

Possible Effects of New National Allocation Policy for Deceased Donor Kidneys in the US

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July 29, 2014





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I have no financial relationships to disclose within the past 12 months relevant to my presentation. The ACCME defines 'relevant' financial relationships as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

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SRTR's complementary role to the OPTN

| OPTN | SRTR |
|--|---|
| Organ Allocation / Policy Development | Research / Policy Evaluation |

When a committee is considering a change to allocation policy, the committee members may wish to simulate what changes may occur if the policy is implemented. SRTR uses Simulated Allocation Modeling Software to accomplish this goal.

The new kidney allocation policy's effects on mortality among older candidates and access to transplant based on dialysis time are unknown.

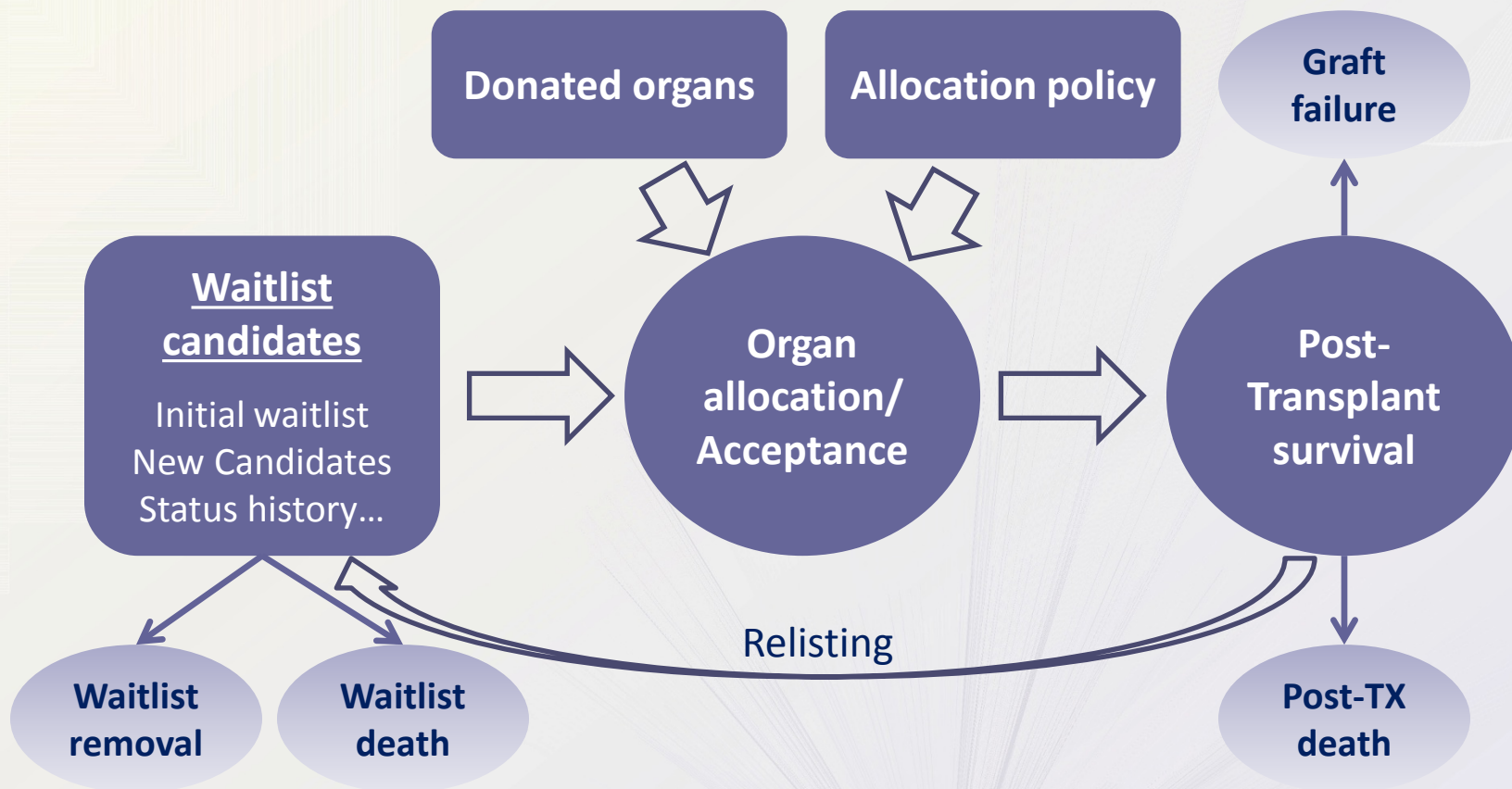
Overview of allocation components by run

| Concepts | Current | New |
|--|---------|-----|
| SCD allocation (defined as KDPI \leq .85 for new policy) | X | X |
| DCD allocation | X | |
| ECD allocation (defined as KDPI $>$.85 for new policy) | X | X |
| Payback system | X | |
| Waiting time since listing | X | |
| Back-dating dialysis time | | X |
| Waiting time points based on fractional years | | X |
| A2/A2B donor to B candidates priority(local, regional, and national) | | X |
| Highest scoring high CPRA classification | X | |
| Pediatrics cannot receive non-0 mm ECD offers | | X |

Overview (continued)

| Concepts | Current | New |
|---|---------|-----|
| Longevity matching (top 20% survivors get first chance at top 20% kidneys) | | X |
| "Share 0.35" pediatric priority in new policy (Donor < 35 yrs for Current) | X | X |
| CPRA sliding scale | | X |
| National priority sharing for CPRA 100%, regional priority sharing for CPRA 99%, local priority for CPRA 98% candidates | | X |
| Regional sharing for marginal kidneys (KDPI>.85) | | X |
| KP/PA System: current | X | |
| KP/PA system: future | | X |

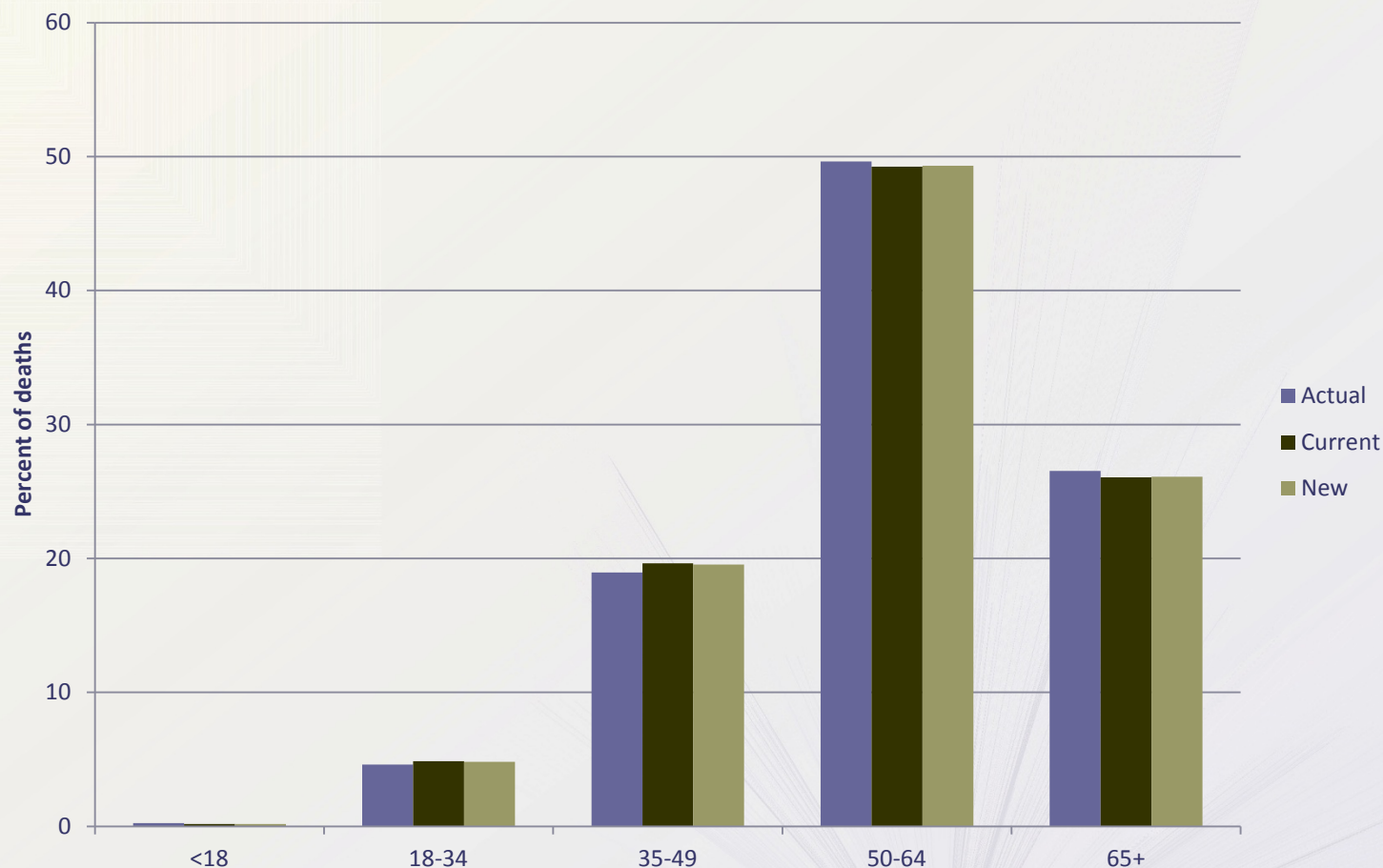
Allocation modeling flow chart



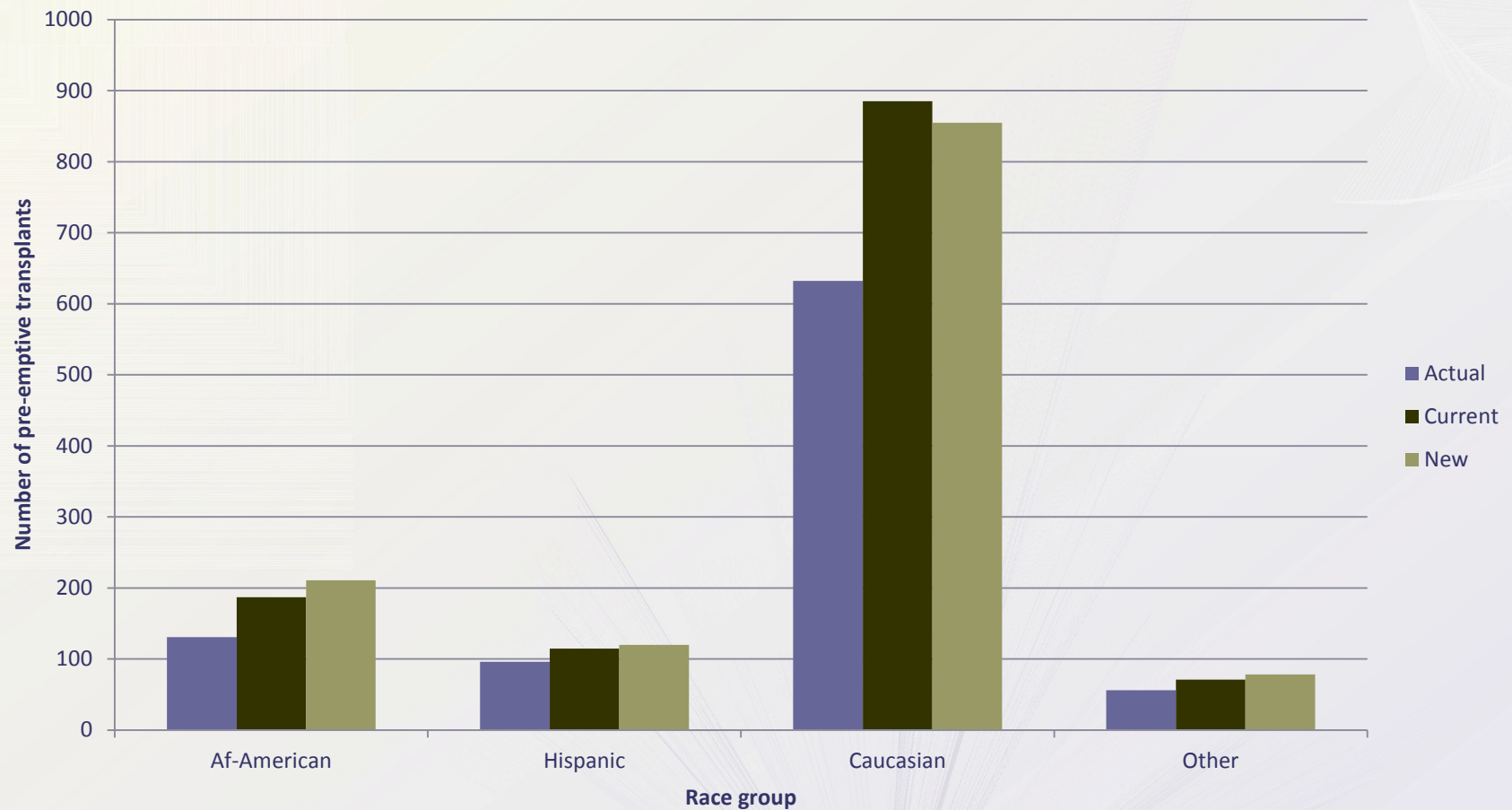
Results of simulations

| Average for 10 iterations | Current | New |
|---|---------------------------|---------------------------|
| Number of candidates (on waitlist at start or joining during run) | 122,669 | 122,669 |
| Average number of primary transplant recipients (KI+KP) | 11,531 (11,463-11,586) | 11,599 (11,538-11,681) |
| Average median lifespan post-transplant (min, max of runs) | 11.82 (11.75 - 11.85) | 12.65 (12.61-12.71) |
| Average median graft years of life (min, max of runs) | 8.82 (8.80-8.84) | 9.07 (9.05-9.08) |
| Average median extra life-years for tx recipient versus waitlist candidate (min, max of runs) | 5.01 (4.99-5.03) | 5.24 (5.22-5.27) |

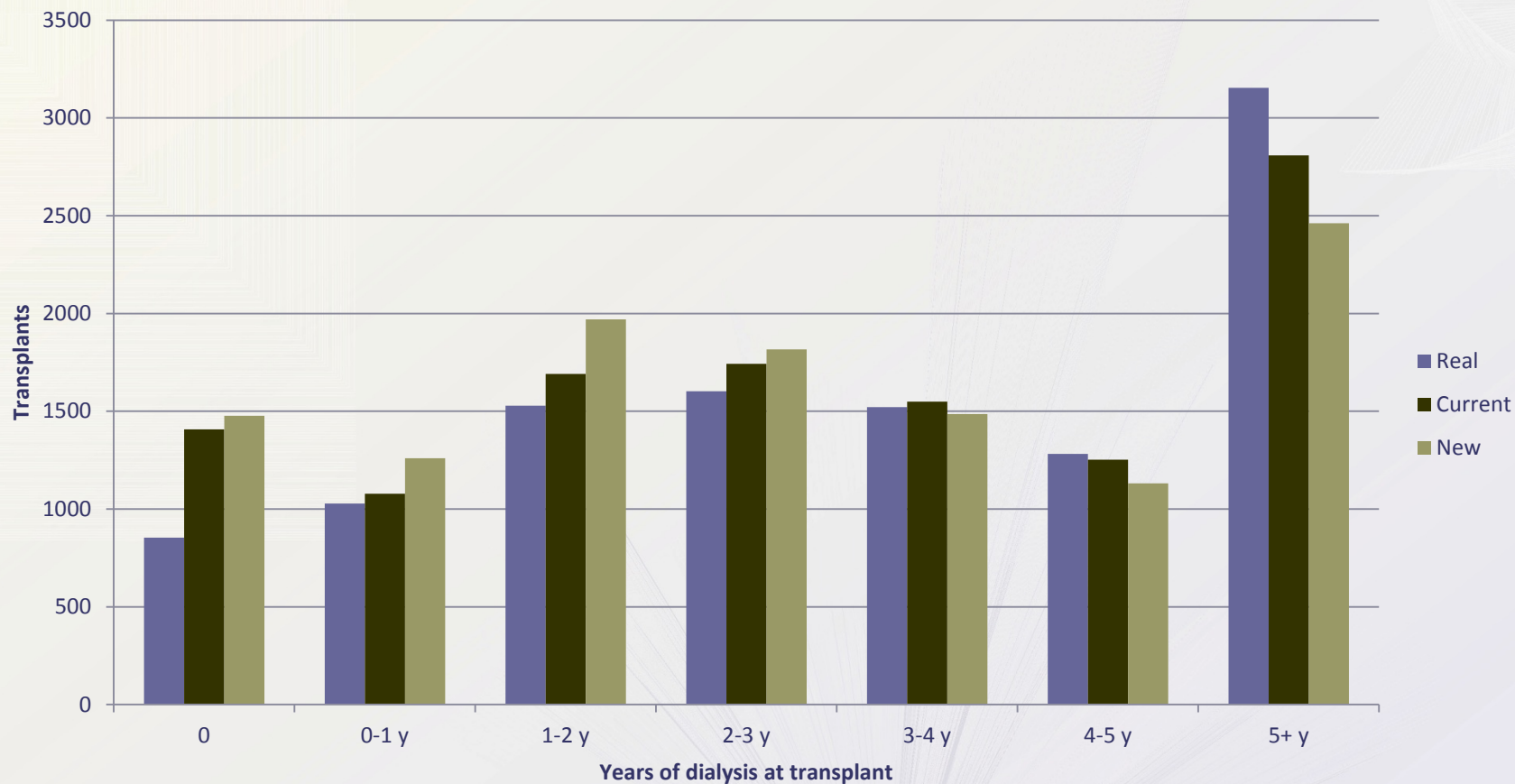
Percentage of deaths on the waiting list: actual 5,444 in 2010



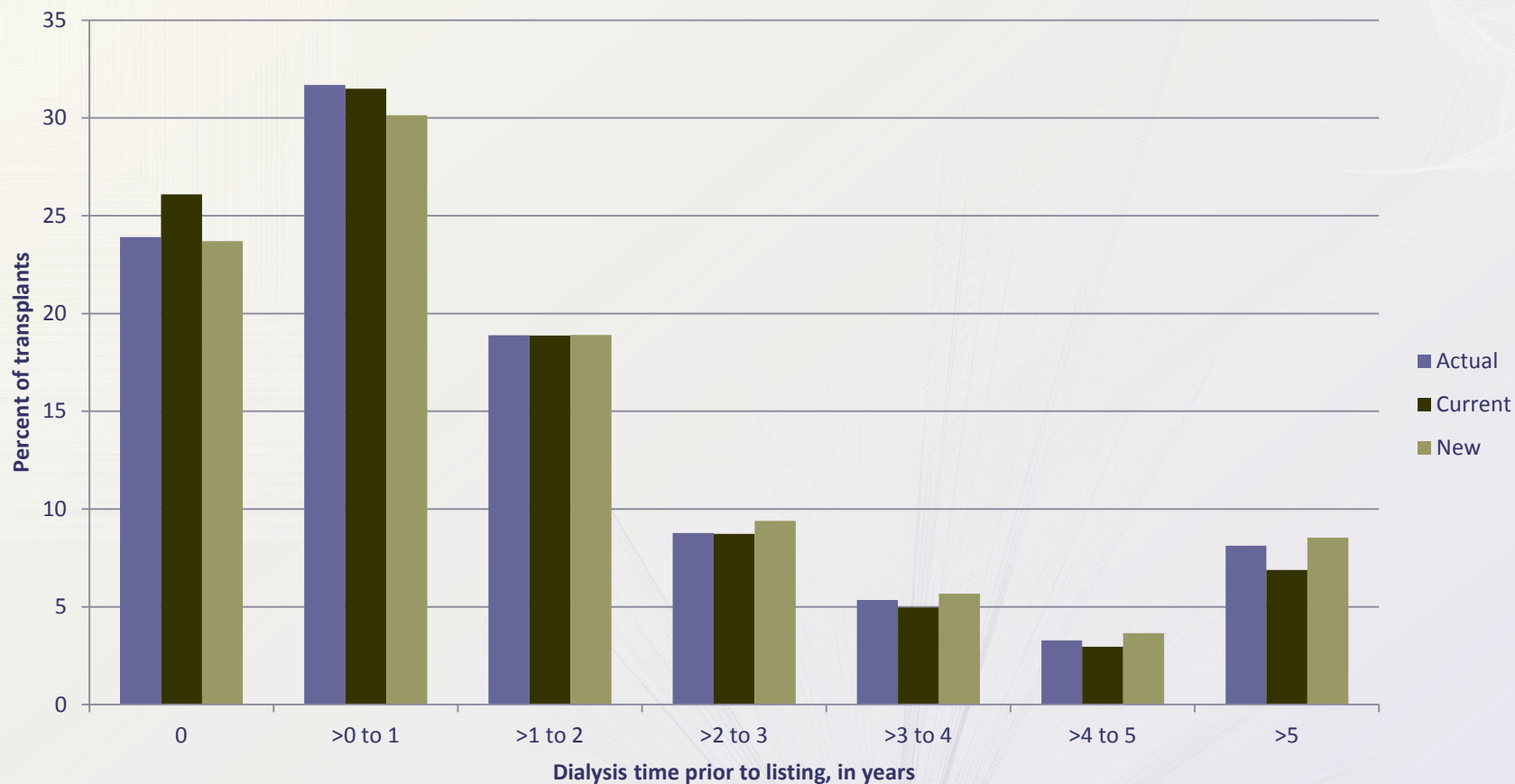
Pre-emptive transplants by race



Number of years of dialysis at transplant



Dialysis time prior to listing



Summary of results for kidney allocation policy

- The new policy simulation showed :
 - No substantial increases in mortality on the waiting list
 - Pre-emptive transplants increase, for Caucasian & African-American
 - Dialysis time at transplant was re-distributed
 - More transplants for candidates with less than 3 years on dialysis
 - Fewer transplants for candidates with more then 3 years on dialysis
 - Dialysis time at time of listing did not change substantially

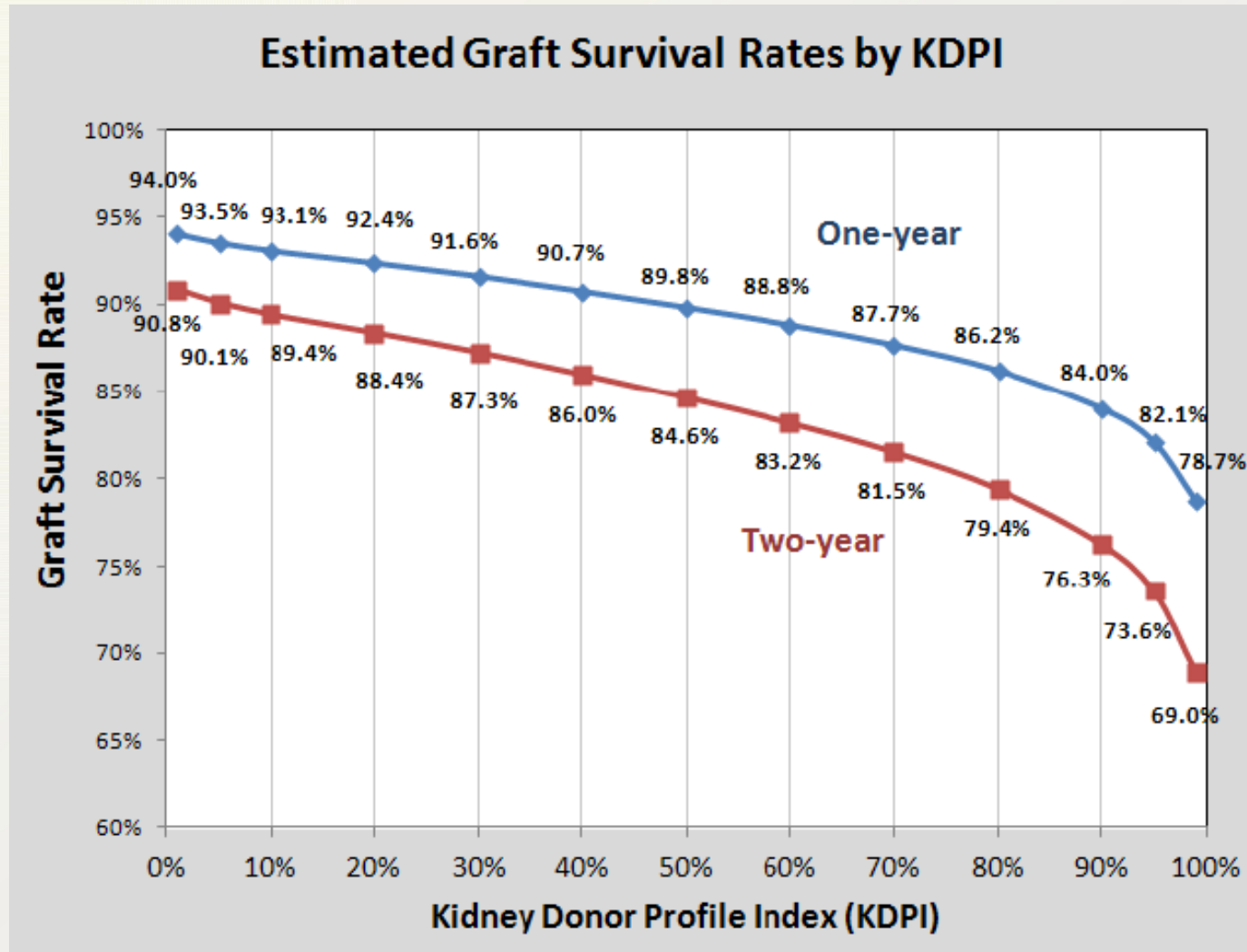
Future directions

- Monitor for expected consequences
- Intended & unintended consequences

Limitations of current system

- Variability in access to transplantation by candidate blood type
- High discard rates of kidneys
- Differences in access to transplantation for populations such as candidates with high CPRA
- Kidneys with long potential longevity allocated to candidates with significantly shorter longevity and vice versa
 - Results in unrealized graft years and high retransplant rates

KDPI: correlated with graft survival



Estimated post-transplant survival (EPTS)

- Based on following recipient factors:
 - Candidate age
 - Length of time on dialysis
 - Prior transplant (any organ)
 - Diabetes status(All negative factors, leading to higher EPTS score)
- Higher EPTS score = lower expected patient survival

New proposed national allocation policy: CPRA sliding scale

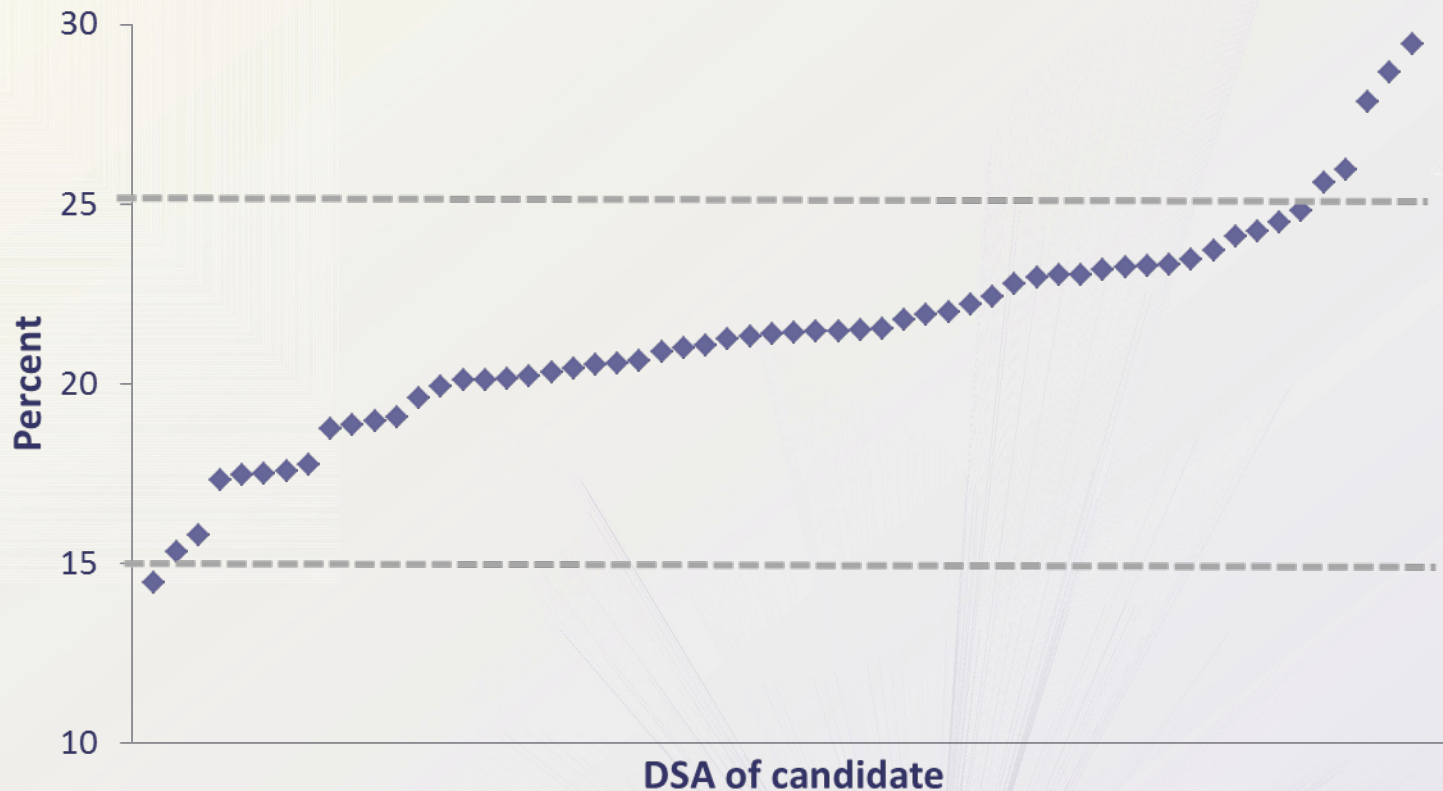
- Currently, candidates with a CPRA of 80% or greater get 4 points; candidates with a CPRA below 80 get no additional points.
- To mediate the “spike” in points at 80, the kidney committee, along with histocompatibility committee, developed the CPRA sliding scale.

| CPRA | Points |
|---------|--------|
| 0-19 | 0 |
| 20 - 29 | 0.08 |
| 30 - 39 | 0.21 |
| 40 - 49 | 0.34 |
| 50 - 59 | 0.48 |
| 60 - 69 | 0.81 |
| 70 - 74 | 1.09 |
| 75 - 79 | 1.58 |
| 80 - 84 | 2.46 |
| 85 - 89 | 4.05 |
| 90 - 94 | 6.71 |
| 95 | 10.82 |
| 96 | 12.17 |
| 97 | 17.3 |
| 98 | 24.4 |
| 99 | 50.09 |
| 100 | 202.1 |

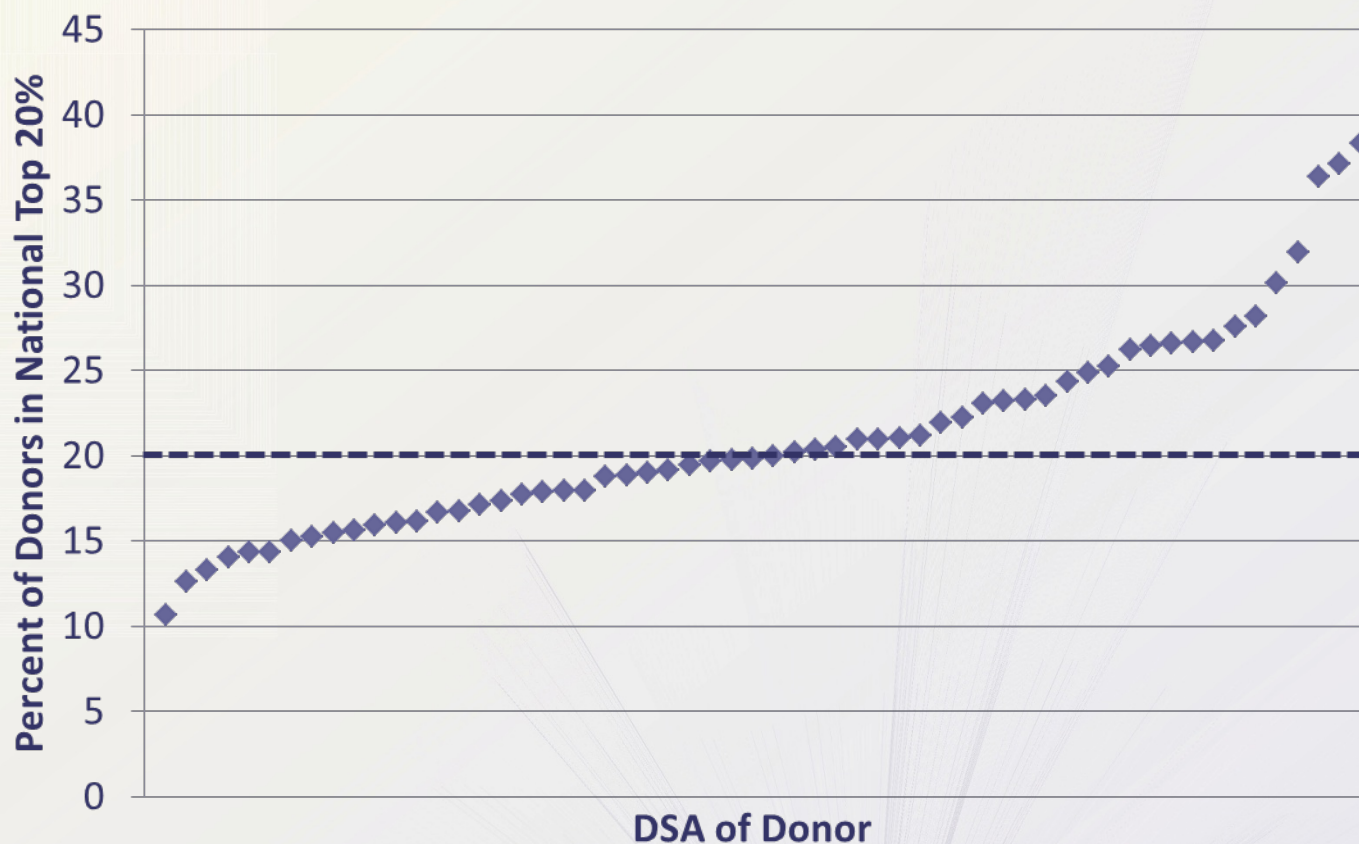
Proposed point system to rank-order within each category

- 1 point per year (awarded as $1/365$ point per day) for qualified time spent waiting
- 0-202 points based on degree of sensitization (CPRA)
- 4 points for prior living organ donors
- 1 point for pediatric candidates if donor is <35 yrs old
- 4 points for pediatric candidates (age 0-10 at time of match) when offered a zero antigen mismatch
- 3 points for pediatric candidates (age 11-17 at time of match) when offered a zero antigen mismatch

Percent of candidates in national top 20%, by Donor Service Area of candidate's listing center



Percent of kidney donors in national top 20% (KDPI<0.20), by DSA of donor



Overview of N4

| KDPI ≤ 0.20 | KDPI 0.21-0.34 | KDPI 0.35-0.85 | KDPI >0.85 |
|---|---|--|---|
| Local CPRA 98+ Reg'l CPRA 99+ Nat' CPRA 100 Omm top 20 Local pediatrics Local top 20 Omm bottom 80 Local bottom 80 Reg'l pediatrics Reg'l top 20 Reg'l bottom 80 Nat'l pediatrics Nat'l top 20 Nat'l bottom 80 | Local CPRA 98+ Reg'l CPRA 99+ Nat'l CPRA 100 Omm Local pediatrics Local adults Reg'l pediatrics Reg'l adults Nat'l pediatrics Nat'l adults | Local CPRA 98+ Reg'l CPRA 99+ Nat'l CPRA 100 Omm Local Reg'l Nat'l | Local CPRA 98+ Reg'l CPRA 99+ Nat'l CPRA 100 Omm Local and reg'l adults Nat'l adults |
| | | <div>Top 20 to Top 20</div> | |

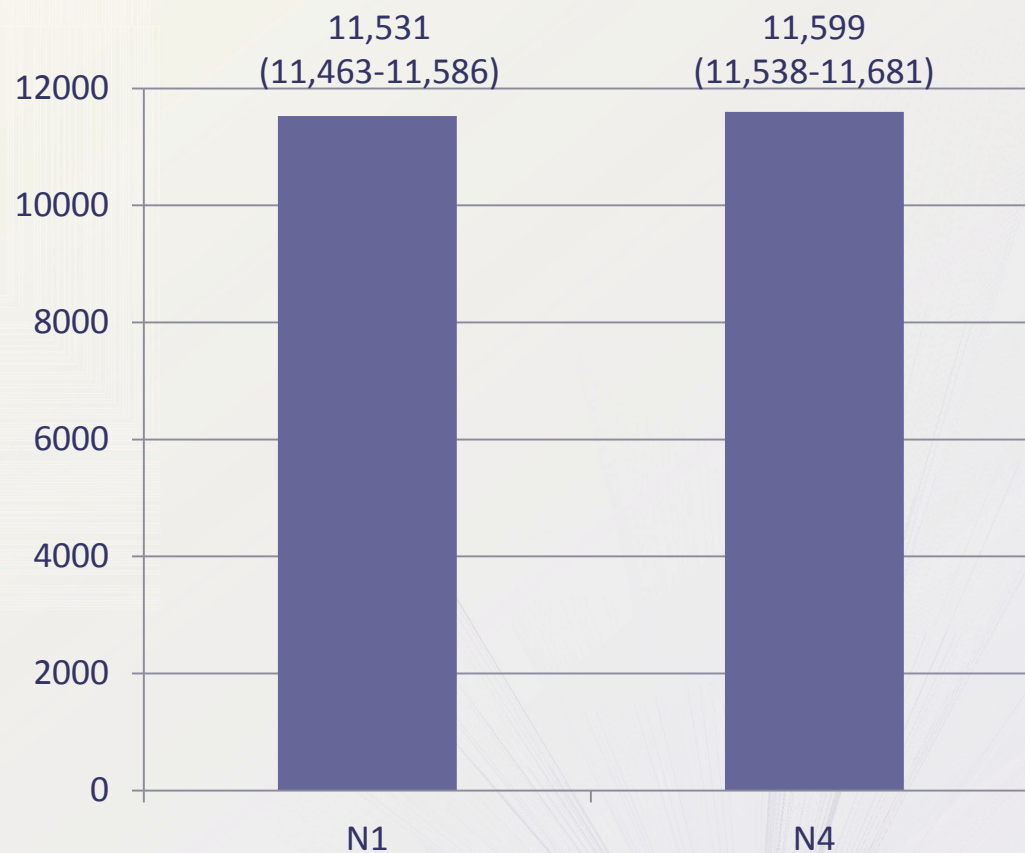
New policy and prioritizing sensitized candidates

N4

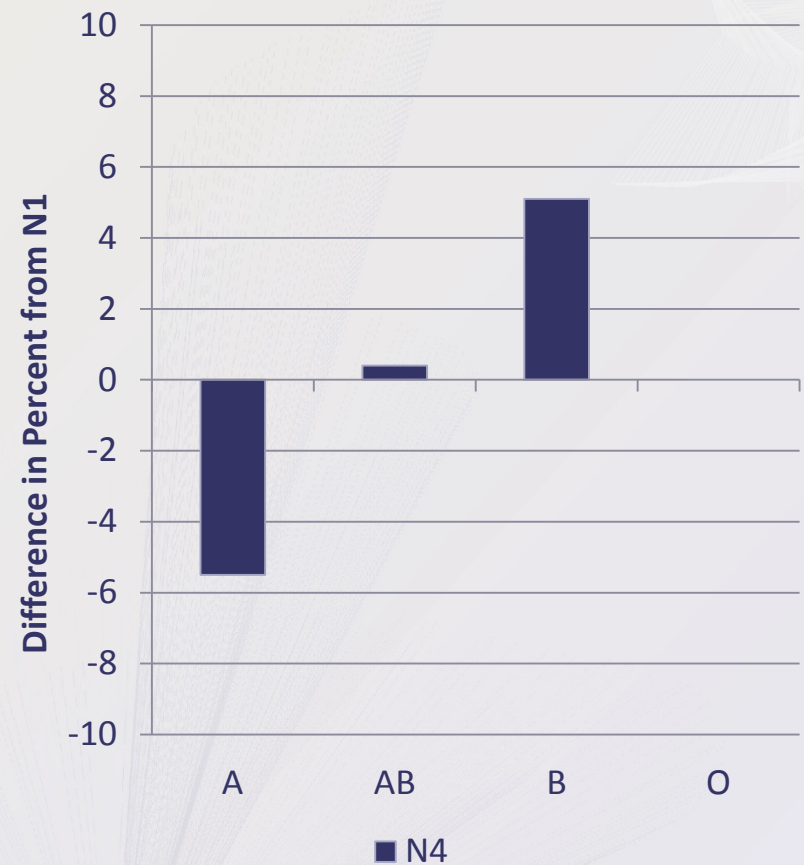
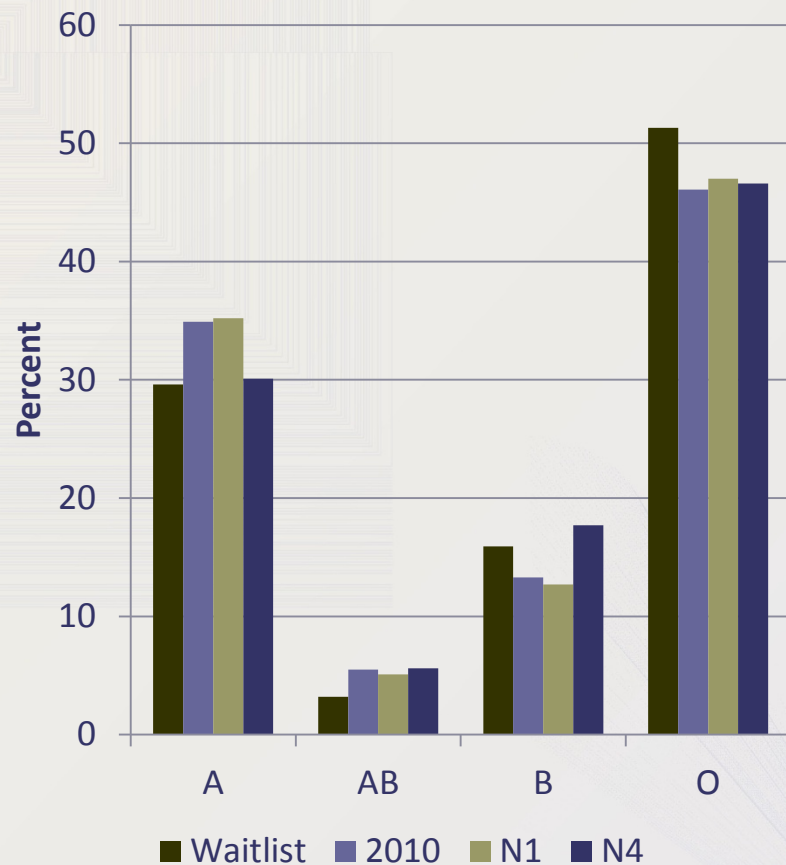
- Local CPRA 100
- Regional CPRA 100
- National CPRA 100
- Local CPRA 99
- Regional CPRA 99
- Local CPRA 98

*first priority for all
kidneys*

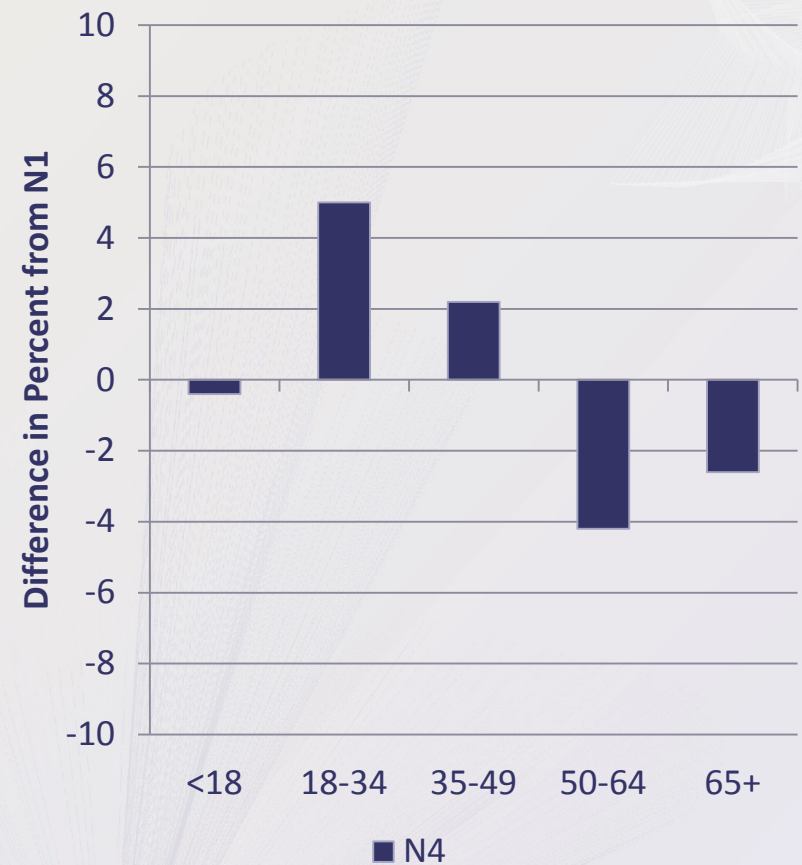
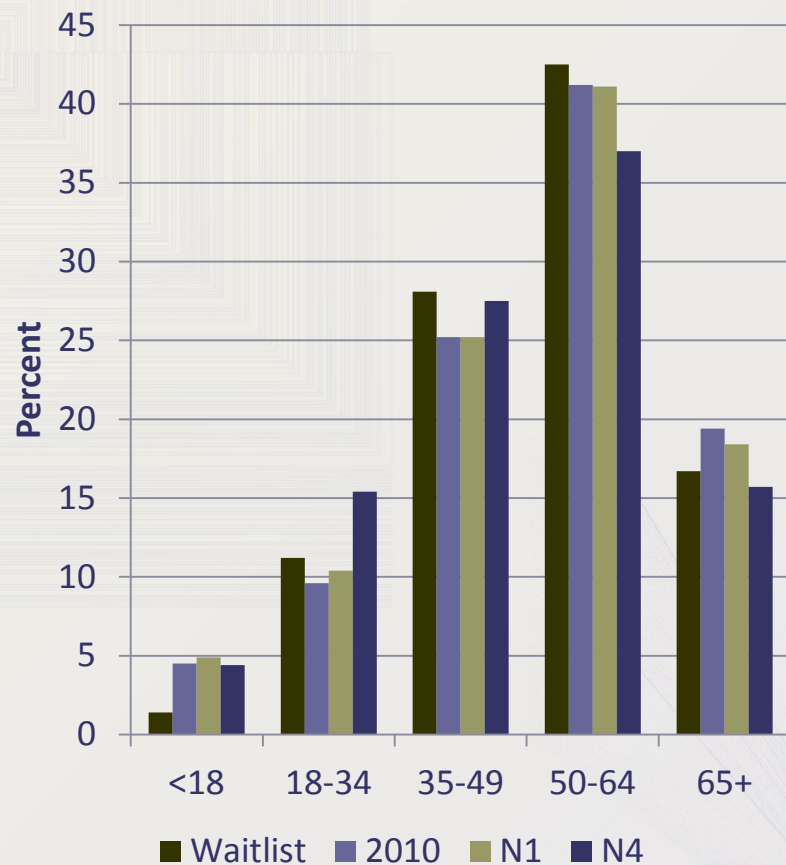
Average primary KI + KP transplants per run



Kidney transplants by recipient blood type



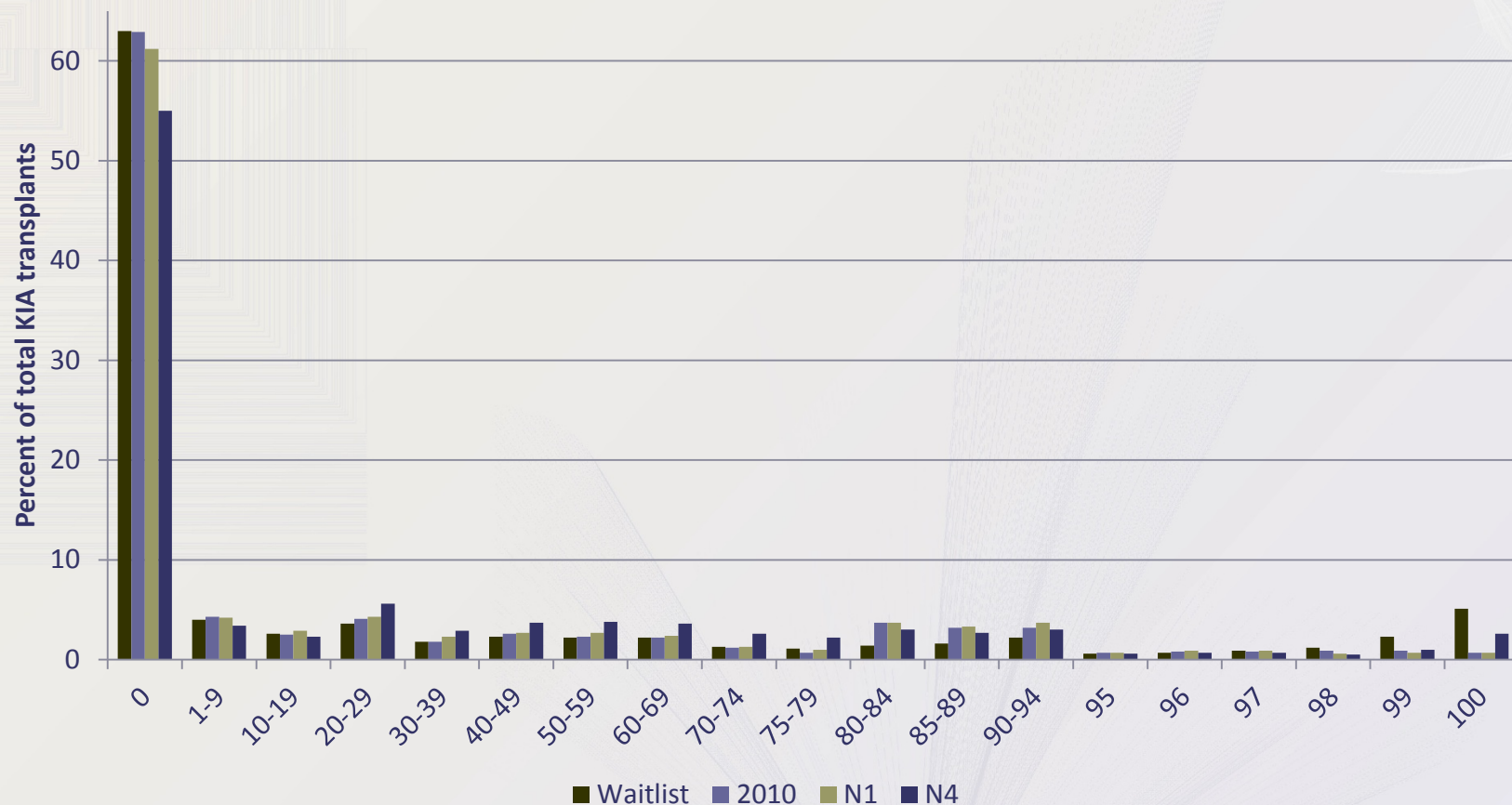
Kidney transplants by recipient age



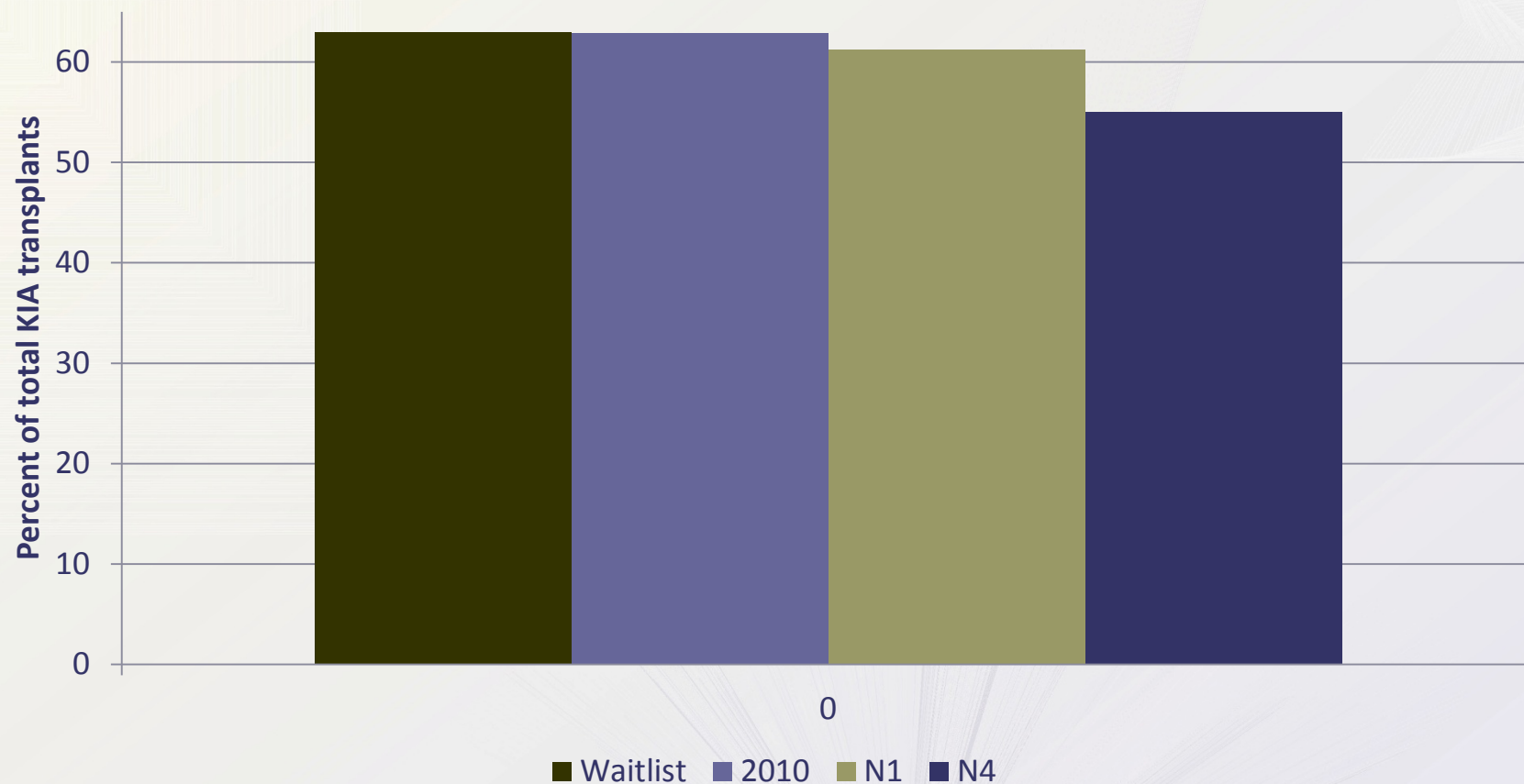
Counts of kidney transplants, by recipient age

| | Age Group | | | | | | | | | |
|-----|-----------|-------|-------|-------|-------|-------|-------|-------|------|-------|
| Run | <18 | vs N1 | 18-34 | vs N1 | 35-49 | vs N1 | 50-64 | vs N1 | 65+ | vs N1 |
| N1 | 529 | | 1120 | - | 2719 | - | 4437 | - | 1991 | - |
| N4 | 487 | -42 | 1692 | +572 | 3015 | +296 | 4054 | -383 | 1723 | -268 |

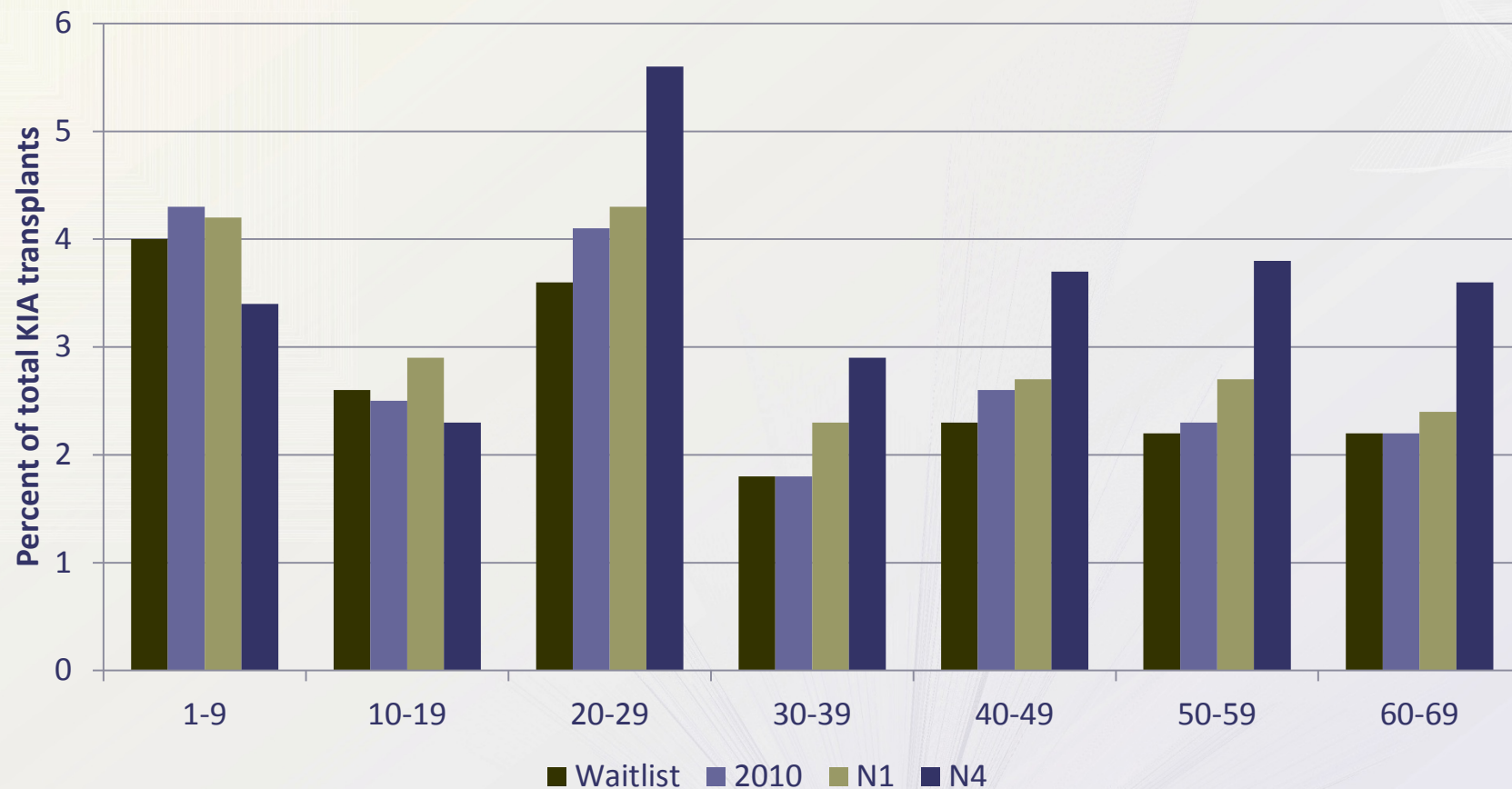
Kidney transplants by recipient CPRA, with waitlist prevalence



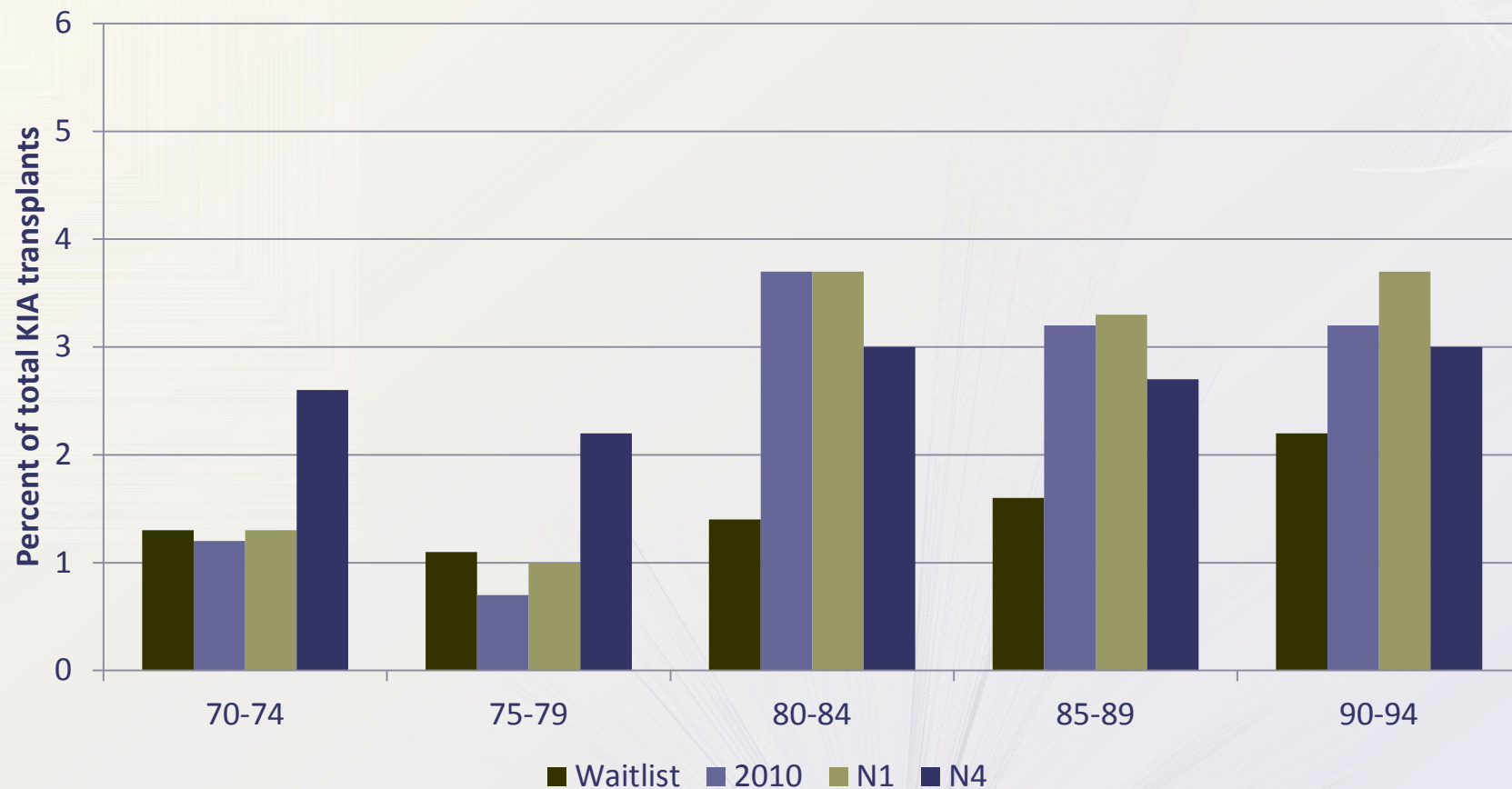
Kidney transplants by recipient cPRA=0



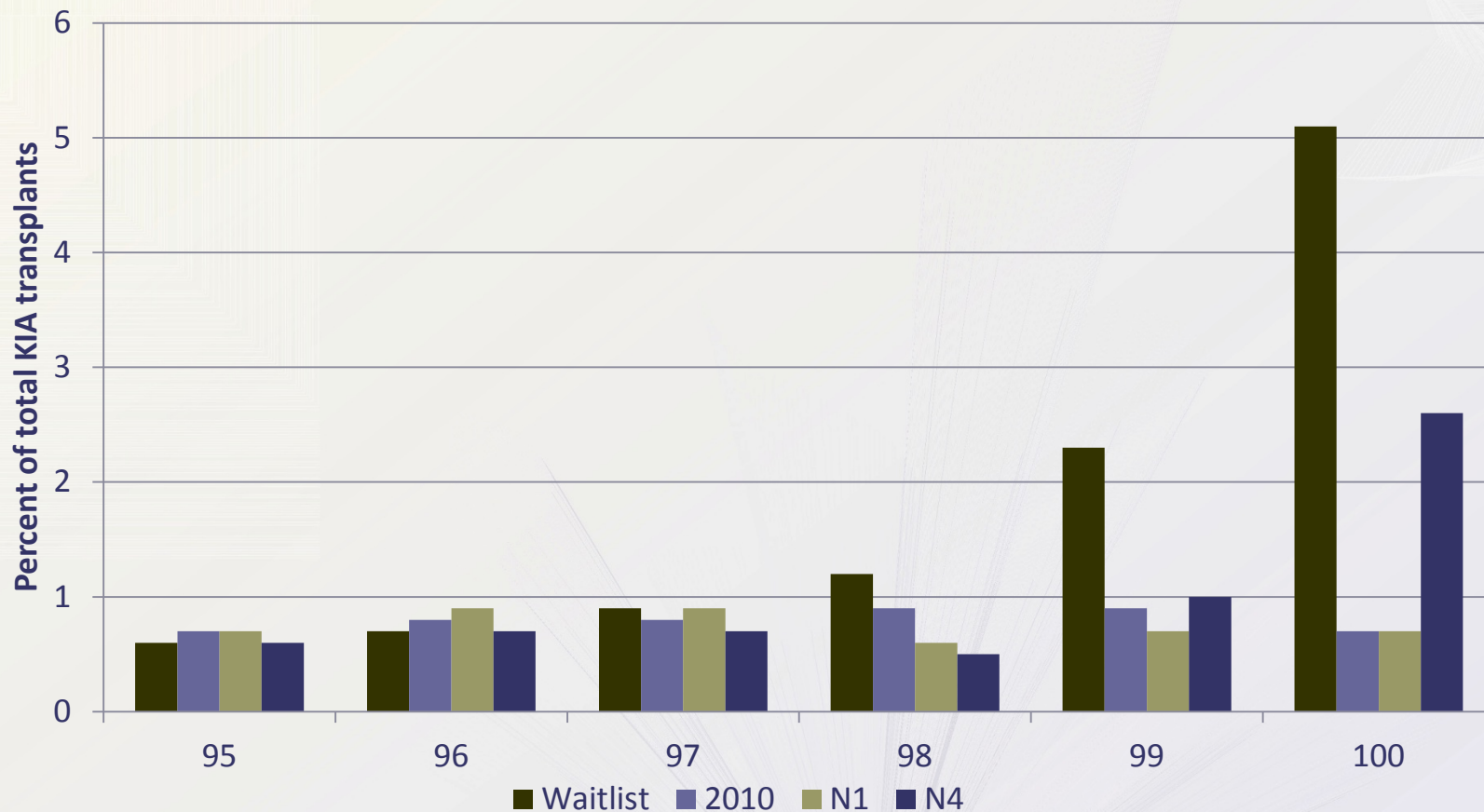
Kidney transplants by recipient cPRA, 1- 69



Kidney transplants by recipient cPRA, 70-94



Kidney transplants by recipient cPRA, 95-100



Kidney donor profile index (KDPI): A continuous scale, correlated with graft survival

- Donor factors used to calculate KDPI:
 - Age
 - Height
 - Weight
 - Ethnicity
 - History of hypertension
 - History of diabetes
 - Cause of death
 - Serum creatinine
 - Hepatitis C virus (HCV) status
 - Donation after circulatory death (DCD) status

Acknowledgments

- Jon Snyder, PhD
- Bertram Kasiske, MD
- Allyson Hart, MD, MS
- Sally Gustafson, MS
- Nicholas Salkowski, PhD