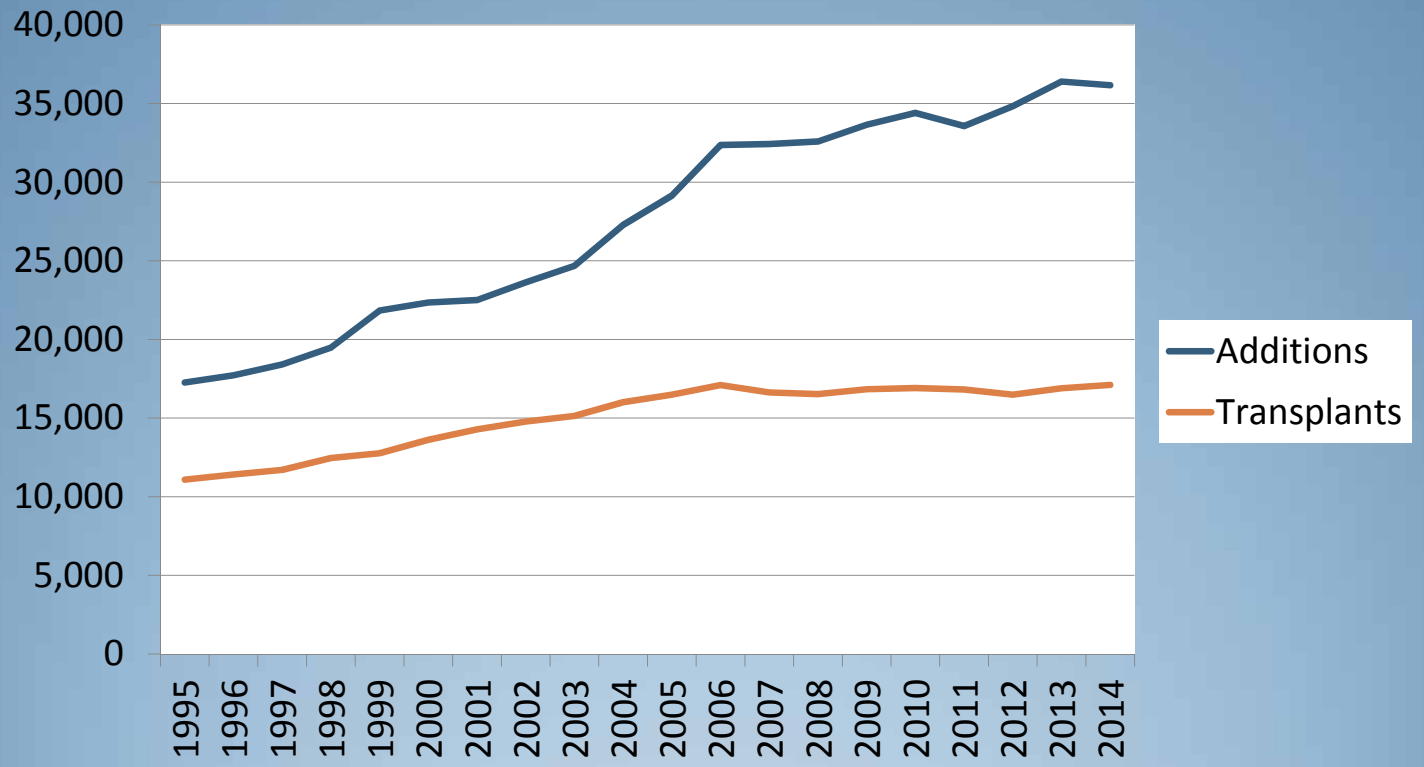
The New Kidney Allocation System:
More than Two Years Later, How's it Doing?

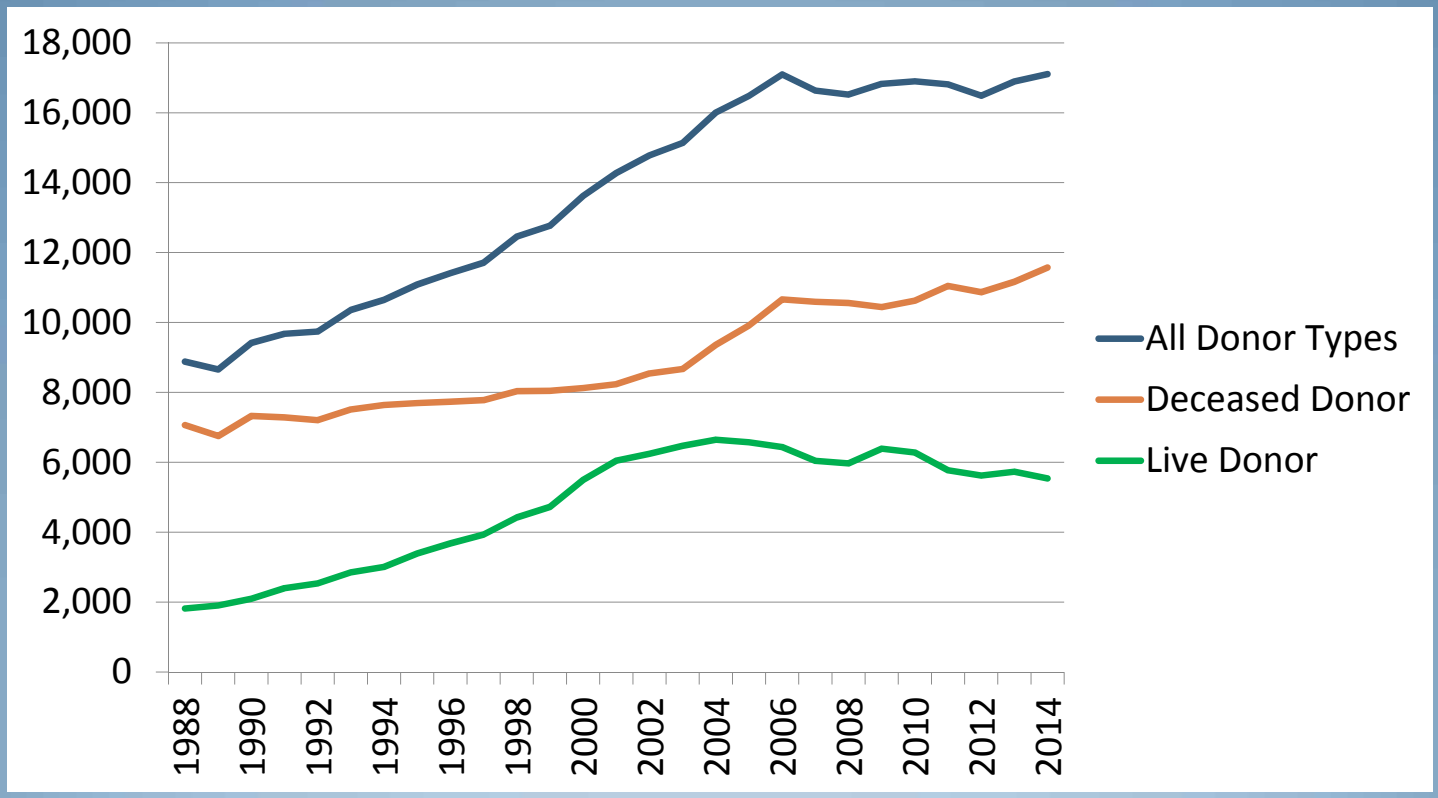
Linda Wright, DrNP, RN, CNN, CCTC
Clinical Manager of Abdominal Organ Transplant
Thomas Jefferson University Hospital

Wait List Growth vs Transplants



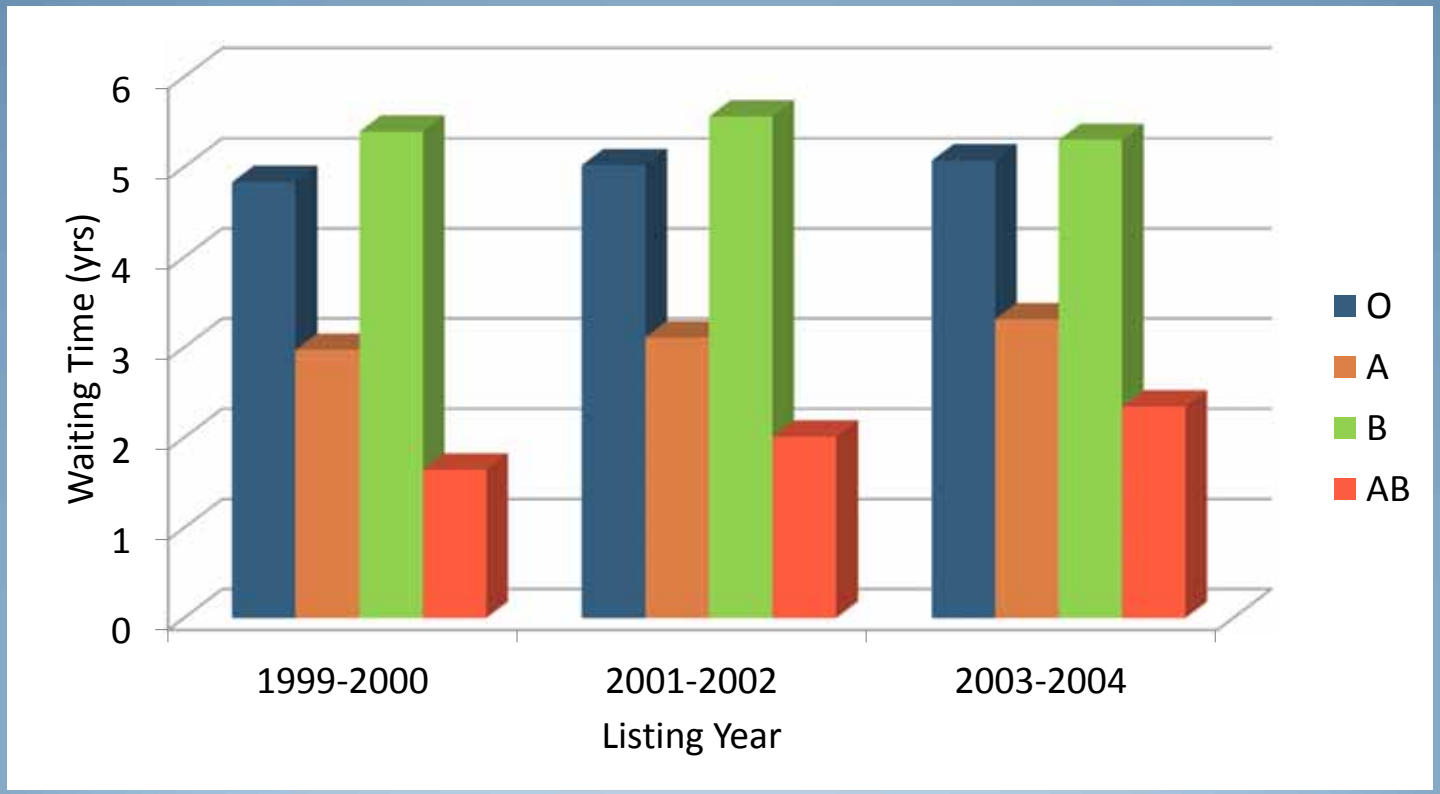
OPTN Data: Transplants 1/1/1988 – 12/31/2014

Kidney Transplants per Year



OPTN Data: Transplants 1/1/1988 – 12/31/2014

Median Waiting Times by Blood Group

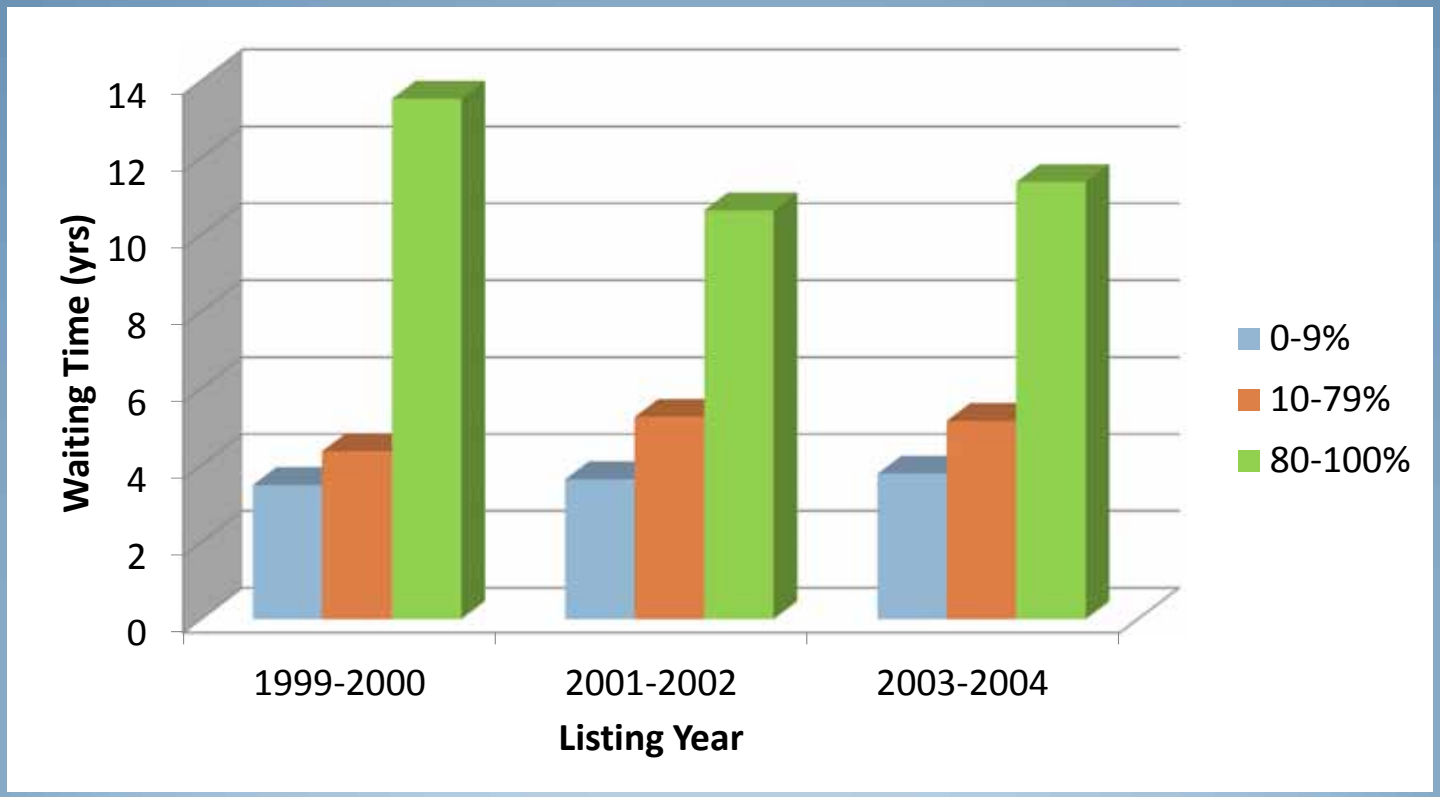


OPTN Data as of 9/4/2015

HLA and PRA: Sensitization

- HLA: Human Leukocyte Antigen
  - Proteins on the surface of WBC and other tissues
  - Involved in immune system's defense against "invaders"
  - HLA antibodies can be formed with exposure to "non-self" HLA antigens
    - Blood transfusion
    - Pregnancy
    - Transplant
- PRA: Panel Reactive Antibody
  - Based on the presence of specific HLA antibodies
  - cPRA (Calculated PRA): Measure of sensitization
    - Estimate of likely cross-match incompatible donors

Median Waiting Times by PRA

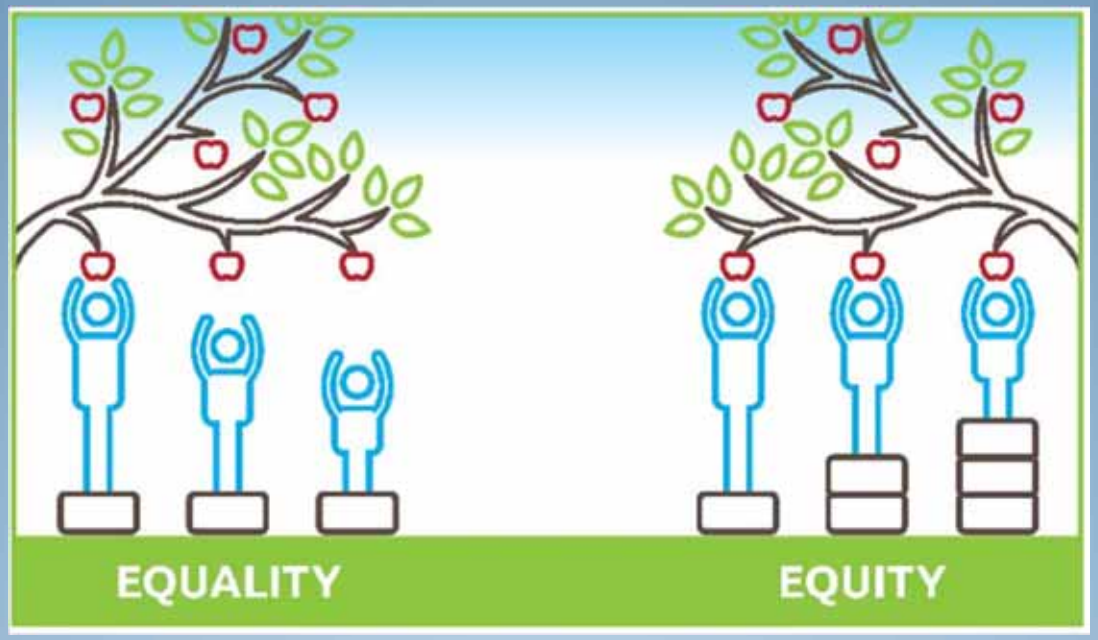


OPTN Data as of 9/4/2015

UNOS: Vision Statement

…to promote long, healthy and productive lives for persons with organ failure by promoting maximized organ supply, effective and safe care, and equitable organ allocation and access to transplantation.

unos.org/about/mission-values/



https://optn.transplant.hrsa.gov/media/2260/equity_in_access_report_201708.pdf

Key Goals of New KAS

- Increase benefit and utilization
  - Make better use of available kidneys
  - Increase transplant opportunities for hard to match patients
  - Increase fairness to patients who may have been referred late
  - Have minimal impact on most candidates

Key Changes with New KAS

- Implementation of new donor and recipient scores
  - Improved longevity matching
- Credit for dialysis time
  - High dialysis mortality
  - Lack of timely referral for transplant
- Increased priority for biologically disadvantaged
  - Sensitized
  - Blood group B

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Kidney Donor Profile Index

- KDPI
  - Uses clinical parameters and demographics to rate the quality of the donor kidneys relative to other donors
  - Estimates how long a deceased donor kidney is expected to function, compared to all of the kidneys recovered in the USA in the previous year
  - Lower value indicates better donor quality, and longer expected function
  - KDPI of 30% is expected to function longer than 70% of the kidneys recovered in the previous year

Expanded Criteria Donors

Donor Condition	< 10 yrs	10-39 yrs	40-49 yrs	50-59 yrs	≥ 60 yrs
CVA + HTN + creat > 1.5mg/dL				X	X
CVA + HTN				X	X
CVA + creat > 1.5mg/dL				X	X
HTN + creat > 1.5mg/dL				X	X
CVA					X
HTN					X
Creat > 1.5mg/dL					X
None of the above					X

OPTN.transplant.hrsa.gov

Kidney Donor Profile Index

- Benefits of KDPI over ECD/SCD Donor System
  - Uses 10 donor factors (ECD used 4)
    - Age, Height, Weight, Ethnicity, History/duration of HTN and/or DM, Cause of death, Serum creatinine, Hep C status, DCD status
  - Continuous “score” versus yes/no
  - Not all ECDs were created equal
    - Some ECD kidneys had good estimated quality
    - Some SCD kidneys had lower estimated quality

Estimated Post-Transplant Survival

- EPTS
  - Clinical formula based on 4 medical factors
    - Age
    - History of diabetes
    - Previous organ transplant
    - Length of time on dialysis
- Estimates how many years a specific waiting list candidate would be likely to benefit from a transplant
  - Lower EPTS percentage indicates likely longer survival
  - EPTS of 20% suggests that the candidate, when transplanted, will survive longer than 80% of other recipients

Longevity Matching

- Candidates with EPTS of ≤ 20% are given priority for donors with KDPI of ≤ 20%
  - Higher priority for pediatric and high cPRA

- "A limited number of kidneys expected to function the very longest will be considered first for the candidates expected to need them for the longest amount of time."

John Friedewald, MD

Chairman, OTPN/UNOS Kidney Transplantation Committee

Key Changes with New KAS

- Implementation of new donor and recipient scores
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- Credit for dialysis time
  - High dialysis mortality
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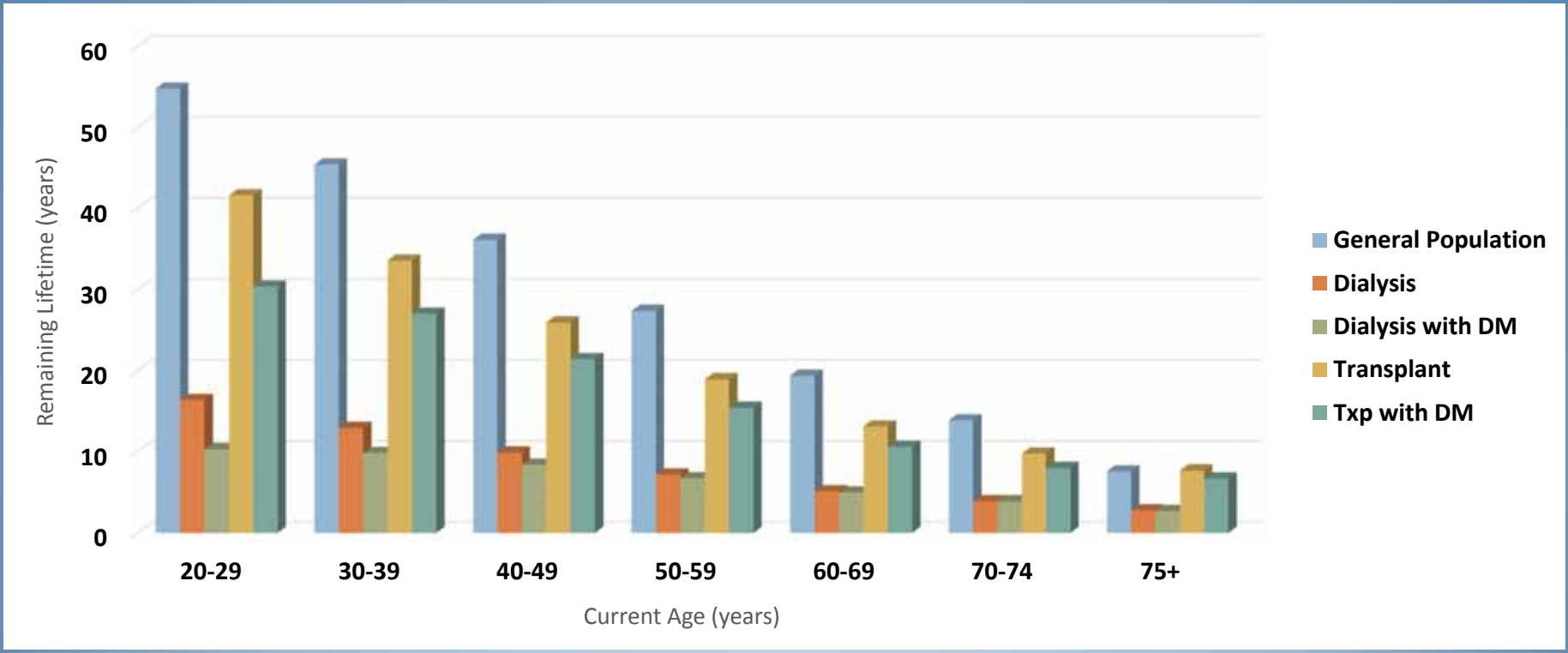
Credit for Dialysis Time

- Waiting Time Calculation
  - Old policy: Waiting time calculated based on:
    - Listing date, with measured/calculated CrCl/GFR of ≤20ml/min
    - Date after listing when CrCl/GFR becomes ≤ 20ml/min
    - Listing date, if candidate is on regular dialysis
  - New policy: Waiting time will be calculated based on "the earlier of the following":
    - Listing date, with measured/calculated CrCl/GFR of ≤20ml/min
    - Date after listing when CrCl/GFR becomes ≤ 20ml/min
    - First date of "regularly administered" dialysis, even if that pre-dates the listing for transplant

Expected Remaining Lifetime



USRDS 2016 Annual Report

Key Changes with New KAS

- Implementation of new donor and recipient scores
  - Improved longevity matching
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  - High dialysis mortality
  - Lack of timely referral for transplant
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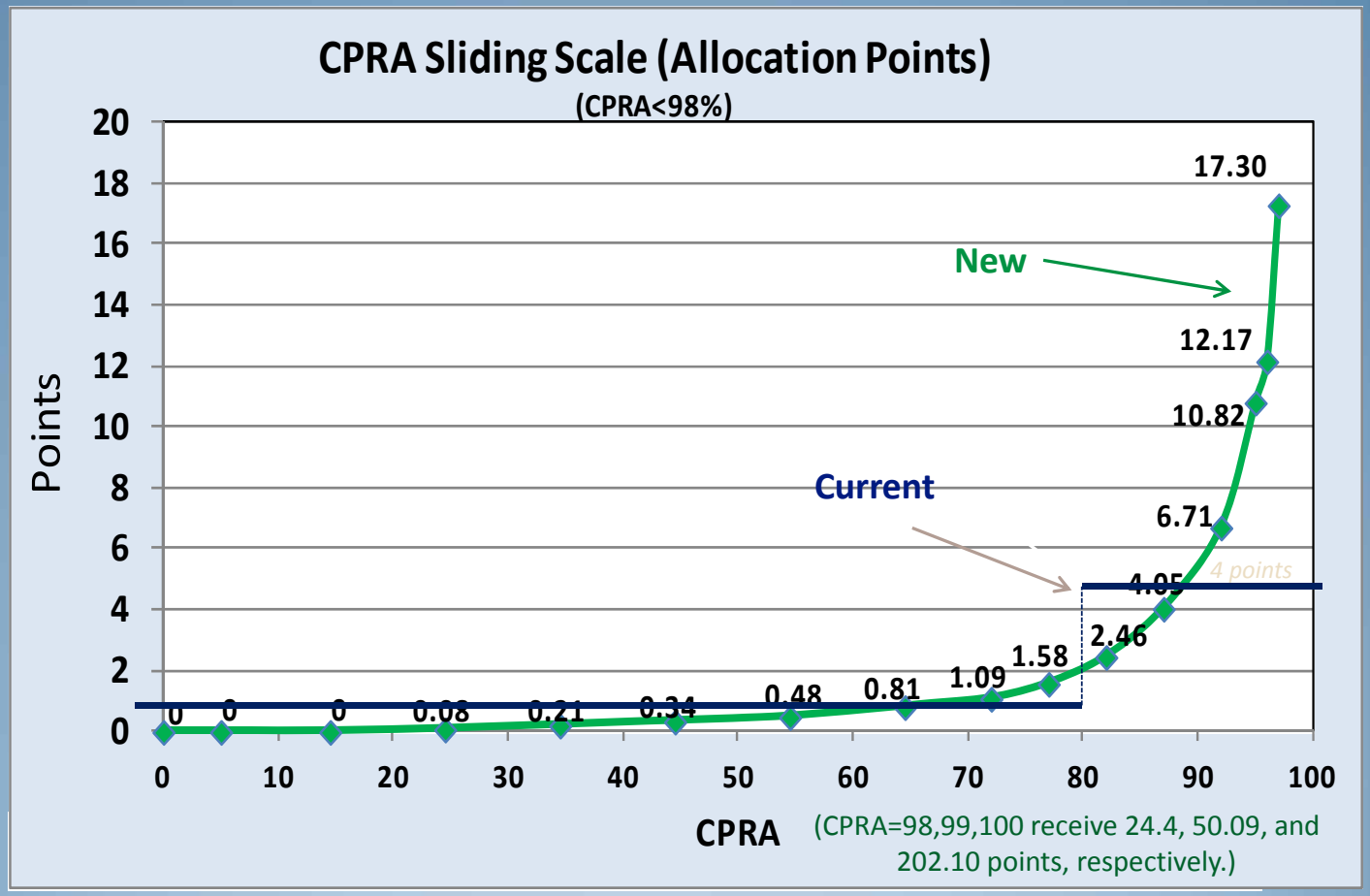
Biologically Disadvantaged

- Sensitization
  - Old policy: Gave priority to cPRA ≥ 80%
  - New policy: Sliding scale of additional priority based on degree of sensitization
    - Highest priority for cPRA ≥ 98%

Sliding Scale Based on cPRA

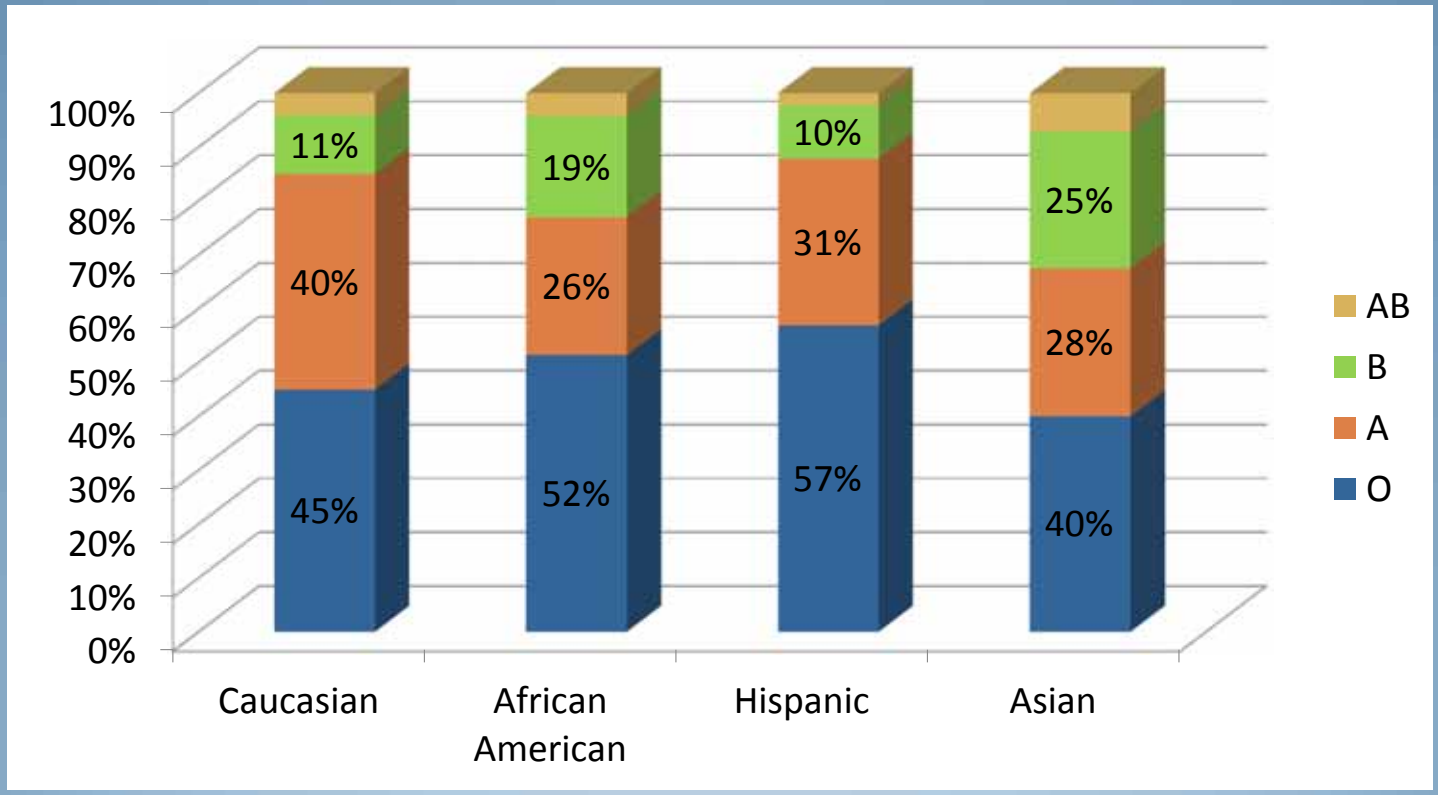


UNOS/OPTN Kidney Transplantation Committee, Fall 2013 Update

Biologically Disadvantaged

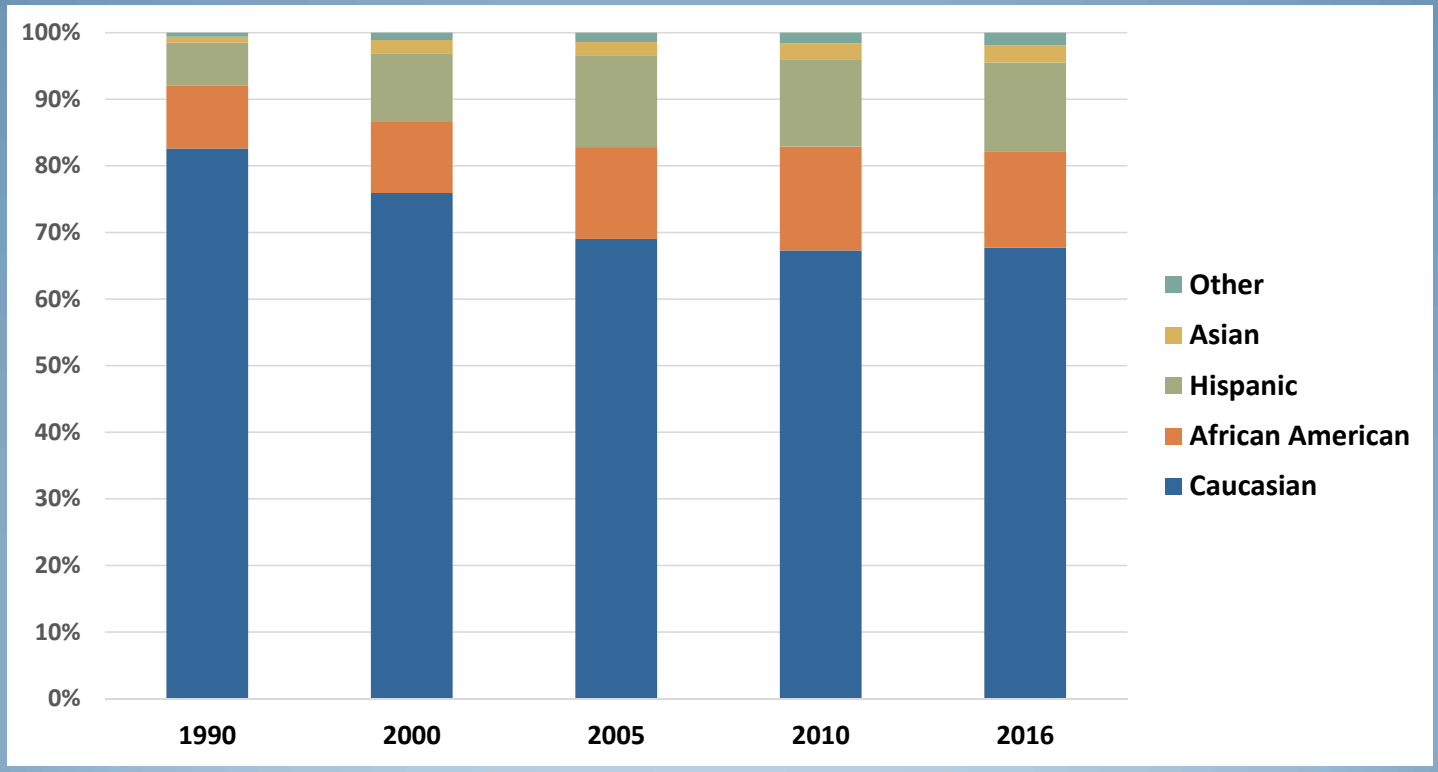
- Blood Group
  - Some B blood group candidates may be compatible with donors with certain sub-type of blood group A
  - New policy facilitates the use of these certain A donors for B recipients
  - Requires specific patient consent

Blood Groups in the US Population



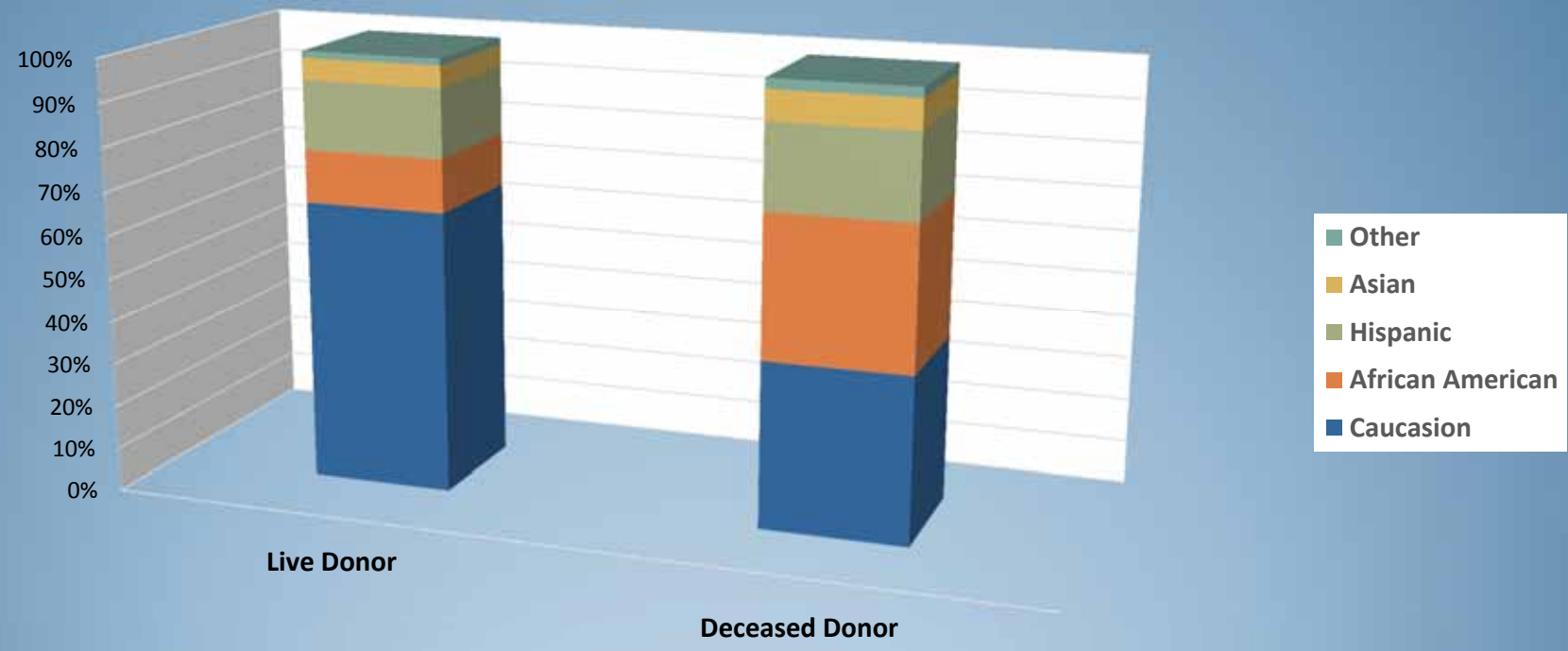
American Red Cross

Deceased Donors by Race



Based on OPTN Data 9/28/2017

Recipient Race by Donor Types: 2016

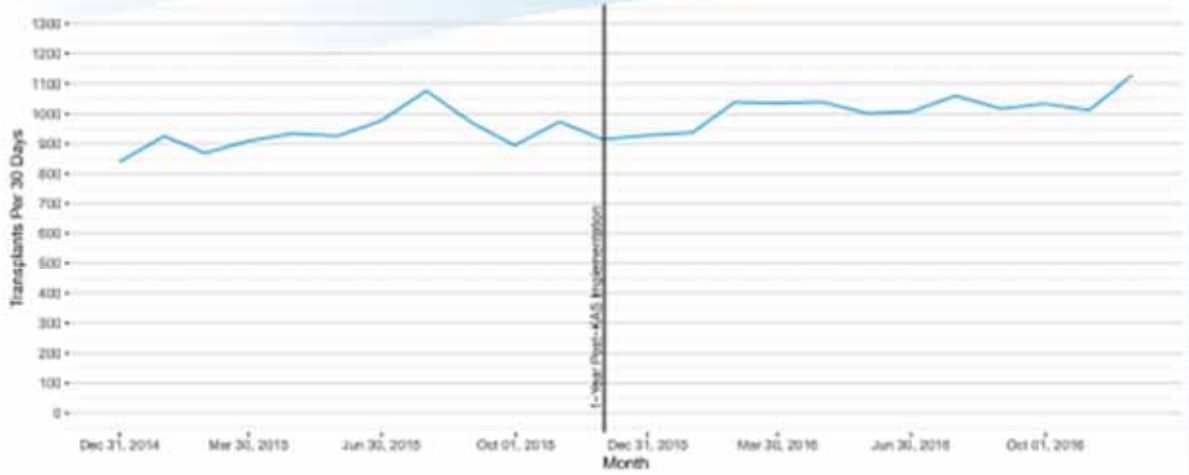


Based on OPTN Data as of 10/12/2017

Trends Under the New KAS

- Waitlist
- Transplants
  - Recipient age
  - A2/A2B to B
  - Highly sensitized
  - Dialysis vintage
- Organ utilization
  - Discard rates
- Outcomes
  - Patient survival
  - Graft survival

Solitary Deceased Donor Transplants Under KAS



Transplants increased 9.1% post-KAS, from 11,392 Post-KAS Year 1 to 12,433 Post-KAS Year 2, though the rise in transplants cannot be entirely attributed to KAS.

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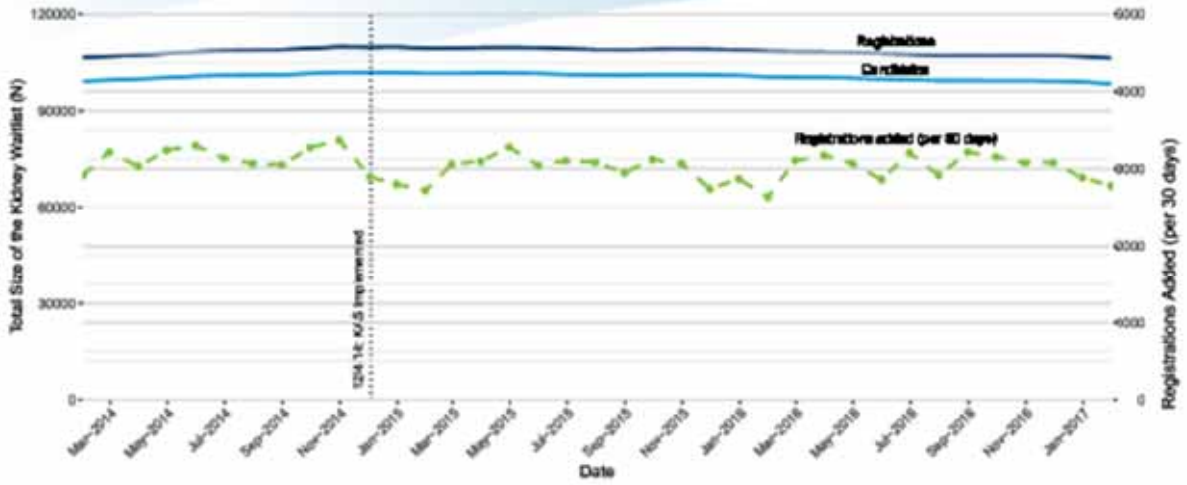
Trends in the Kidney Waiting List



The size of the kidney waiting list is slowly yet steadily decreasing; less than 1% new kidney registrations were added post-KAS Year 2 vs. Year 1.

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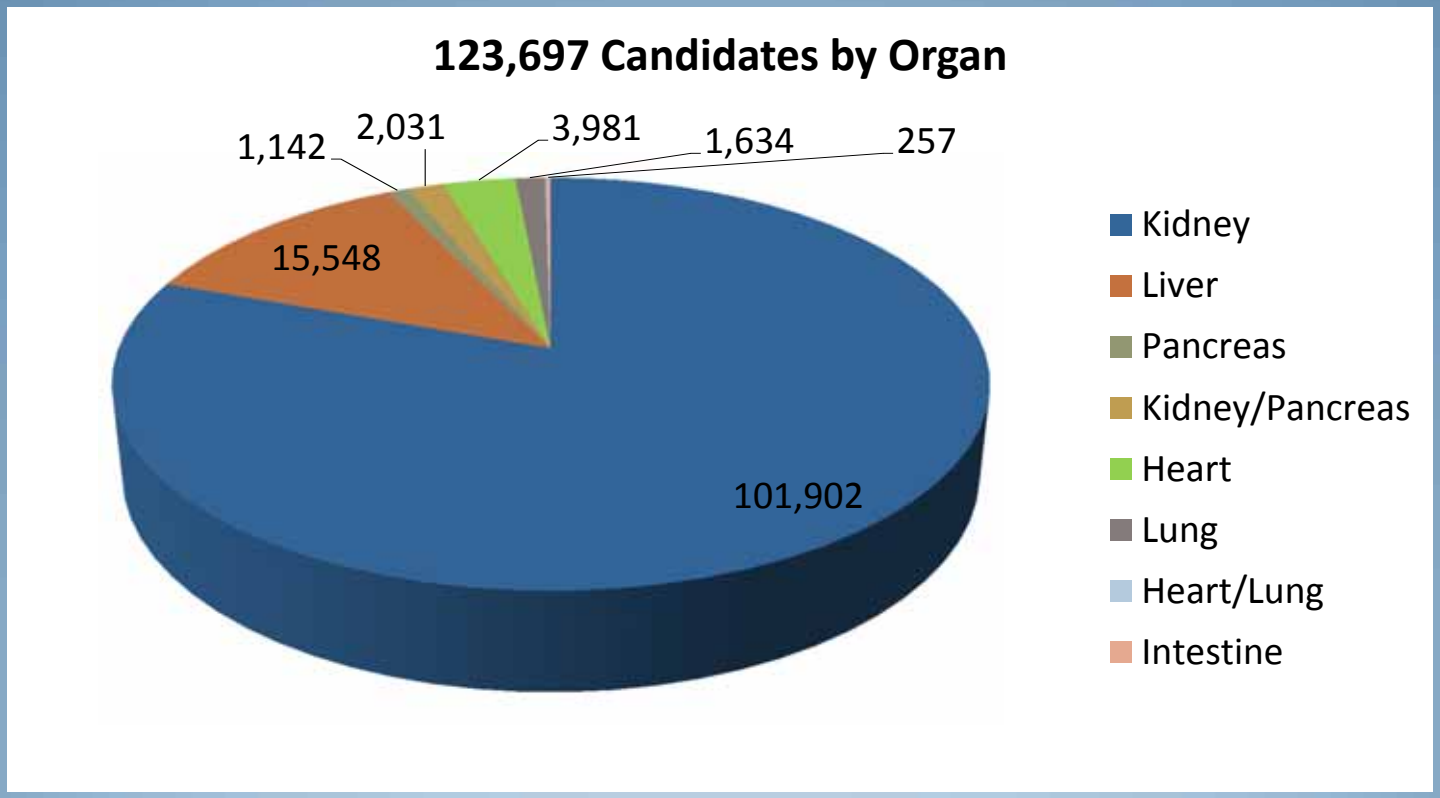
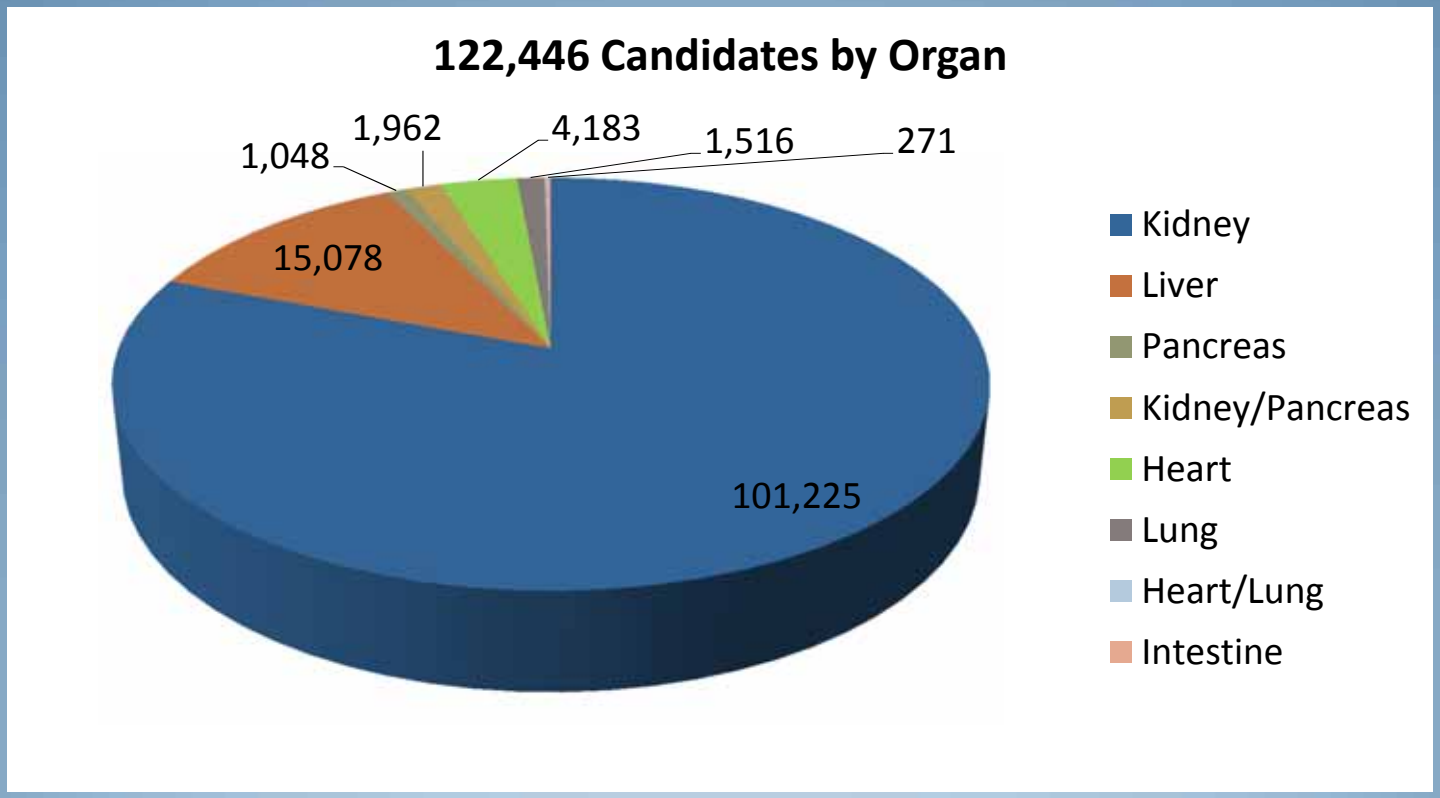
Transplant Waiting List: 11/30/2014



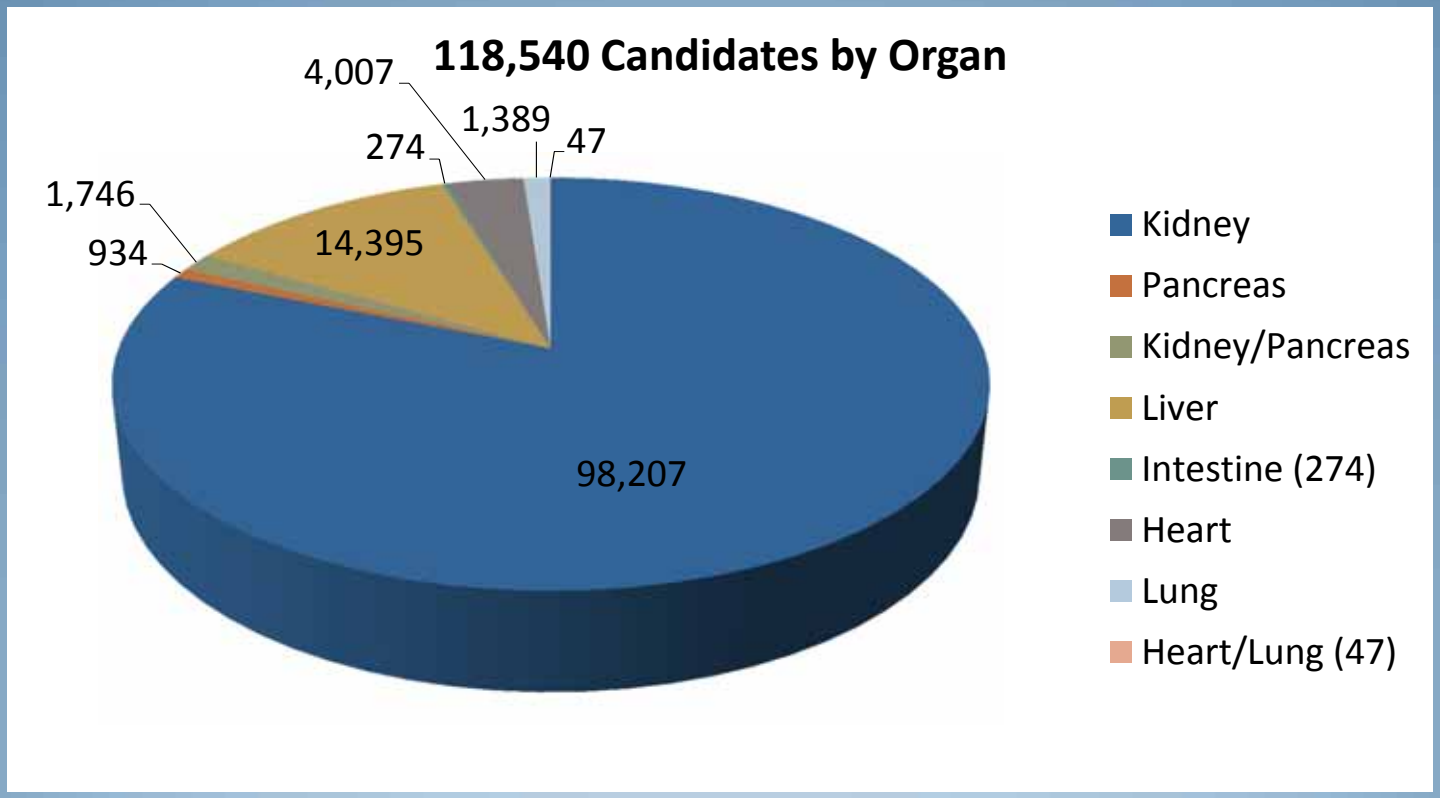
OPTN Data 10/16/2015

Transplant Waiting List: 10/16/2015



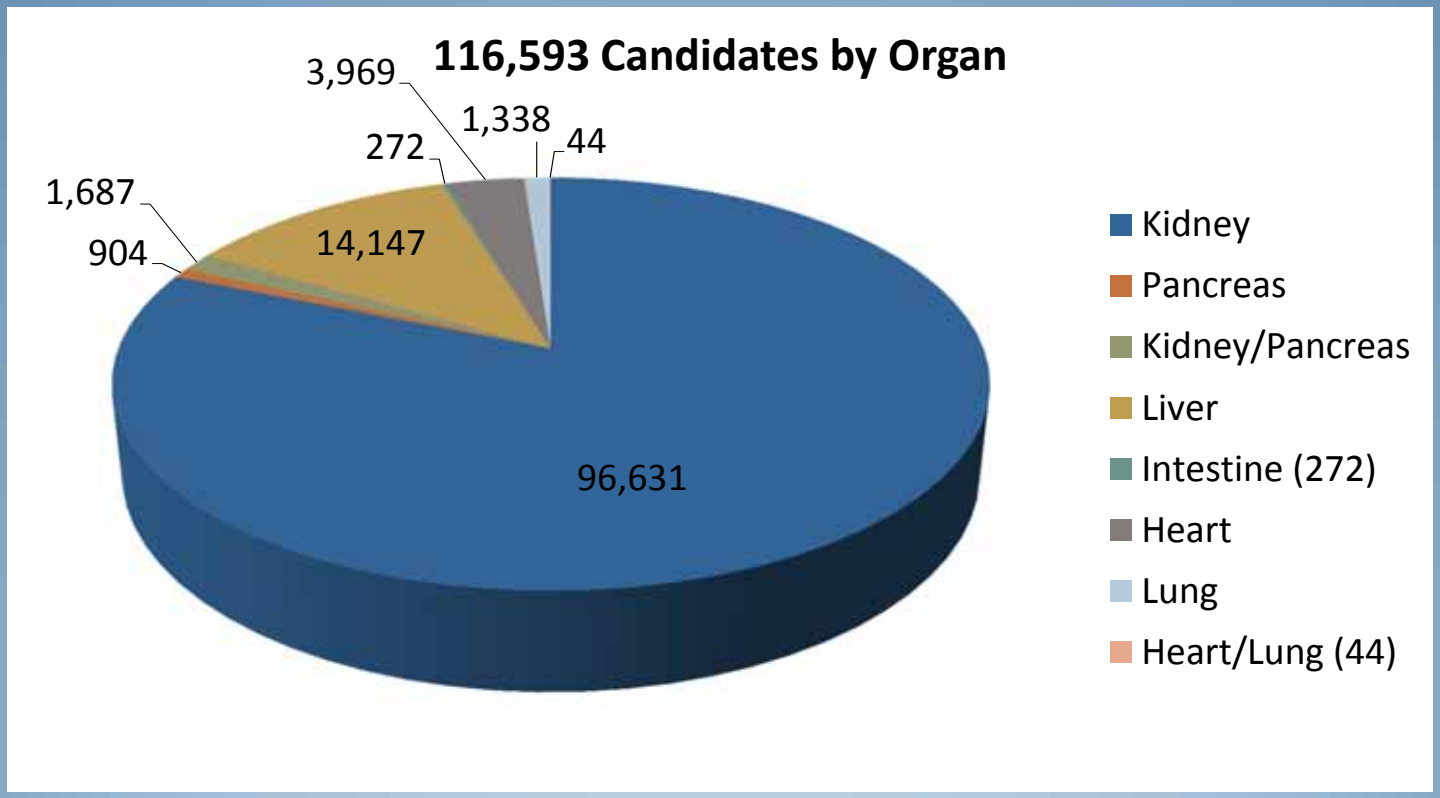
OPTN Data 10/16/2015

Transplant Waiting List: 3/4/2017



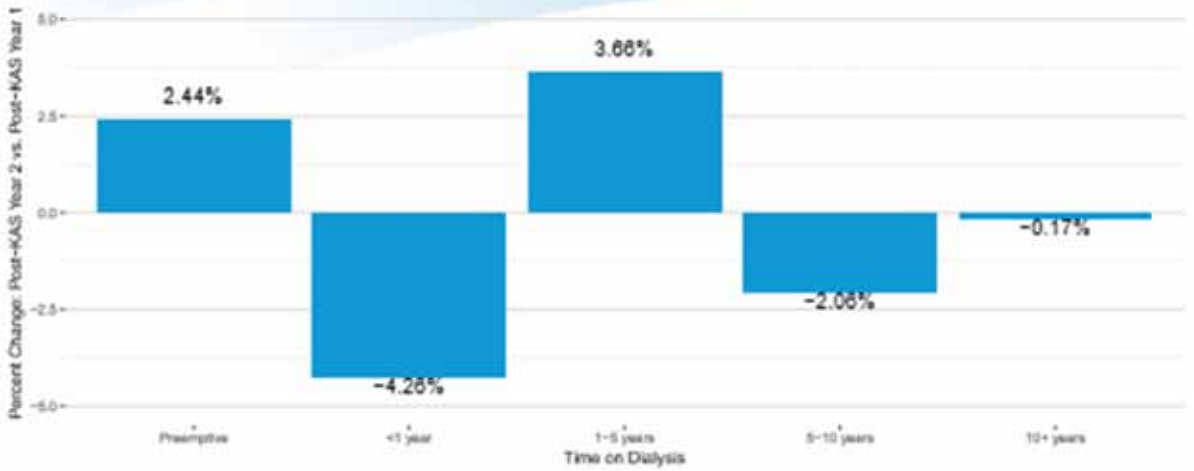
OPTN Data 3/4/2017

Transplant Waiting List: 9/30/2017



OPTN Data as of 9/30/2017

Changes in Dialysis Listing Patterns, Post-KAS



Pre-emptive listings are still increasing. Candidates with longer dialysis time decreased with subsequent increases for candidates with 1-3 years.

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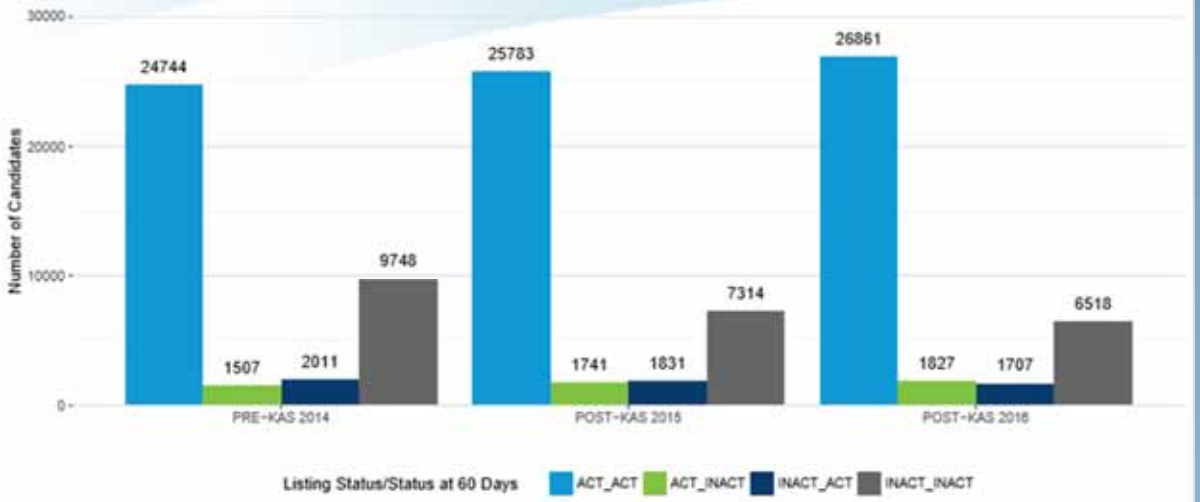
Switching Status Within 60 Days of Listing



The number and percent of candidates listed as active and remaining active at 60 days post-listing has been increasing.

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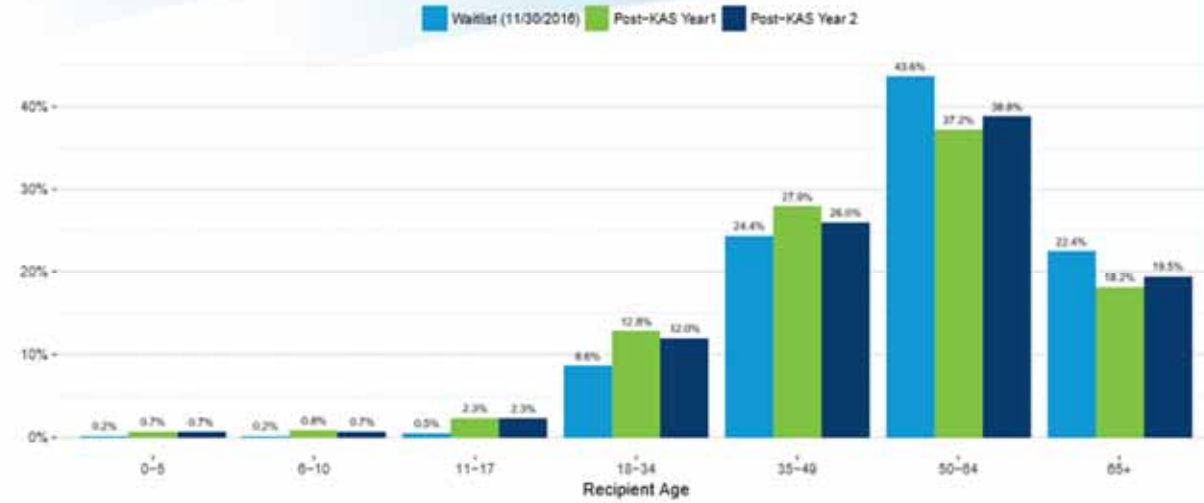
Deceased Donor Transplants by Recipient Age



The percent of transplants to younger candidates (18-49) decreased slightly, and transplants to 50+ candidates increased slightly.

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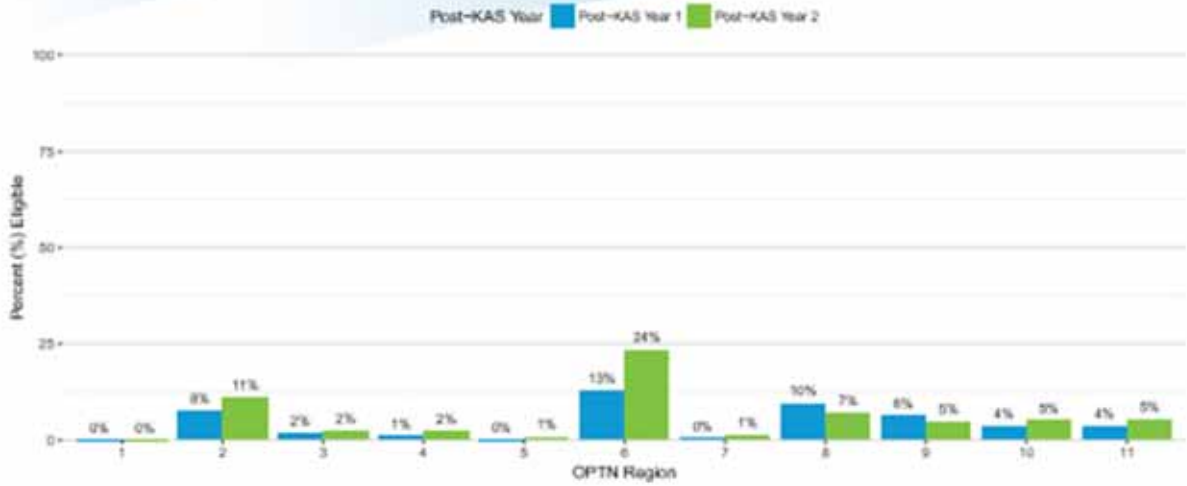
A2/A2B Subtype to Blood Type B Recipients

KAS Year	# A2/A2B to B Transplants	% of Transplants
Pre-KAS	19	0.2%
Post-KAS Year 1	109	1.0%
Post-KAS Year 2	168	1.4%

A2/A2B to B transplants continue to slowly increase under KAS.

A2/A2B Waiting List Eligibility by OPTN Region



As of 11/30/16, 4.5% of blood type B registrations on the WL were indicated as eligible for A2/A2B kidneys.

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Public Comment Proposal

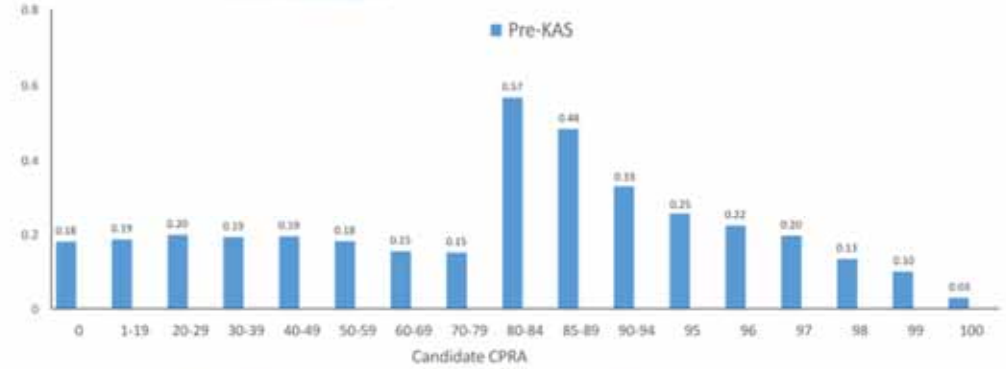
Guidance for Transplant Program Participation in the Transplantation non-A1/non-A1B (A2/A2B) Donor Kidneys into Blood Group B Candidates

OPTN/UNOS Minority Affairs Committee

Prepared by: Emily D. Ward, MPA
UNOS Policy Department

Contents

Transplant rates (per active patient-year) by candidate CPRA



- Pre-KAS, candidates with CPRA just over 80% had a marked advantage in access to transplantation.
- CPRA 99-100% patients had very little access.

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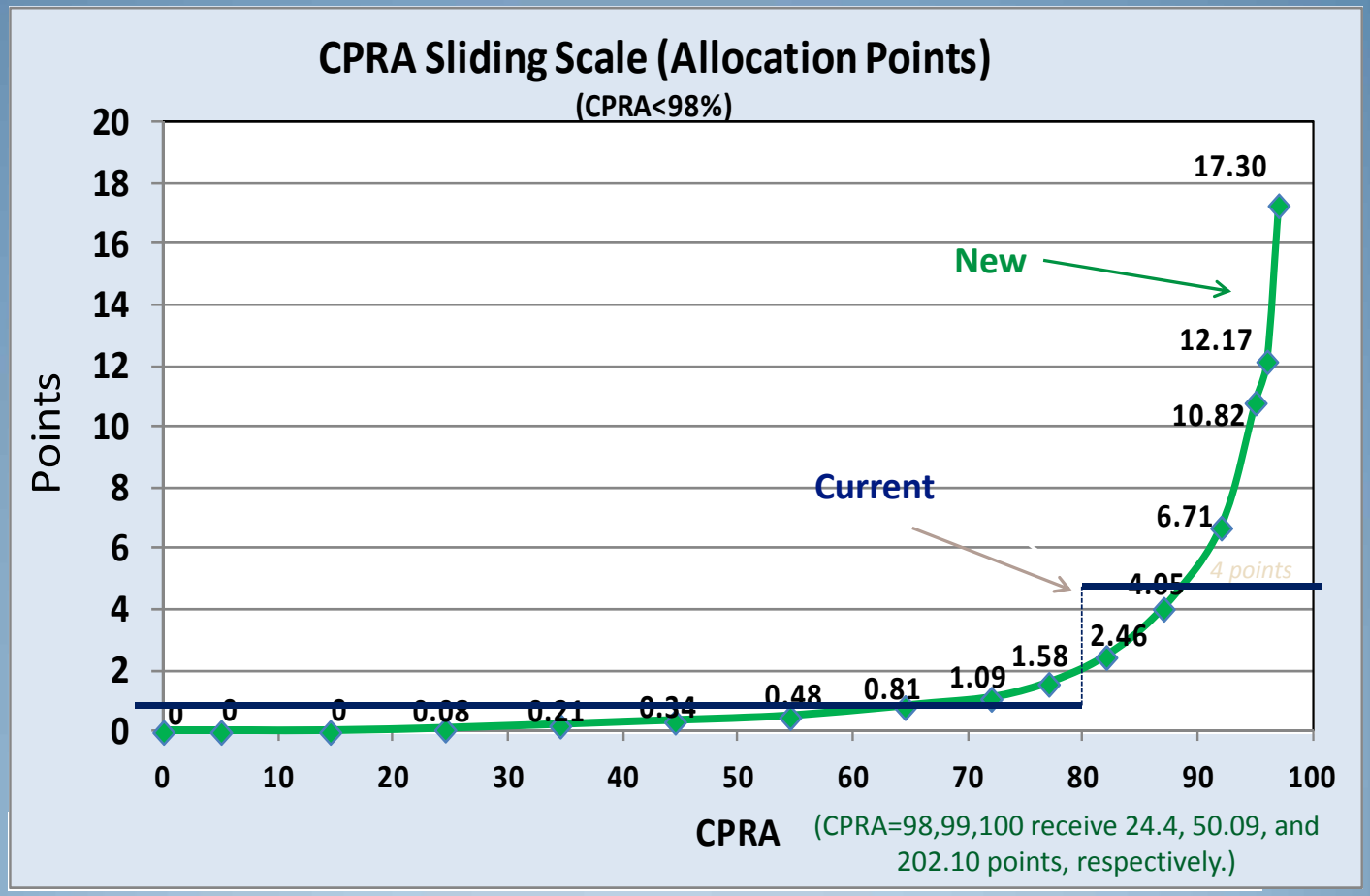
Table 4.12

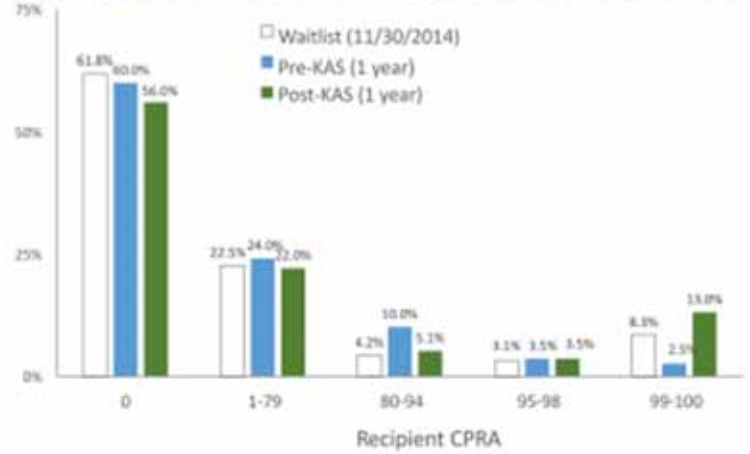
Sliding Scale Based on cPRA



UNOS/OPTN Kidney Transplantation Committee, Fall 2013 Update

Who's getting transplanted under KAS?

Percentage of Deceased Donor Kidney Transplants by Recipient CPRA



- Transplants increased sharply for CPRA 99-100% patients but have tapered during the 2nd six months.
- Pre-KAS 12.2% of recipients had a prior transplant; this rose to 15.8% of transplants.

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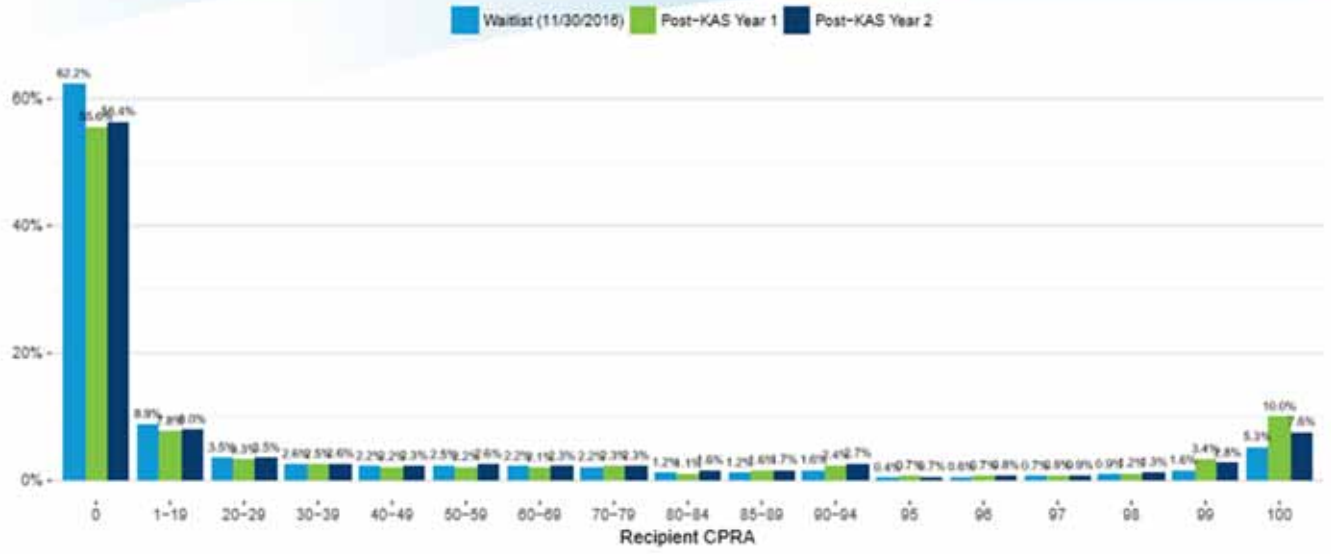
Deceased Donor Transplants by Recipient CPRA



Transplants dropped for CPRA 99-100% in the 2nd year post-KAS.

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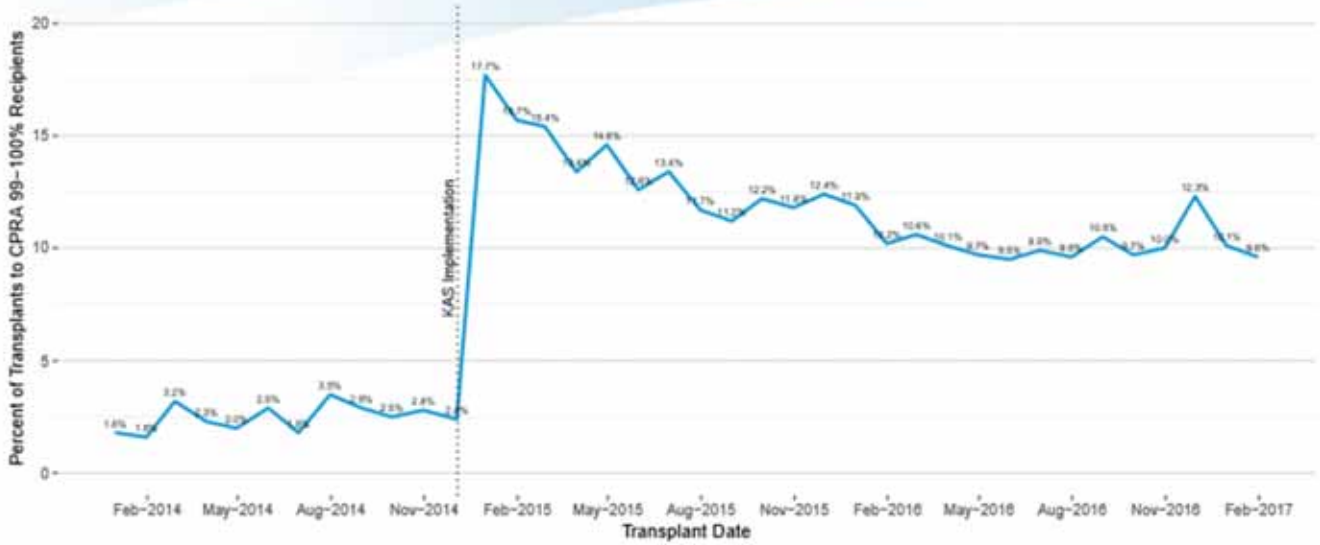
CPRA 99-100% Recipient "Bolus Effect"



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

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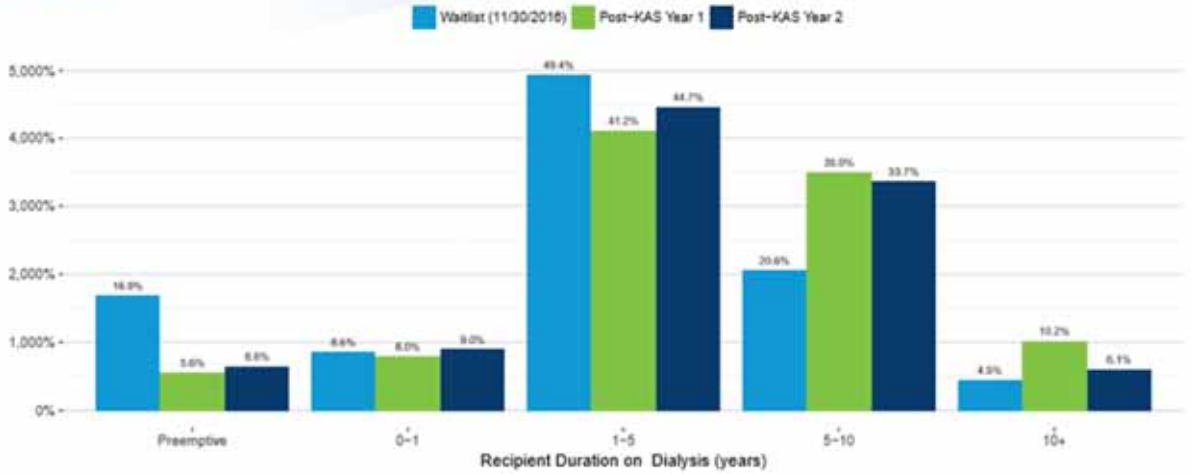
Deceased Donor Transplants by Recipient Duration on Dialysis



Transplants to long dialysis duration recipients decreased in the 2nd year post-KAS. Compared to pre-KAS (not shown), transplants remain higher for recipients with 5+ years of dialysis.

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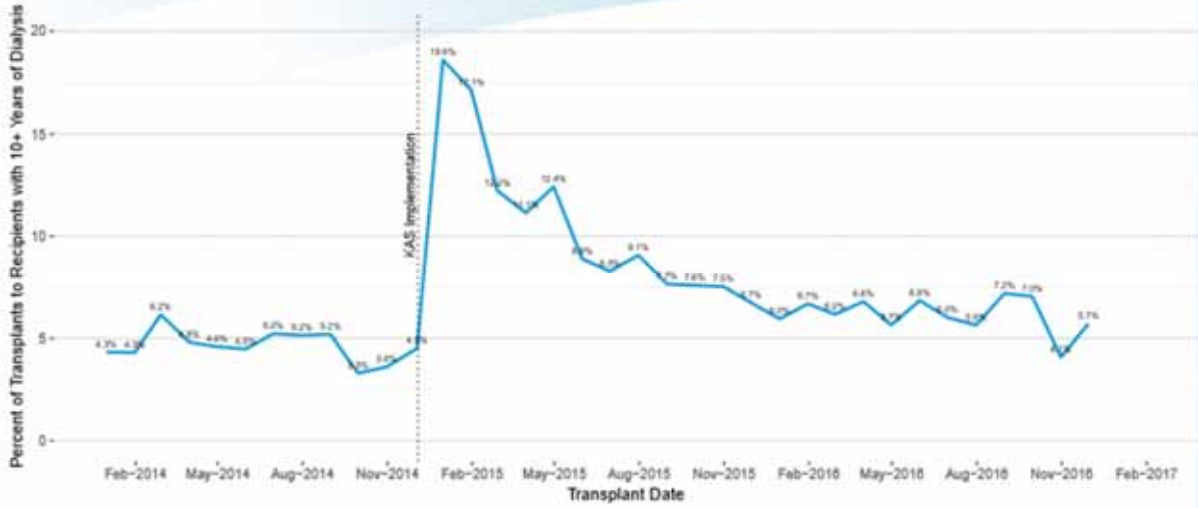
High Dialysis Time Recipient "Bolus Effect"



Transplants to candidates with 10+ years of dialysis rose sharply after KAS but have tapered substantially to around 6%.

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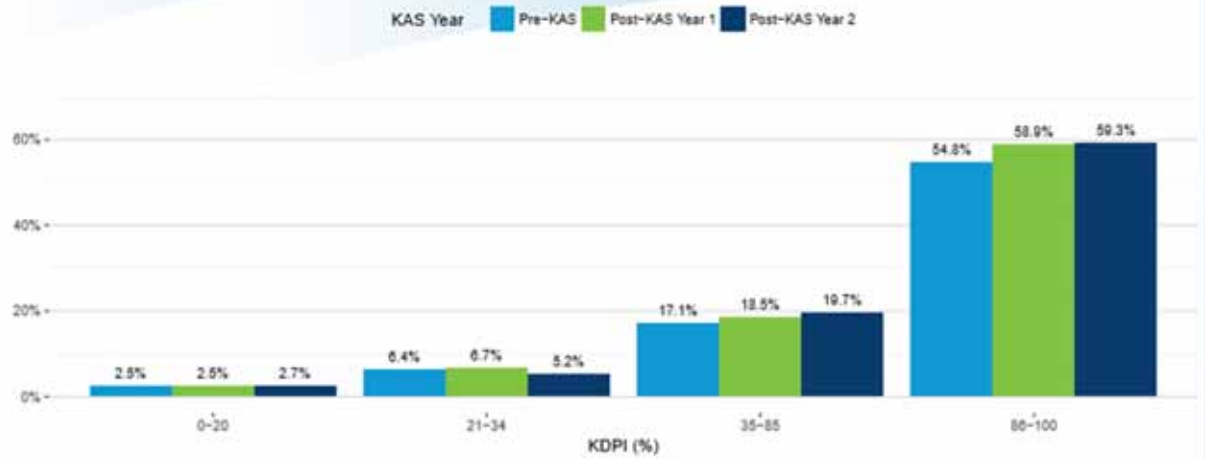
Kidney Discard Rate by KDPI



The overall discard rate increased from 19.3% post-KAS Year 1 to 19.9% post-KAS Year 2. KDPI 21-34% kidneys saw a decrease in discard rate in the most recent year, while KDPI 35-85% kidneys discard rates increased again. KDPI 0-20% and 86-100% remain fairly stable in the post-KAS era.

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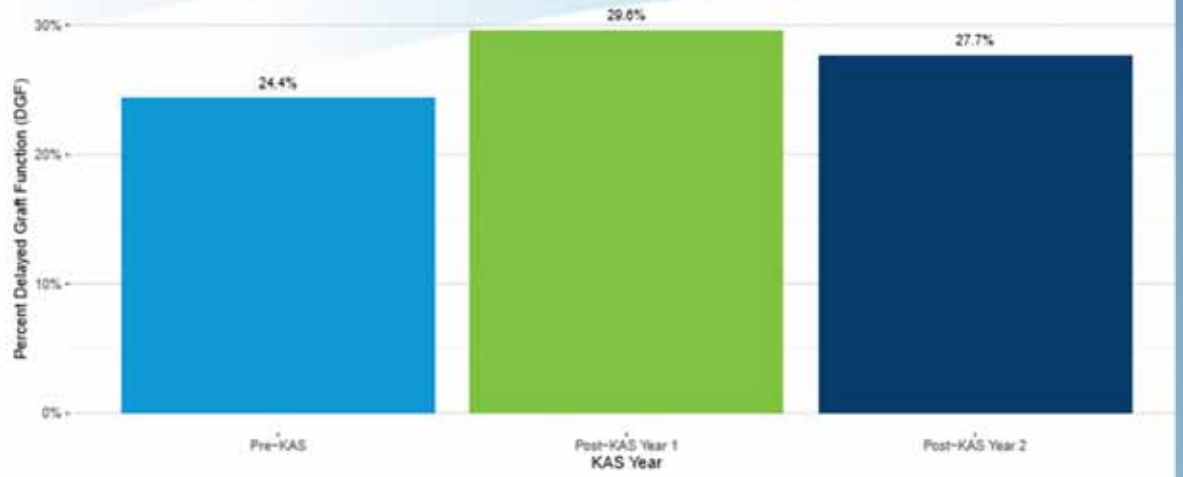
Delayed Graft Function (DGF) Rates



The percentage of recipients requiring dialysis within the first week after transplant decreased from 29.6% post-KAS Year 1 to 27.7% post-KAS Year 2, but remains higher than pre-KAS. The decrease was significant (p = 0.0010).

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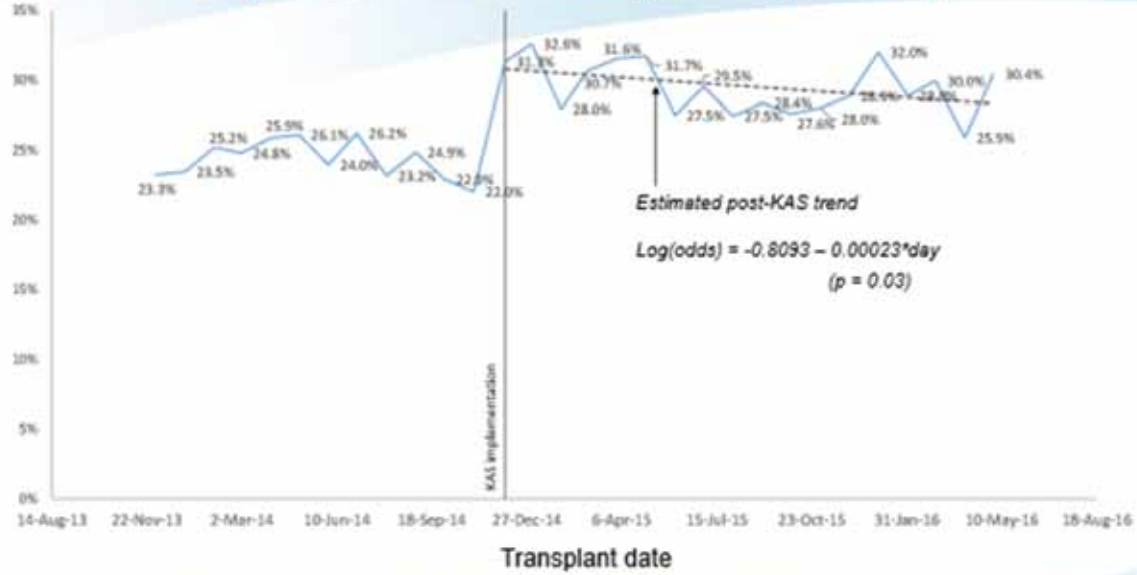
DGF Trend (transplants through May, 2016)



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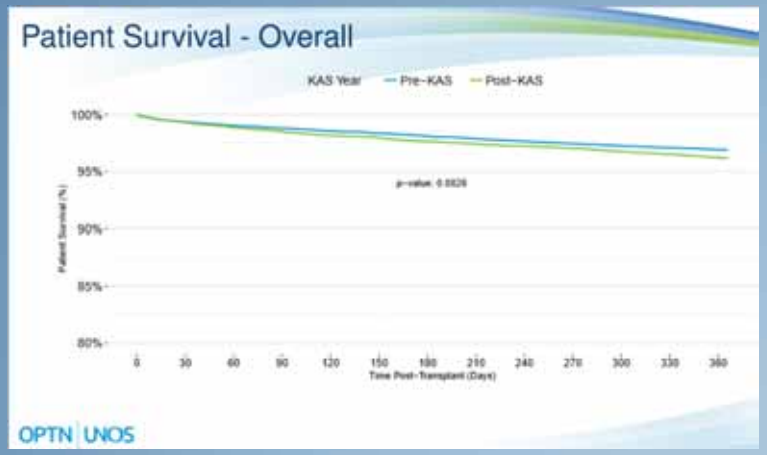
- Slight decline in DGF rate post-KAS (p=0.03), likely due to diminishing bolus effects (e.g., fewer high dialysis time recipients).

Patient Survival - Overall



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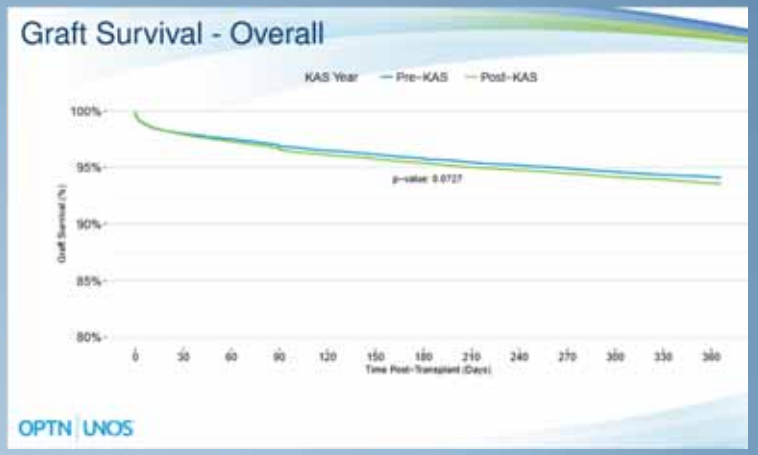
Graft Survival - Overall



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Survival

- Decreased slightly but remain high
- Affected by multiple factors
  - Recipient age
  - Organ preservation time (cold ischemia time)
  - Recipient sensitivity
  - Recipient dialysis vintage
- Highly sensitized and longer-term dialysis patients were transplanted with the implementation of the KAS
  - Bolus effects may affect patient and graft survival

Access to Transplant

- Access to Transplant Score
  - A numerical measure that quantifies the variability in expected waiting times for deceased donor transplant for candidates on the transplant list

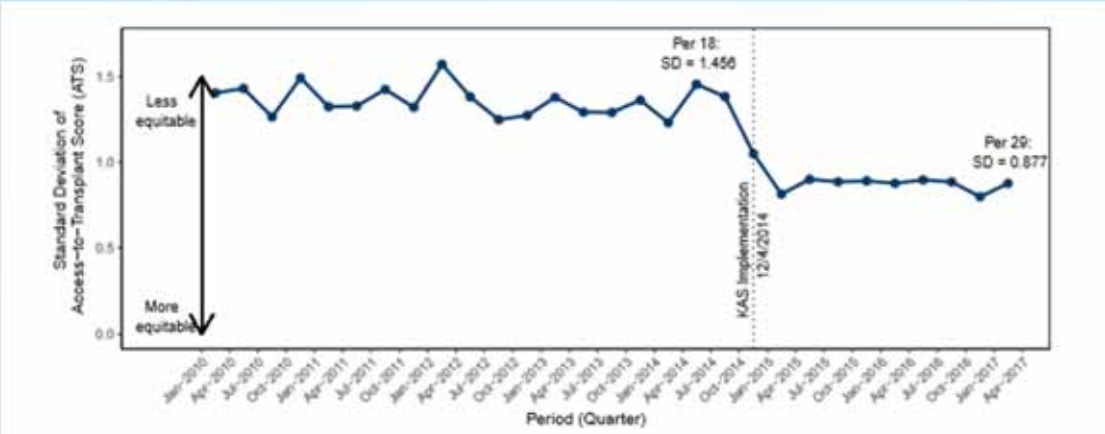

Figure 1: Tracking Variability in Access-to-Transplant Score (ATS) Among Waitlisted Kidney Candidates by Quarter (Jan 2010 - Mar 2017)

OPTN: Report on Equity in Access

Characteristics Most Associated with Disparity in Access to Transplantation

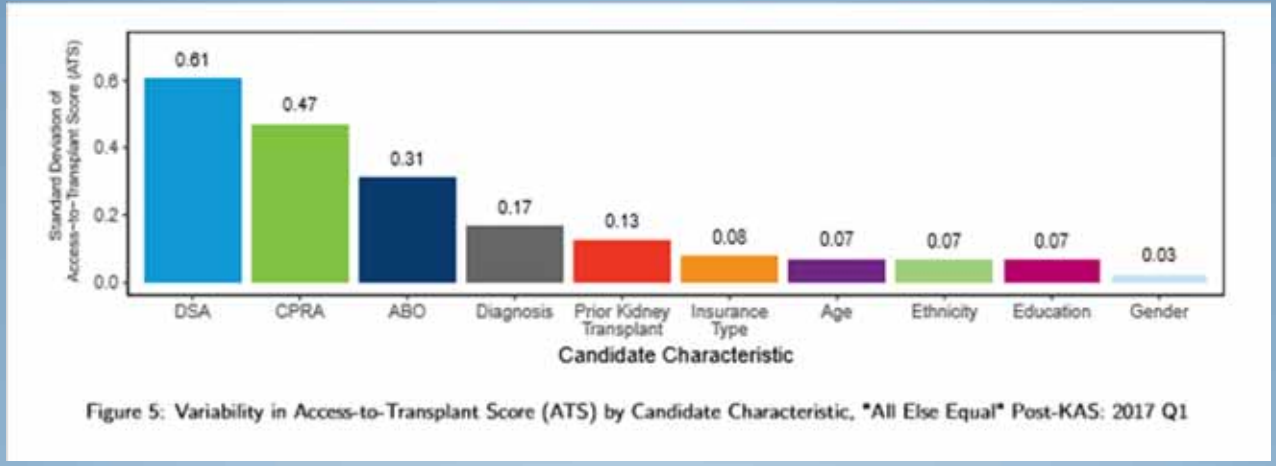

Figure 5: Variability in Access-to-Transplant Score (ATS) by Candidate Characteristic, "All Else Equal" Post-KAS: 2017 Q1

OPTN: Report on Equity in Access

unos.org/transplantation/matching-organs/regions

Region 2 Profile

Donors versus Organs Donated in 2016

Programs	Donors	Organs
All Donors	2,099	5,298
Kidney	1,880	3,023
Liver	1,172	1,172
Heart	369	369
Pancreas	148	148
Lung	302	573
Intestine	13	13

Based on OPTN data as of 10/15/2017

Organ registrations on waitlist as of 10/15/2017

Programs	Counts
All Organs	17,081
Kidney	13,830
Liver	2,054
Pancreas	159
Kidney / Pancreas	201
Heart	409
Lung	284
Heart / Lung	4
Intestine	140

Based on OPTN data as of 10/15/2017

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Based on OPTN data as of 10/15/2017

Region 9 Profile

Donors versus Organs Donated in 2016

Programs	Donors	Organs
All Donors	985	1,908
Kidney	879	1,258
Liver	372	372
Heart	122	122
Pancreas	49	49
Lung	58	104
Intestine	3	3

Based on OPTN data as of 10/15/2017

Organ registrations on waitlist as of 10/15/2017

Programs	Counts
All Organs	9,839
Kidney	7,997
Liver	1,108
Pancreas	173
Kidney / Pancreas	145
Heart	339
Lung	63
Intestine	14

Based on OPTN data as of 10/15/2017

KAS 2 Years Later:

- Deceased donor kidney transplants increased 9.1%
- Longevity matching performing as expected
  - More than half of adult recipients with EPTS <20% received kidneys from a donor with KDPI <20%
- Significant bolus effects occurred for candidates who received priority under the new KAS
  - Transplant rates have declined as fewer candidates are left on the list
  - Transplant rates remain higher than pre-KAS
- Discard rates are slightly higher, but are largely linked to KDPI scores
  - <3% of kidneys with <20% KDPI are discarded
  - 60% of kidneys with >85% KDPI are discarded
- Survival rates have decreased slightly, but remain high

optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system

References

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  https://optn.transplant.hrsa.gov
- United Network for Organ Sharing (UNOS)
  https://www.unos.org
- United States Renal Data System (USRDS)
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