution of SCD Kidney Recipients Changes When LYFT* Is Used

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*LYFT does not add 4 points for PRA 80+ candidates

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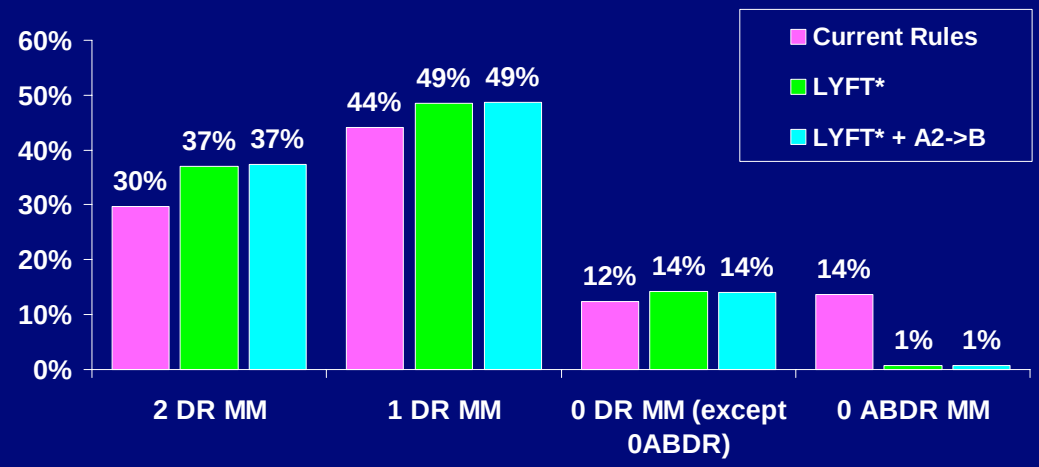
## HLA Distribution of SCD Kidney Recipients Changes When 0MM Priority is Eliminated

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*This LYFT run also includes runs that eliminate paybacks and 0MM priority.

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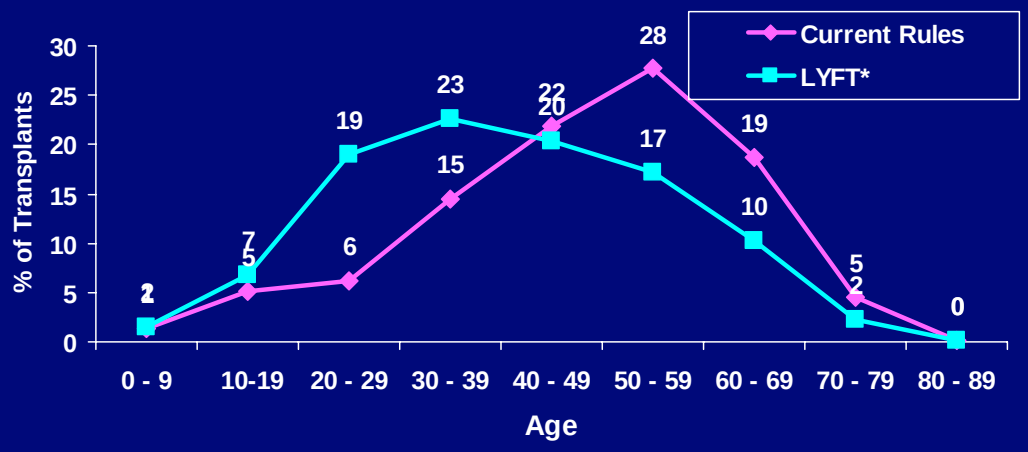
## Age Distribution of All Kidney Alone Recipients Changes When Allocation Incorporates LYFT

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*LYFT also includes runs that eliminate paybacks and 0MM priority, and incorporate A2->B.

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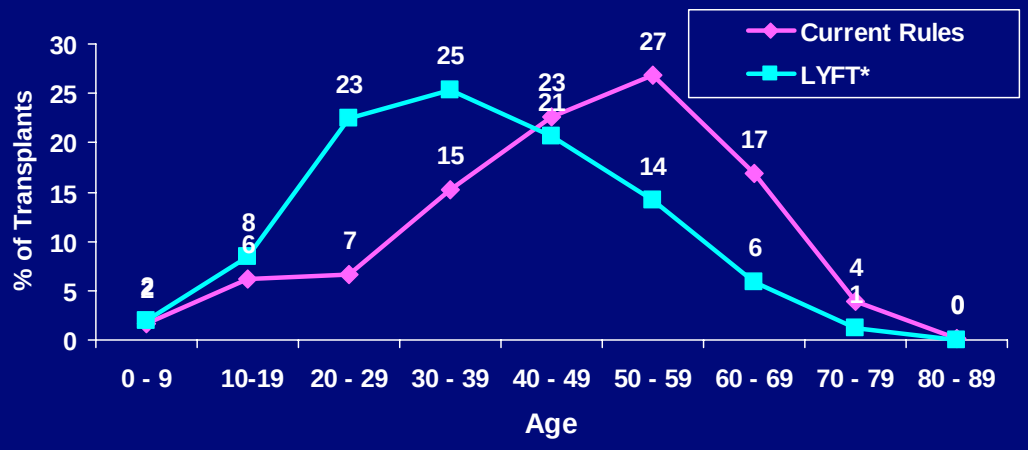
## Age Distribution of SCD Kidney-Alone Recipients Changes When Allocation Incorporates LYFT

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*LYFT also includes runs that eliminate paybacks and 0MM priority, and incorporate A2->B.

Slide 20

## Summary of KPSAM Demographic Results

- When compared to the current system, SCD kidney allocation incorporating LYFT results in
  - similar recipient racial and ethnic distributions
  - similar recipient blood type distributions
  - fewer transplants among diabetics (especially diabetics age 50 or older)
  - fewer transplants among high PRA candidates
  - fewer zero MM HLA transplants
  - shift towards younger recipients

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## Conclusions

- When compared to the current system, SCD kidney allocation incorporating LYFT would
  - Increase the number of years of life that can be achieved each year with the current donor pool by more than 10,000 life years
  - Have little effect on the racial and blood type distribution of recipients
  - Shift kidney transplants towards non-diabetics and lower PRA candidates
  - Reduce (with elimination of zero HLA MM priority) the number of zero HLA MM kidney transplants
  - Increase the percentage of higher LYFT recipients
  - Shift kidney transplants towards younger recipients
- Wider geographic sharing would increase life years gained from transplantation
- Future runs will test the consequences of allocation incorporating time on dialysis, PRA, medical urgency, quotas, and discounting of future life-years

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# Simulations Integrating a Measure of Life Years From Transplant (LYFT) into Deceased Donor Kidney Allocation

Kidney Allocation Review Subcommittee
Public Forum
February 8, 2007

Alan Leichtman, M.D.
Scientific Registry of Transplant Recipients

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## Ethical Considerations in Organ Allocation

Michael Shapiro, MD

OPTN

## "Men are not indifferent to how the greater benefits produced by their joint labors are distributed."

OPTN

## An Organ Allocation System Should:

- Be Fair
  - Equity, Justice
- Provide Value, Be Useful
  - Utility

OPTN

## The "Final Rule"

- The OPTN Shall:
  - Develop…policies for the equitable allocation of cadaveric (sic) organs. (Equity)
  - Be based on sound medical judgment.
  - Be designed to avoid wasting organs, avoid futile transplants, promote patients access, promote efficient management… (Utility)

OPTN

## Current Kidney Allocation

- Based primarily on Waiting Time
  - 1 point for each year waiting
- Influence of Utility measures has decreased from original system.
  - Originally 7 points for 4 BDR match
  - Now 2 points maximum for 2 DR match
- Additional considerations for equity –
  - 4 points for high PRA patients
  - Paybacks for 0-MM kidneys
- Relatively limited geographic sharing – possible inequity.

OPTN

## Extra-Renal Organ Allocation

- Primarily designed to avoid wait-list deaths
- In some cases, may sacrifice long-term utility (survival) for short term utility.
- Waiting time only as tie-breaker for patients of like severity of illness, and generally only time in class, not overall time.
- Equity recently addressed by increasing the geographic sharing areas.

OPTN

## How to consider "Fairness" (Equity)

- All Patients might have an equal chance of getting an organ
  - Lottery
    - No attempt to get the right organ to the right patient.
    - Patients might never win in the lottery.
  - Waiting List
    - Not all patients have the same potential to wait for an organ.
    - Some patient's "window of opportunity" may close while waiting.

OPTN

## "Fairness" (Equity), Cont'd

- All Patients should have an equal chance of living a "normal lifespan".
  - 30 yr-old has more claim to an organ for "dialysis-free years" than 70 yr-old with recent onset renal disease
  - Older patient might do just as well with an organ with shorter predicted survival to get to same age as younger patient with longer-lasting kidney.

OPTN

## Utility in Allocation

- The goal of allocation from a *Utility* perspective should be to do as much *net good* as possible.
- With kidney transplantation, as opposed to extra-renal organs, the goal is to improve quality of life and survival compared to the alternative therapy, i.e., dialysis.
- The existence of dialysis both creates the problem with allocation and provides an alternative therapy, which might be better for some patients.

OPTN

## Measures of Medical Utility

- Graft (kidney) survival
- Patient survival
- Improved Quality of Life
- Years added to Life
- Avoid medically inefficient use of scarce resource.

OPTN

## Inappropriate to Use for Organ Allocation

- Ethnicity (Race)
  - Difficulty of objective definition.
  - May already be disadvantaged in referral and listing for transplantation.
- Gender
- Socioeconomic status
- Social Utility of Recipient
  - Who would decide?
  - Who's value system?

OPTN

**If a system of kidney allocation based largely on "net benefit" (a utility measure) is likely to save 11,000 life-years annually, is there sufficient "unfairness" (inequity) in that system to suggest it shouldn't be enacted? Can we address any potential inequity and still achieve significant net benefit?**

OPTN