

Proposal to Substantially Revise the National Kidney Allocation System

Sponsored by: The OPTN Kidney Transplantation Committee

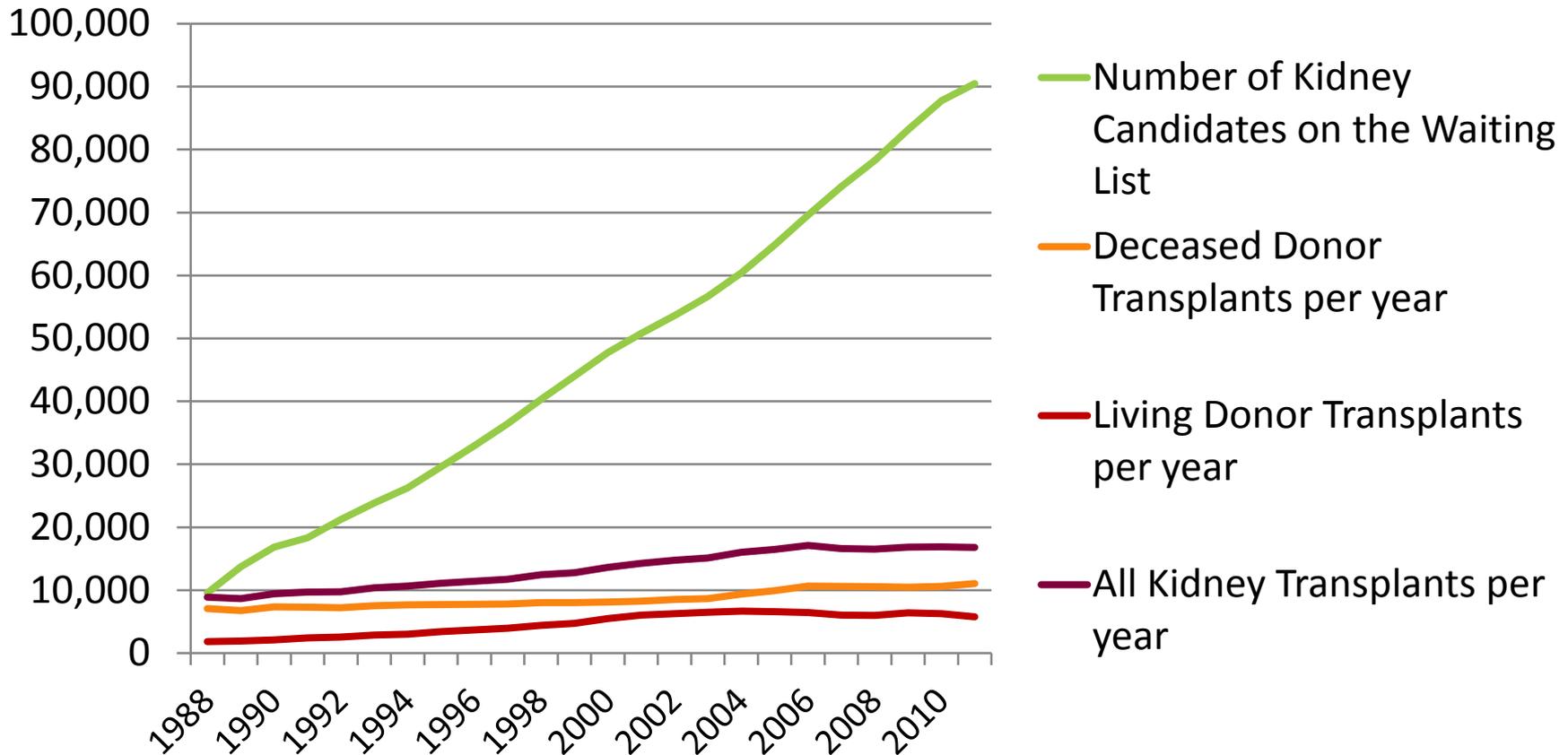
*John J. Friedewald, MD
Chair*

Current System Limitations

- Mismatch in graft/patient survival
- Access variability due to geography and biology
- High discard rates

The Growing Waiting List

Kidney Waiting List and Transplants



OPTN data as of September 1, 2012

Unbalanced System Components

- Over time, waiting time has become the primary driver of kidney allocation
 - Histocompatibility components have diminished over time
- This overreliance led to a system that does not accomplish any goal other than transplanting the candidate waiting the longest
 - Doesn't recognize that not all can wait the same length of time
 - Fails to acknowledge different needs for different candidates (e.g., speed over quality)

Proposed Policy Objectives

- Make the most of every donated kidney without diminishing access
- Promote graft survival for those at highest risk of retransplant
- Minimize loss of potential graft function through better longevity matching
- Improve efficiency and utilization by providing better information about kidney offers

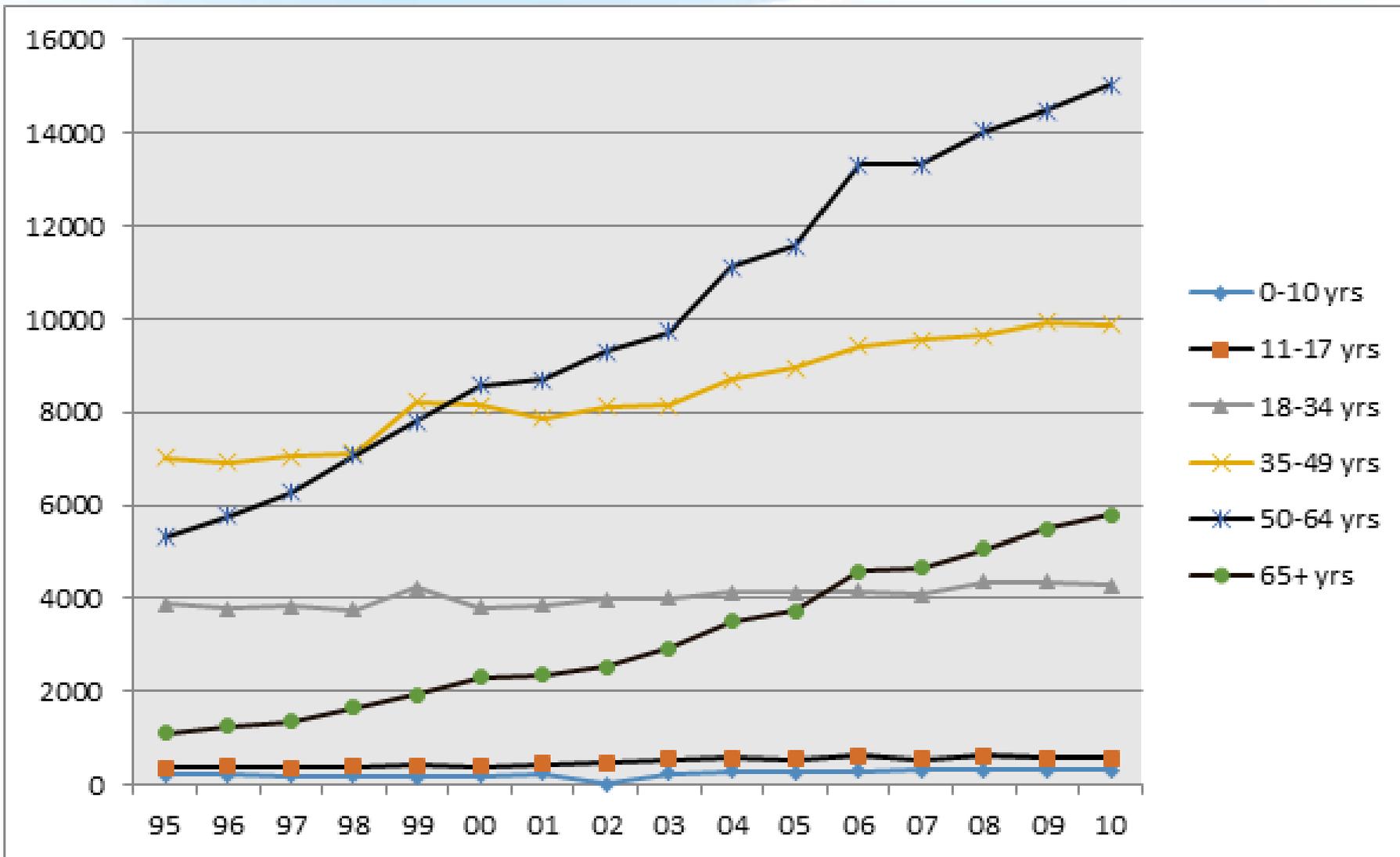
Proposed Policy Objectives

- Provide comprehensive data to guide transplant decision making
- Reduce differences in access for ethnic minorities and sensitized candidates

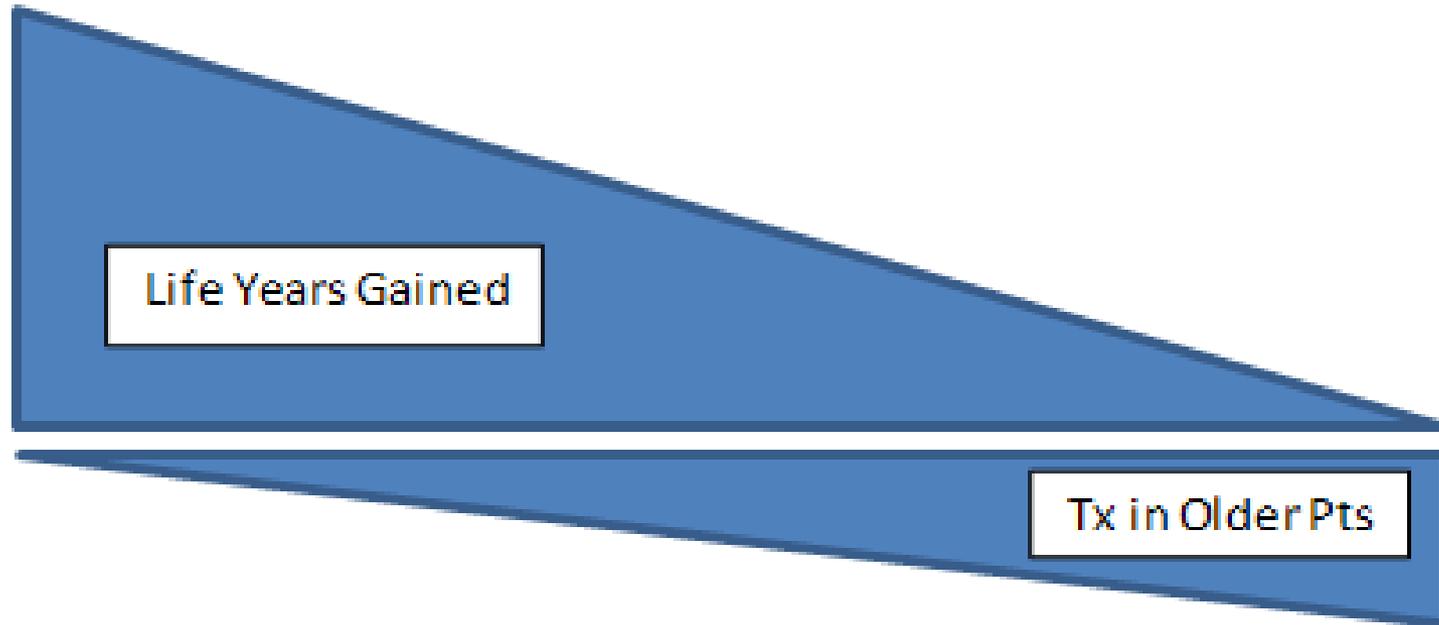
The course of policy development

Date	Sentinel Event
2003	Board requests review of kidney allocation system; public hearings held
2004	Board directs investigation of benefit use in a kidney allocation system
2007	Public Forum held in Dallas; main topic LYFT
2008	RFI released: main topics KDPI/LYFT
2009	Public Forum held in St. Louis; main topics LYFT/KDPI
2009	Donor/recipient age matching reviewed as possibility
2011	Concept document released: main topics EPTS/age matching/KDPI
2011	Age matching no longer under consideration
2012	Public comment proposal

New Registrants by Year and Age Group



Determining a Balance: Equity and Utility



Evolution of Proposal

	<i>National Sharing +LYFT</i>	<i>LYFT</i>	<i>Age Matching+ Longevity Matching</i>	<i>Age Matching</i>	<i>Longevity Matching</i>
Gain in life years	34,026	25,794	15,223	14,044	8,380
Transplants to 50+ year old recipients	10%	29%	46%	45%	52%

Proposal Summary

- The existing kidney allocation system has many strengths but needs to be improved.
- We are proposing a series of improvements to enhance the long-term benefit of kidney transplantation, make better use of available kidneys, and increase transplant opportunities for hard-to-match candidates.
- The way we match kidneys will not change for the majority of kidneys. Candidates who will see potential changes should see benefits in terms of better long-term kidney function or a possible reduction in waiting time for a transplant.

Proposal Summary

- The age of the candidate is not the sole determinant of transplant priority. While the proposed policy may affect some proportion of patients who receive a transplant, it will continue to provide transplants for people of all ages.
- We used informed commentary from interested parties to guide the development of this final proposal.

Preview of Expected Outcomes

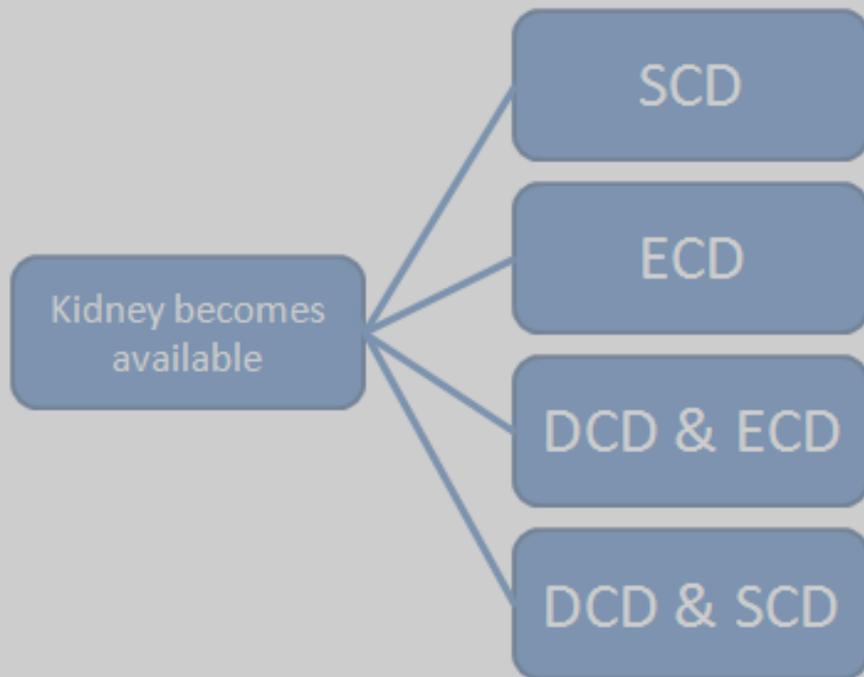
- New system forecasted to result in:
 - Approximately 8,000 additional life years gained annually
 - Improved access for moderately and very highly sensitized candidates
 - Improved access for ethnic minority candidates
 - Comparable levels of kidney transplants at regional/national levels

SYSTEM DESIGN

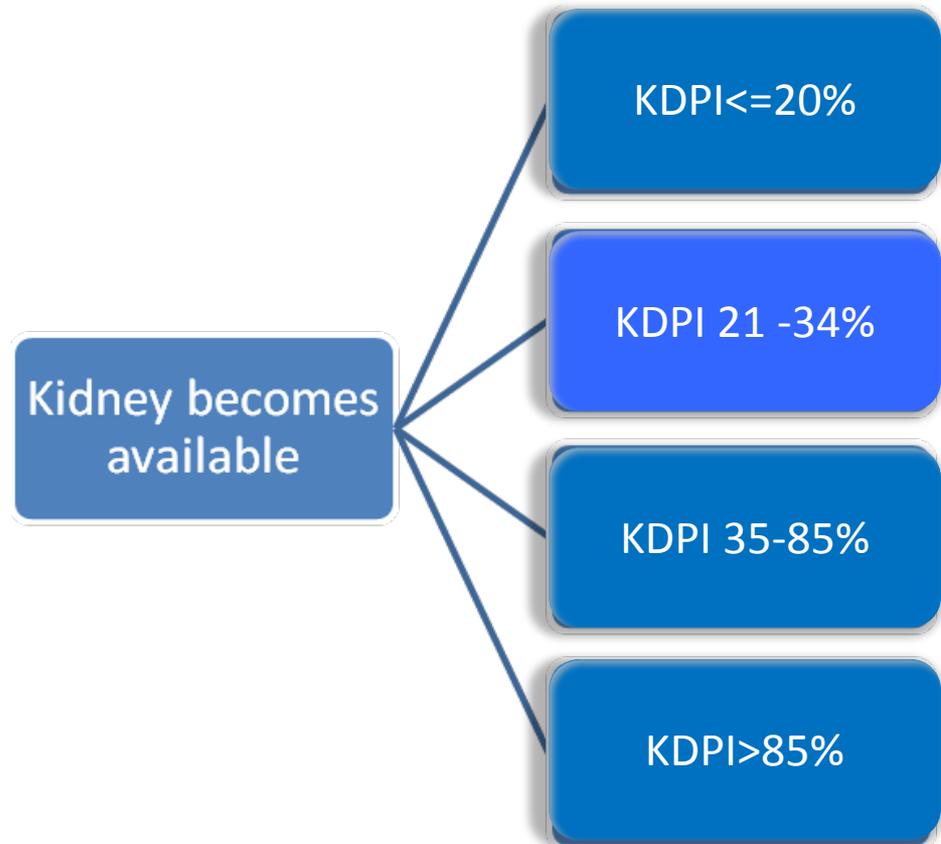
OPTN

Overview of proposed policy

Current



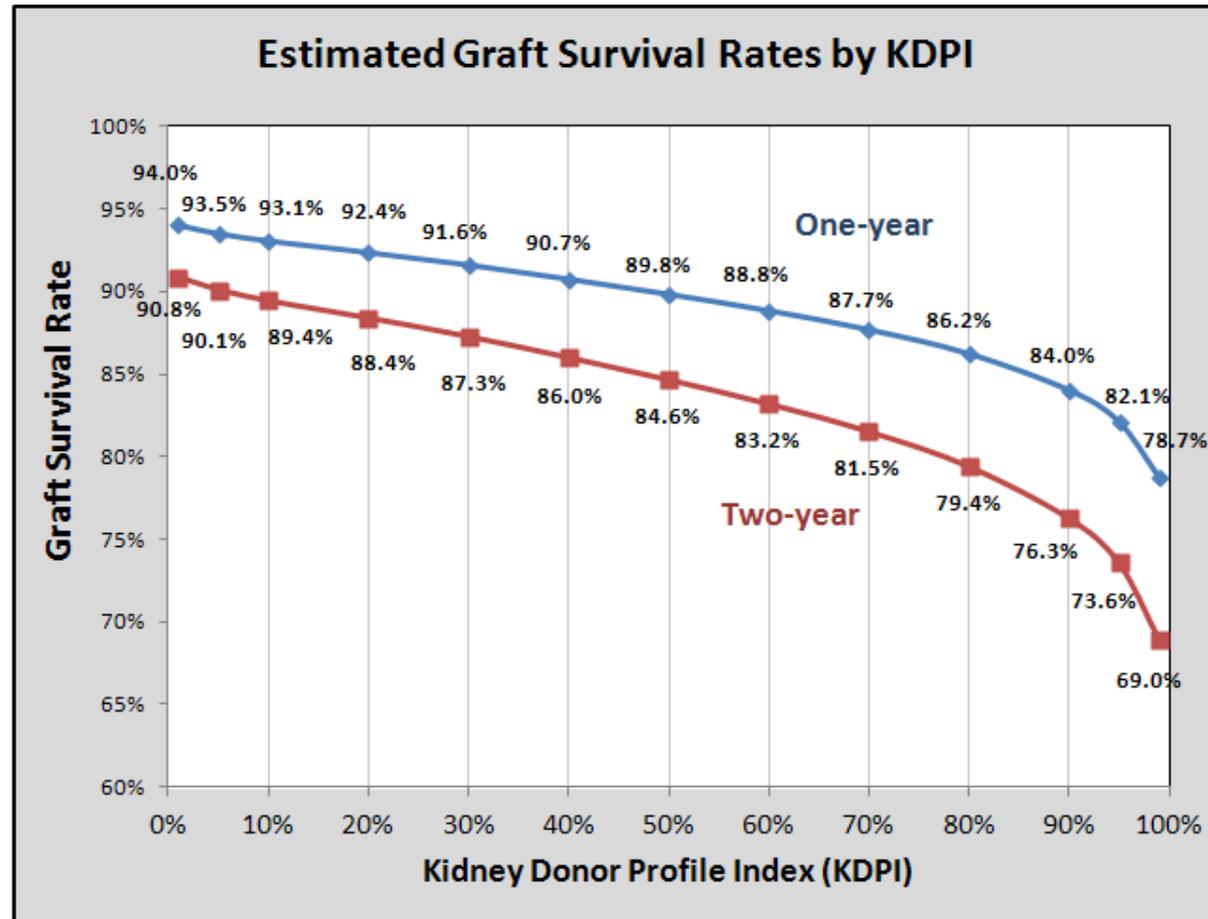
Proposed



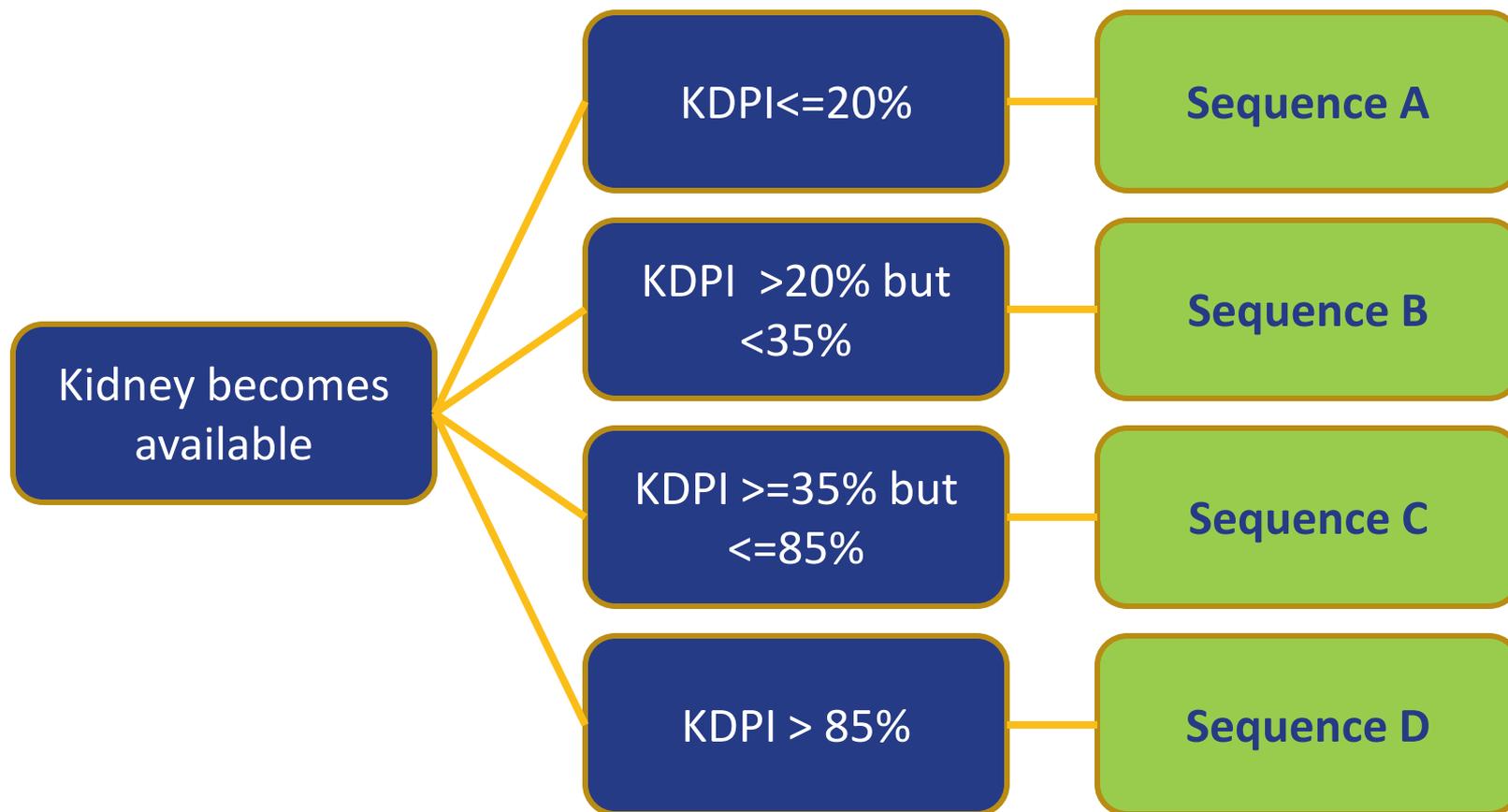
Kidney Donor Profile Index (KDPI)

KDPI Variables

- Donor age
- Height
- Weight
- Ethnicity
- History of Hypertension
- History of Diabetes
- Cause of Death
- Serum Creatinine
- HCV Status
- DCD Status



Sequences based on KDPI



Sequences based on KDPI

Sequence A
KDPI $\leq 20\%$

Sequence B
KDPI $> 20\%$ but $< 35\%$

Sequence C
KDPI $\geq 35\%$ but
 $\leq 85\%$

Sequence D
KDPI $> 85\%$

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

Once in a category, candidates are rank ordered according to points

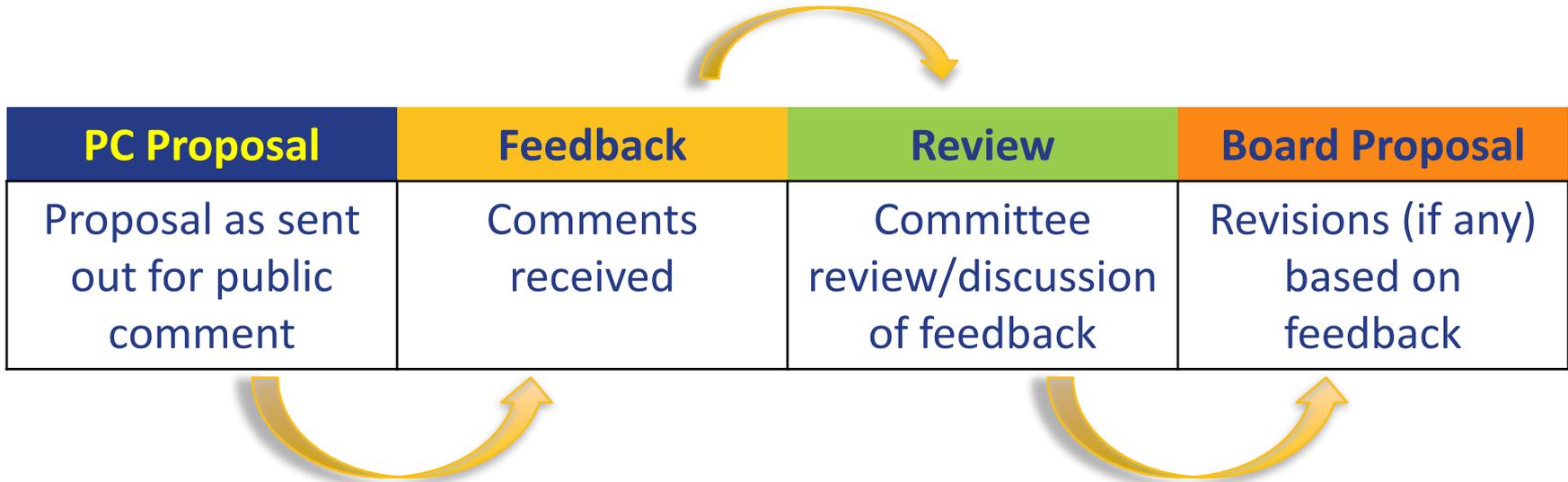
PROPOSAL COMPONENTS

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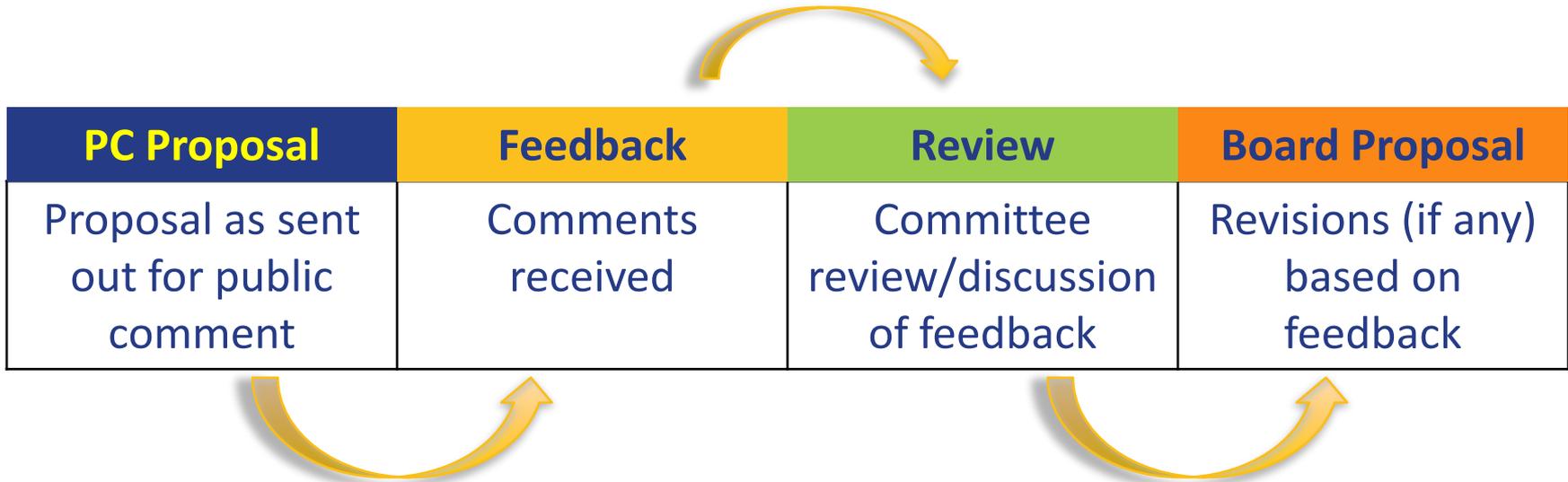
Major Proposal Components

- Replace SCD/ECD with KDPI
- Add longevity matching
- Increase priority for sensitized candidates/CPRA sliding scale
- Include pre-registration dialysis time
- Incorporate A₂/A₂B to B
- Base pediatric priority on KDPI
- Eliminate payback system
- Eliminate variances

Deliberative Process



Deliberative Process

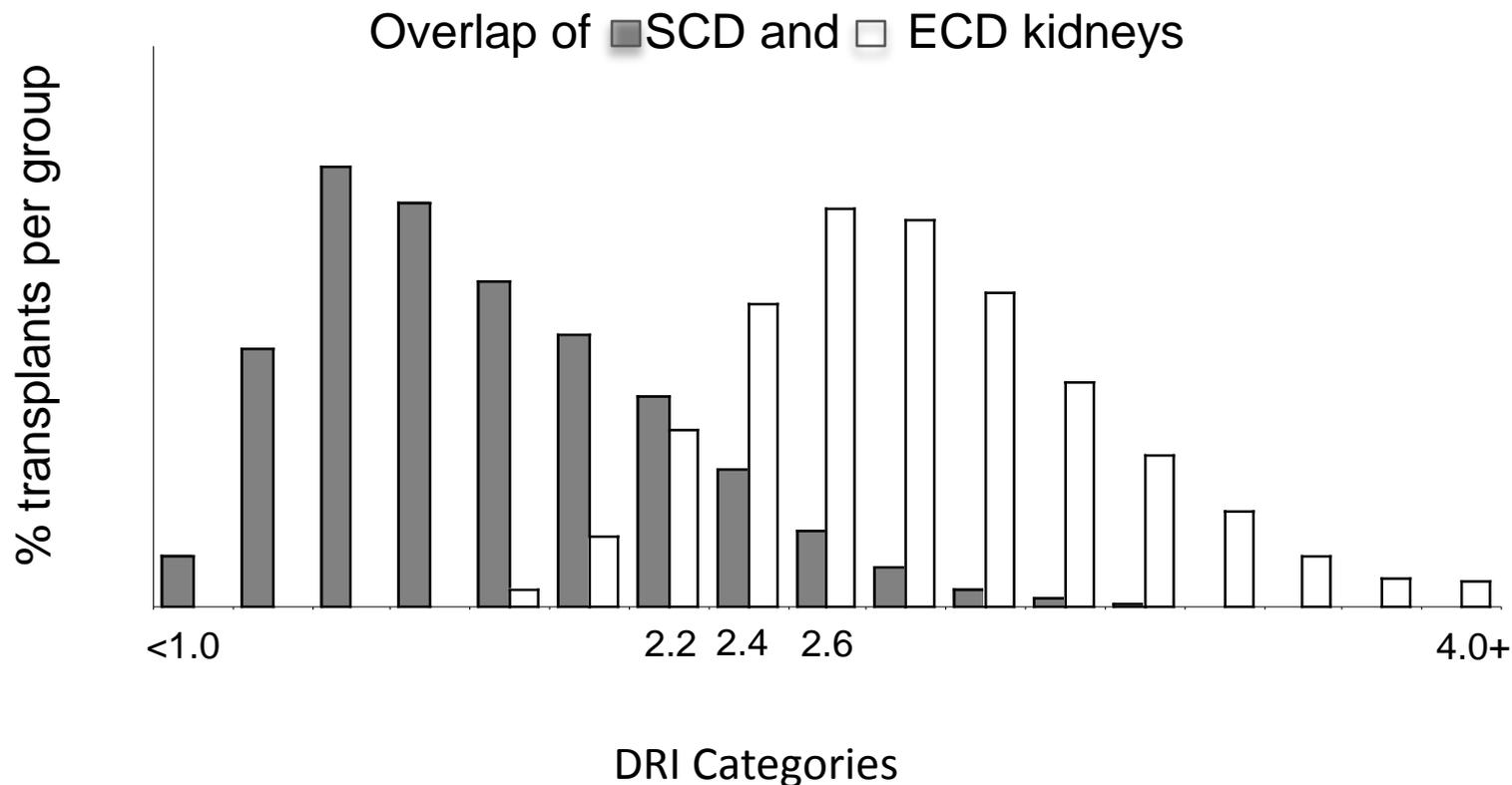


REPLACE ECD/SCD WITH KDPI

Replace SCD/ECD with KDPI

- Current system divides kidneys into two categories
- Function of ECD/SCD kidneys overlaps
- A continuous metric would better describe kidney function
- KDPI has been available in DonorNetsm for over 1 year

Overlap between SCD and ECD kidneys

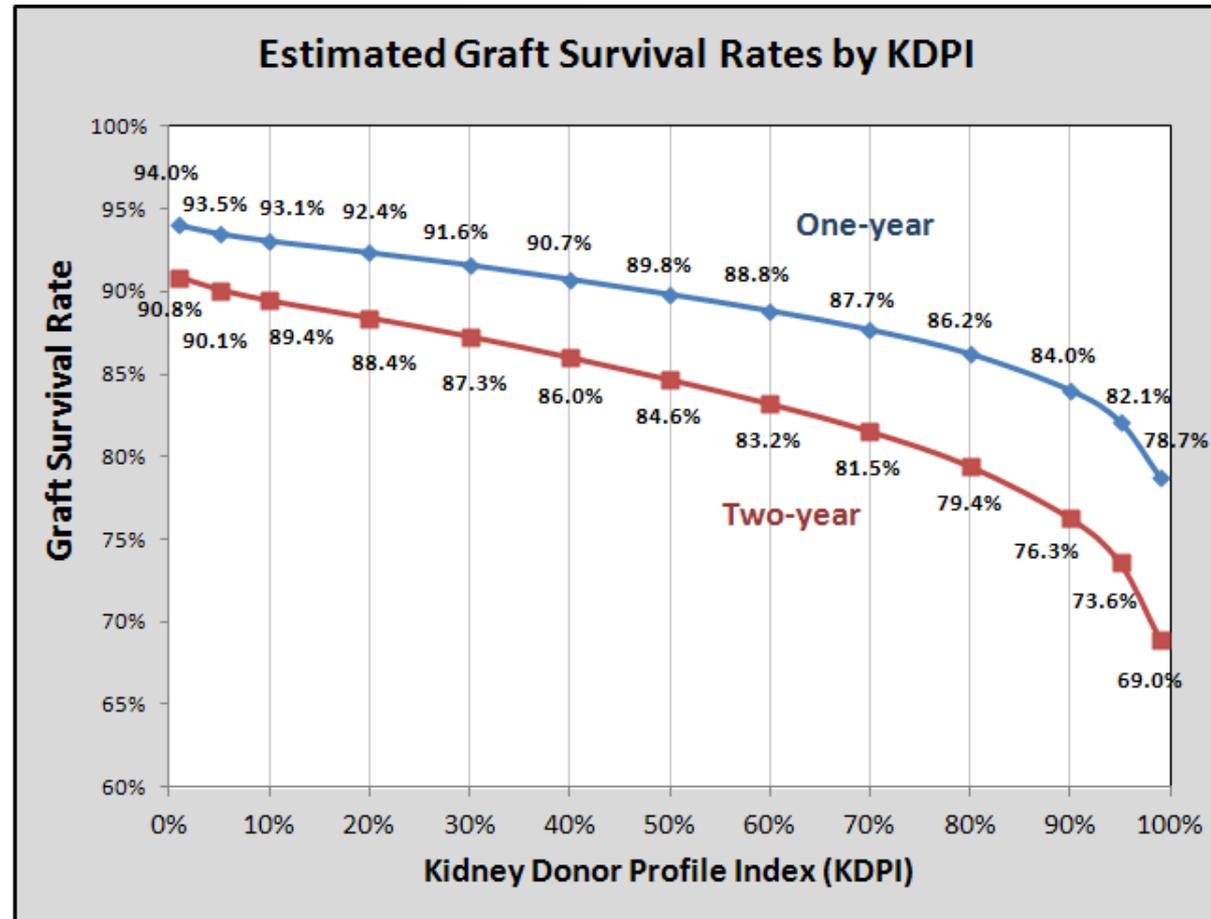


This leads to changes in physician behavior and the break down of the ECD list concept.

Kidney Donor Profile Index (KDPI)

KDPI Variables

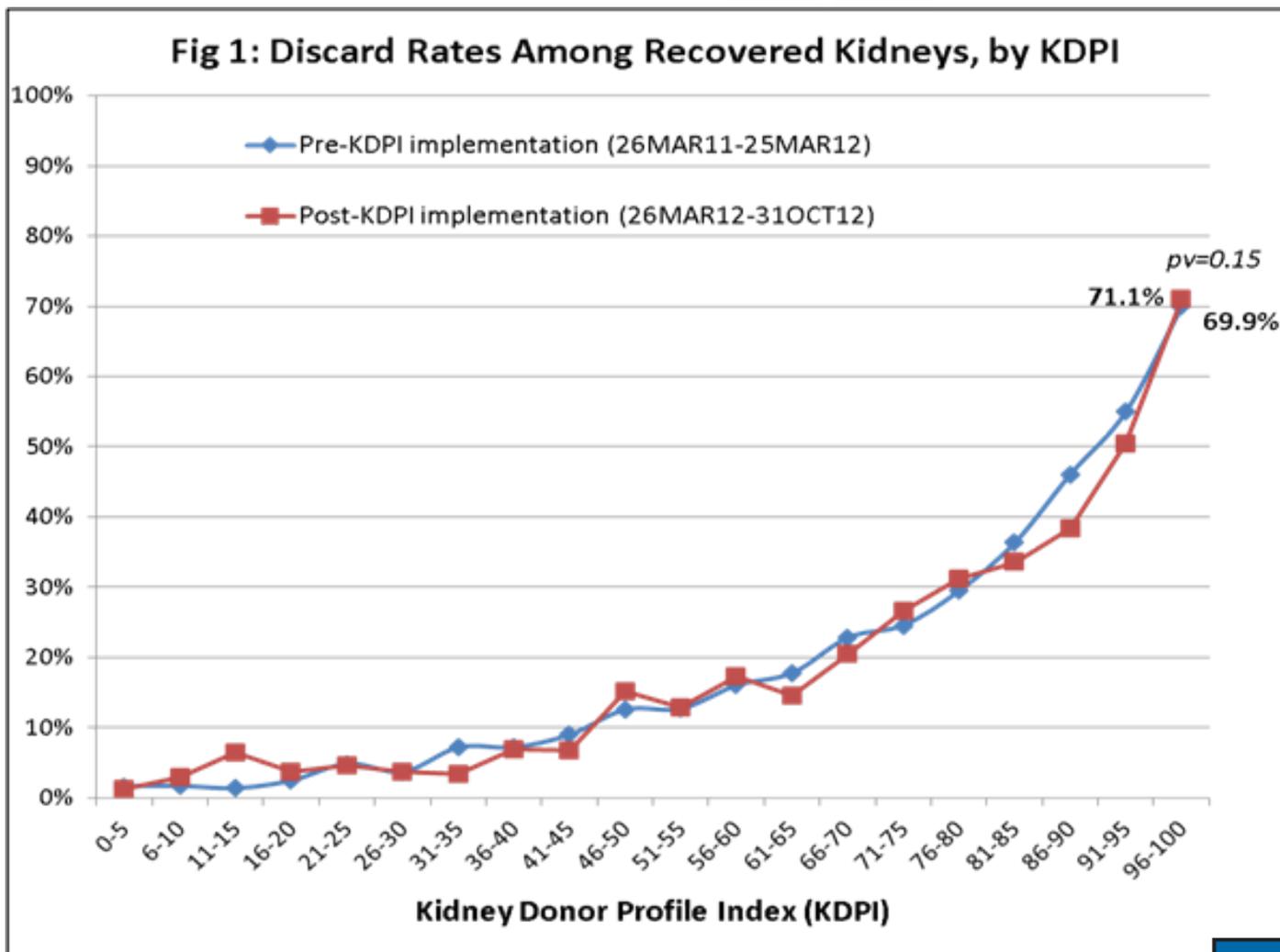
- Donor age
- Height
- Weight
- Ethnicity
- History of Hypertension
- History of Diabetes
- Cause of Death
- Serum Creatinine
- HCV Status
- DCD Status



Replace SCD/ECD with KDPI

- Concern that KDPI will lead to increased discards and harder to place kidneys
- Request to limit consent requirement to only highest KDPI kidneys

No increase in discard rates after displaying KDPI in DonorNet[®]



Replace SCD/ECD with KDPI

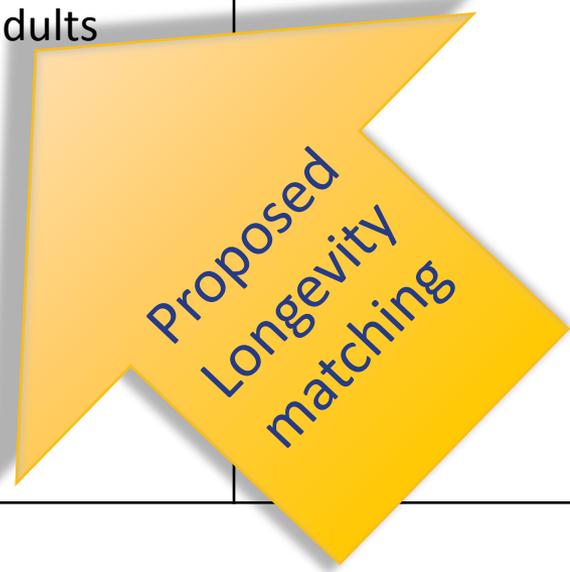
- Consent requirement limited to kidneys with KDPI scores >85%

ADD LONGEVITY MATCHING

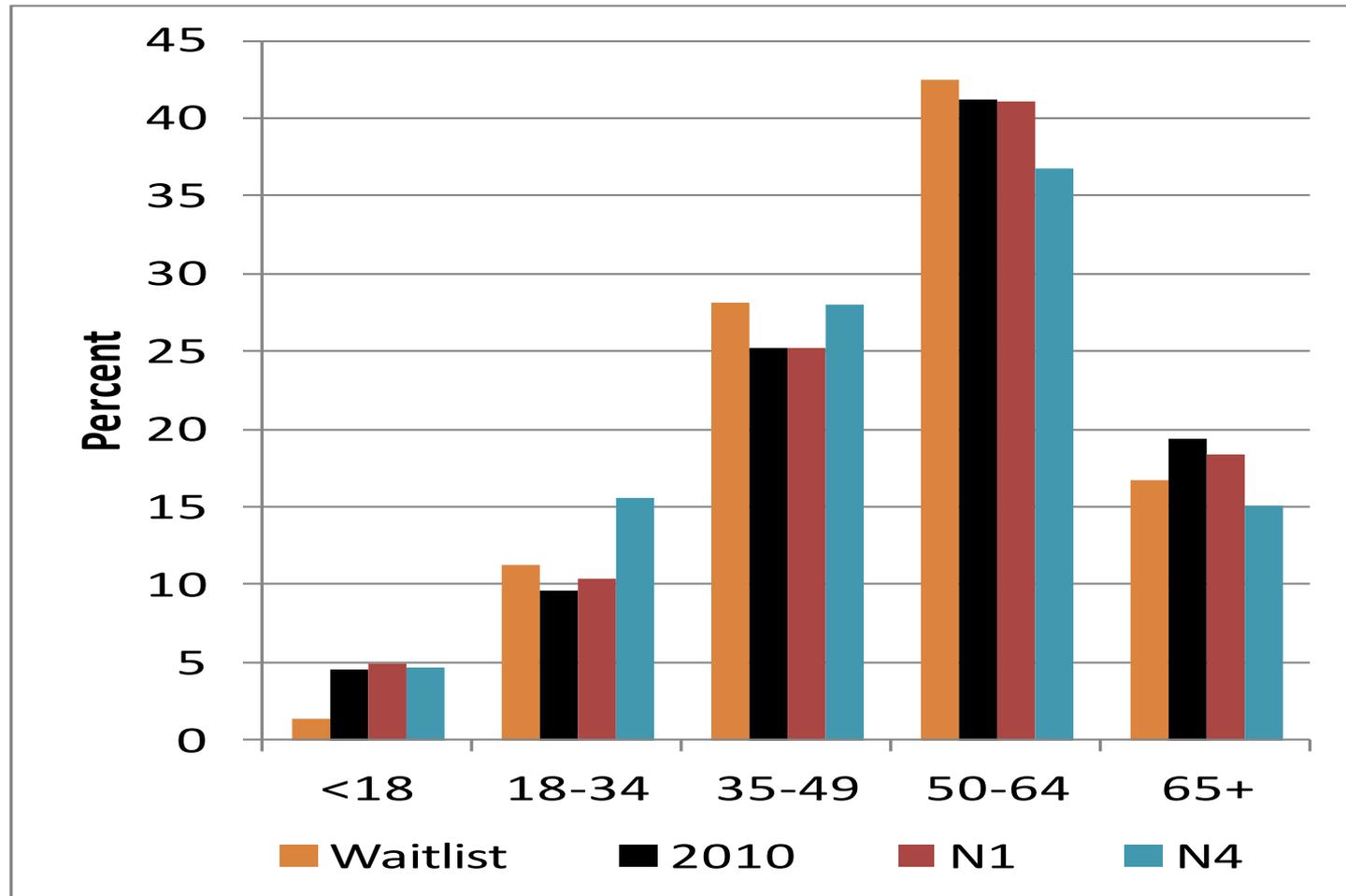
Proposed Classification: *Longevity Matching*

- Estimated Post-Transplant Survival (EPTS)
 - Candidate age, time on dialysis, prior organ transplant, diabetes status
 - More predictive than age alone, uses only 4 variables to limit confusion
- Top 20% of candidates by EPTS to receive kidneys matched on longevity (KDPI<20%)
 - Candidates can have an EPTS score in the top 20% even at age 50
- Applies only to kidneys with KDPI scores $\leq 20\%$ not allocated for multi-organ, very highly sensitized, or pediatric candidates

Sequence A KDPI ≤20%	Sequence B KDPI >20% but <35%	Sequence C KDPI ≥35% but ≤85%	Sequence D KDPI >85%
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KPSAM results by candidate age



Comments on EPTS (n=16)

- Questions regarding degree of predictive ability of EPTS (c-statistic)
- Concerns that candidates will fluctuate in and out of the top 20% EPTS category
- Concern about use of age

Relationship of EPTS and Age

EPTS “Vignettes”: Top 20%

Age	Yrs on RRT	DM	Prior Txp	EPTS
18	0	No	No	1%
25	0	No	No	1%
18	2	No	No	2%
25	5	No	No	5%
25	2	No	Yes	7%
40	0	No	No	8%
18	0	Yes	No	12%
25	0	Yes	No	12%
40	5	No	No	17%
50	0	No	No	18%

EPTS Distribution by Candidate Age

Age at Snapshot	N on WL (adults)	% on WL	% in EPTS Top 20
18-25	2,742	2.8	96.7%
26-35	8,256	8.4	80.6%
36-45	16,136	16.3	43.8%
46-55	25,094	25.4	10.1%
56-65	29,469	29.8	0.0%
66-75	14,762	14.9	0.0%
76+	1,516	1.5	0.0%
All	98,848	100.0	20.0%

Add longevity matching

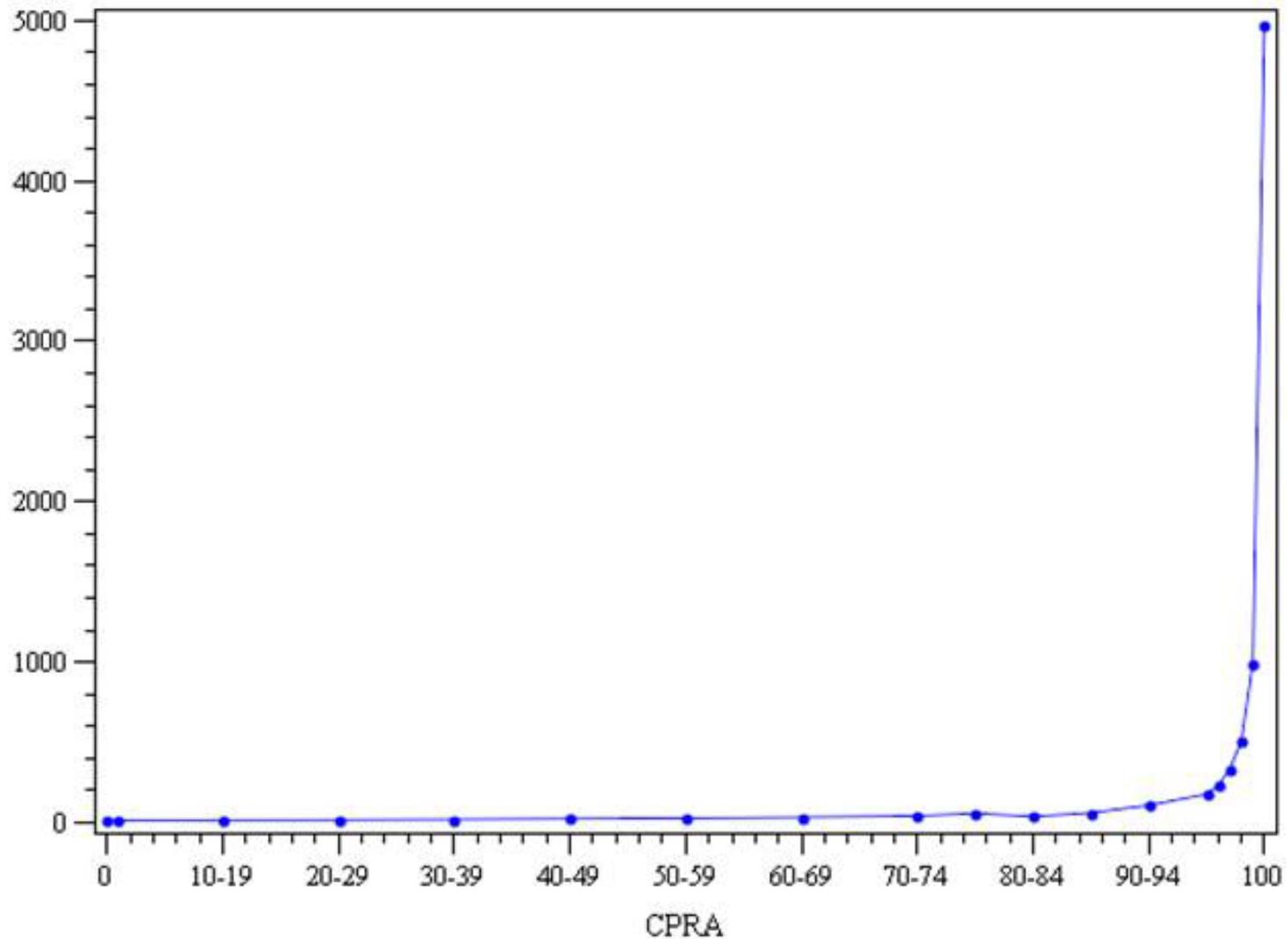
- EPTS included without modification

Proposed changes to allocation classifications

INCREASE PRIORITY FOR SENSITIZED CANDIDATES

OPTN

Median Time to Offer (Days)



● Median Time-to-Offer (Days)

Proposed Classifications: *Very Highly Sensitized*

- Candidates with CPRA $\geq 98\%$ face immense biological barriers
- Current policy only prioritizes sensitized candidates at the local level.
- Proposed policy would give following priority

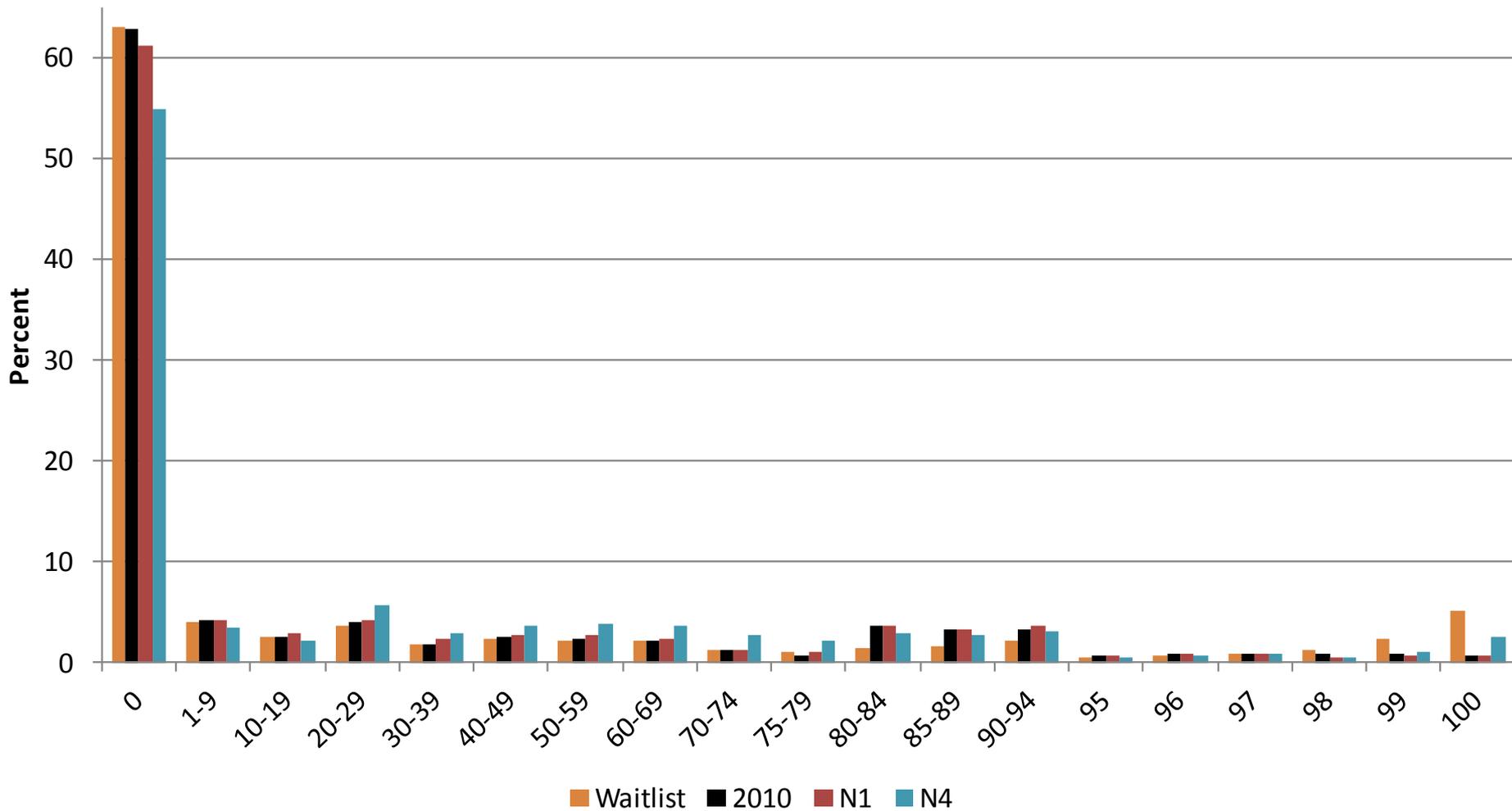
CPRA=100%	National
CPRA=99%	Regional
CPRA=98%	Local

- To participate in Regional/National sharing, review & approval of unacceptable antigens will be required

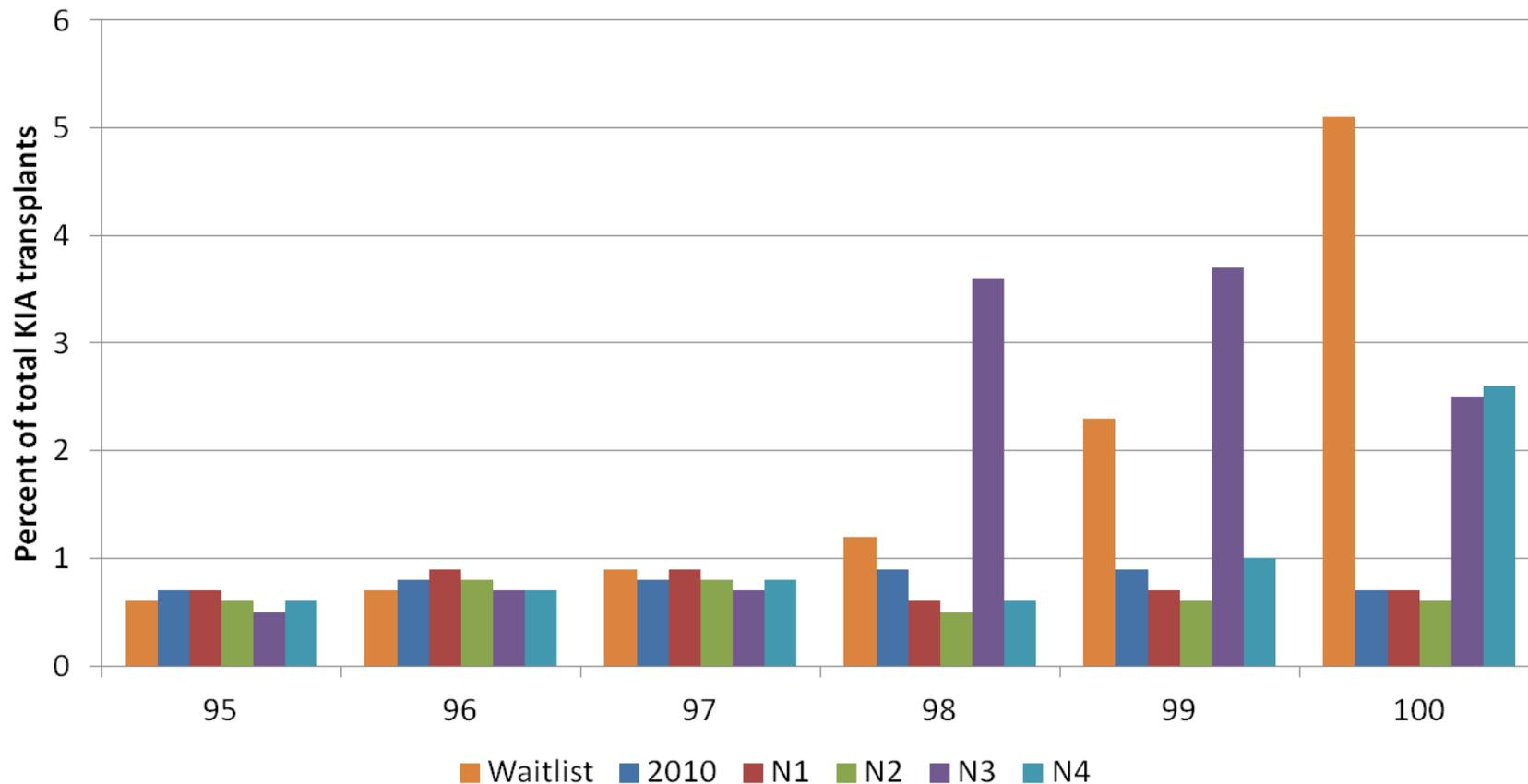
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New categories for highly sensitized candidates

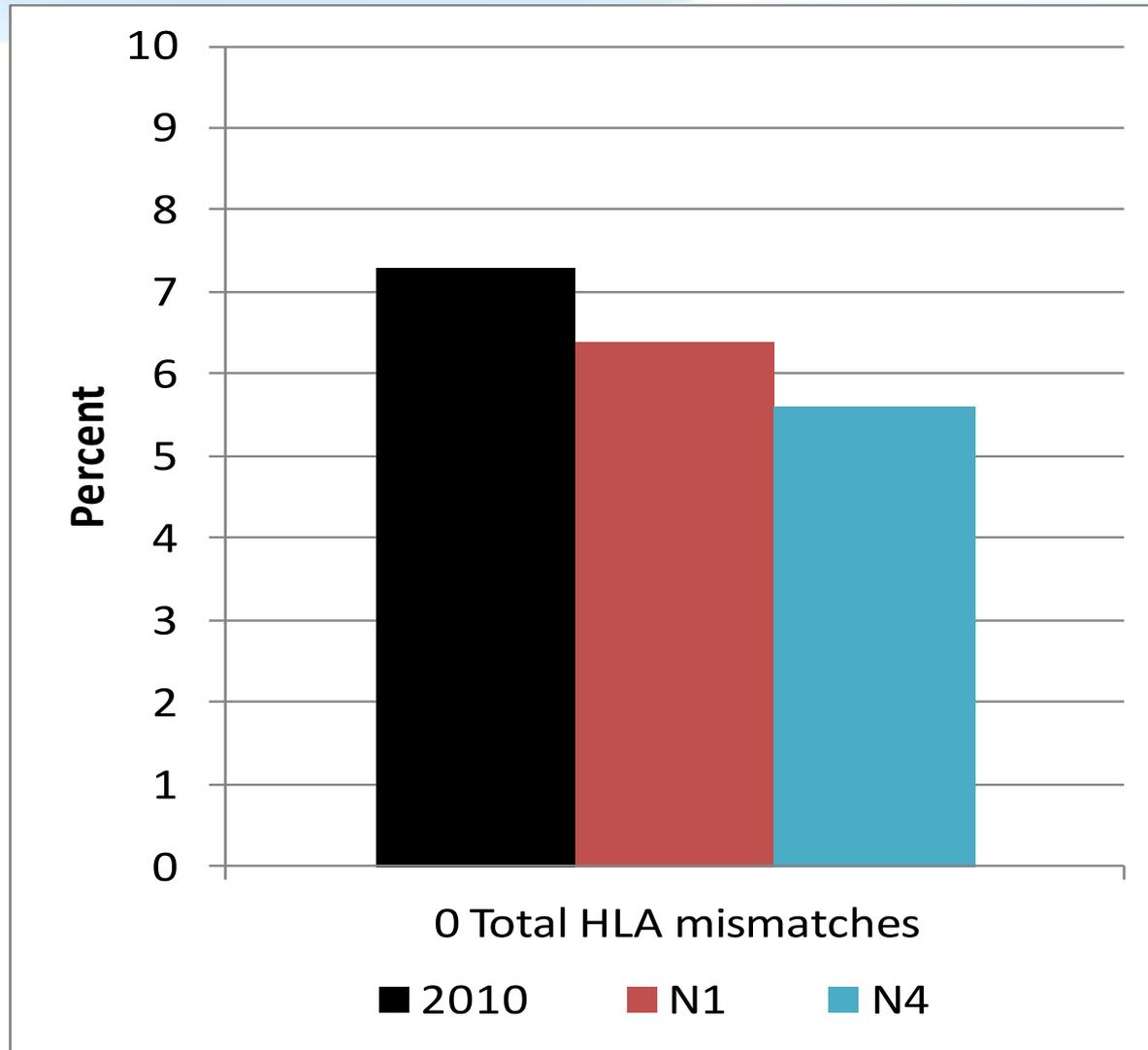
KPSAM results by CPRA



KPSAM results by CPRA (95-100%)



KPSAM results by 0-ABDR mismatch



Increase priority for sensitized candidates

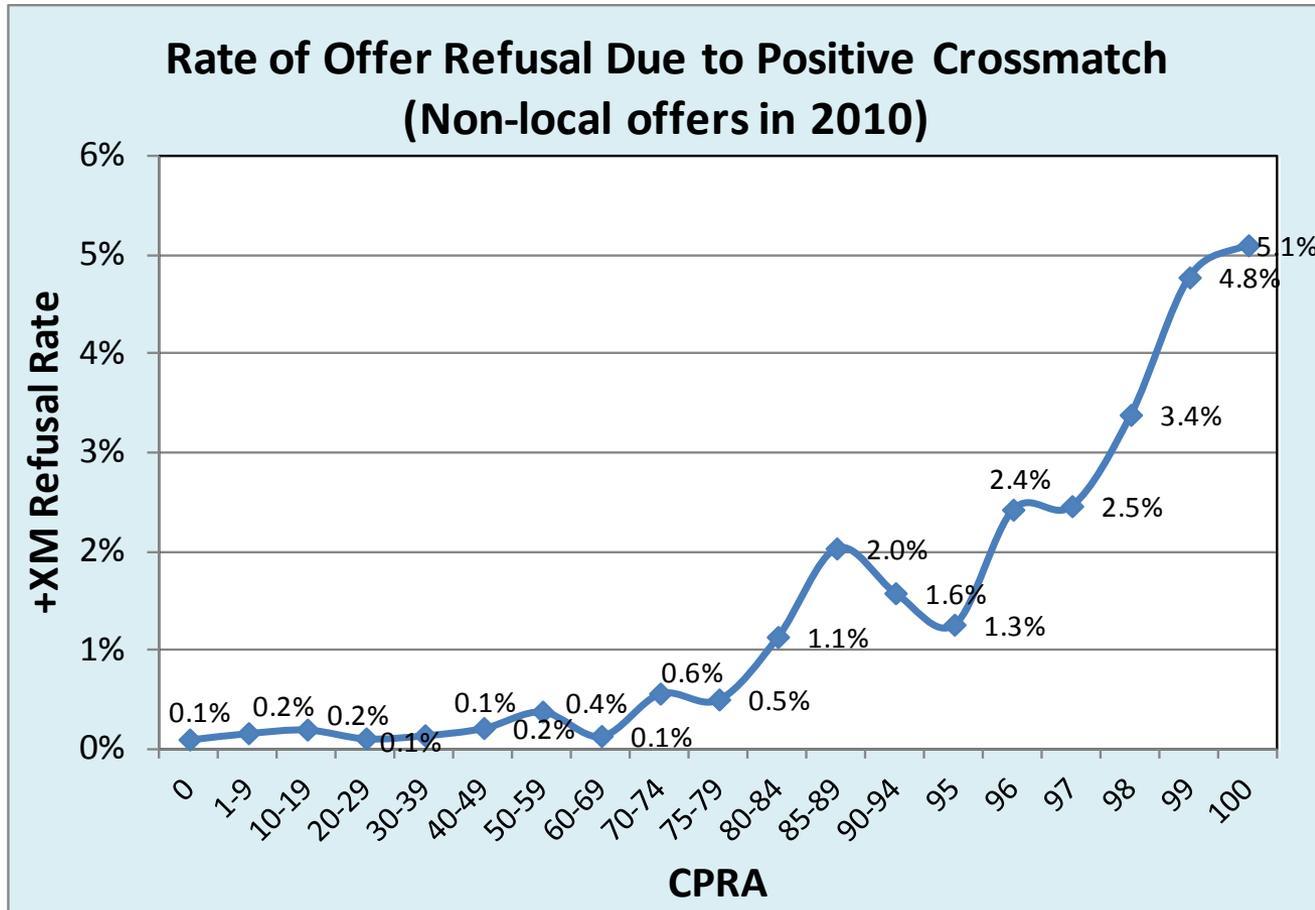
- Concern that highly sensitized candidates will “draw” regional/national offers (Regions 1, 8)
- Recommendations for additional steps to reduce unexpected positive crossmatches (Regions 2, 4)
- Request for additional priority for 0-ABDR mismatches within highly sensitized categories (Histo Committee)

Positive Crossmatch Rate by CPRA

- In 2010, the rate of offer refusal due to + crossmatch...
 - Increased as CPRA increased
 - Was much higher for local offers (1.5%) than non-local offers (0.2%).
- Local +XM refusals generally occur *before* final acceptance and organ shipment.
- Non-local +XM refusals are often *after* final acceptance and shipping.
 - Risk of discard, increased CIT, redirection

POSITIVE CROSSMATCH REFUSALS BY CPRA (NON-LOCAL OFFERS)

CPRA	0	1-69	70-94	95	96	97	98	99	100	Total
+XM refusals	331	124	116	4	9	8	13	15	10	629
Offers	332,058	69,515	9,814	317	371	325	384	314	196	412,279
Rate	0.1%	0.2%	1.2%	1.3%	2.4%	2.5%	3.4%	4.8%	5.1%	0.2%



Attempted Kidney Placements for CPRA 98+ Patients in 2010

- **38/894 (4%)** of non-local offers were refused due to “positive crossmatch.”
- A total of **35** non-local kidneys were accepted but not transplanted into the accepting patient (discarded, or tx in other patient).
- **130** were transplanted with non-local kidneys.

Increase priority for sensitized candidates

- Under new system, CPRA 98+ patients will receive more offers.
- Actions to reduce unexpected positive crossmatches:
 - Required sign-off on unacceptable antigens by physician/surgeon and HLA laboratory director
 - CPRA sliding scale
 - Voluntary reporting of DQA/DPB
- Committee will monitor rates of placement failures due to +XM for highly sensitized candidates.

Increase priority for sensitized candidates

- Highly sensitized categories stratified to prioritize 0-ABDR mismatches ahead of non 0-ABDR mismatches

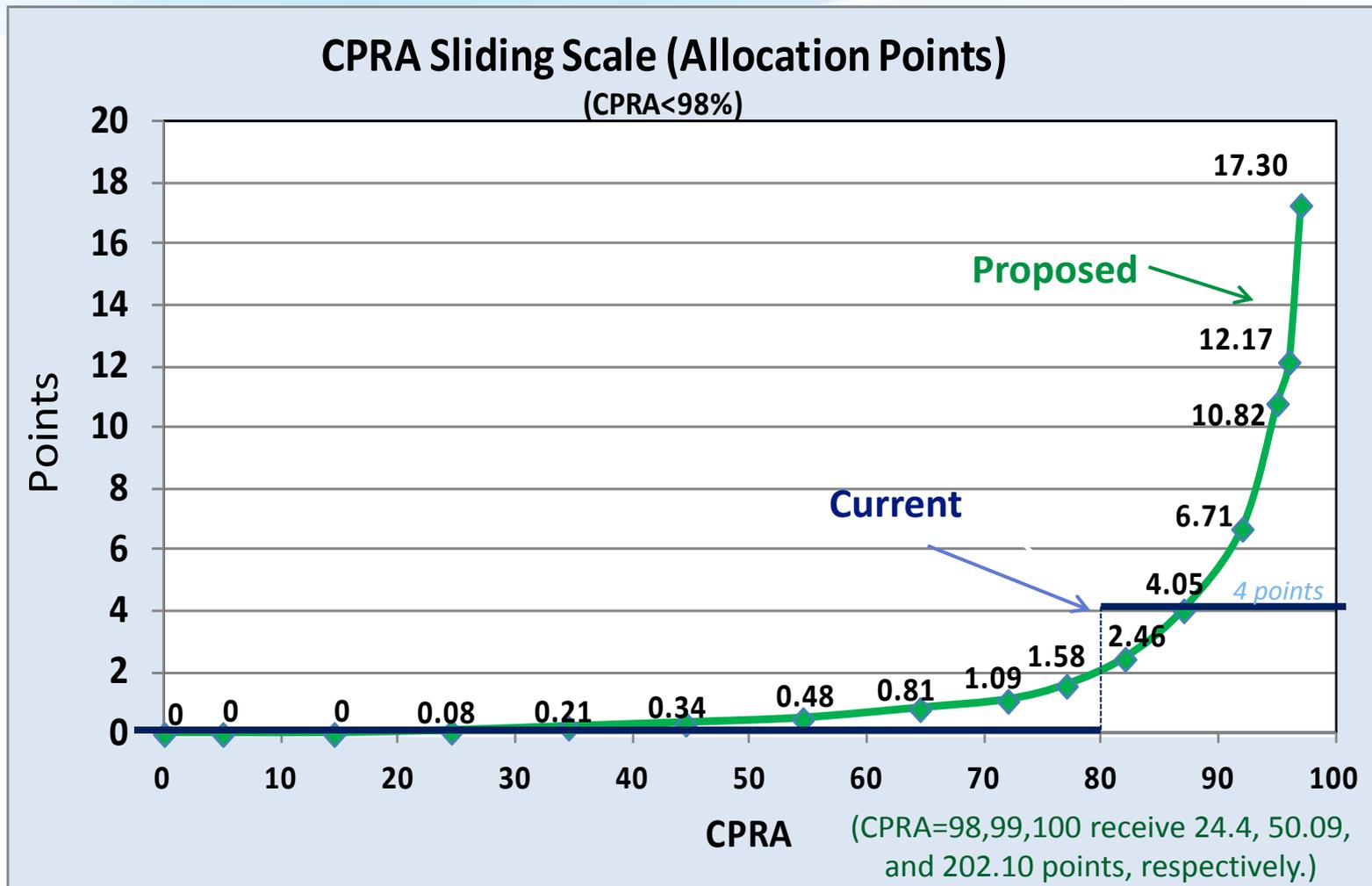
Proposed changes to point system

USE A SLIDING SCALE FOR CPRA

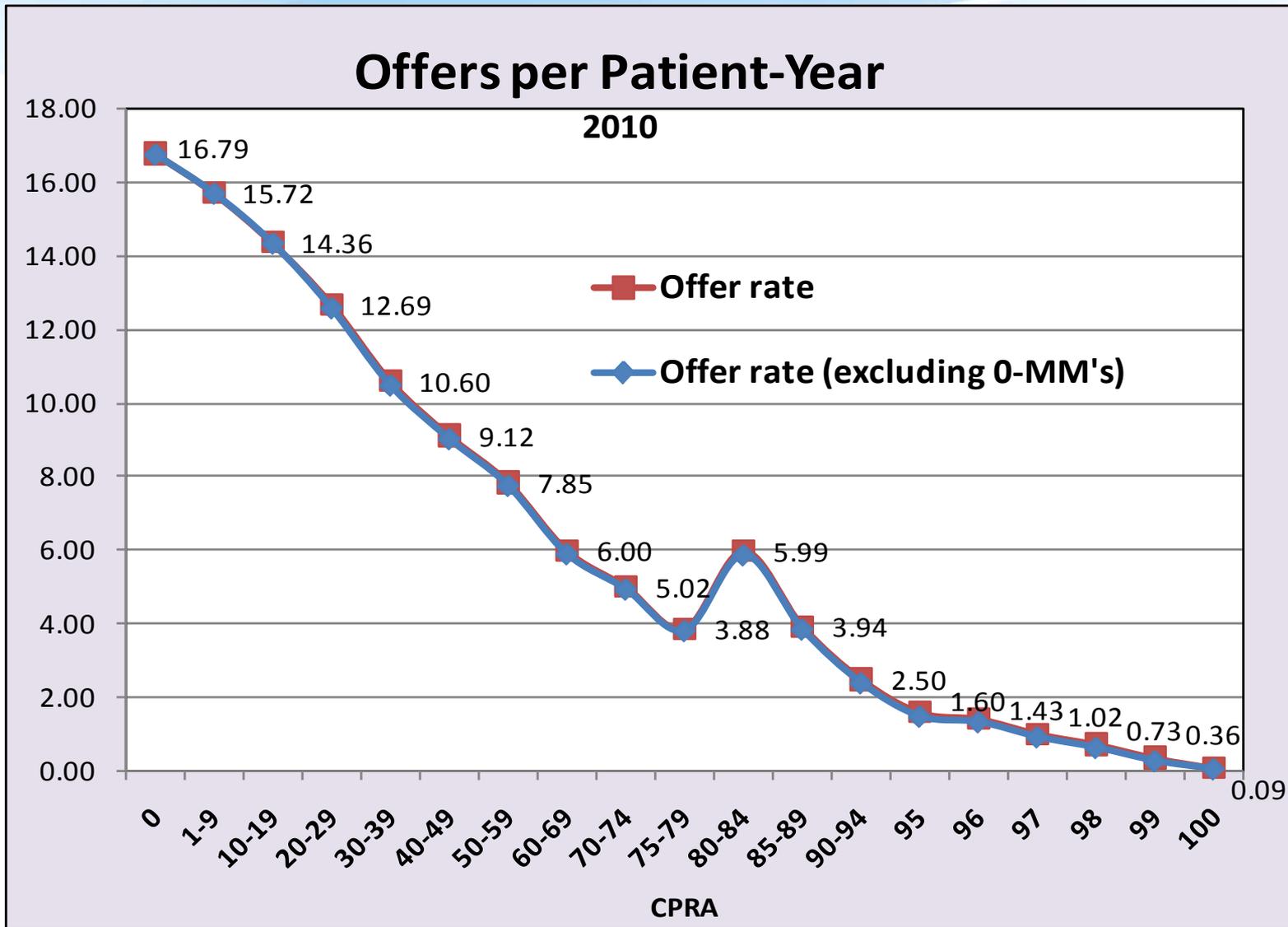
Proposed Point Change: Sensitization

- Current policy awards 4 points for CPRA $\geq 80\%$
- Diminished access for moderately sensitized patients not accounted for in current system
- A sliding scale based on candidate CPRA score would recognize access issues from CPRA of 20%

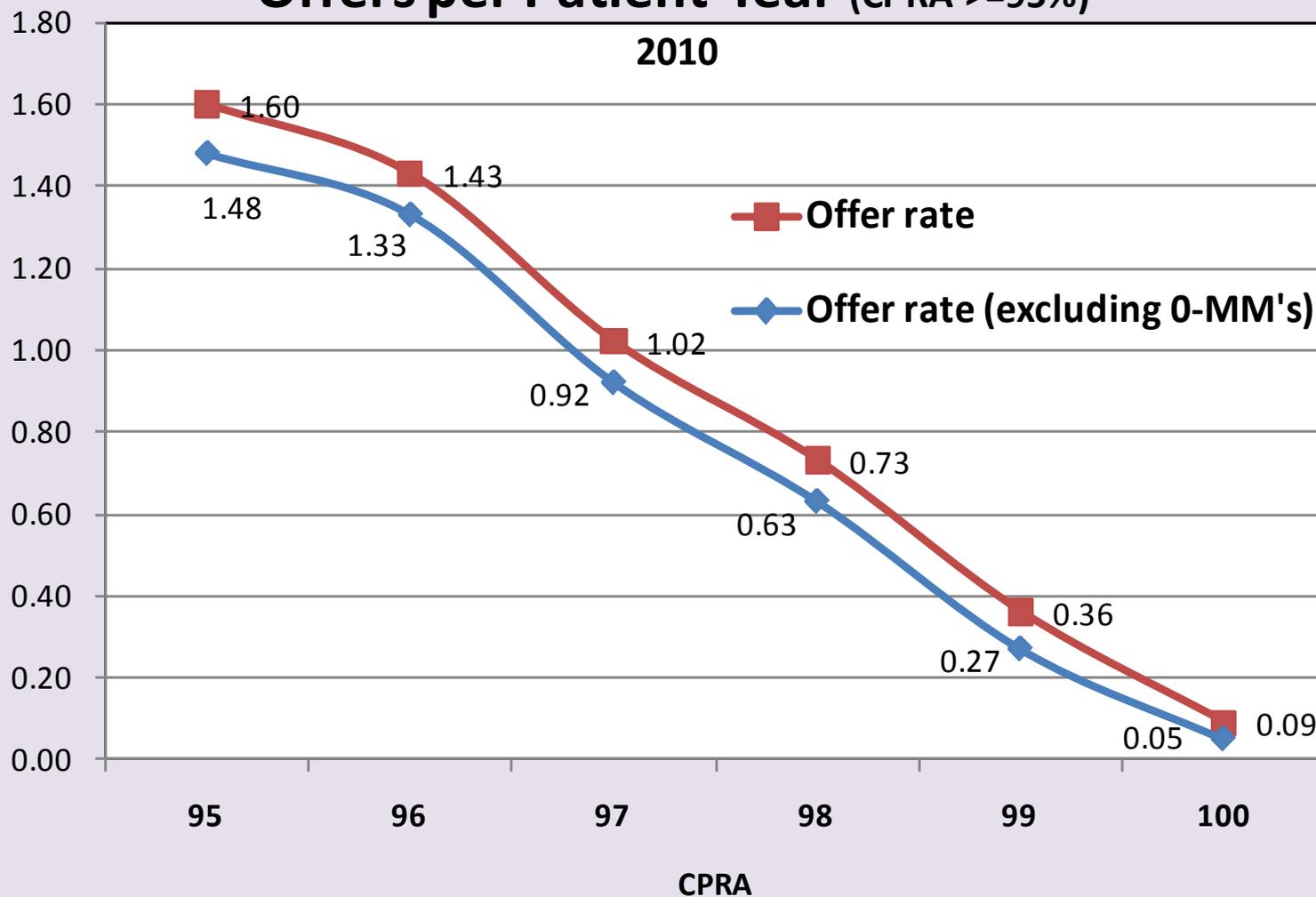
Proposed Point Change: *Sensitization*



- Current policy: 4 points for CPRA ≥ 80%. No points for moderately sensitized candidates.
Proposed policy: sliding scale starting at CPRA ≥ 20%



Offers per Patient-Year (CPRA >=95%)



Overview of Feedback

- Very positive, no opposition to sliding scale
- Included as proposed

INCLUDE PRE-REGISTRATION DIALYSIS TIME

Point Changes: *Waiting Time*

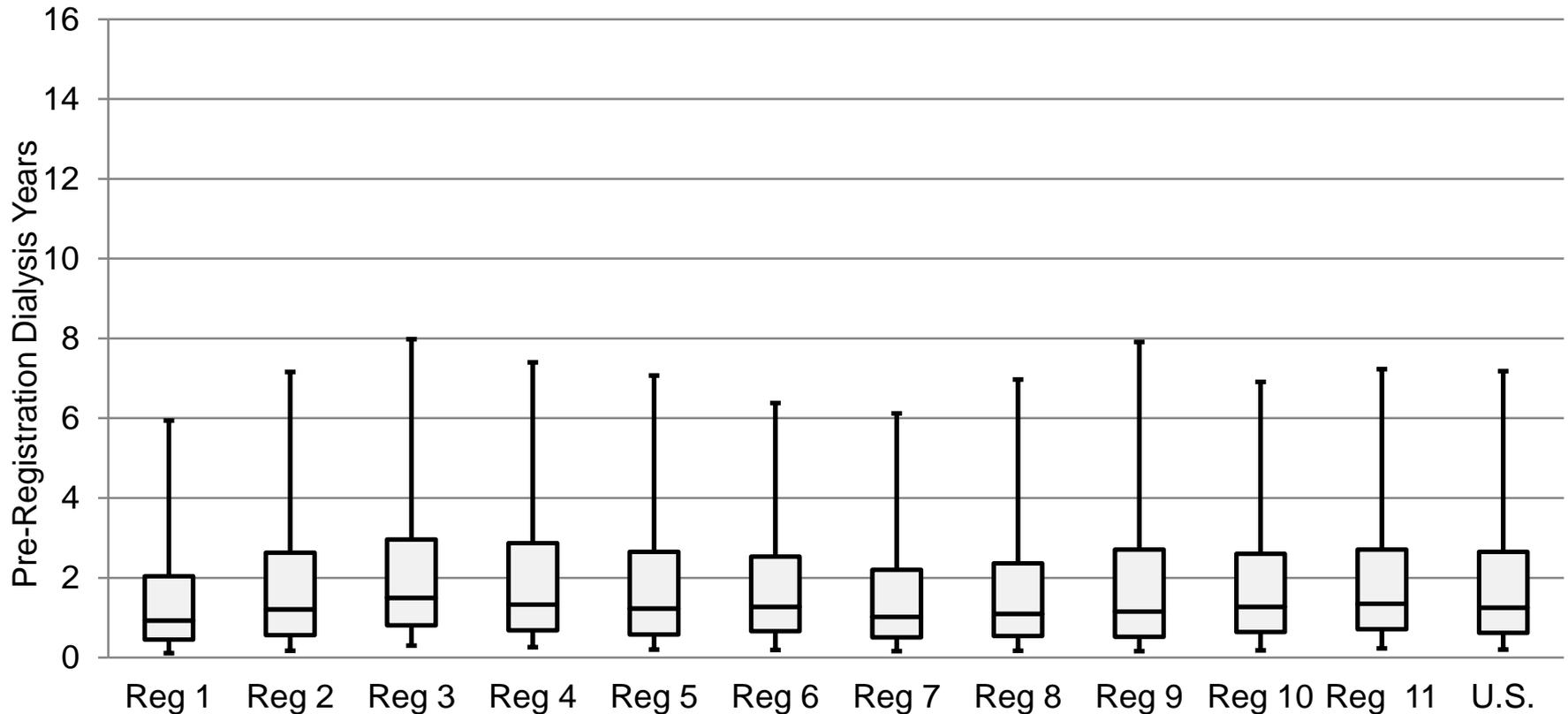
- Current policy begins waiting time points for adults at registration with:
 - $GFR \leq 20$ ml/min
 - Already on dialysis
- Proposed policy would also award waiting time points for dialysis time prior to registration
 - Applies to both pediatric and adult candidates
 - Better recognizes time spent with ESRD as the basis for priority
- Pre-emptive listing would still be advantageous for O-ABDR mismatch offers

Overview of Feedback

- Strongly supported by Minority Affairs Committee
- Opposition to including pre-registration dialysis time (n=8), (Regions 4, 11)
- Recommendation to cap pre-registration time (Operations Committee member)
- Recommendation to allow for backdating of $GFR_{\leq 20} \text{ml/min}$ (Region 9)
- Concern that including pre-registration time would provide disincentive for early referral

Distribution of Pre-Registration Dialysis Years by Region

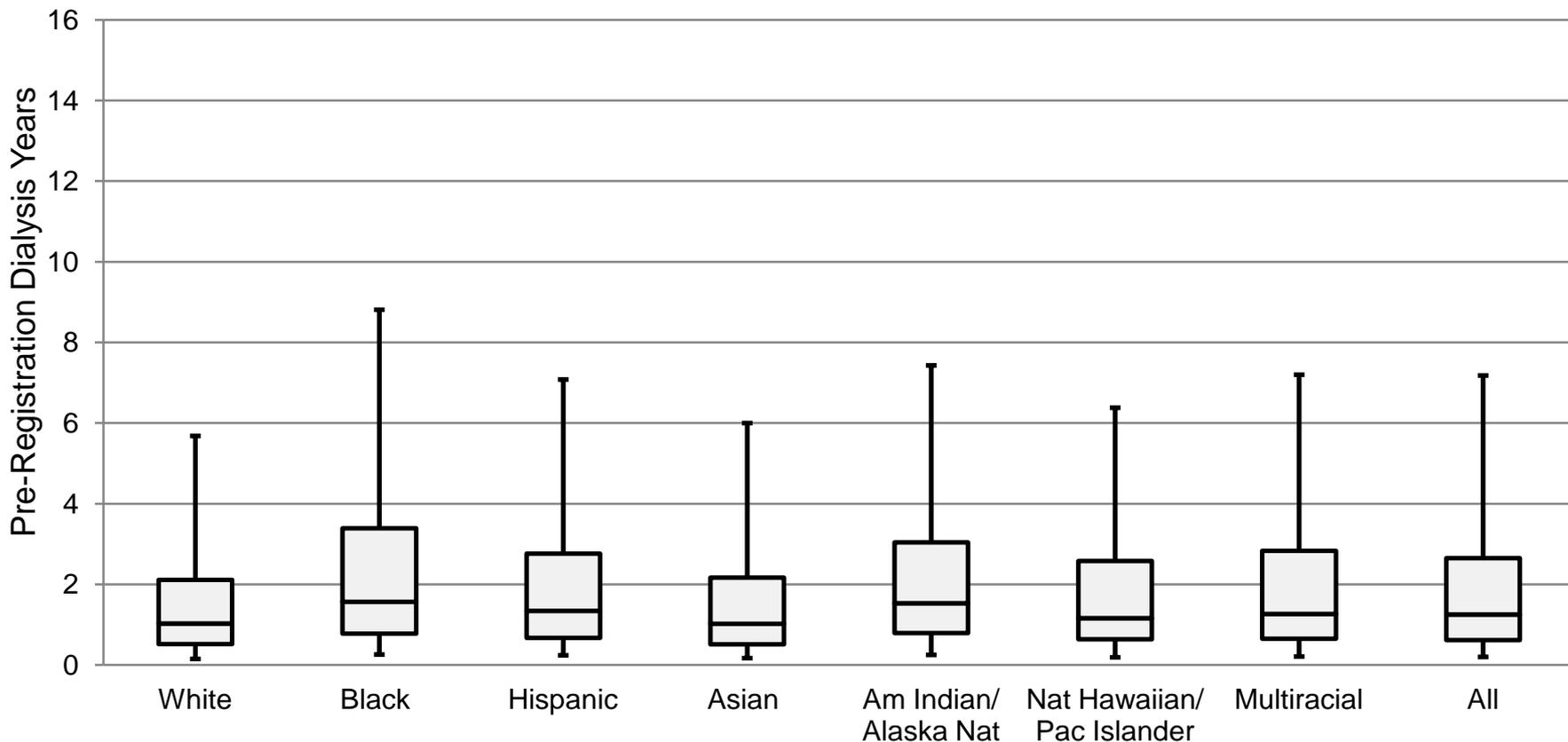
Adult Kidney Additions, 1/1/07-12/31/12 (N=138,133)



Rectangular boxes represent the 25th and 75th percentiles; horizontal lines inside the boxes represent the median values; vertical lines represent the 5th and 95th percentiles

Distribution of Pre-Registration Dialysis Years by Ethnicity

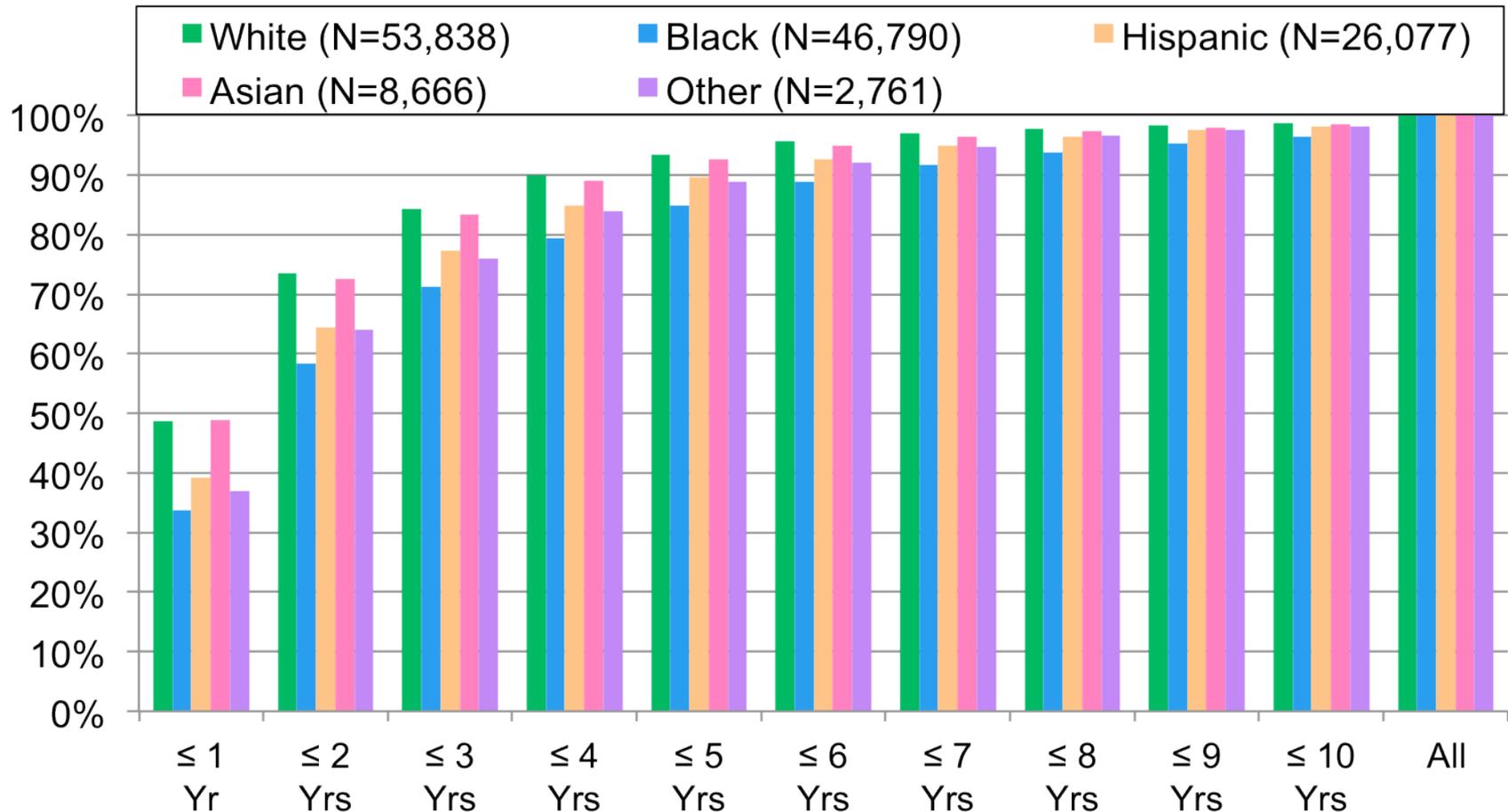
Adult Kidney Additions, 1/1/07-12/31/12 (N=138,132)



Rectangular boxes represent the 25th and 75th percentiles; horizontal lines inside the boxes represent the median values; vertical lines represent the 5th and 95th percentiles

Cumulative Distribution of Pre-Registration Dialysis Years by Ethnicity

for Adult Kidney Additions with Pre-Registration Dialysis, 1/1/07-12/31/12



Findings

- Capping/eliminating pre-registration dialysis time disproportionately harms minority candidates
- Allocation system must be based on objective medical criteria
- No reliable source documentation/criteria for GFR backdating
- OPTN study of registrations under Dialysis Waiting Time study inconclusive

Include pre-registration dialysis time

- No changes made

INCORPORATE A_2/A_2B

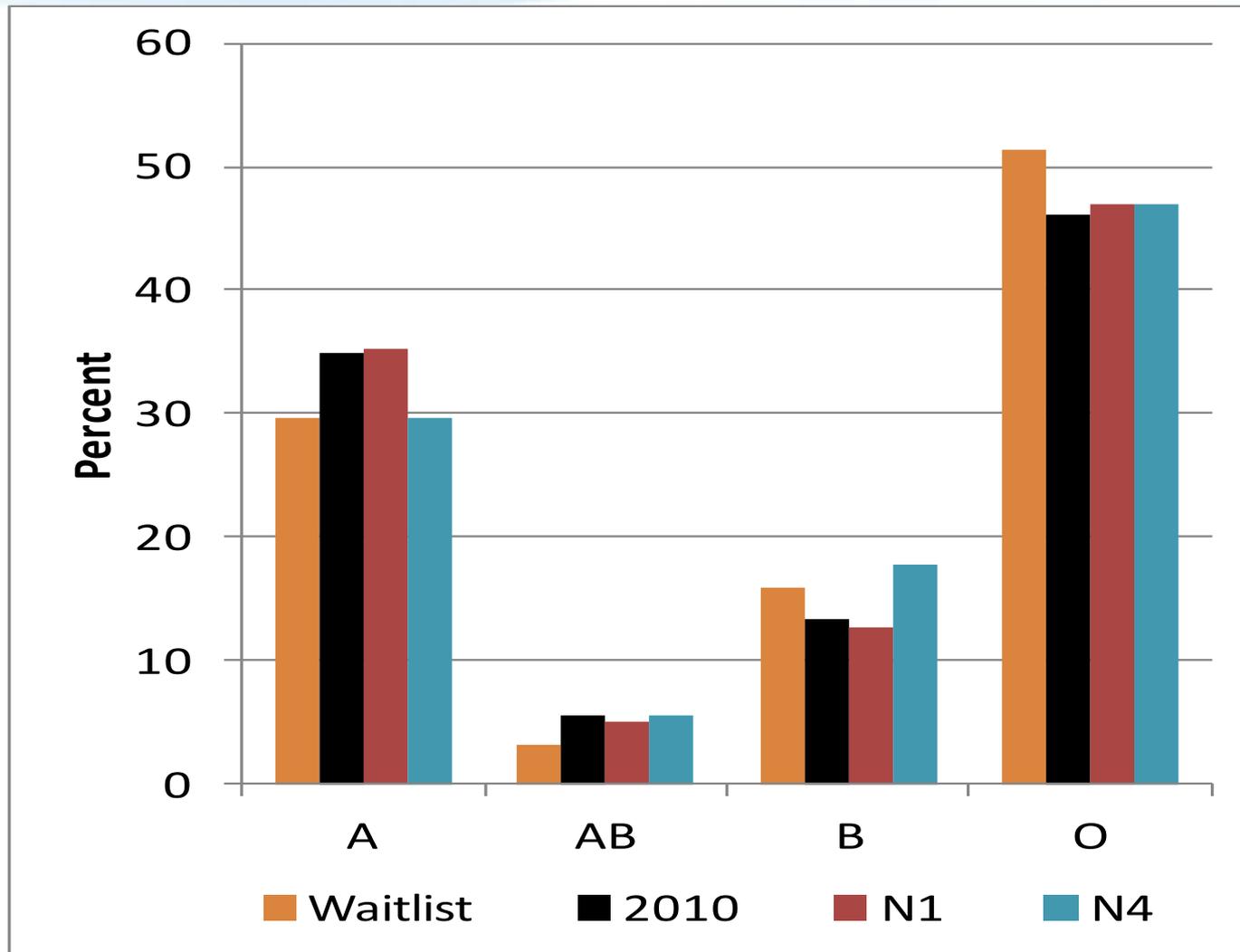
OPTN

Modified Classification:

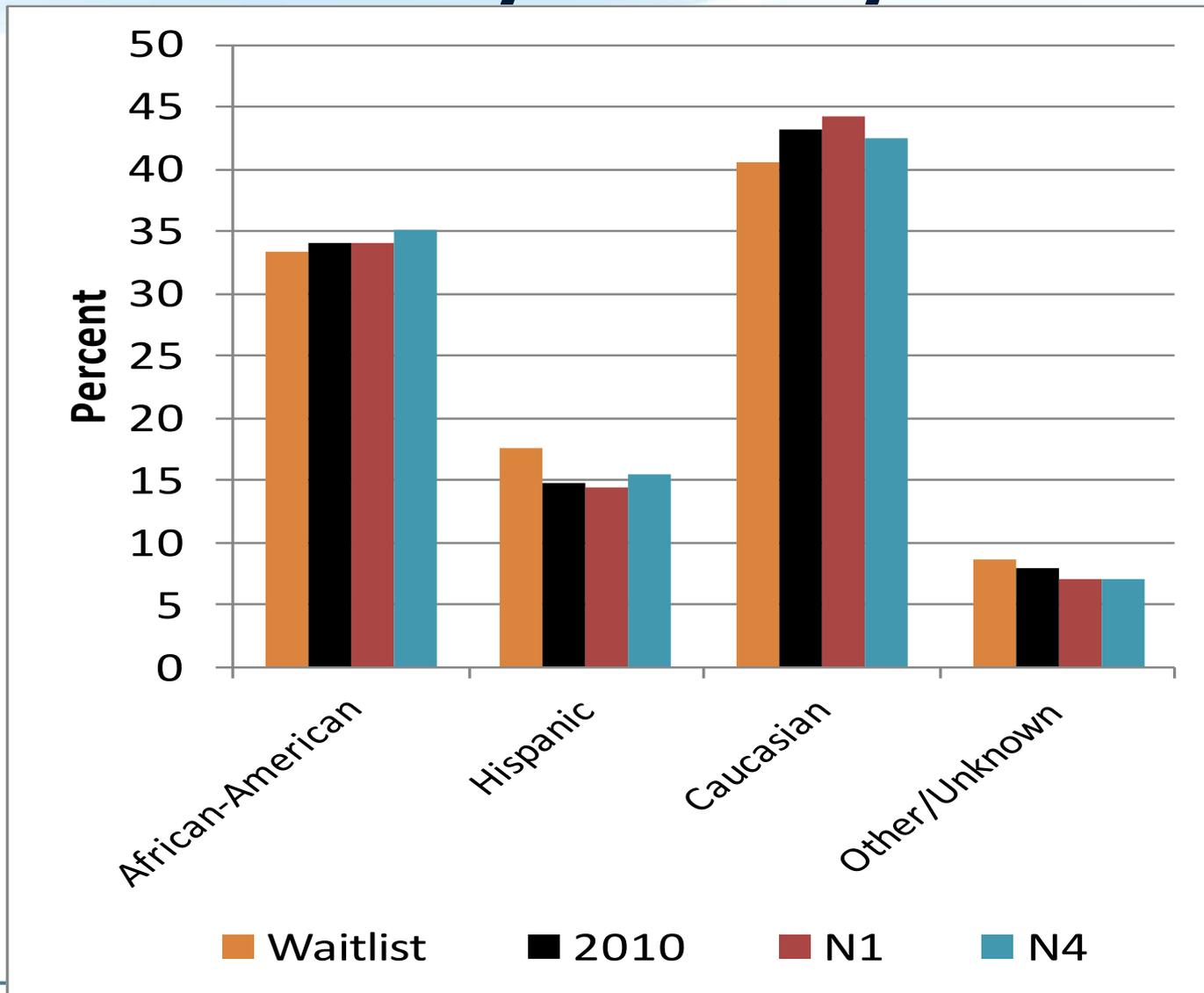
B Candidates receiving A₂/A₂B Kidneys

- Candidates with blood type B who meet defined clinical criteria will be eligible to accept kidneys from donors with blood type A₂ or A₂B
- Reported anti-A titer values required on regular schedule
- No titer values of greater than or equal to 1:8 allowed for candidate participation

KPSAM Results by blood type



KPSAM results by ethnicity



Overview of Feedback

- Recommendation to extend priority to O candidates (Region 4)
- Recommendation to drop titer requirements

Discussion

- Purpose of component is to expand access for minority candidates (primarily blood type B)
- B candidates more likely to have low anti-A titers than O candidates
- Multiple methods exist for assessing titers
- Precedent exists for allowing transplant programs to set thresholds and use medical judgment (e.g., unacceptable antigens)

Modifications made

- Titer thresholds removed
- Transplant programs must establish written policies and recertify candidate eligibility every 90 days (+/- 20 days)

BASE PEDIATRIC ALLOCATION ON KDPI INSTEAD OF DONOR AGE

OPTN

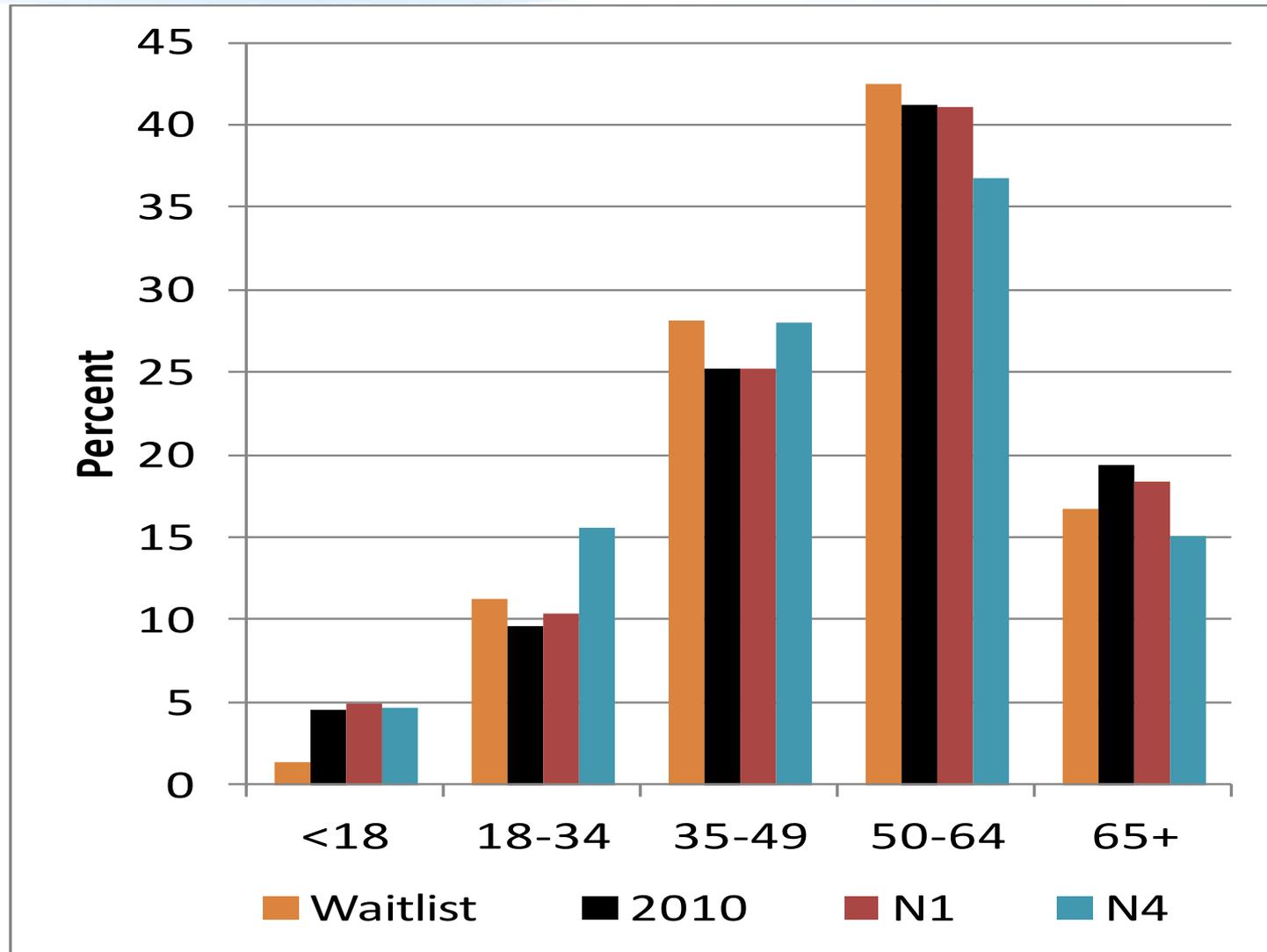
Modified Classification: *Pediatric*

- Current policy prioritizes donors younger than 35 to candidates listed prior to 18th birthday
- Proposed policy would
 - Prioritize donors with KDPI scores <35%
 - Eliminate pediatric categories for non 0-ABDR KPDI >85%
- Provides comparable level of access while streamlining allocation system

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Continued
 priority
 pediatric
 candidates
 (now based
 on KDPI)

KPSAM results by candidate age



Modifications to Pediatric Priority

- Pediatric Committee recommended also including priority for highly sensitized 0-ABDR pediatric candidates for KDPI > 85%
-
- Above recommendation incorporated into proposal

ELIMINATE KIDNEY PAYBACKS

OPTN



Removed Classification: *Kidney Paybacks*

- Current payback policy was evaluated and found to be
 - Administratively challenging
 - Unfair in that it affected all candidates in an OPO even if only one center was responsible for accruing debt
 - Ineffective in improving outcomes of recipients
- Kidney paybacks would no longer be permitted.
- All payback credits and debts would be eliminated upon the implementation of the revised kidney allocation system.

Comments received

- Eliminating payback system removes disincentive for accepting kidney and transplanting into backup candidate (Regions 1, 8)
- Eliminating payback system disproportionately harms small programs

Deliberation

- Committee considered:
 - Applying paybacks in certain circumstances
 - Developing a mechanism (other than paybacks) for addressing kidneys shipped but not transplanted into the intended recipient
 - Retaining the existing payback system

Final Recommendation

- Eliminate the payback system as initially proposed

ALLOCATE HIGH KDPI KIDNEYS TO COMBINED LOCAL/REGIONAL

OPTN

Modified Classification:

Local + Regional for High KDPI Kidneys

- KDPI >85% kidneys would be allocated to a combined local and regional list
- Would promote broader sharing of kidneys at higher risk of discard
- DSAs with longer waiting times are more likely to utilize these kidneys than DSAs with shorter waiting times