Kidney Allocation-
Optimal Use of Deceased Donors
The New US System
…..and impact on wait list management

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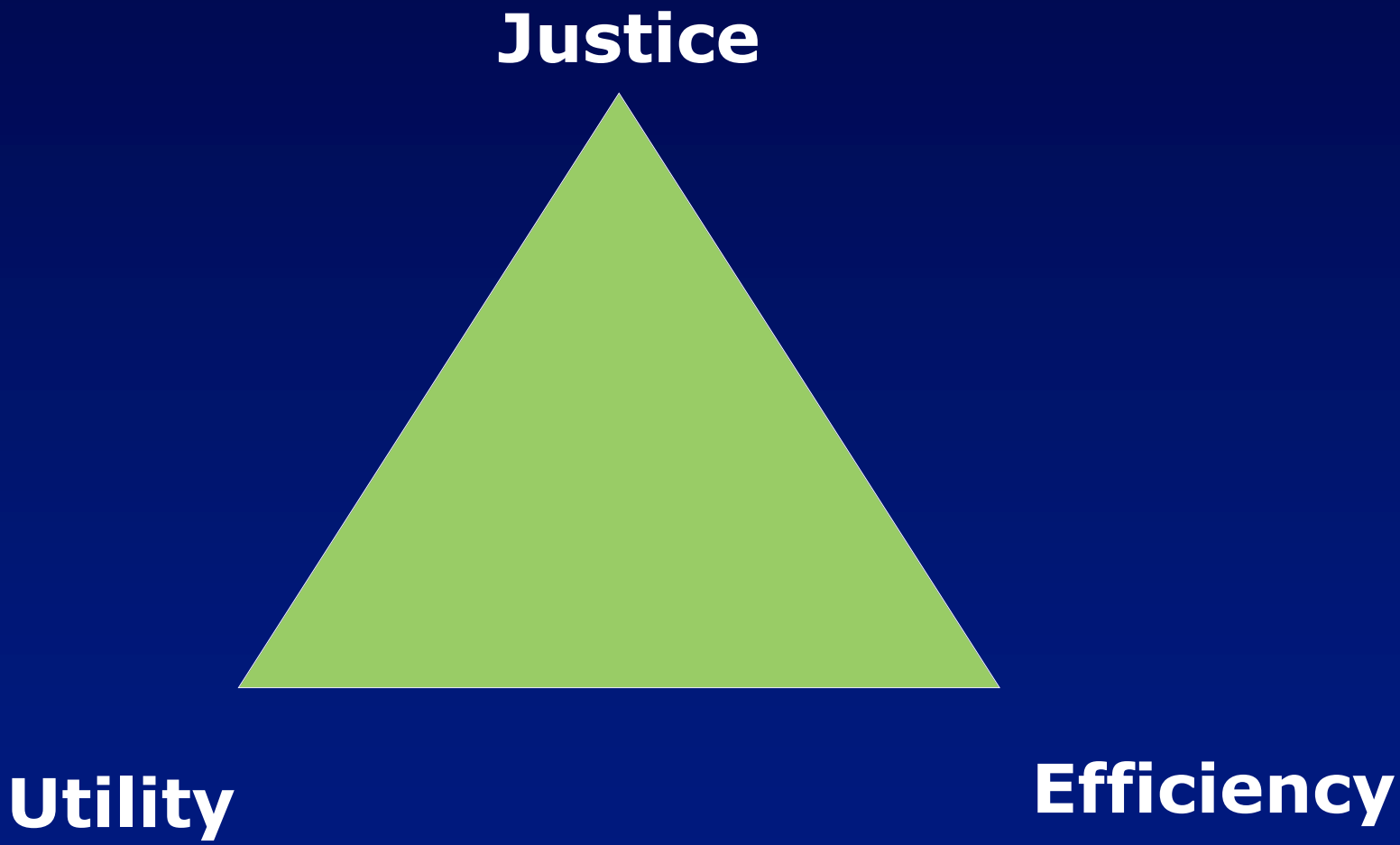
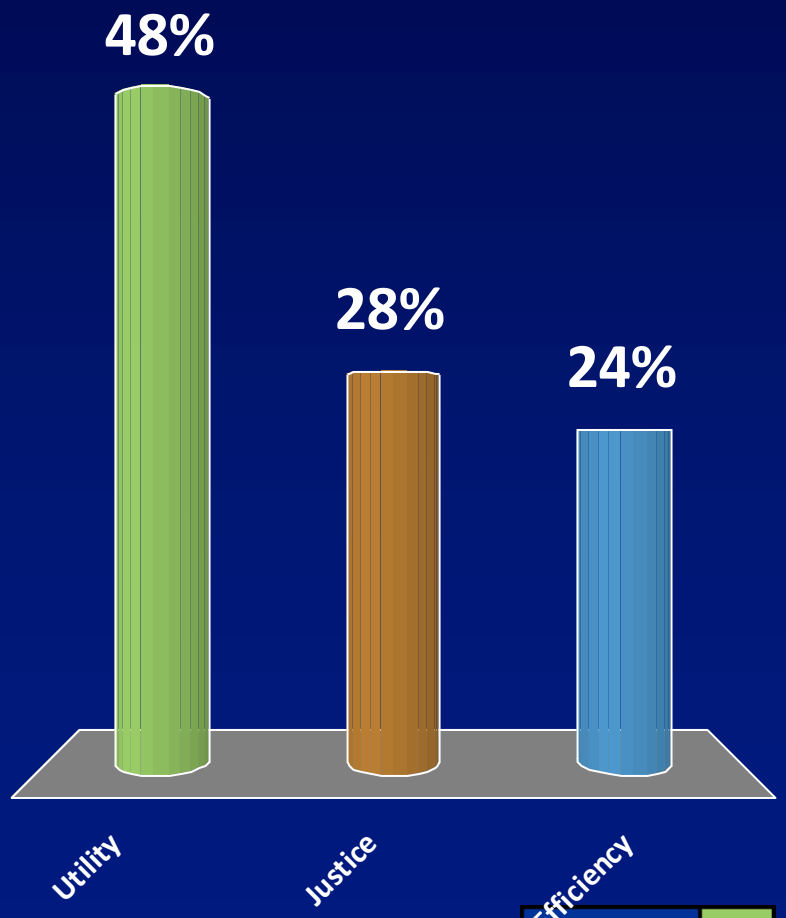
Three Sides to Allocation



Question 1: What factor would you consider the most important in the design of a new allocation system for kidneys?

A. Utility
B. Justice
C. Efficiency



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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

Evolution of Proposal

	National Sharing +LYFT	*LYFT*	*Age Matching+ Longevity Matching*	*Age Matching*	*Longevity Matching*
Gain in life years	34,026	25,794	15,223	14,044	8,380
Proportion of kidneys transplanted into recipients >50 years old	10	29	46	45	52

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Different Allocation Factors

Liver

- Serum creatinine
- Bilirubin
- INR
- Waiting time for tie-breakers

Kidney

- Waiting time
- PRA
- HLA match
- ECD – alternative list

Kidney Allocation
SCD versus ECD

Standard Criteria Donor (SCD)

- Waiting time
- PRA (>80% get 4 pts = 4 years)
- HLA (1 point for each HLA DR match=1 year)

Extended Criteria Donor (ECD)

- Waiting time

ECD – Extended Criteria Donor

- **ECD**
  - Donor Age
    - >60 alone
  - Donor Age
    - >50 with two below:
      - Cr >1.5
      - HTN
      - CVA
  - RR of graft failure >1.7 compared to the ‘ideal’ donor age 35 (16 – 17%)

Upcoming Changes to the Kidney Allocation System

Current Status

- June 2013: OPTN Board of Directors approves substantial revisions to the kidney allocation system
- Two phased implementation

Phase I	Phase II
• Data updates required • New reports released • Calculators made available	• New allocation rules applied • Variances turned off • Payback system turned off
Anticipated mid 2014	*Anticipated end 2014*

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 A_2/A_2B to B
- Base pediatric priority on KDPI
- Remove payback system
- Remove variances

KDPI vs ECD

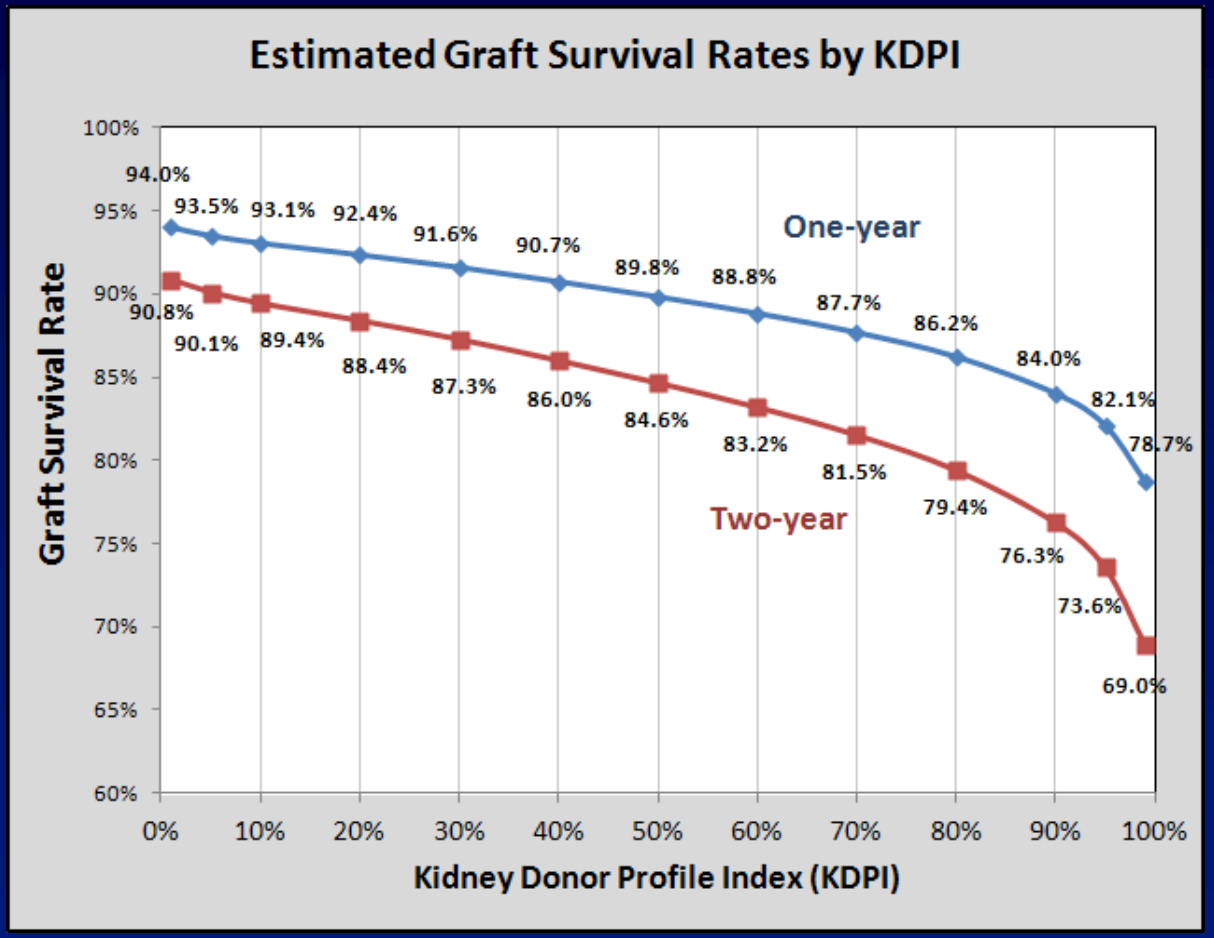
- **KDPI**
  - Donor age (c)
  - Race/ethnicity
  - Hypertension
  - Diabetes
  - Serum creatinine (c)
  - COD CVA
  - Height
  - Weight
  - DCD
  - HCV

- **ECD**
  - Donor Age
    - >60 alone
  - Donor Age
    - >50 with two below:
      - Cr >1.5
      - HTN
      - CVA
  - RR of graft failure >1.7 compared to the ‘ideal’ donor age 35 (16 – 17%)

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



KDPI values now displayed with all organ offers in DonorNet®

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Table 2: Estimated Kidney Graft Survival Rates, by Donor KDRI

KDPI	KDRI	Estimated Kidney Graft Survival Rates by KDRI			
		1 Year	3 Years	5 Years	8 Years
1%	0.55	94.0%	87.8%	80.5%	68.7%
5%	0.61	93.5%	86.7%	78.8%	66.2%
10%	0.65	93.1%	85.9%	77.6%	64.4%
20%	0.73	92.3%	84.4%	75.3%	61.1%
30%	0.81	91.5%	82.9%	73.0%	57.9%
40%	0.90	90.5%	81.1%	70.4%	54.4%
50%	1.00	89.5%	79.2%	67.6%	50.8%
60%	1.10	88.6%	77.4%	65.2%	47.6%
70%	1.23	87.3%	75.1%	61.9%	43.6%
80%	1.39	85.8%	72.4%	58.3%	39.2%
90%	1.62	83.7%	68.7%	53.3%	33.6%
95%	1.85	81.6%	65.2%	48.9%	28.9%
99%	2.30	77.7%	58.8%	41.1%	21.4%

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

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

Longevity Matching

- Estimated Post-Transplant Survival (EPTS)
  - Candidate age, time on dialysis, prior organ transplant, diabetes status
- 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 <=20% not allocated for multi-organ, very highly sensitized, or pediatric candidates

The new allocation system will reduce the number of extreme "longevity-mismatched" transplants.

New Classifications: Very Highly Sensitized

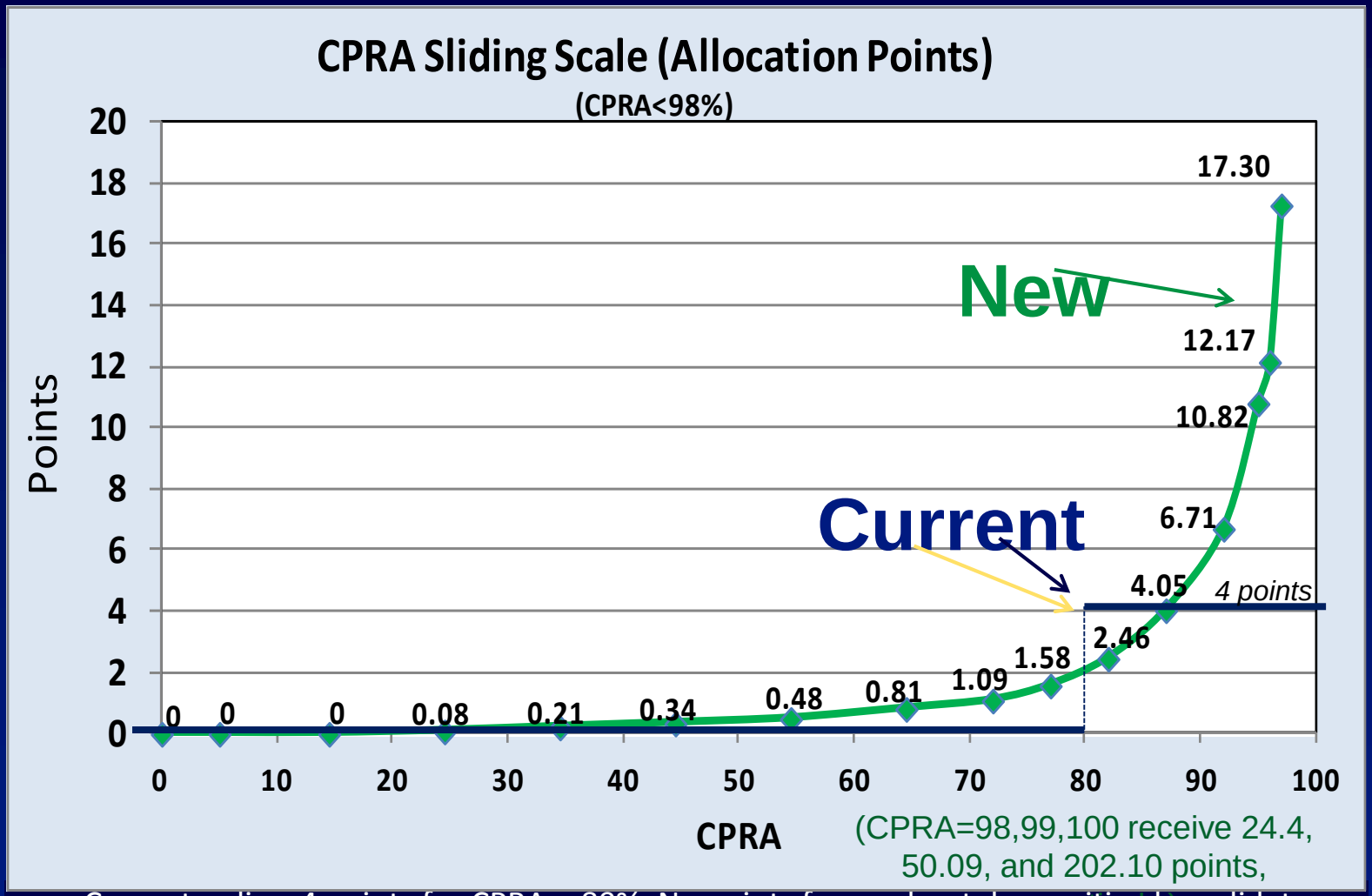
- Candidates with CPRA >=98% face immense biological barriers
- New classifications ahead of 0-ABDR mismatch classifications

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

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

Within each category 0-ABDR mismatches come first

Sliding Scale Based on CPRA



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

Waiting Time Definition Expanded

- 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
- Candidates may still be listed preemptively and accrue time with a GFR<=20ml/min

Should we list these potential recipients?

- Recipient 1: 48 y/o obese Type 2 diabetic male on HD X 1 year with BMI 44
- Recipient 2: 73 y/o Type 2 diabetic female with CAD and stent X2, no potential living donors, blood Type O, on CAPD
- Recipient 3: 32 y/o with h/o graft loss secondary to non-complicance at the age of 30, on HD
- Recipient 4: 55 y/o smokes cigarettes 2 PPD, Type 2 diabetes, BMI 32, on HD

Pediatric Offers Based on KDPI

- Pediatric priority for kidneys from donors with KDPI scores <35%
- Pediatric candidates no longer offered non 0-ABDR mismatch kidneys with KDPI >85%

Local + Regional Distribution for High KDPI Kidneys

- KDPI >85% kidneys will be allocated to a combined local and regional list

Variances Removed

DONOR A (Questions 2-3):
A 31 y/o male (5”10, 77 kg) blood Type O) is declared brain dead following head trauma from a skiing injury. Previously healthy with no significant medical history. Terminal creatinine is 1.3
KDPI 22%
Serogies are negative for CMV, HBV, HCV,HIV.

Sequence A KDPI <=20%	Sequence B KDPI >20% but <35%	Sequence C KDPI >=35% but <=85%	Sequence D KDPI>85%
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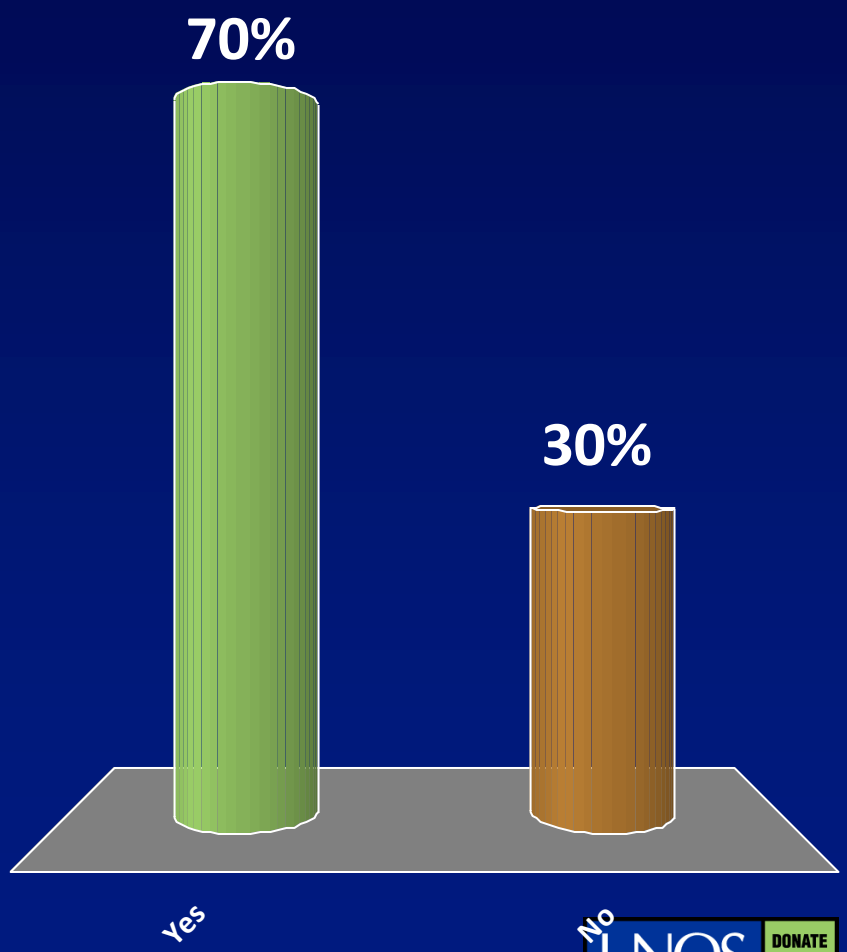
Once in a category, candidates are rank ordered according to points

Question 2: This 38 y/o deceased donor kidney (O mismatch) from a local donor is allocated to a 72 y/o unsensitized caucasian woman (blood Type O) who has just been listed

Would you accept this offer?

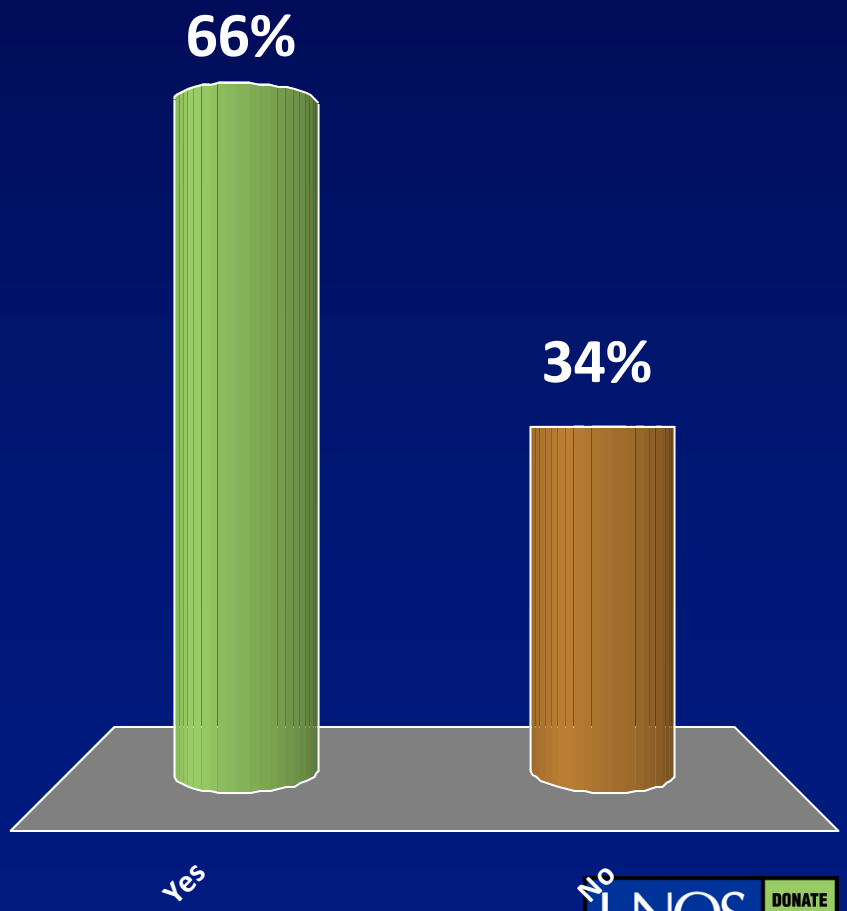
A. Yes
B. No



Question 3: The second patient on the list is a 36 year old male with ESRD secondary to GN. Would you skip the 72 year old (ESRD from Type II diabetes) to give this 38 y/o donor kidney to the younger recipient listed at your center?

Would you?

A. Yes
B. No



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DONOR B (Questions 4-5): A 56 y/o petite female smoker (5”3,54 kg , no h/o hypertension or diabetes) has an MI, is resuscitated, but becomes brain dead secondary to anoxia. Terminal creatinine is 1.3. KDPI 83%

Serologies are negative for HCV, HIV, and CMV. Donor team tells you the aorta was had severe plaque.

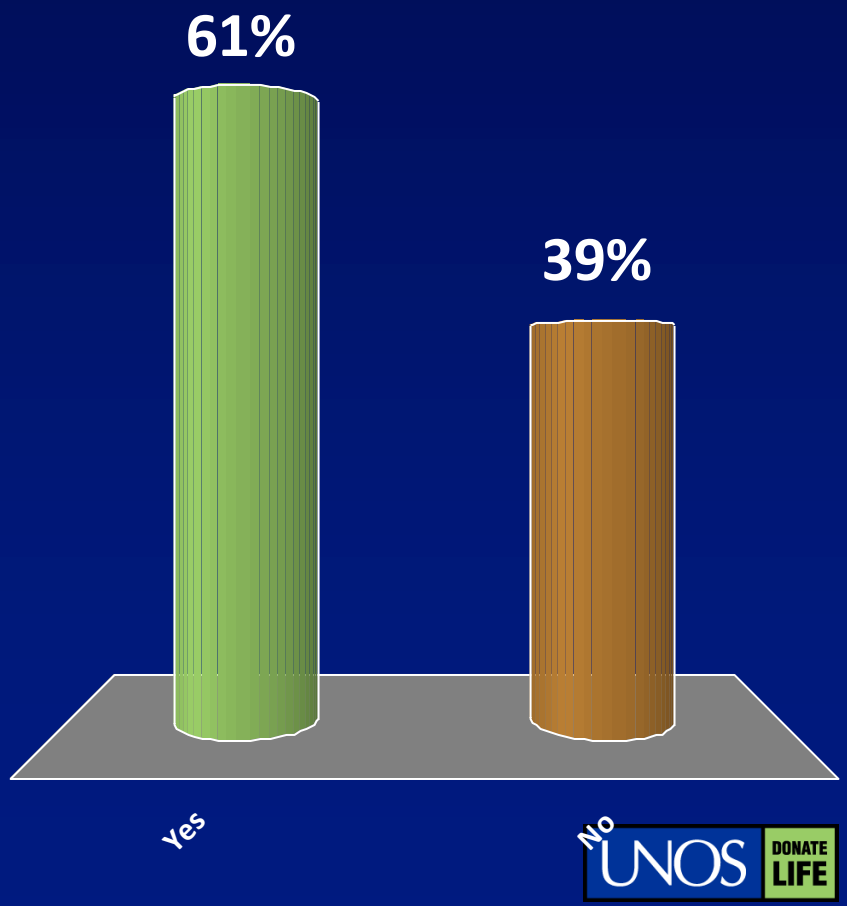
Sequence A KDPI <=20%	Sequence B KDPI >20% but <35%	Sequence C KDPI >=35% but <=85%	Sequence D KDPI>85%
Highly Sensitized 0-ABDRmm (top 20% EPTS) Prior living donor Local pediatrics Local top 20% EPTS 0-ABDRmm (all) Local (all) Regional pediatrics Regional (top 20%) Regional (all) National pediatrics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

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

Question 4: This KDPI 83% kidney is offered to a 42 y/o male (6 ft, 95 kg) with ESRD secondary to GN. He is unsensitized and has been waiting 7 years for a kidney.

Would you accept this offer?

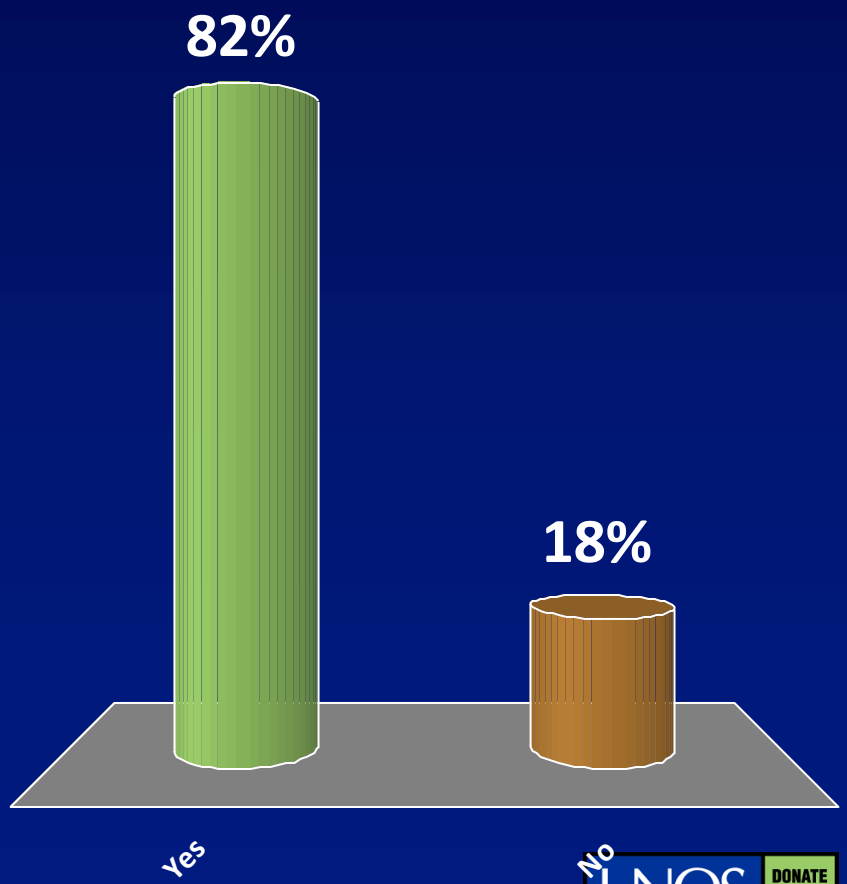
A. Yes
B. No



Question 5: This KDPI 83% kidney is offered to a 56 y/o female (5 ft, 55kg) with ESRD secondary to hypertension. She is unsensitized and has been waiting 7 years for a kidney.

Would you accept this offer?

A. Yes
B. No



DONOR C (Question 6): Donor is classified as an ECD. She was a 69 y/o female (5'6 ft, 68 kg) with h/o hypertension who died from a CVA. Donor team tells you there is adherent fat and a markedly atherosclerotic aorta. Terminal creatinine is 1.2.

KDPI 93% (ECD in new system)

All serologies negative.

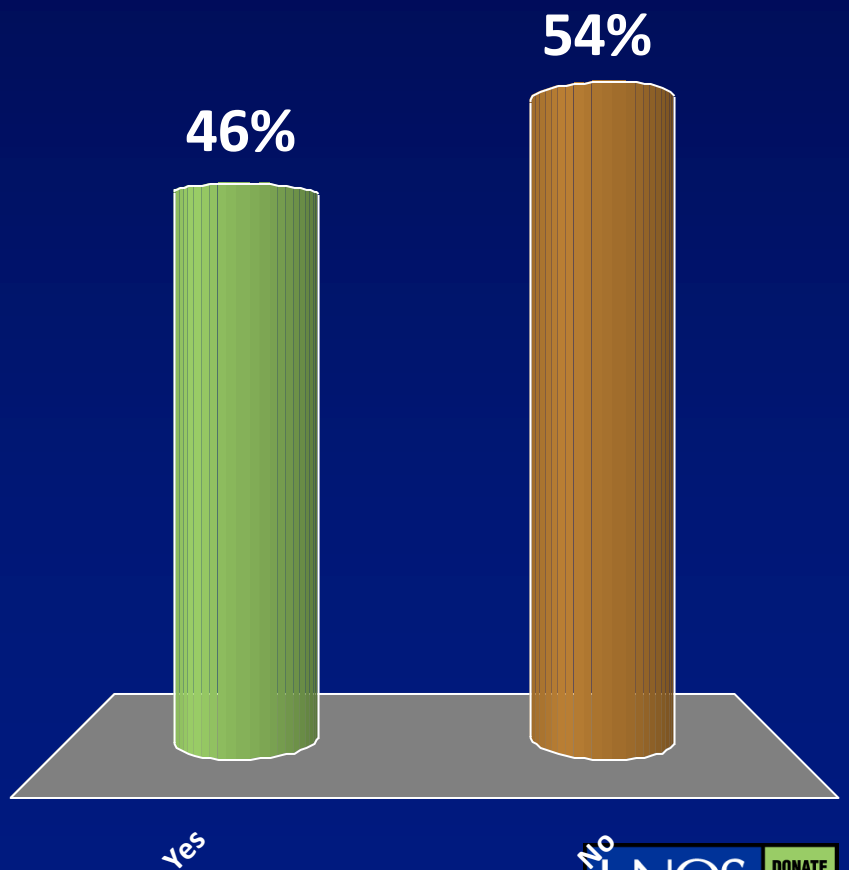
Sequence A KDPI <=20%	Sequence B KDPI >20% but <35%	Sequence C KDPI >=35% but <=85%	Sequence D KDPI>85%
Highly Sensitized 0-ABDRmm (top 20% EPTS) Prior living donor Local pediatrics Local top 20% EPTS 0-ABDRmm (all) Local (all) Regional pediatrics Regional (top 20%) Regional (all) National pediatrics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

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

Question 6: This ECD kidney is allocated to a 55 y/o diabetic male (5”11, 90 kg) who has consented to receive an ECD kidney and has been waiting three years and is now at the top of the ECD list.

Would you accept this offer?

A. Yes
B. No



DONOR D (Question 7): 28 y/o male (6”1, 94 kg) professional athlete (blood Type O) with no significant medical history was declared brain dead following head trauma at an athletic event.

SH: multiple heterosexual partners and recent h/o of treated gonorrhea.

Terminal creatinine is 1.0.

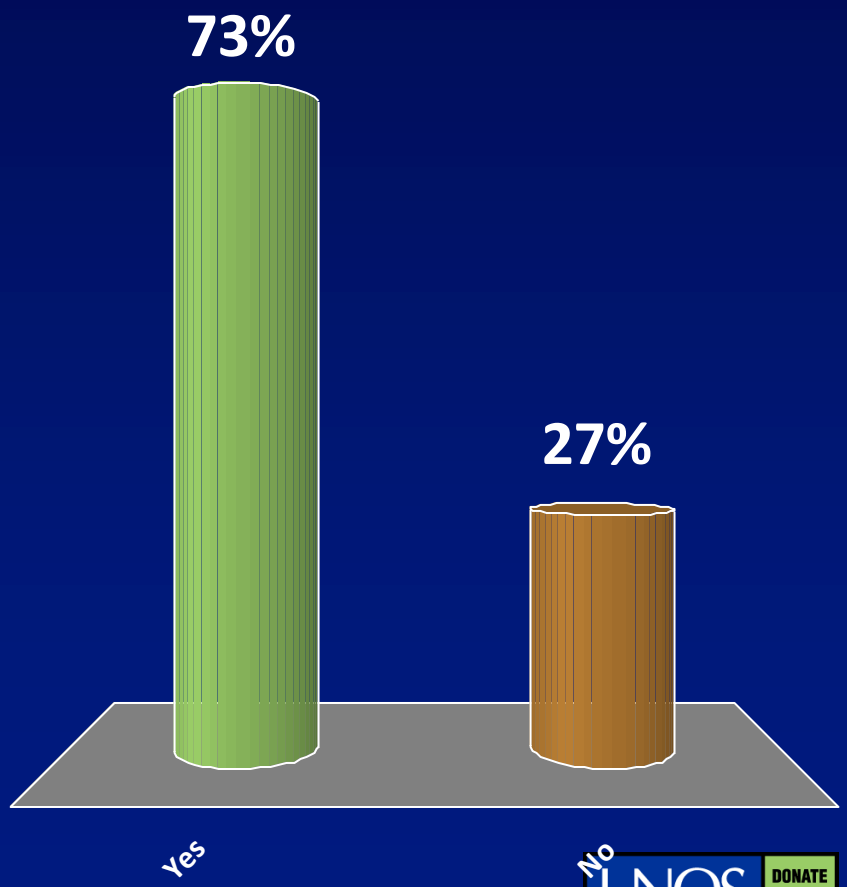
KDPI 25%

NAT testing negative for HBV, HCV, HIV.

Question 7: A 42 y/0 male with ESRD 2ary to GN (6'1, 95kg) has NOT consented to receive a CDC high risk donor.

Would you try to convince your recipient to accept this offer?

A. Yes
B. No



DONOR E (Questions 8 and 9): 23 y/o male (6”0, 75 kg) with a h/o active IV drug abuse becomes brain dead following an anoxic event associated with an overdose. Donor is hemodynamically stable with a creatinine 0.9.

NAT testing POSITVE for HCV.

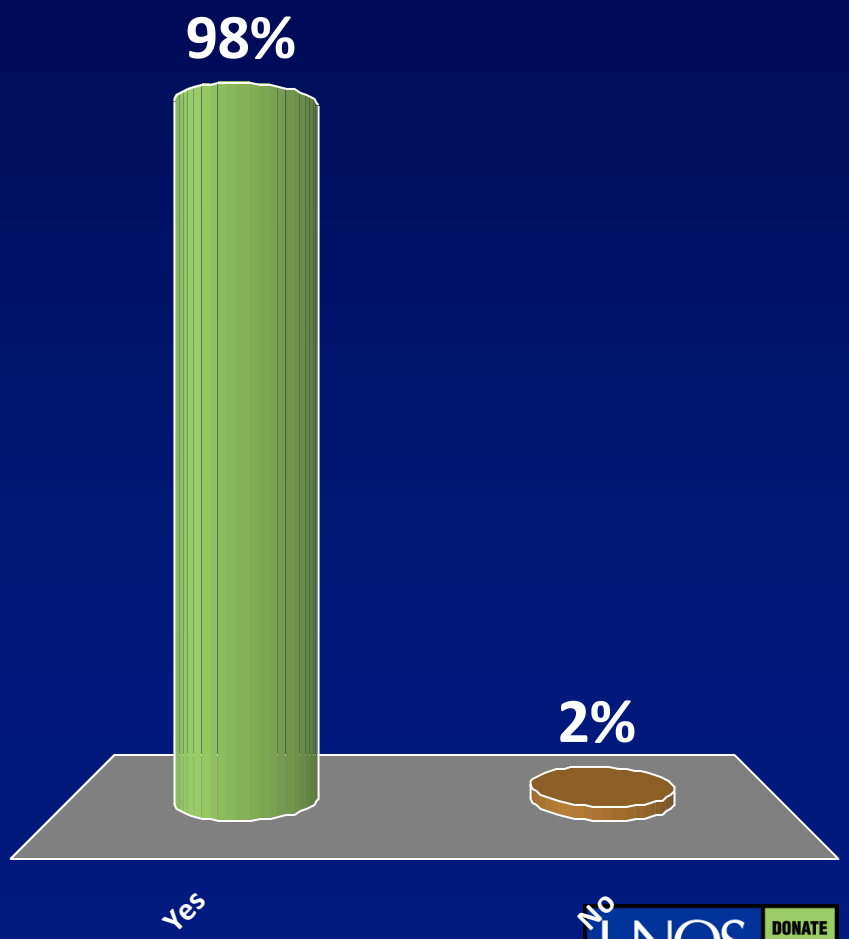
KDPI 24%

NAT testing NEGATIVE for HIV, HBV.

Question 8: Kidney is offered to a 50 y/o male with ESRD secondary to hypertension. He is HCV positive and has consented to receive a CDC high risk donor and an HCV positive donor.

Would you accept this donor?

A. Yes
B. No



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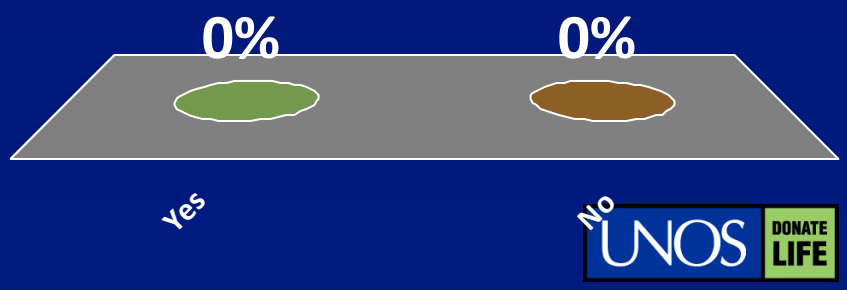
Question 9: You just heard about the HCV pt that got tx within 6 months of listing – What do you recommend to your HCV positive pt (blood type O) who was just listed regarding new therapy to eliminate HCV? (if successful will wait >8yrs for tx!)

Would you?

A. Yes
B. No



Conclusions

- Need to do what is best for the patient who gets the kidney offer (i.e. 72 year old offered the 21 year old donor)
- UNOS Kidney Committee will initiate new allocation algorithm to prevent major donor/recipient age mismatches
- Not all SCD kidneys are created equally – and you need to pay attention to the quality of kidney being offered to a person who has waited a long time !

Conclusions

- New allocation system being developed which uses a donor risk index (donor profile index) which is a continuum
- But even in the new system--need to make sure that an ECD is appropriate for your recipient---unfortunately not all ECDs are created equally. Need to know what risk your recipient is willing to take to get an expedited transplant

Conclusions

- Utilization of the CDC high risk donor can be a valuable source of high quality kidneys – but be aware of the CDC high risk label
- Bottom line – Need to know BEFORE the time of an offer what type of donor a recipient is willing to accept

  - CDC high risk (how high a risk?)
  - ECD or SCD, but ultimately Donor Profile Index