

Kidney Transplantation Committee Update

Board of Directors Meeting

June 27-28, 2011

Ken Andreoni, MD, Chair

Major Progress

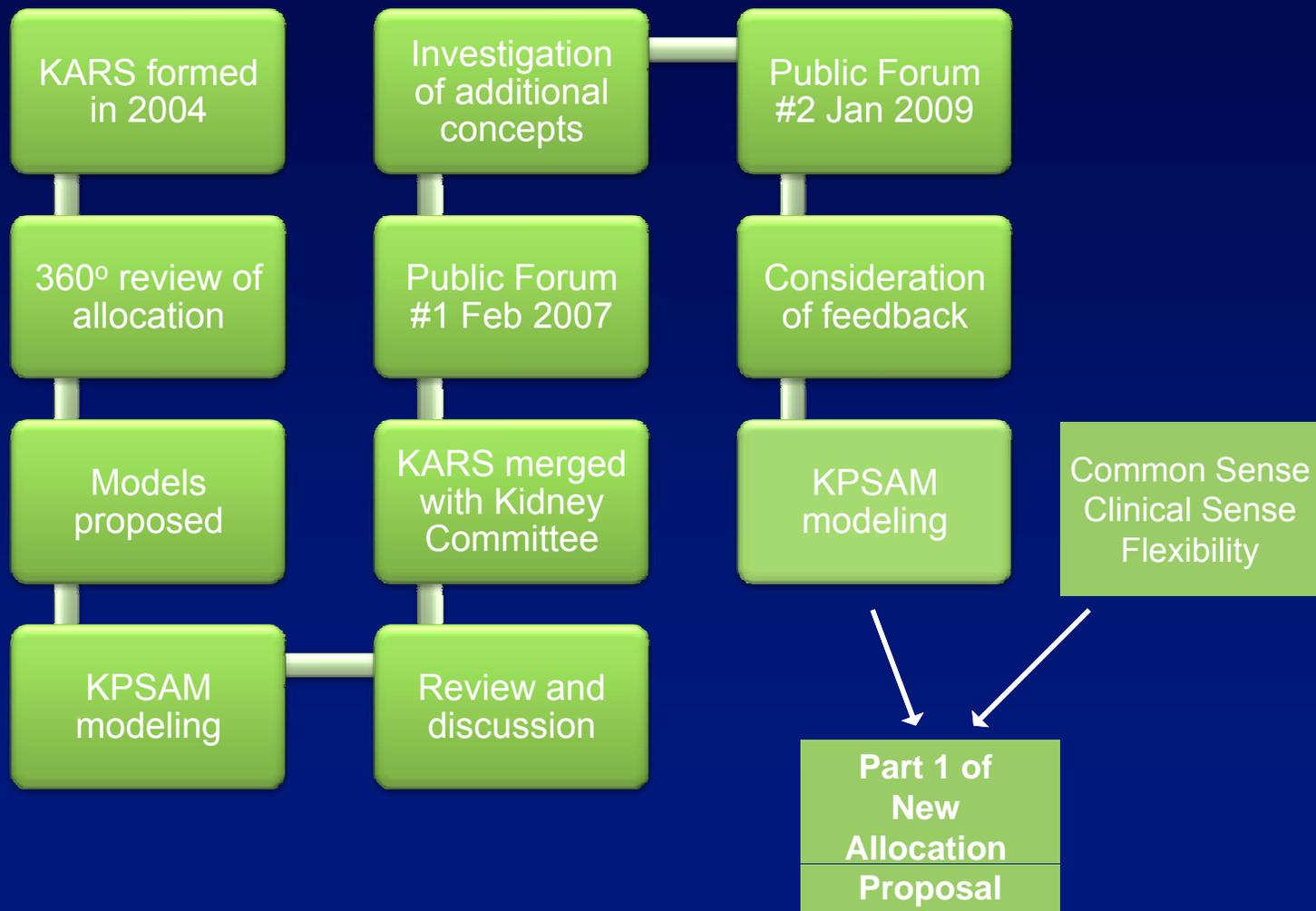
- Kidney Allocation Policy
 - Comments received on concept document
- Kidney Paired Donation Pilot Program
 - Matches run
 - Chains incorporated

KIDNEY ALLOCATION POLICY

OPTN



Process to date



Addressing Current System Limitations

- mismatch between potential survival of the kidney and the recipient which increases the need for retransplant and results in hundreds of potential life years not being realized
- variability in access to transplantation by blood group and geographic location
- high discard rates of kidneys (especially ECD) that could benefit candidates on the waiting list

Major Goals for Kidney Allocation

- Better match graft longevity and recipient longevity within biological reason and acceptable levels of accessibility
 - Decrease return to wait list
 - Minimize loss of potential graft function
- Improve system efficiency and organ utilization
- Make comprehensive data better available to patients and transplant programs
- Address differences in accessibility for populations described in the National Organ Transplant Act

A plan for reaching these goals

- Utilize a kidney donor profile index (KDPI) to better characterize donor kidneys and to provide additional clinical information for patients and providers to consider during the transplant evaluation process and organ offer process.
- Allocate the majority of organs (80%) by age matching so that candidates within 15 years (older and younger) of the donor are prioritized.
- Allocate some kidneys (20%) by a kidney donor profile index (KDPI) and estimated recipient post-transplant survival.
 - Longest lived recipients receiving kidney with longest potential function

CONCEPT DOCUMENT FEEDBACK

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ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Concepts for Kidney Allocation

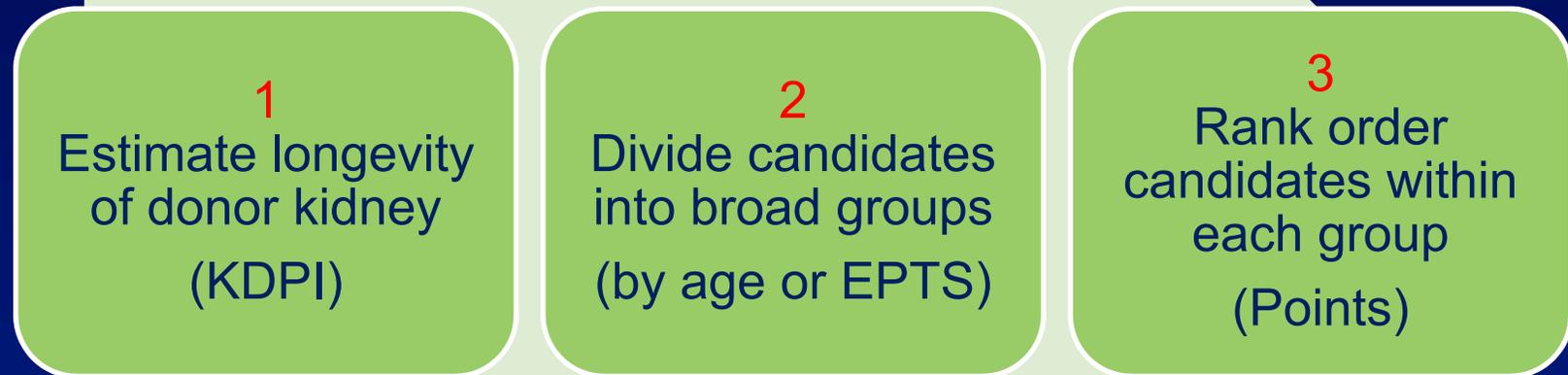
The Organ Procurement and Transplantation Network (OPTN) is seeking feedback regarding the use of two concepts in the allocation of deceased donor kidneys. Any feedback obtained will be used by the Kidney Transplantation Committee in its work to develop a revised kidney allocation system.

Concept
document
released
February 15-
April 1, 2011

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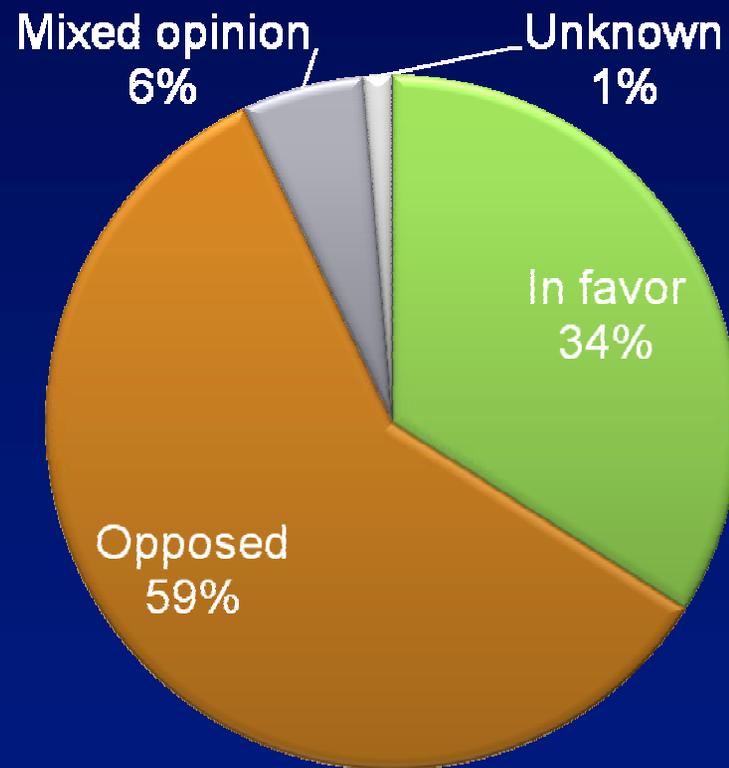
UNOS DONATE LIFE

In three steps: How does this system work?



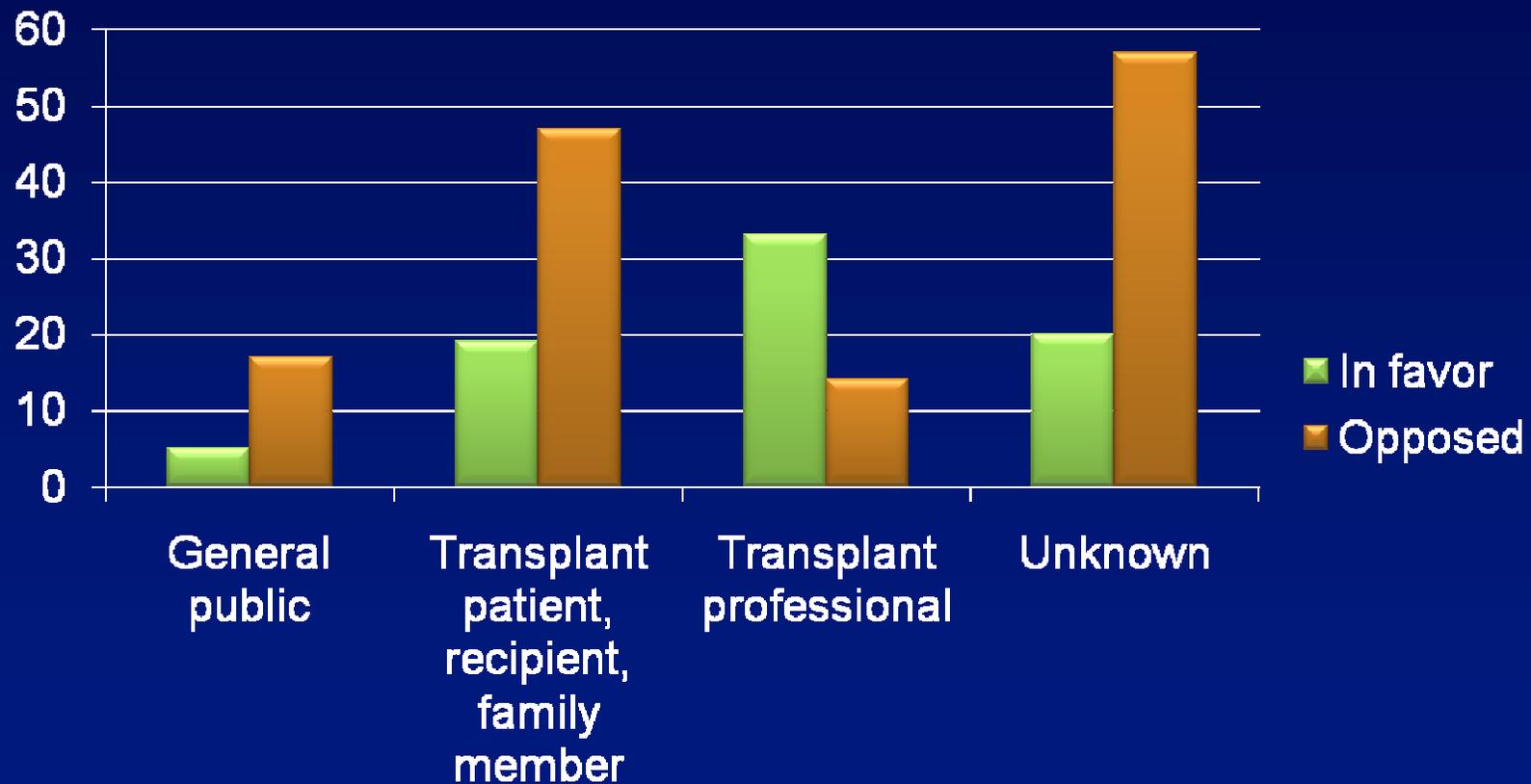
The concept document covered Steps 1 and 2. Step 3 (rank ordering) will be addressed in the future.

Comments Received



n=264 comments

Comments Received



Transplant professionals were more likely to be in favor of the concepts than the general public or transplant patients, recipients, family members

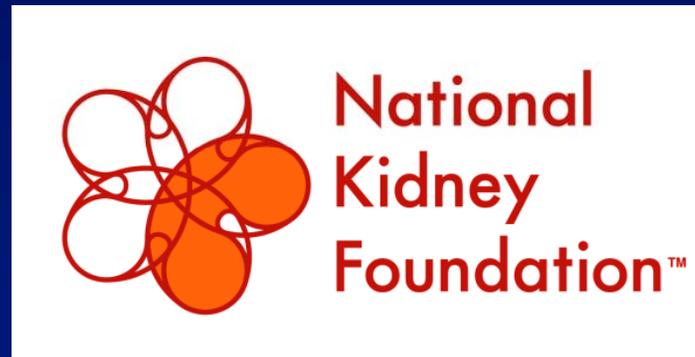
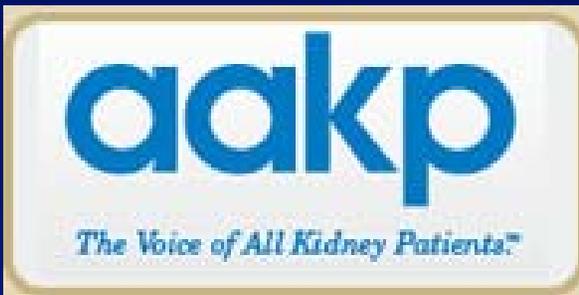
Plausible New Suggestions

N= 0 comments

OPTN

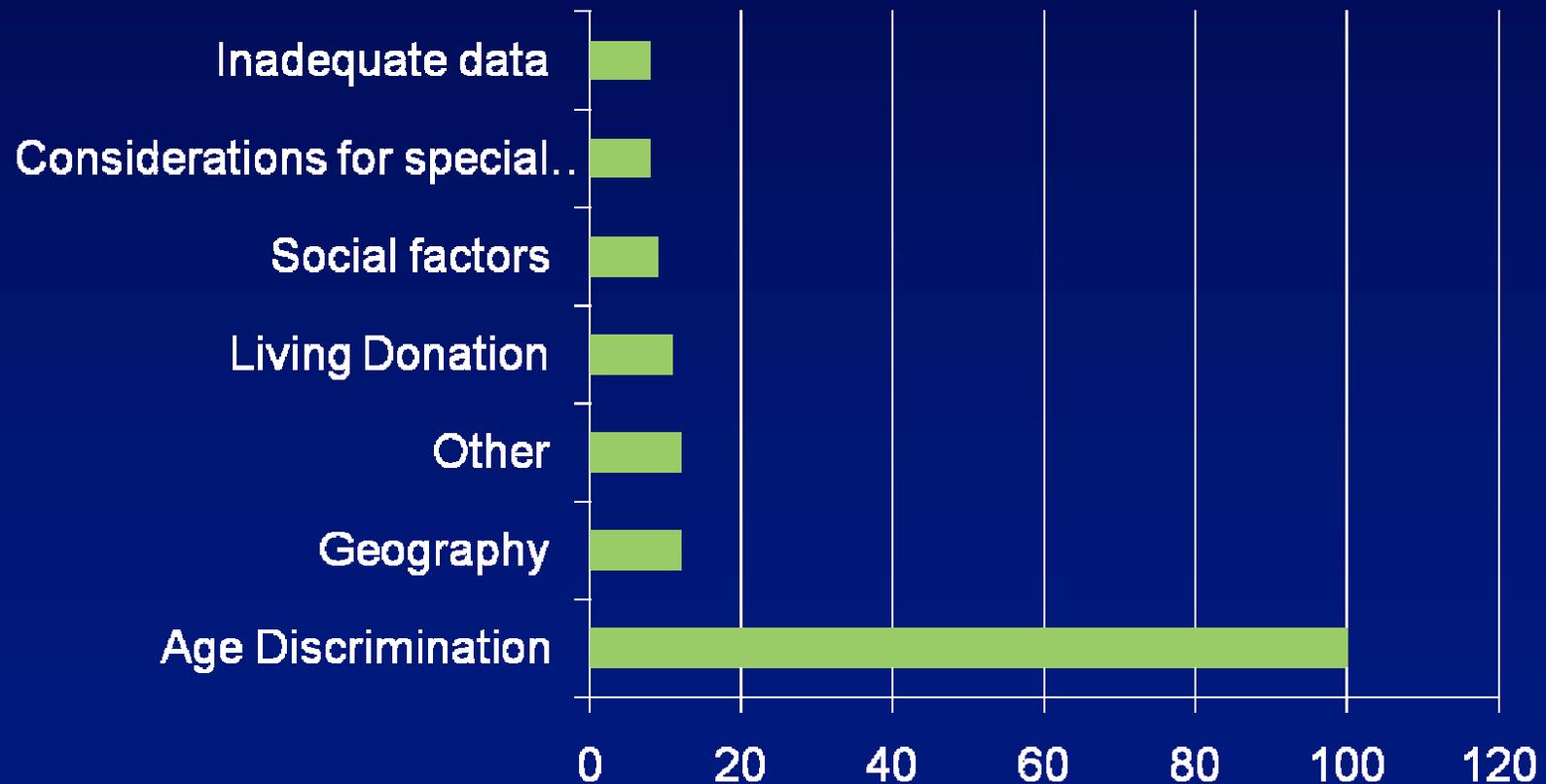


Comments Received from Organizations



Professional organizations were more likely to support the concepts than organizations representing patients. This is an opportunity for future engagement.

Major Concerns

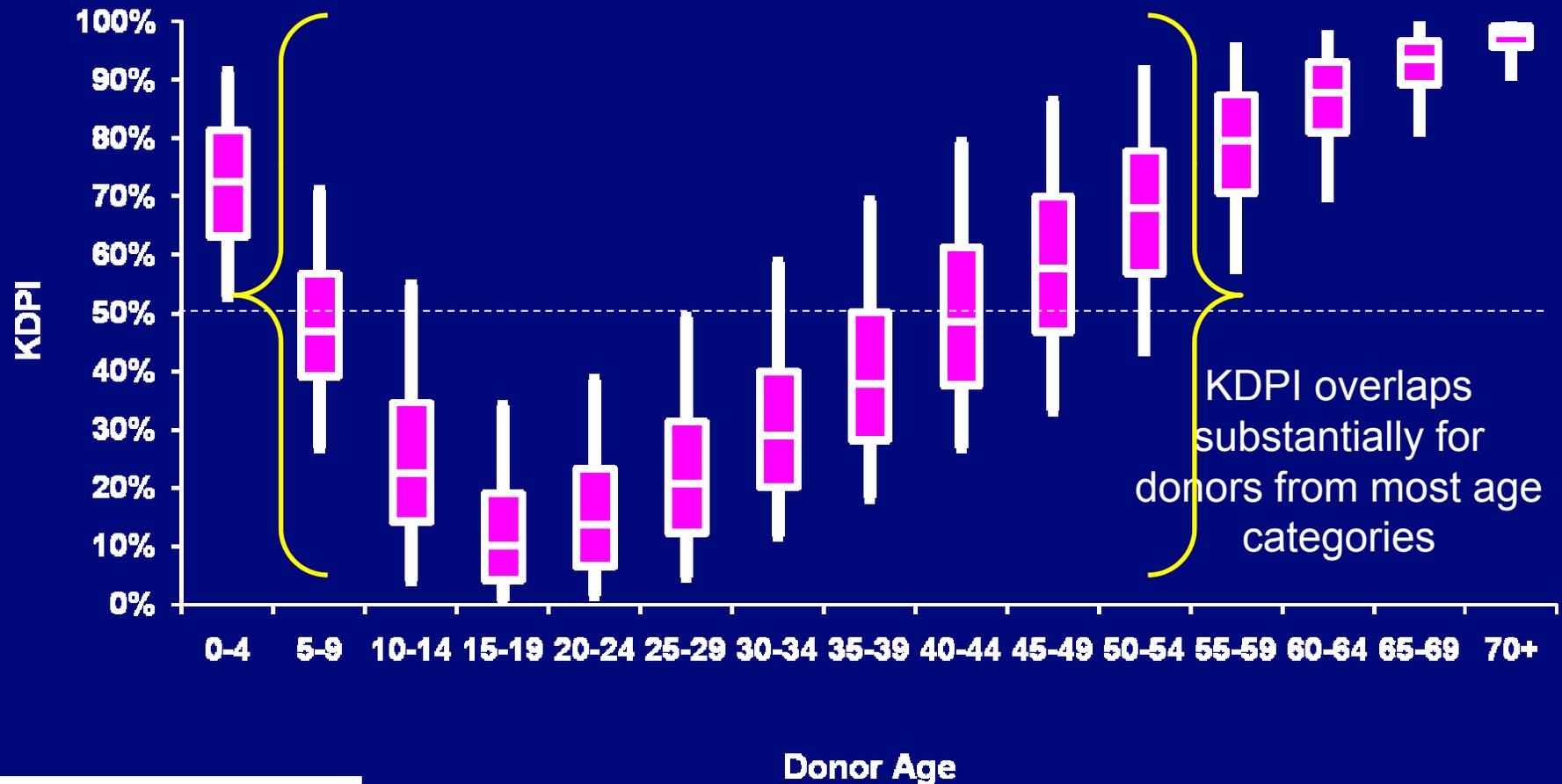


Concerns about Age Discrimination

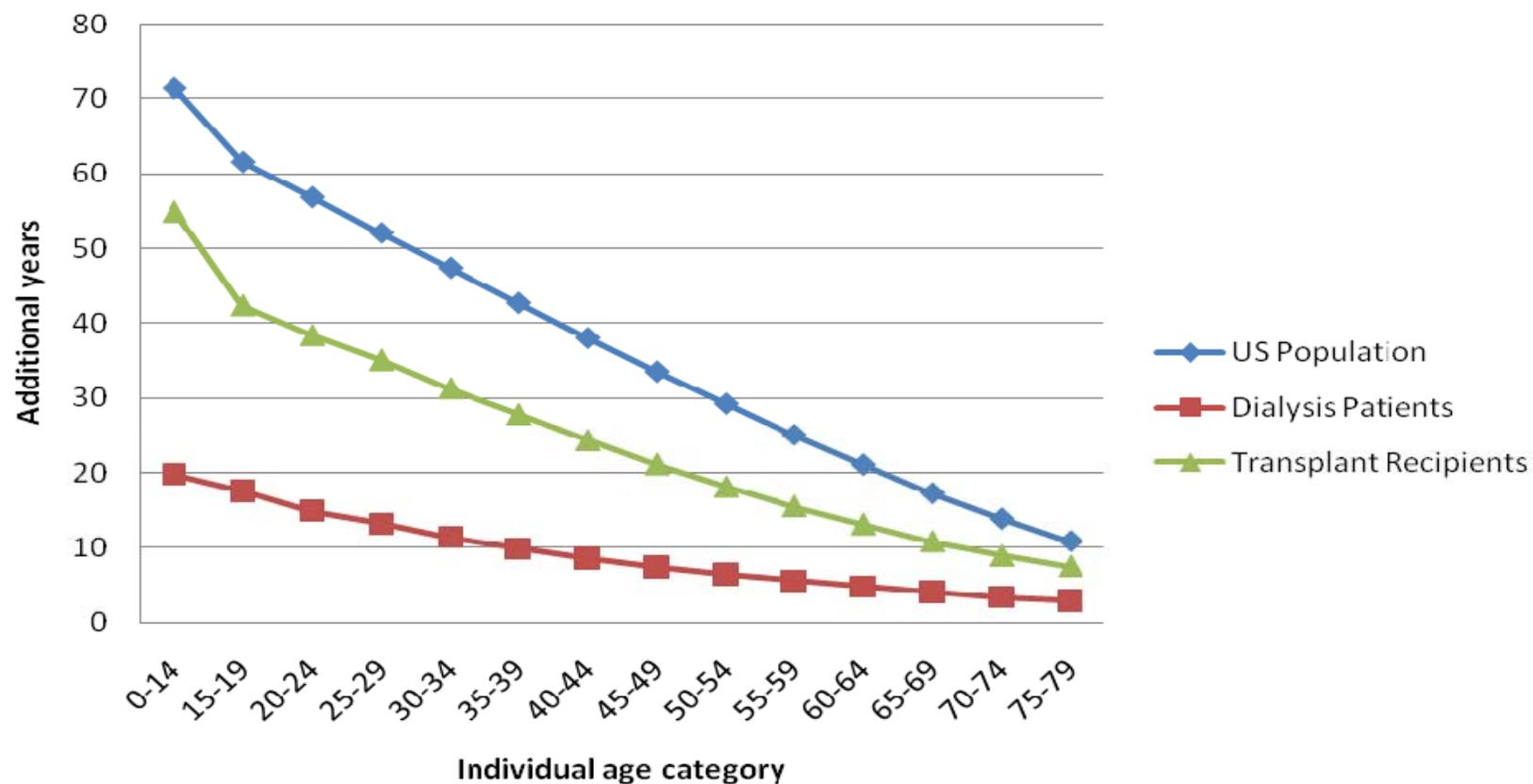
- Comments seemed to be focused not on use of age in an allocation system, but on access for candidates of all ages
- Confusion still exists over types of kidneys that older candidates would receive

Donor Age v. KDPI

2005-2007 Kidneys Removed for Transplant



Expected Remaining Lifetimes



VARIANCE REVIEW

OPTN



Variance Review: Phase 1

- Committee intends to incorporate
 - A2/A2B
 - Dialysis waiting time
- OPOs with other variances will have opportunity to propose that their variance be incorporated into national policy.

Variance Review: Phase 2

- ALUs and sharing arrangements
- OPOs wishing to maintain variances due to unique geographical constraints will be asked to submit a rationale.

Variance Review: Recommendations

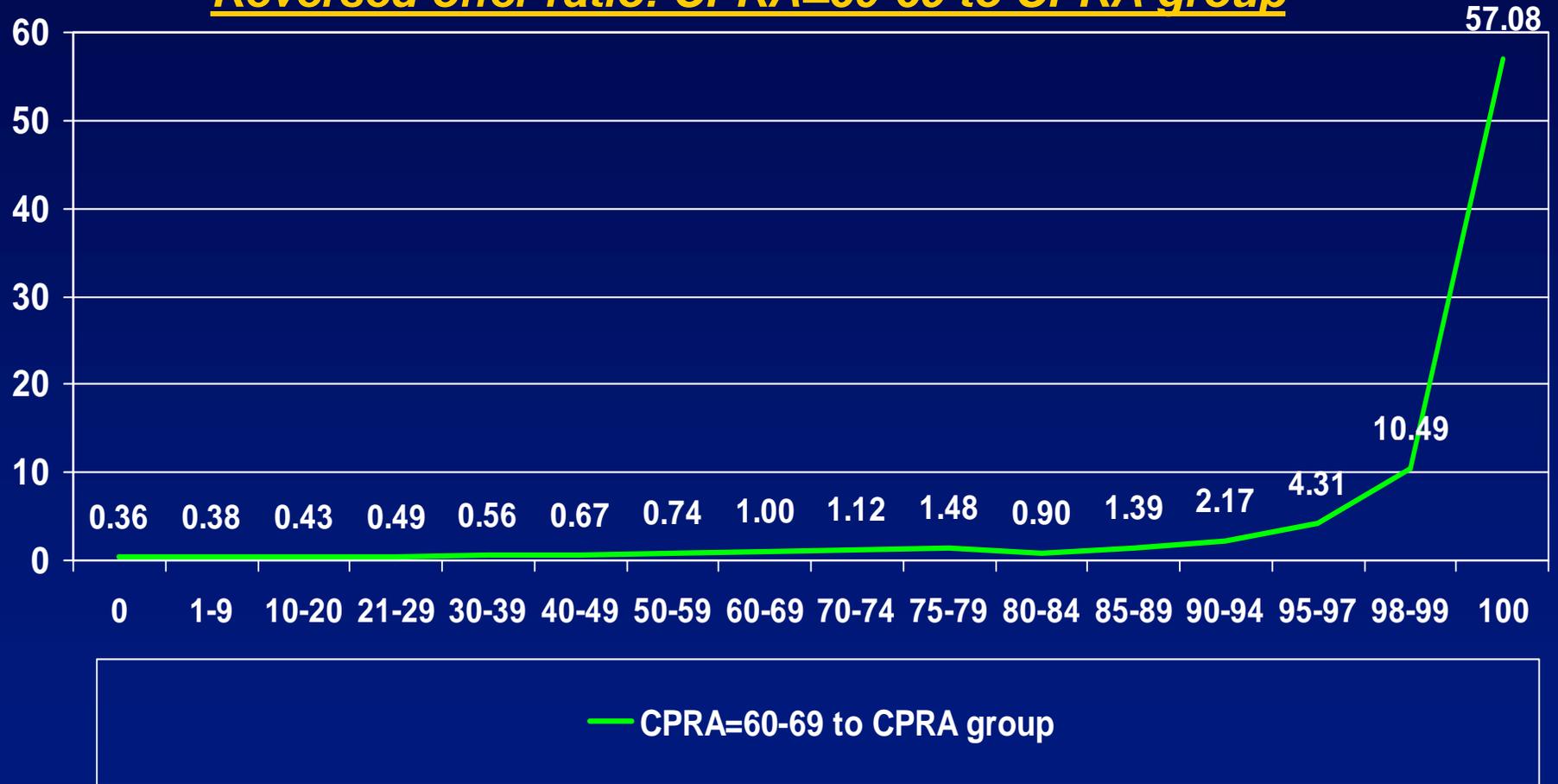
- Committee will recommend to BOD for each variance:
 - incorporate into national kidney allocation policy
 - acknowledge that the OPO has a permanent need for an alternative arrangement and codify in policy
 - discontinue the variance

Path Forward

- Committee moving forward with policy development
 - Next phase will address rank-ordering
- Increased effort to work with patient organizations
 - Plans for webinars prior to any public comment release

Offer Rate per 1,000 Active Patient Years for Adult Kidney Alone Registrations on the Waiting List by CPRA, 10/01/2009-07/31/2010

Reversed offer ratio: CPRA=60-69 to CPRA group



Kidney Paired Donation Pilot Program Update

Board of Directors Meeting
June 28-29, 2011

Major Updates since the November 2010 Board Meeting

- Implementation of donor chains in May 2011
- Hiring of a KPD Program Manager
 - Ruthanne Hanto, RN, MPH
- Development of KPD screens in UNet has begun
 - Some screens will be released by the end of the year.

List of Coordinating Centers

- Alliance for Paired Donation
- Johns Hopkins Hospital
- New England Program for Kidney Exchange (NEPKE)
- UCLA Medical Center/ California Pacific Medical Center

*Represent **82** participating centers from all 11 regions

June 2011 Match Run Results

Participants included in the match

132 candidates

142 total donors

5 NDDs (1 blood type O, 2 blood type A, 2 blood type B)

41 centers from 11 regions had at least one eligible pair.

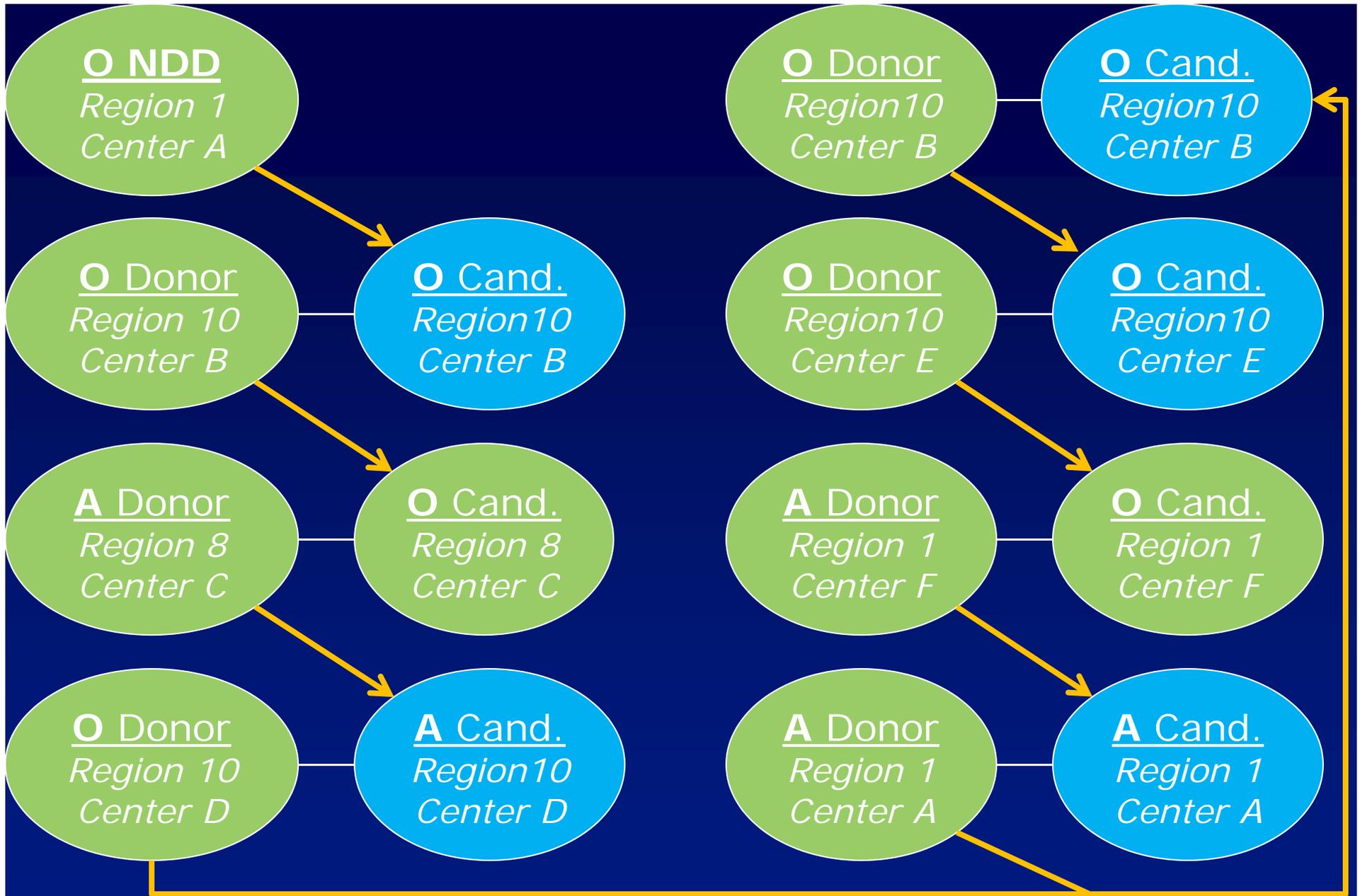
Results

18 pairs from 7 regions matched

Chain with 16 links (1 NDD, 15 pairs, 1 waiting list candidate)

1 three-way match

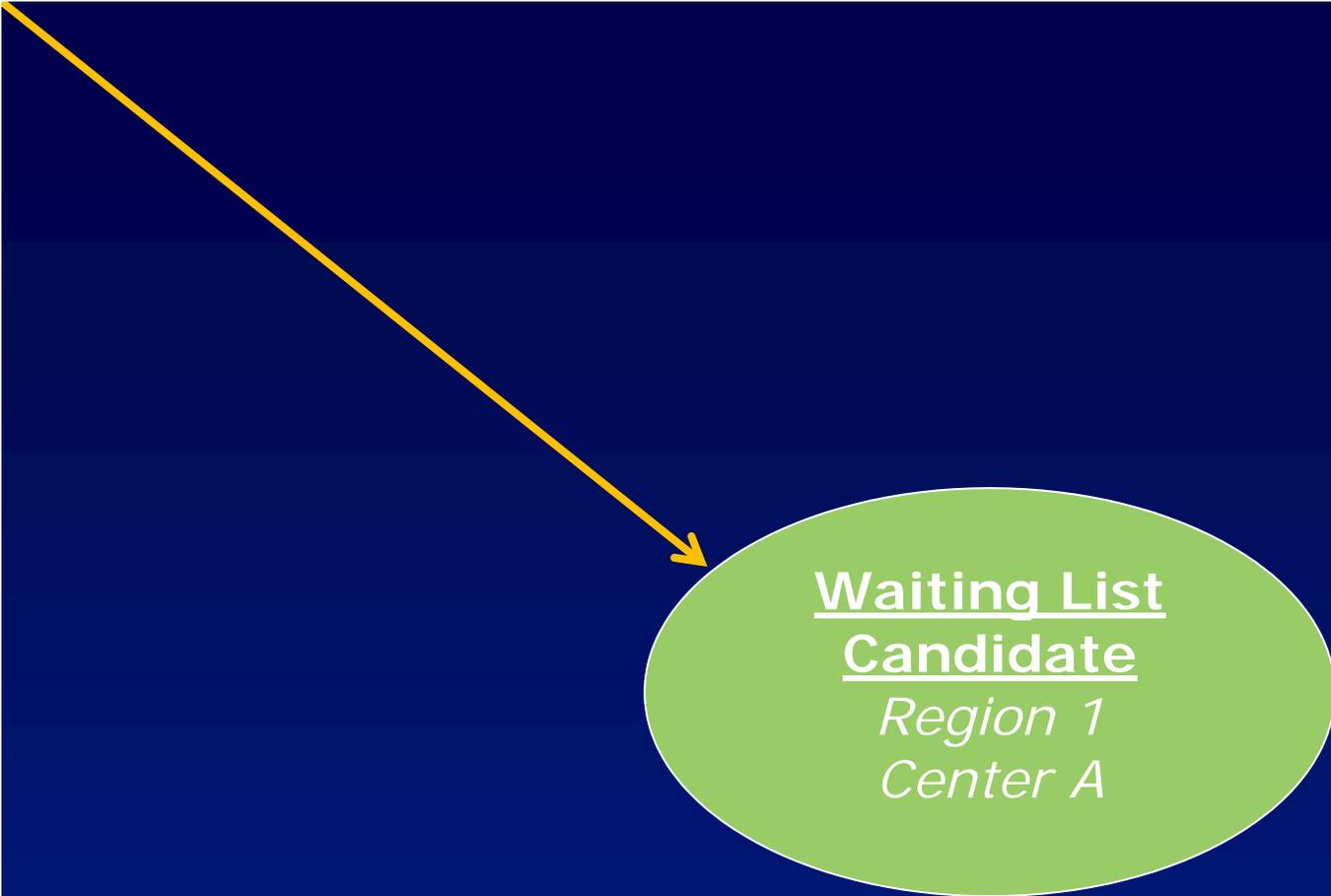
8 highly sensitized candidates matched



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*Blue circles indicate a highly sensitized (CPRA ≥ 80) candidate





Waiting List
Candidate
Region 1
Center A

Previous Match Run Results

Match Run Date	Candidates	Donors	Pairs Matched	Pairs Transplanted
October 27, 2010	43	45	7	2
December 8, 2010	60	62	12	0
January 19, 2011	66	69	11	0
February 23, 2011	76	78	0	0
March 23, 2011	88	90	3	0
April 28, 2011	106	109	6	3 scheduled for 07/19/2011
May 26, 2011	117	124	7	3 under consideration

Why did matches fall apart?

- Most matches fell apart because there was a positive crossmatch between one matched pair in a 3-way match.
 - Large number of sensitized candidates in the KPDPP.

3-Way Match Results

	Candidate 1 CPRA	Candidate 2 CPRA	Candidate 3 CPRA	Refusal Reason
October	73	95	99	Expected positive crossmatches
December	0	92	99	Positive crossmatch
December	0	94	96	Candidate and Donor cannot be contacted
December	0	58	86	Number of mismatches unacceptable
December	83	84	94	Positive Crossmatch
January	70	81	94	Positive Crossmatch
January	58	88	99	Positive Crossmatch
January	73	88	98	Positive Crossmatch
March	29	85	99	Unacceptable BMI and BP
April	0	85	86	New unacceptables identified

Candidate Characteristics

Candidates entered in May Match Run

Characteristic	Candidates
Total	117
Blood Type O	65.8% (77)
CPRA \geq 80%	66.7% (78)
Ethnicity- Black	16.2% (19)
Ethnicity- Hispanic	7.7% (9)
Age over 50	34.2% (40)
DD Waiting Time > 1 year	27.4% (32)
Previous Kidney Transplant	62.4% (73)
Willing to accept a shipped kidney from any center	92.3 (108)

Donor Characteristics

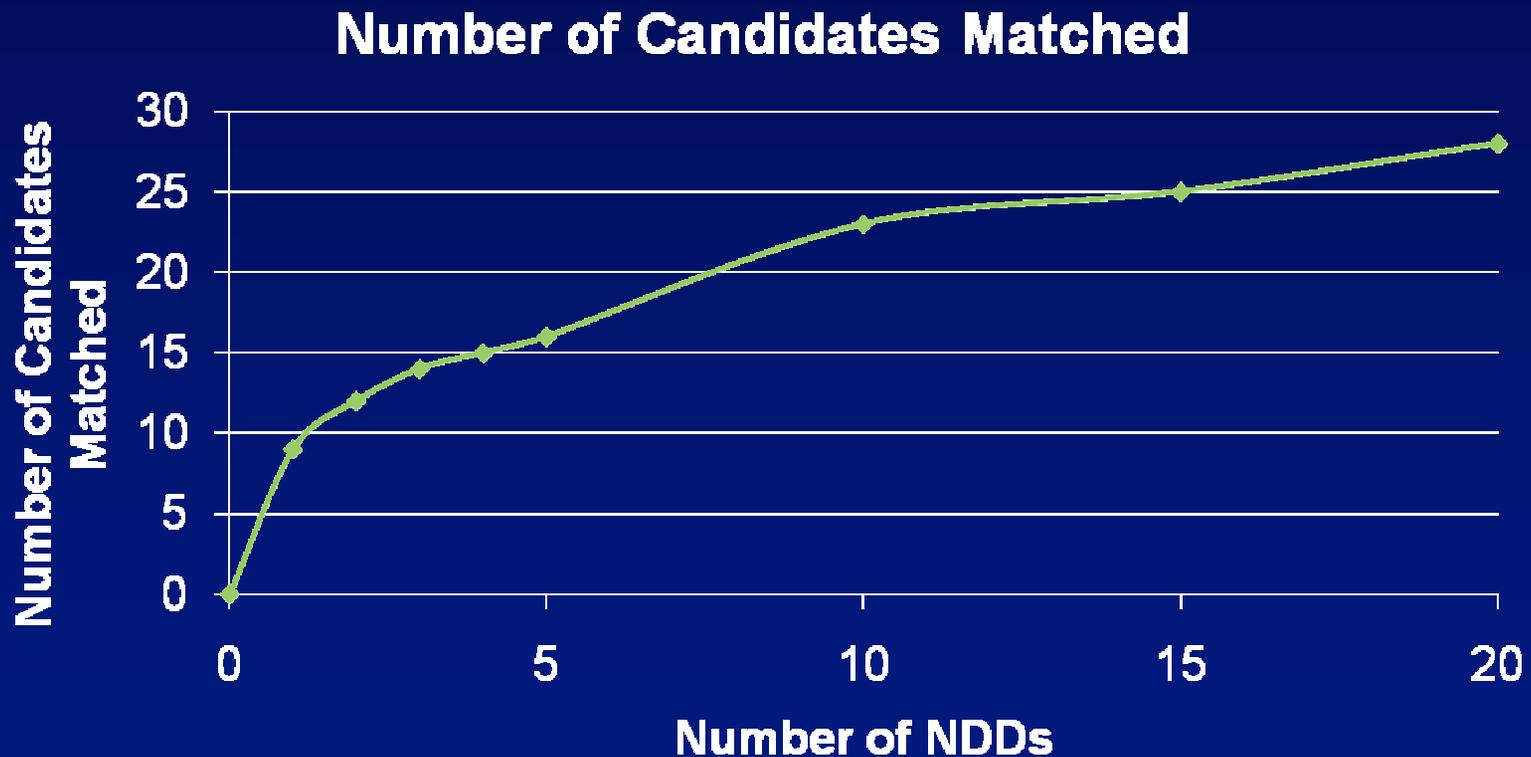
Donors entered in May Match Run

Characteristic	Donors
Total	124
Blood Type O	39.5% (40)
Age over 50	24.2% (30)
BMI over 30	21.0% (26)
Willing to ship a kidney	98.4% (122)
Willing to travel to any center	37.1% (46)
Non-directed donor	1.6% (2)

Why weren't there more matches?*

- Lack of inclusions of non-directed donors and chains
- Many pairs are hard to match
- Not enough pairs being added in between match runs to yield more matches

Potential Impact of NDDs

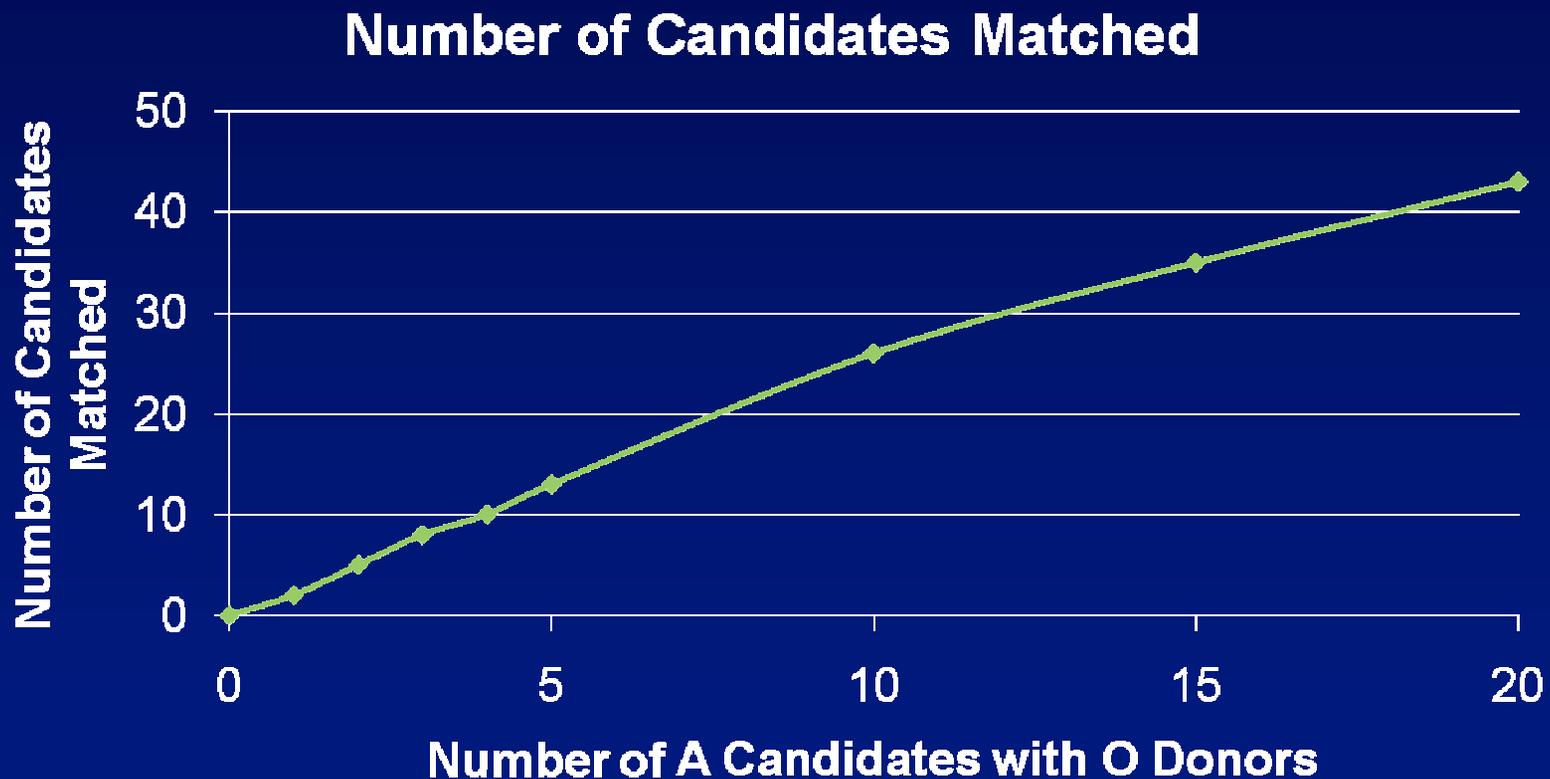


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Uses data from candidates and donors entered in February 2011 match run

UNOS DONATE LIFE

Potential Impact of A Candidates with O Donors



OPTN

Uses data from candidates and donors entered in February 2011 match run

UNOS DONATE LIFE

Ways to Improve the KPDPP

- Implement chains- May 2011
- Encourage entry of more pairs
 - Kidney Committee suspended the requirement for DP typing for 6 months
- Hire a dedicated KPD Program Manager
- Automate the KPDPP
 - Data entry screens will be released this year.

KPD Automated Solution

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KPD Automated Solution Project

- Converting the KPD Manual Solution into a KPD system integrated with UNetSM
- Functionality will be released in batches

First Release of Screens

- Candidate and Donor record data entry screens
- Print functionality
- Eliminates need for Access databases for data entry

External User Demos

- UNOS Staff held demonstrations of these screens for Pilot participants to gather feedback on the data entry screens.
- The design of the screens has been modified based on feedback from these end users.

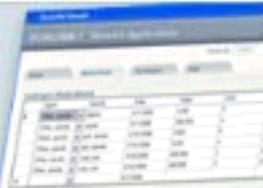


Quick Search

[Click here to search for a KPD candidate or donor](#)

KPD Resources

[Click here to access KPD Pilot Program documentation, templates and FAQs](#)



Announcements

5/17/2011 KPD Match Run Schedule

Pair eligibility report post date: 06/13/2011
Last day for pair data entry: 06/15/2011
Match run date: 06/22/2011
Match results post date: 06/24/2011
Preliminary match response deadline: 06/29/2011
Final match response deadline: 07/21/2011

ABO Pending Candidates

To verify the ABO, select the candidate's KPD ID below. The ABO must be verified by a second user before the candidate can be eligible for KPD match runs.

KPD candidate ID	Name	SSN	Center	Add date
123456	Brown, Tom	123-45-6789	ALUA-TX1	5/17/2011
765432	Smith, Scott	222-33-4444	ALUA-TX1	5/17/2011

4/1/2011 Donor Chains functionality is now available.

ABO Pending Donors

To verify the ABO, select the donor's KPD ID below. The ABO must be verified by a second user before the donor can be eligible for KPD match runs.

KPD donor ID	Name	SSN	Center	Add date
76584	Jones, Anne	998-88-8888	ALUA-TX1	5/18/2011
44356	Steele, Pete	987-65-4321	ALUA-TX1	5/15/2011

Donor name: Simpson, Marge B KPD donor ID: 654321 KPD candidate ID: 778899 Candidate name: Simpson, Homer J

[Donor Summary](#) | [Matches](#) | [Historical Donor Data](#)

[Details](#) | [Medical and Social History](#) | [Vital Signs](#) | [Labs](#) | [Serologies](#) | [Tests and Attachments](#) | [HLA](#) | [Donor Choices](#)

INSTITUTION

Home transplant center: ALUA-TX1

DEMOGRAPHIC INFORMATION

Last name: ^R

First name: ^R

Middle initial:

SSN: ^R

Date of birth: ^R  (MM/DD/YYYY)

Current age: 54 years

Gender: ^R Male Female

Center's patient ID:

Ethnicity/race: ^R

American Indian or Alaska Native

- American Indian
- Eskimo
- Aleutian
- Alaska Indian
- American Indian or Alaska Native: Other
- American Indian or Alaska Native: Not Specified/Unknown

Asian

- Asian Indian/Indian Sub-continent
- Chinese
- Filipino
- Japanese
- Korean
- Vietnamese

Candidate name: Simpson, Homer J

KPD candidate ID: 654321

Waitlist ID: 123456

Related Links

[Return to Search](#)

[Return to List](#)

[Candidate Summary](#) | [Matches](#) | [Historical Candidate Data](#)

[Details](#) | [Candidate Choices](#) | [HLA and Unacceptables](#) | [Titers](#) | [Donor Information](#)

INSTITUTION

Home transplant center: ALUA-TX1

KPD CANDIDATE CHOICES

Candidate willing to travel? ^R YES NO

If yes, to which center(s) is the candidate willing to travel? ^R

Available options:

All centers
Any center within 50 miles
Any center within 100 miles
Any center within 250 miles
Any center within 500 miles
AZMC-Mayo Clinic Hospital
CAGH-Scripps Green Hospital
CAPM-California Pacific Medical Center

Add

Remove

Your selections:

ALUA-University of Alabama Hospital
CTHH-Hartford Hospital
MABU-Boston Medical Center

Would candidate be willing to travel further if funding were provided? ^R YES NO

Candidate will accept a shipped kidney? ^R YES NO

Ongoing Work

- Working with the Living Donor Committee to address issues around transportation, psychosocial outcomes, and informed consent
- Continuing discussion on the potential use of bridge donors
- Addressing questions that arise from what we are learning through the Pilot
- Converting the Operational Guidelines to interim policy

KPD Financial Subcommittee

- In the short term, the subcommittee is developing KPD financial best practices and templates.
- The subcommittee is also discussing recommendations for the overall structure of financing for KPD.

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Backup Slides

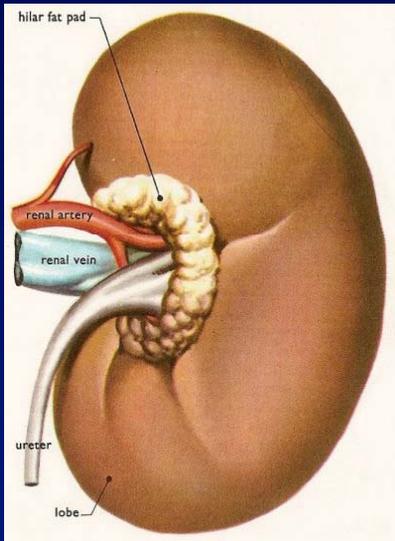
Current Allocation Sequence

- Zero-antigen mismatches
- Local prior living organ donor
- Highly sensitized candidates
- Payback debts
- Local pediatric (donor age <35)
- Local all candidates
- Regional pediatric (donor age <35)
- Regional all candidates
- National pediatric (donor age <35)
- National

Proposed Allocation Sequence

- Group A zero-antigen mismatches (peds then adults)
- Local prior living organ donor
- Local pediatric (for certain range of KPDI kidneys)
- Local Group A
- Local Group B (all remaining Group A Candidates)
- Group B zero antigen mismatches
- Regional pediatric (KPDPI range)
- Regional Group A
- Regional Group B (All remaining Regional Candidates)
- National pediatric (KPDPI range)
- National Group A
- National Group B (All remaining Candidates)

Example 1: KDPI >20%

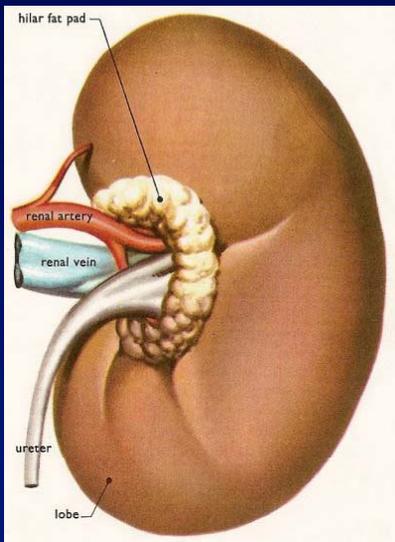


KDPI >20%

Candidates within 15 years of the donor's age are GROUP A

If a kidney is not accepted by a candidate in Group A, it is then allocated to all other candidates (Group B).

Example 2: KDPI \leq 20%



KDPI \leq 20%



Candidates with
post-tx survival in
Longest 20% are
GROUP A

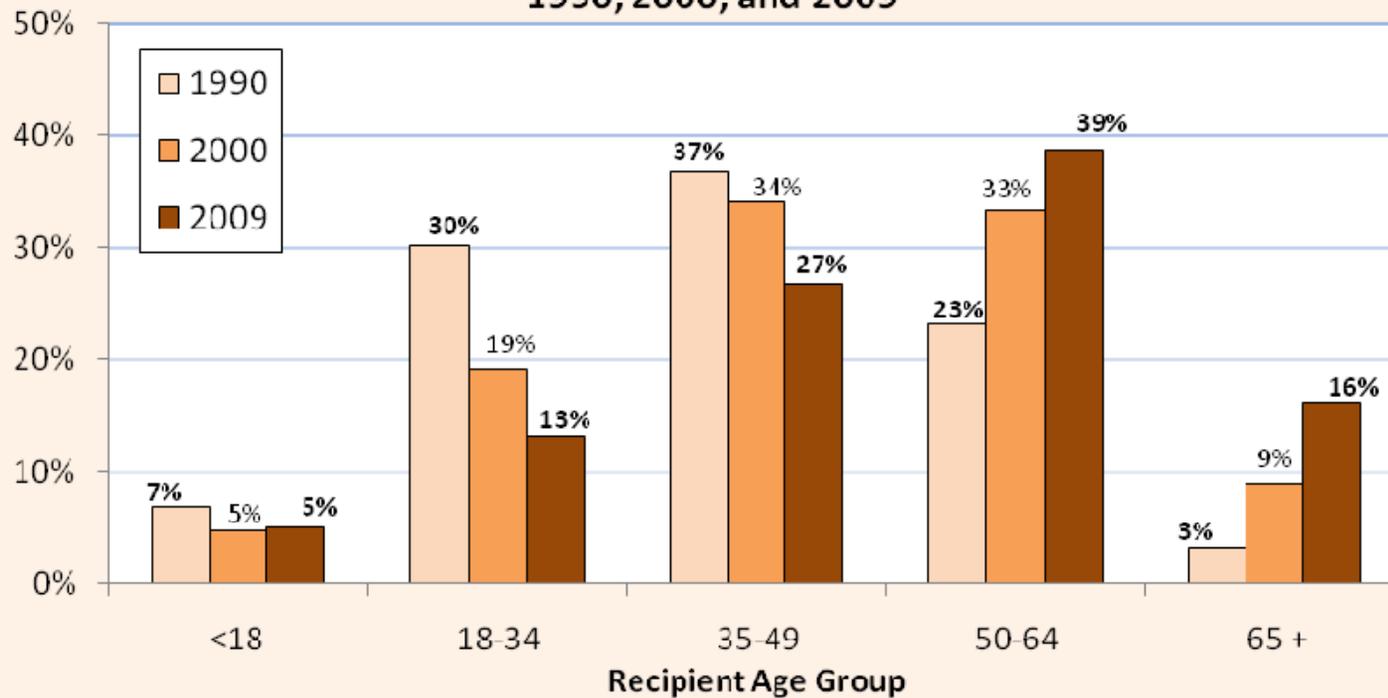


If a kidney is not accepted by a candidate in Group A, it is then allocated to all other candidates (Group B).

Who gets priority for which kidneys?

Kidney	Group A	Group B
KDPI \leq 20%	Candidates with longest 20% estimated post-transplant survival	Candidates with 21%-100% estimated post-transplant survival
KDPI $>$ 20%	Candidates within +/- 15 years of donor's age	Candidates more than 15 years older/younger than the donor

Recipient Age Distribution for U.S. Kidney Transplants 1990, 2000, and 2009

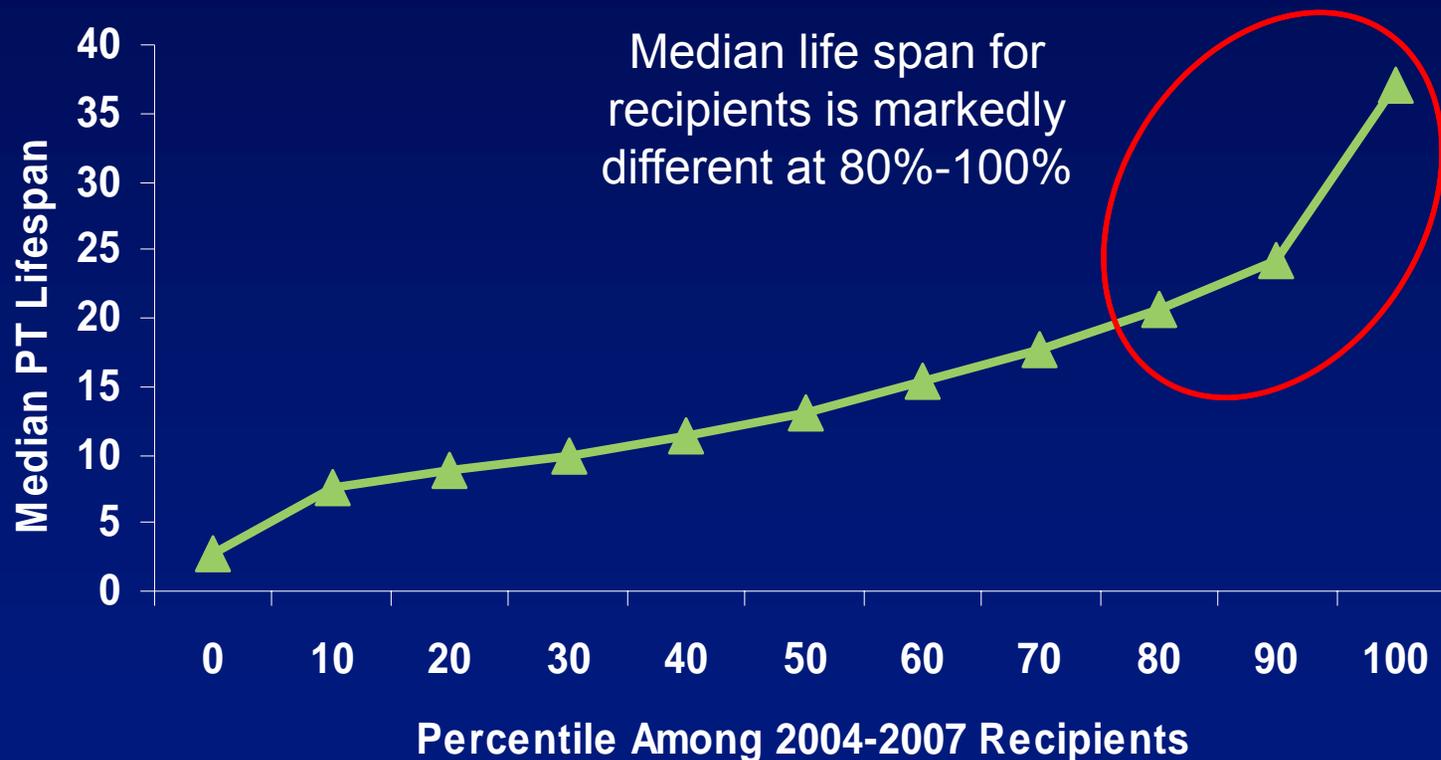


Based on OPTN data as of November 6, 2009

How were the 20% thresholds for KDPI and post-tx survival chosen?

- Median life span for recipients is markedly different at 80%-100%
- Relative Risk for graft failure is not markedly different for top 20% of kidneys

Distribution of Projected Median Recipient Lifespans: 2004-2007

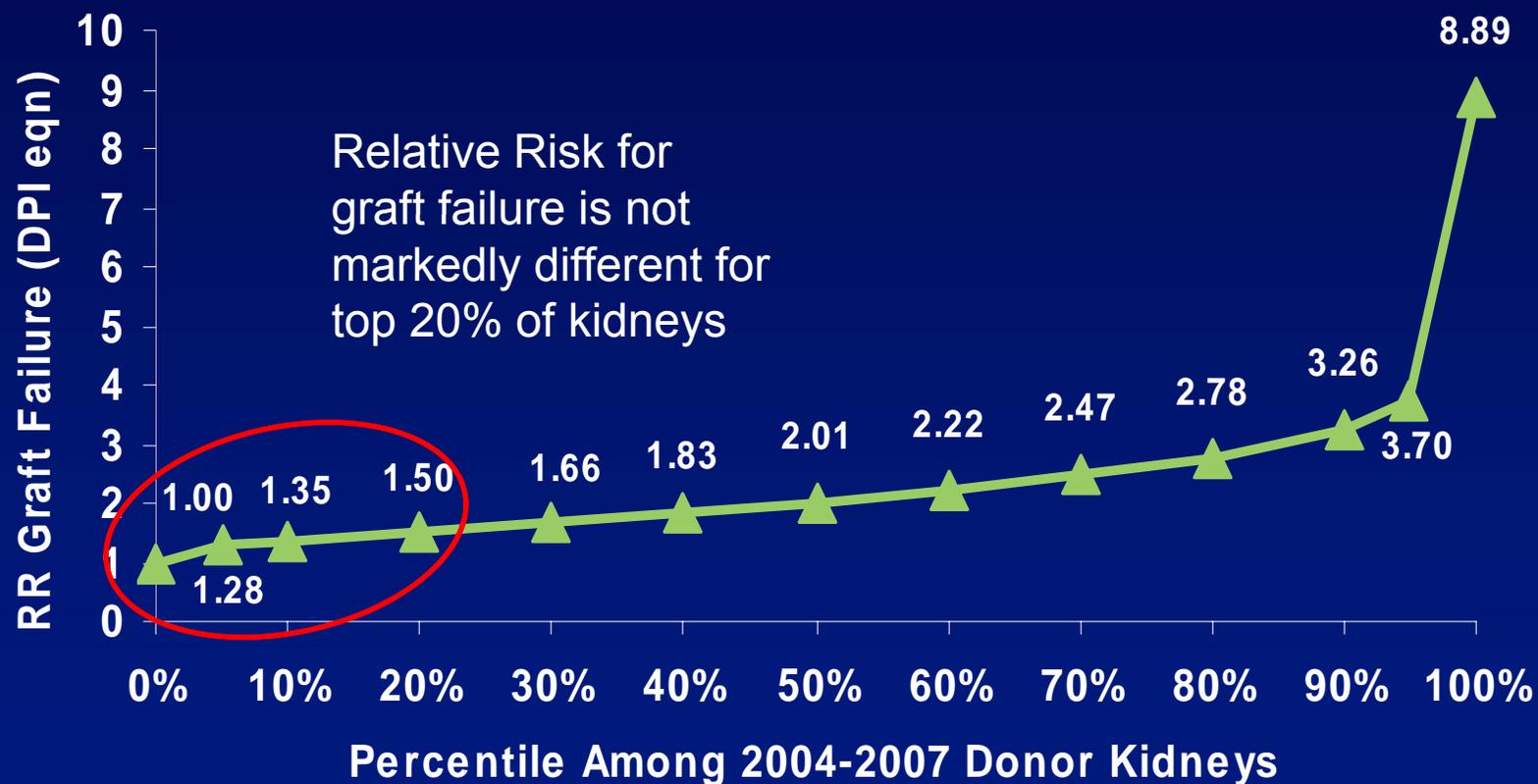


OPTN

Uses patient factors only



Distribution of Relative Risks for Donor Kidneys: 2004-2007



Example: Who gets priority?

Kidney with a KDPI of 30%

		Donor A Age: 34	Donor B Age: 15	Donor C Age: 55
Group A	Age	19 to 49	0 to 30	40 to 70
Group B	Age	<19 or >49	>30	<40 or >70
Candidates	Age			
Mary	30	A	A	B
David	60	B	B	A
Manuel	39	A	B	B
Sophia	21	A	A	B

Example: Who gets priority?

Kidney with a KDPI of 10%

		Donor X KDPI: 10%
Candidates	Post-transplant survival	
Mary	19%	A
David	35%	B
Manuel	27%	B
Sophia	12%	A

**Policy Language Correction to
3.5.5.3
(Kidney Payback Debt Limit)**

Board of Directors Meeting
June 27-28, 2011

Problem Description

- Policy 3.5.5.3 (Kidney Payback Debt Limit) was not changed to reflect the removal of regional and national allocation categories for adult, unsensitized, zero-mismatched candidates in 2008.
- The language continues to state the candidates in these categories will be reprioritized if an OPO exceeds the kidney payback debt limit.

Proposed Solution

- Remove the out-of-date reference to the reprioritization

****RESOLVED, that effective pending notice to the membership, the language in Policy 3.5.5.3 (Kidney Payback Debt Limit) be amended as set forth below.**

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered longterm debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. ~~Additionally, priority for offers of zero-antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3.~~