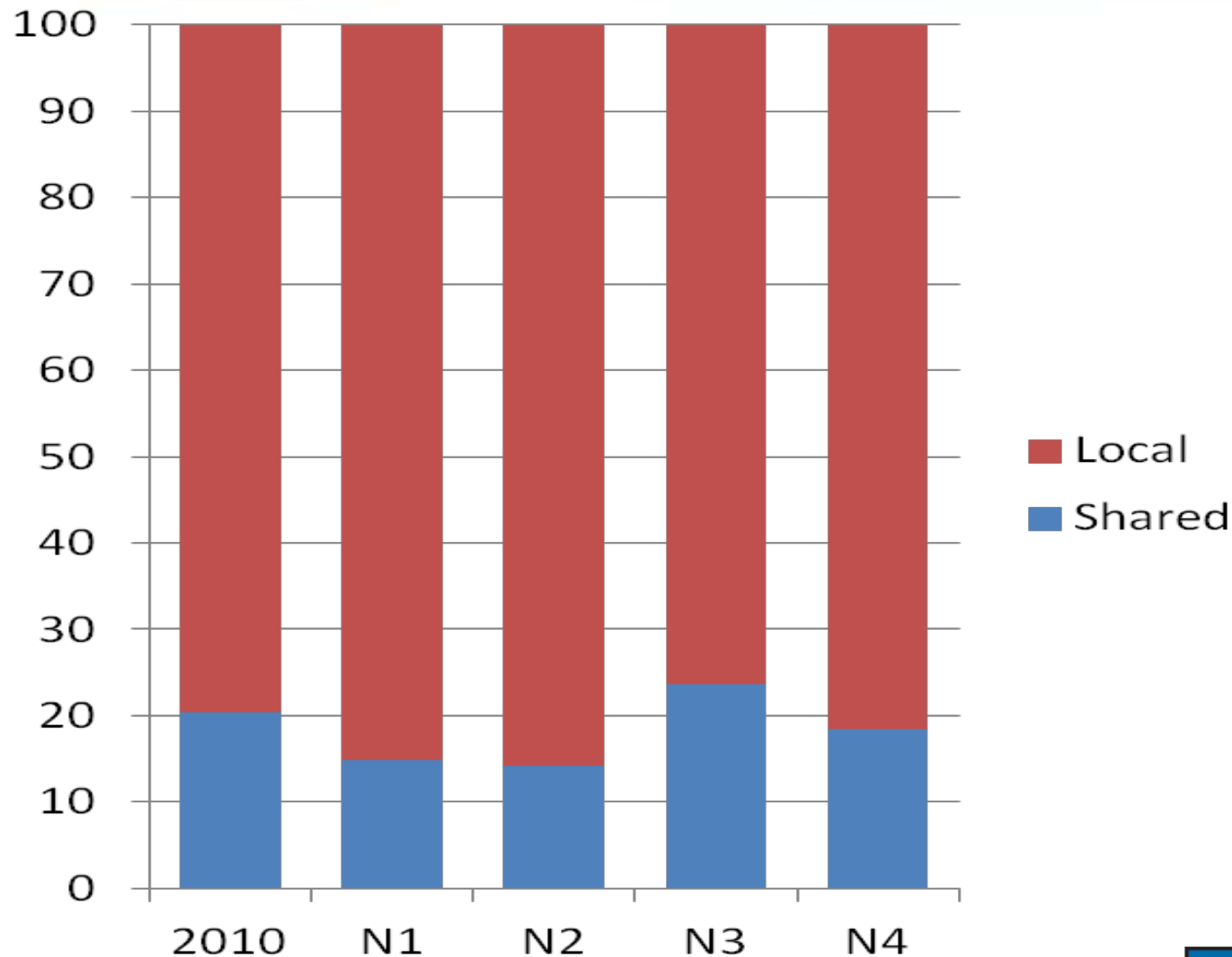


Sequence A KDPI ≤20%	Sequence B KDPI >20% but <35%	Sequence C KDPI ≥35% but ≤85%	Sequence D KDPI >85%
Highly Sensitized O-ABDRmm (top 20% EPTS) Prior living organ donor Local pediatrics Local top 20% EPTS O-ABDRmm (all) Local (all) Regional pediatrics Regional (top 20%) Regional (all) National pediatrics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

Proposed
Regional
Sharing

KPSAM results by degree of sharing



Comments Received

- May lead to inefficiency in placement, increased CIT and discards
 - Candidates in regions with extreme variations in waiting times may be shut out of receiving high KDPI kidneys
-
- No changes made to proposal

ELIMINATE VARIANCES

OPTN

Eliminate Variances

- Numerous variances to existing kidney allocation system
- Many instituted prior to OPTN Final Rule
- Designed to address limitations of current system
- Necessary to eliminate variances
 - To establish a baseline from which to evaluate new variances
 - To bring new variances into alignment with OPTN Final Rule requirements
- Two requests for transition circulated for public comment
 - Region 1 (Ex Com approved 2/2013)
 - Southwest Transplant Alliance (TXSB) request not forwarded

Eliminate Variances

- Requests to retain ALUs
 - TXSB, PATF, PADV, TXGC, OKOP
- Request to retain intended candidate variance (VATB)
- Concerns cited regarding
 - patient access
 - effects on smaller transplant programs in non-metropolitan areas
 - Increased waiting time in subunits

Eliminate Variances

- Proposal makes DSA first level of allocation
 - Need a geographic metric to better assess disparity before variances can effectively address
 - Variances add significant cost/time to national policy revisions
-
- No changes made to proposal—recommendation to eliminate variances

OVERVIEW OF OUTREACH AND FEEDBACK

OPTN

Public Comment Overview

- Individuals
 - 225 responses (54% in favor, 43% opposed, 4% no opinion)
- Regions
 - 9 in favor, 1 in favor as amended, 1 opposed
- Committees
 - 6 in favor, 2 in favor as amended, 1 opposed
- Comments from:
 - AST, ASTS, NATCO, AAKP, PKD Foundation

Media outlets



DENVERPOST The New York Times



Detroit Free Press

OPTN

Balancing Equity and Utility

TWO TAKES

Is the New Kidney Allocation Proposal Fair?

An organization that manages organ donation in the United States has proposed changes to how donated kidneys are allocated. Proponents say the proposal to match donors to patients based on certain attributes will make the system more efficient. Opponents say it's unfair. Edited by Kira Zalan



John Friedewald
OPTN/UNOS Kidney
Transplantation
Committee Chair

COURTESY OF
NORTHWESTERN MEMORIAL HOSPITAL

YES

For most of human history, kidney failure was a death sentence for those who encountered it. Today dialysis is effective in supporting people with kidney failure, but it too comes with limitations and potential complications. Kidney transplantation offers many the most effective long-term improvement in length and quality of life.

The way kidneys from deceased donors are matched to patients in the United States has not changed fundamentally in the last 25 years. The existing policy has facilitated more than 200,000 transplants over the years and has many well-designed features. Yet there are specific opportunities for improvement.

The Organ Procurement and Transplantation Network (OPTN), managed under federal contract by the non-profit United Network for Organ Sharing (UNOS), matches deceased donor kidneys with transplant candidates nationwide. The OPTN is seeking public comment on a proposal to make needed improvements to kidney allocation policy.

The proposal is the result of eight years of study and discussion among transplant professionals and patient advocates. Under the proposal, the 20 percent of kidneys likely to have the longest function would be offered first (but not exclusively) to the 20 percent of candidates [READ MORE](#)



Lainie Ross
Associate Director of
the MacLean Center
for Clinical Medical
Ethics, University of
Chicago

COURTESY OF
UNIVERSITY OF CHICAGO MEDICINE

NO

Three facts about end stage renal disease (ESRD) shape the kidney allocation debate. First, individuals with ESRD have two therapeutic options: dialysis or kidney transplantation. Second, virtually all individuals with ESRD, regardless of age, have a better quality of life and lower mortality and morbidity with kidney transplantation. Third, demand for kidney transplantation far exceeds supply.

The current allocation system is based mainly on time on the kidney waitlist. Critics object to the inefficiencies of the current system because a candidate who has a short life expectancy may be allocated a healthy deceased donor kidney that can be expected to outlive the recipient by years, maybe decades. The Kidney Committee has proposed a 20/80 allocation method. The "20" stands for the top 20 percent of kidneys (based on 10 donor traits that estimate expected graft survival) that are to be allocated to the top 20 percent of candidates (defined by four recipient traits—age, diabetes, dialysis time, and prior transplant status—that help determine post-transplant survival). The remaining 80 percent of kidneys will be allocated mainly on dialysis time, a variant of waiting time.

While the 20 percent rule will improve efficiency, it is unjust for three distinct reasons. First, it is [READ MORE](#)

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14 U.S. NEWS WEEKLY | NOVEMBER 2, 2012 | www.usnews.com/subscribe

OPTN

US News and World Report. 2 November 2012.

UNOS **DONATE LIFE**
UNITED NETWORK FOR ORGAN SHARING

Chicago Tribune

- “We understand why some people are nervous about these changes. In a fairer world, there would be enough kidneys to go around. But there aren't. This is about maximizing the years that a kidney will work inside someone's body, not rendering a judgment about how any recipient uses that time. Officials have spent the last nine years seeking to make the system more efficient. Let's not wait another nine. The board that oversees transplants in the U.S. can — and should — make these changes next summer. Thousands of people are on kidney transplant waiting lists. Every day, every week, that officials delay, people die waiting.”

The New York Times

“A previous proposal to increase survival rates was abandoned after federal officials warned that it violated age discrimination laws because most of the kidneys were to be distributed based on age, to patients no more than 15 years older or younger than the donor. The new proposal avoids that problem by making age only one of many factors considered. If this proposal, too, doesn’t pass muster, Congress ought to pass a law exempting this sensible approach from age discrimination laws.”

IMPLEMENTATION PLAN

OPTN

Scope of Project

- Enterprise level project (~10,500 hours)
- Significant resources required to program system and to educate/assist transplant community
- Expected to *reduce* resources required to program future policy modifications

Two Phase Approach

- Phase I (estimated time period 6 months)
 - Educate and assist transplant programs with data updates
 - New reports made available
 - Training and tools for data uploads made available
 - EPTS calculator made available
- Phase II
 - Begin allocating according to new rules
 - Variances removed
 - Payback system removed

Communication/Education Vehicles

- UNOS Update
- Transplant Pro
- Distribution Lists
- Policy and System notices
- Updated kidney allocation brochure
- Webinars
- Educational sessions at professional meetings

IN RECOGNITION

OPTN

Countless individuals gave time and talent to this proposal

- Over 250 Committee members, HRSA representatives, SRTR and UNOS staff
- All who participated in forums, regional meetings, and public comment
- Prior Committee Chairs



Mark Stegall, MD



Peter Stock, MD, PhD



Ken Andreoni, MD

Resolution 14

RESOLVED, that Policy 3.5 (Allocation of Deceased Kidneys) is struck in its entirety and replaced with Policy 3.5 (Allocation of Kidneys), and modifications to Policies 3.1.13 (Definition of Directed Donation), 3.2.4.2 (Waiting Time Reinstatement for Kidney Recipients), 3.3.5 (Transplant Recipient Backups for Organ Offers), 3.4.2 (Time Limit for Acceptance), 3.8.1.4 (Criteria to Accrue Kidney-Pancreas Waiting Time), 3.8.3.2 (Blood Type O Kidney-Pancreas Allocation), 3.8.3.5 (Organ Offer Limits), 3.8.4.1 (CPRA), 3.8.4.2 (Waiting Time), 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates), 6.4.1.1 (Requirements for Importing Deceased Donor Organs through a Formal Agreement), 9.6.8, 12.5.6 (Placement of Non-directed Living Donor Organs), and 12.9.4 (Exception for Prior Living Donor Organs), as set forth in Resolution 14, are hereby approved, effective pending programming and notice to OPTN membership.

** Page 24 of Board Book*

Resolution 14

FURTHER RESOLVED, the variances, as set forth in Resolution 14, are terminated, effective pending programming and notice to OPTN membership.

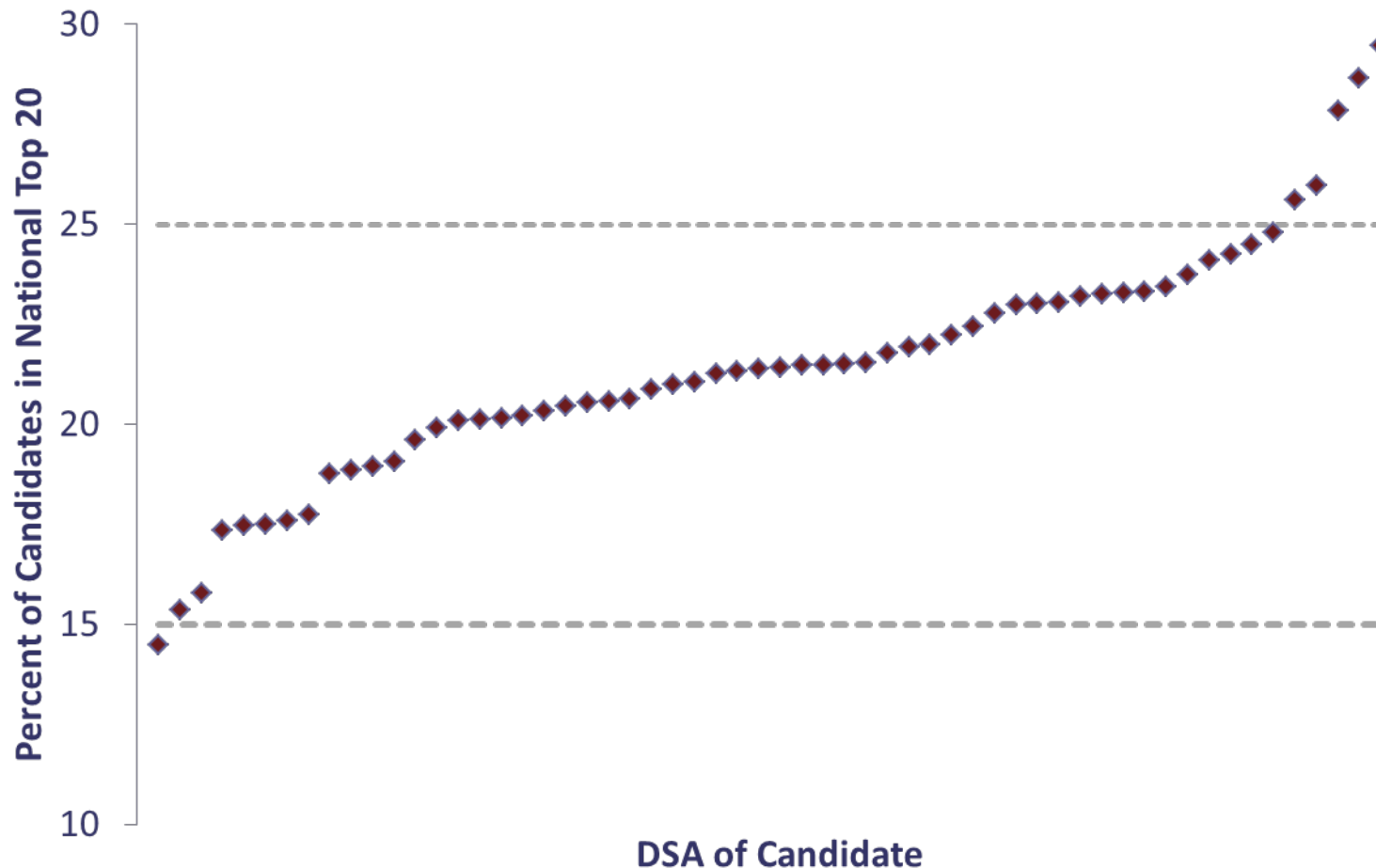
**Page 66 of Board book*

Committee Leadership and Support

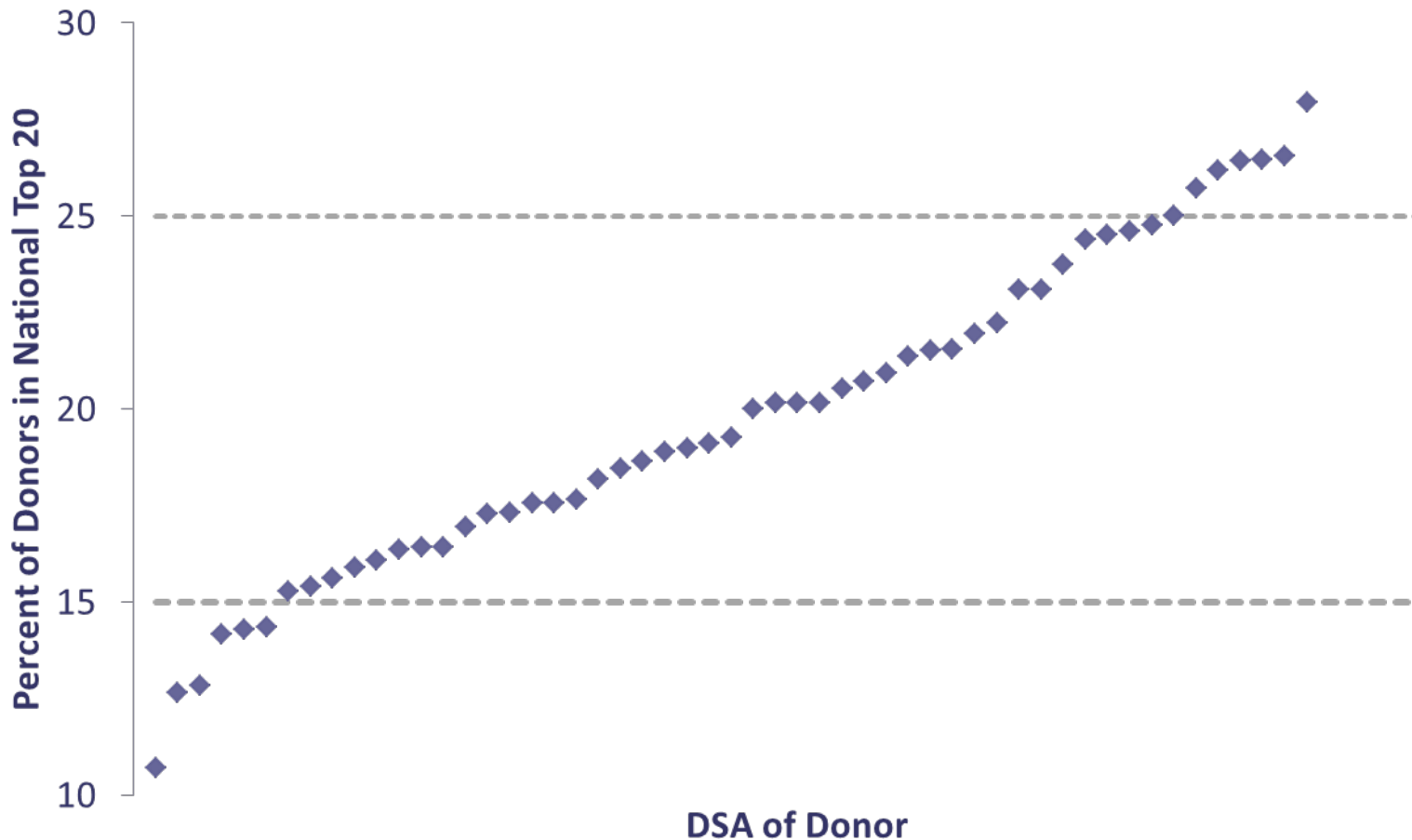
- **John J. Friedewald, MD**
Committee Chair
- **Richard N. Formica, Jr, MD**
Committee Vice Chair
- **Ciara J. Samana, MSPH**
UNOS Committee Liaison
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804-782-4073
- **Wida Cherikh, PhD and Darren Stewart, MS**
UNOS Biostatisticians

BACKUP SLIDES

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



Percent of kidney donors in national top 20%, by DSA of donor



DEEPDIVE INTO POSITIVE CROSSMATCH REFUSAL RATES BY CPRA

*DERIVED FROM CPRA ANALYSIS PRESENTED AT SEP 19, 2011
KIDNEY COMMITTEE MEETING ("TABLE 18")*

Darren Stewart, Anna Kucheryavaya, Wida Cherikh
UNOS Research Department

Prepared for
Kidney Transplantation Committee
February 6, 2012
(Super Bowl Monday)

DATA REQUESTS FROM MARCH 21, 2011

5. Offers refused for “positive crossmatch” by CPRA

- 0-mismatches and non-0-mismatches
- Purpose: are positive crossmatch results occurring too often for very highly sensitized (95%+) candidates to give them national priority?

DATA/METHODS

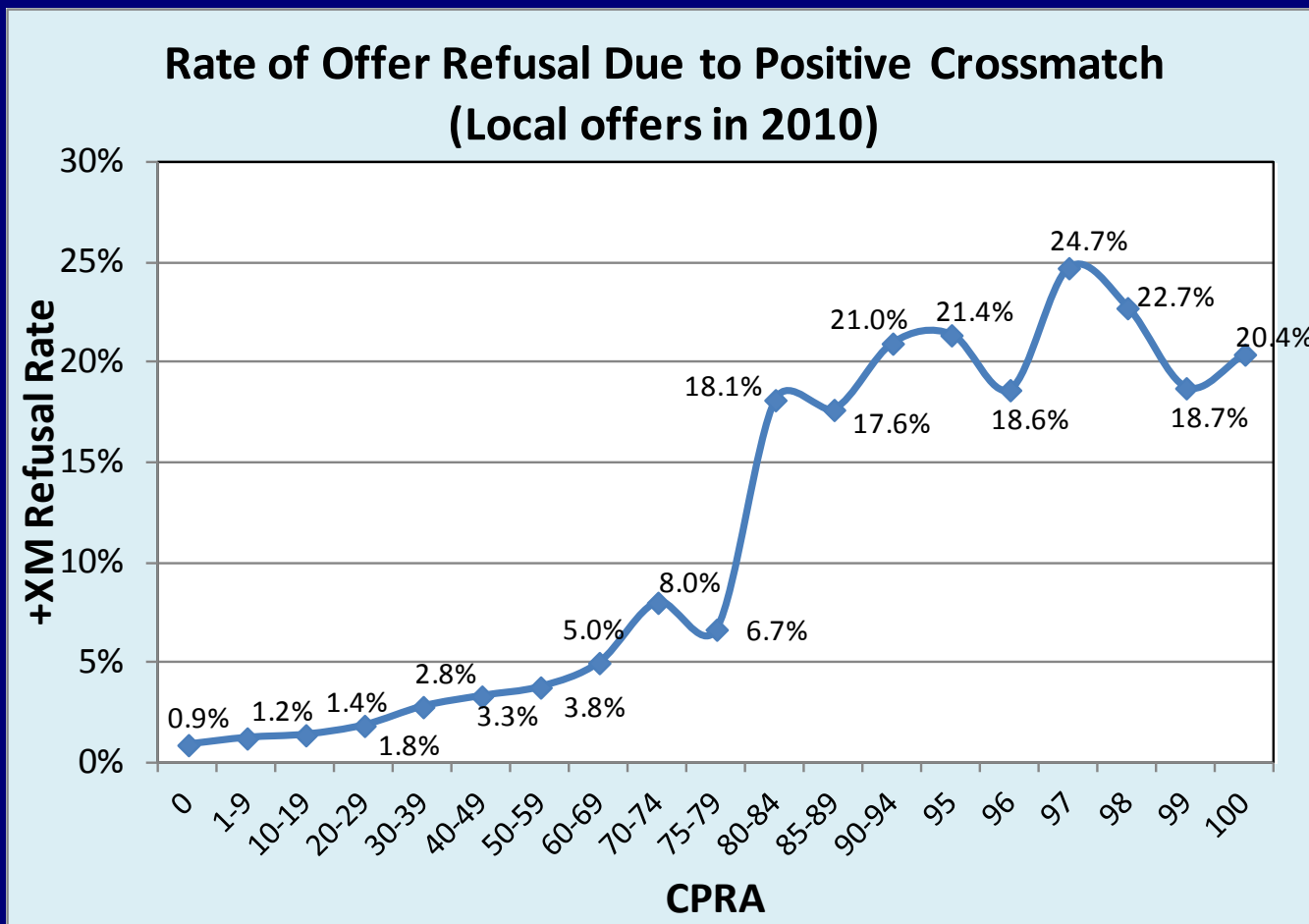
- All analyses are for adult, kidney-alone registrations.
 - Considered adult if listed when age 18 or greater.
 - Based on year 2010 data.
 - Refusals due to “positive crossmatch” that occurred after a “final acceptance” are identifiable if on a subsequent match to reallocate the kidneys, the accepting candidate is refused for this reason.
 - Results are based on the OPTN database as of August 5, 2011.
- See formal reports (.pdfs) for more detailed information about data and methodology.

REQUEST #5: POSITIVE CROSSMATCH REFUSALS BY CPRA RESULTS

- Overall, 0.7% of offers were refused due to +XM.
 - N=5,106 positive crossmatch refusals.
- However, for very highly sensitized candidates (CPRA \geq 95%), over 10% of offers were refused due to +XM.
- Though zero-mismatch offers had a higher rate of refusal due to +XM (3.6%), they only accounted for 73 (1.6%) of the 5,106 +XM refusals.
- The rate of refusal due to positive crossmatch was higher for local offers (1.5%) than non-local offers (0.2%).

POSITIVE CROSSMATCH REFUSALS BY CPRA (LOCAL OFFERS)

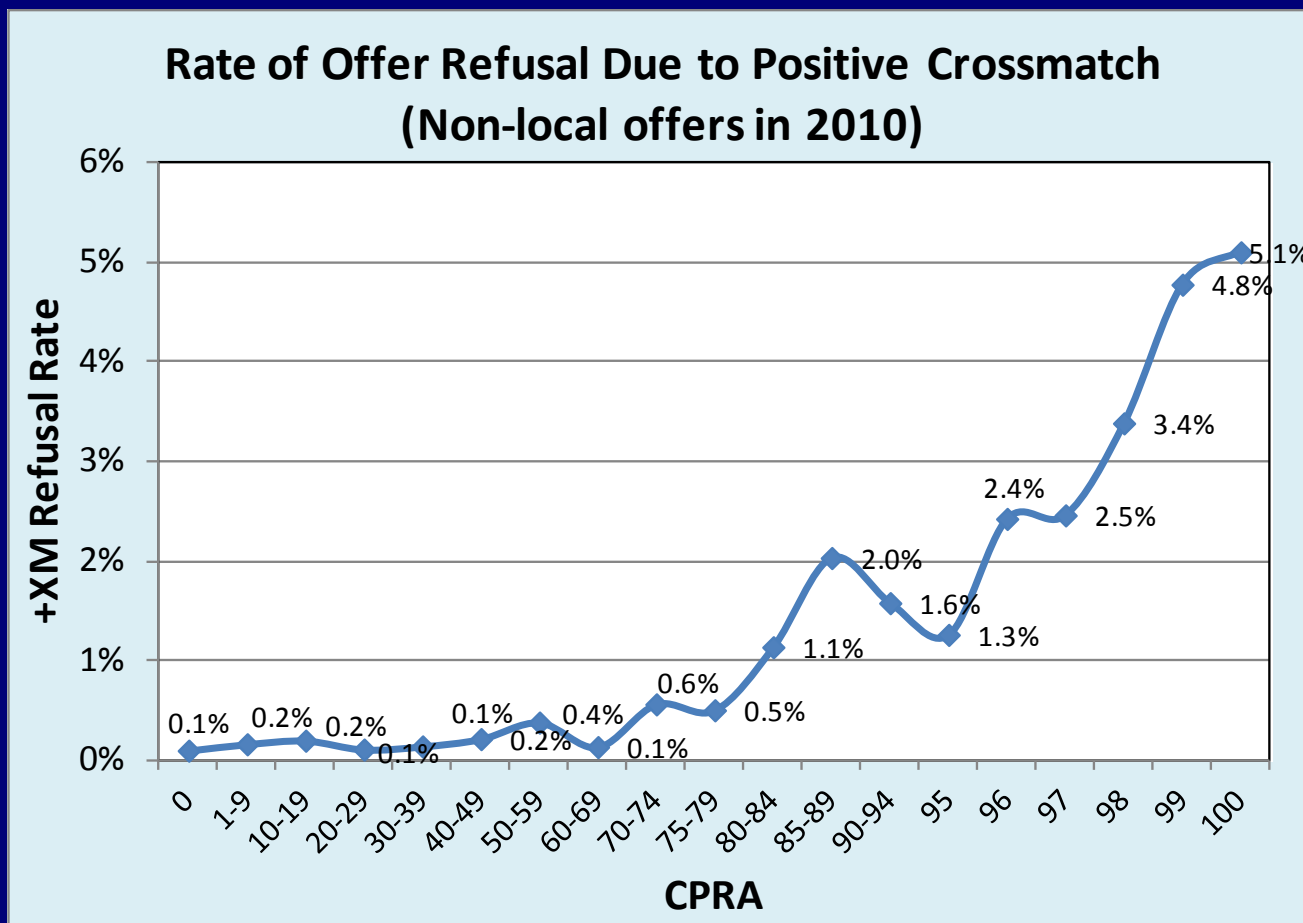
CPRA	0	1-69	70-94	95	96	97	98	99	100	Total
+XM refusals	2,071	992	1,107	53	57	68	65	44	20	4,477
Offers	234,814	45,437	7,367	248	306	275	286	235	98	288,973
Rate	0.9%	2.2%	15.0%	21.4%	18.6%	24.7%	22.7%	18.7%	20.4%	1.5%



OPTN • None of these refusals came after final acceptance.

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	9814	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%



➤ **59** +XM refusals for CPRA of 95+

(About half were OMM)

➤ **38** +XM refusals for CPRA of 98+

OPTN

• For CPRA=98+, 22/38 (58%) of refusals came after final acceptance.

POSITIVE CROSSMATCH REFUSALS – SUMMARY

- ✓ Rate of offer refusal due to + XM in 2010...
 - ✓ Increased as CPRA increased
 - ✓ Was much higher for local offers (1.5%) than non-local offers (0.2%).
- ✓ However, none of the local refusals came after a final acceptance.
- ✓ Of 894 non-local offers to CPRA=98+, 38 were refused due to positive crossmatch. Many were after final acceptance.

➤ For more details on these results, see associated formal (.pdf) version of this report from September 19, 2011 meeting.

CPRA Update: 30 Month Follow Up Center Specific Variable Use of Listing UAs

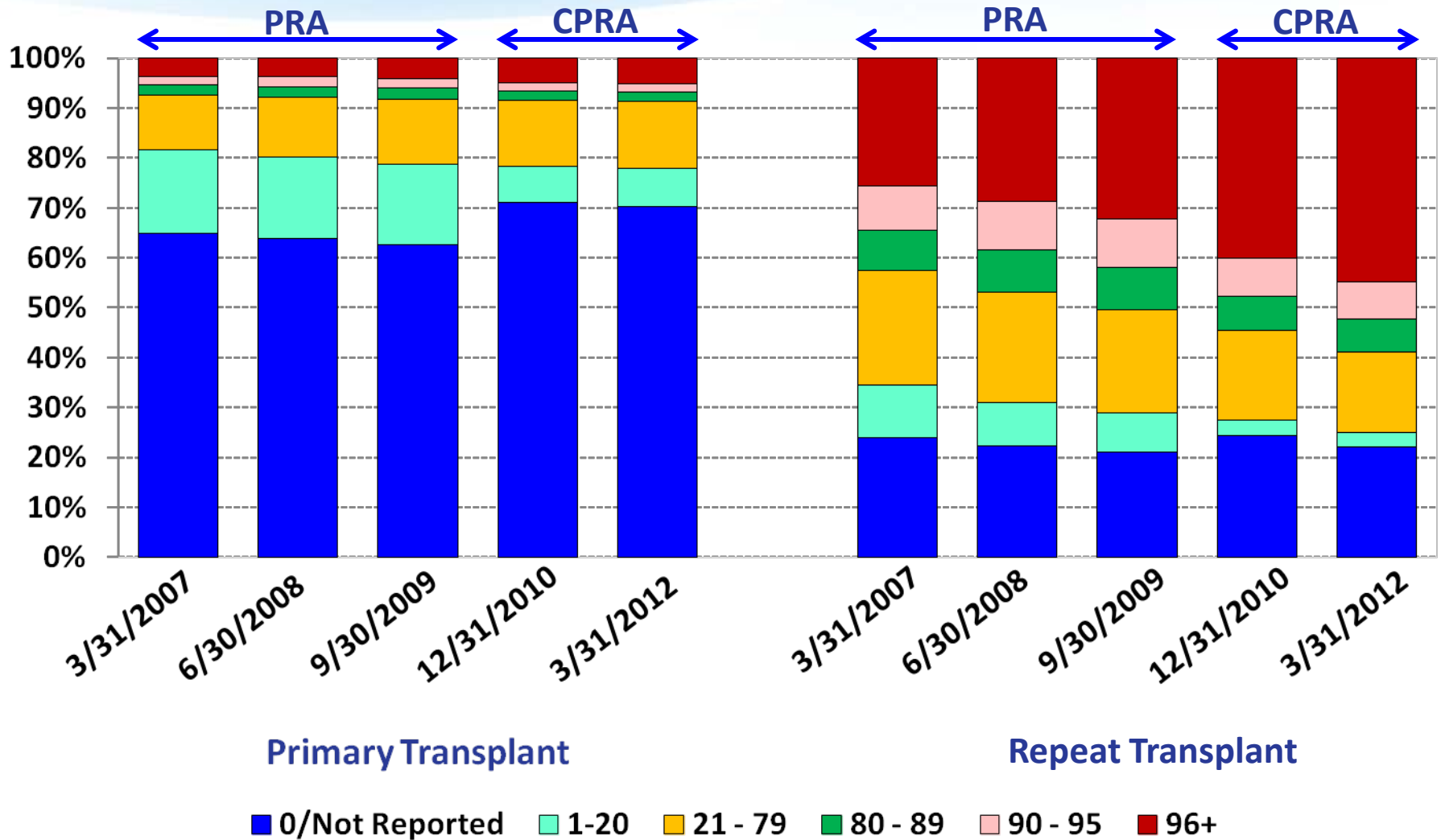
Kidney Committee,

August 27, 2012

Nancy L. Reinsmoen, PhD

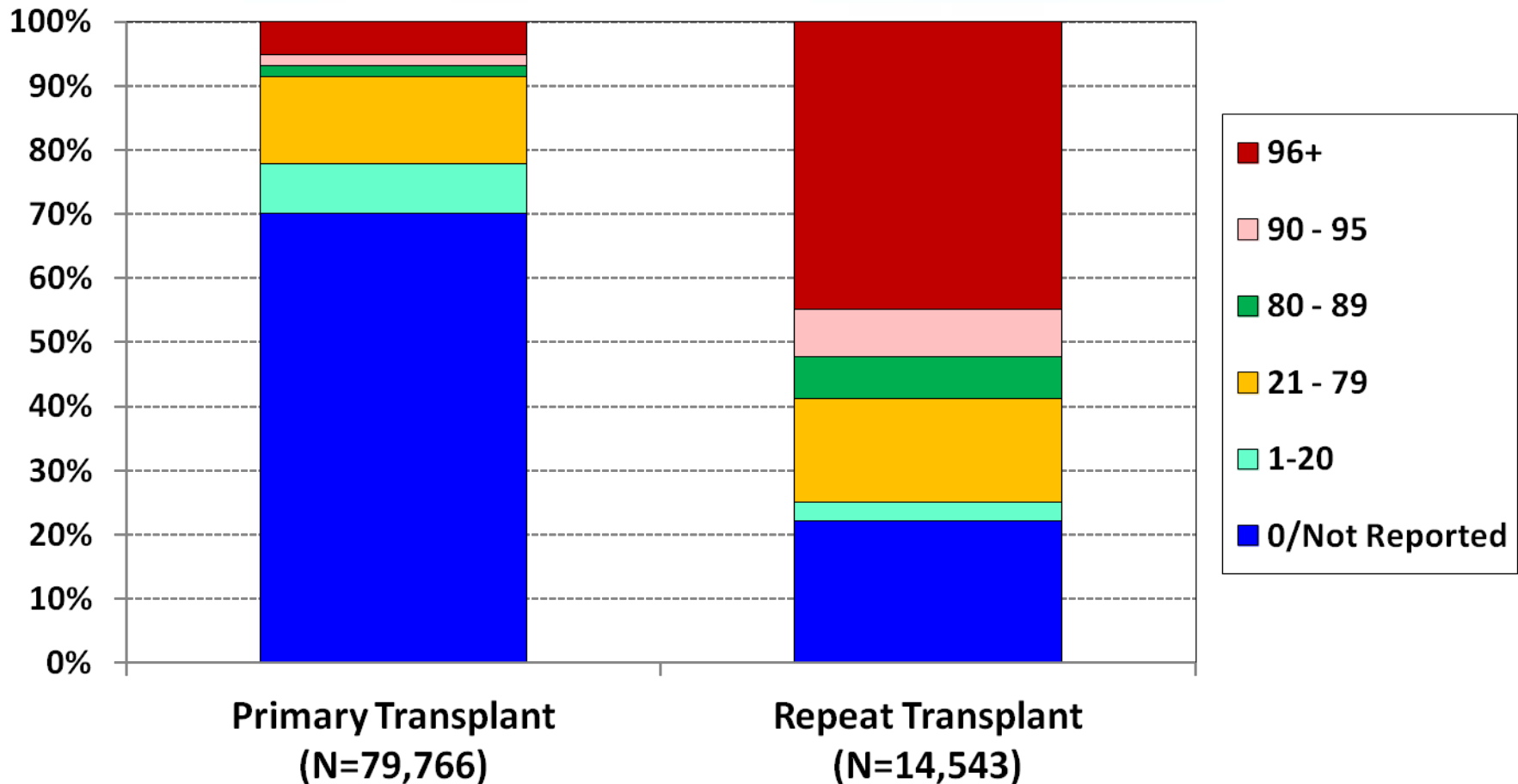
Anna Y. Kucheryavaya, MS

PRA/CPRA distribution for primary vs. repeat transplant*



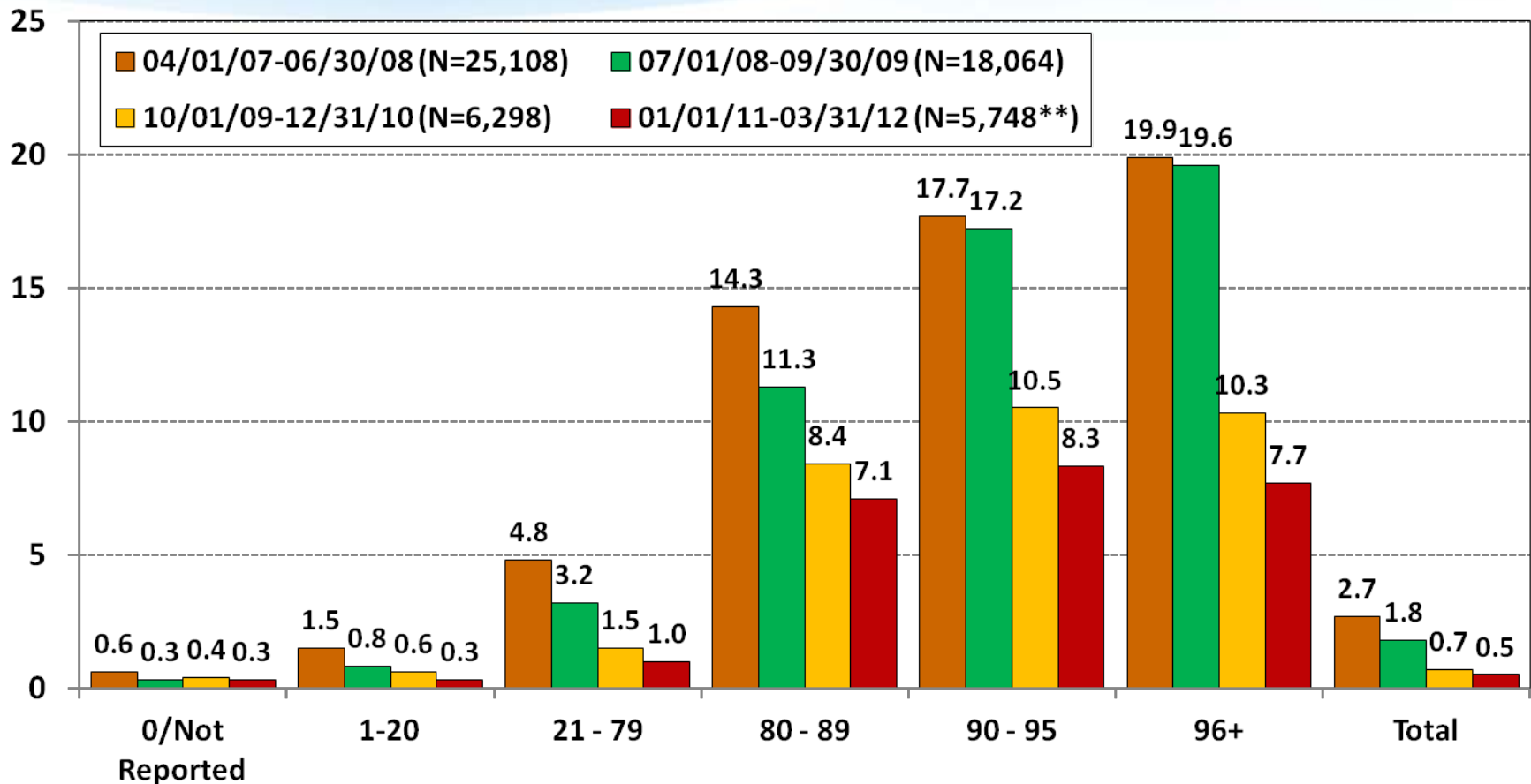
*Based on adult kidney alone registrations on the waiting list

CPRA distribution for primary vs. repeat transplant on 03/31/2012*



Total N= 94,309

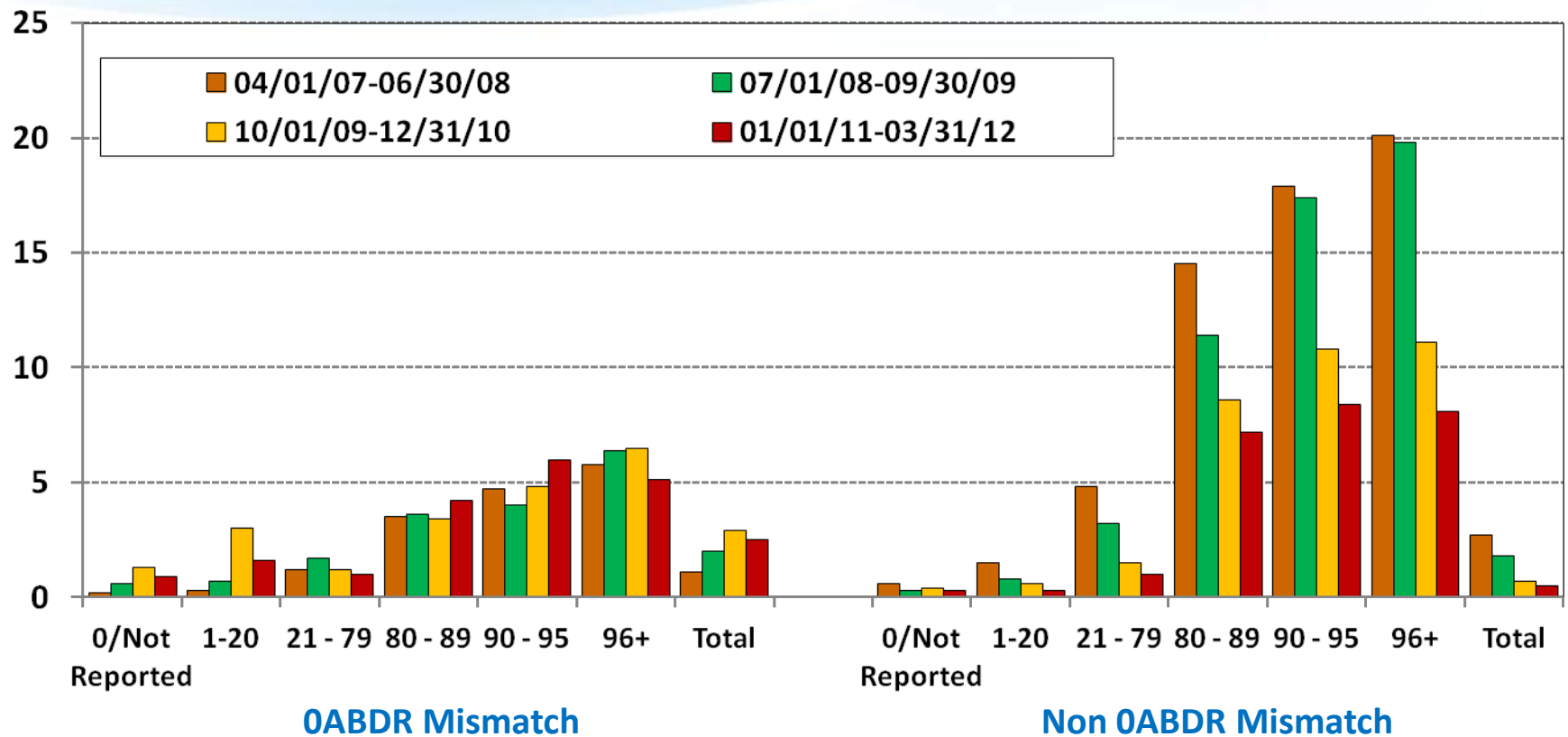
% of kidney offers refused due to a positive crossmatch*



During 15 months prior to policy implementation, the number of offers refused due to a positive crossmatch decreased by 28%. It further decreased in the first and second 15 months after the change (by 65% and 9%, respectively).

Overall percentage of offers refused due to a positive crossmatch significantly decreased in each era.

% of kidney offers refused due to a positive crossmatch for OABDR mismatch vs. non OABDR mismatch*

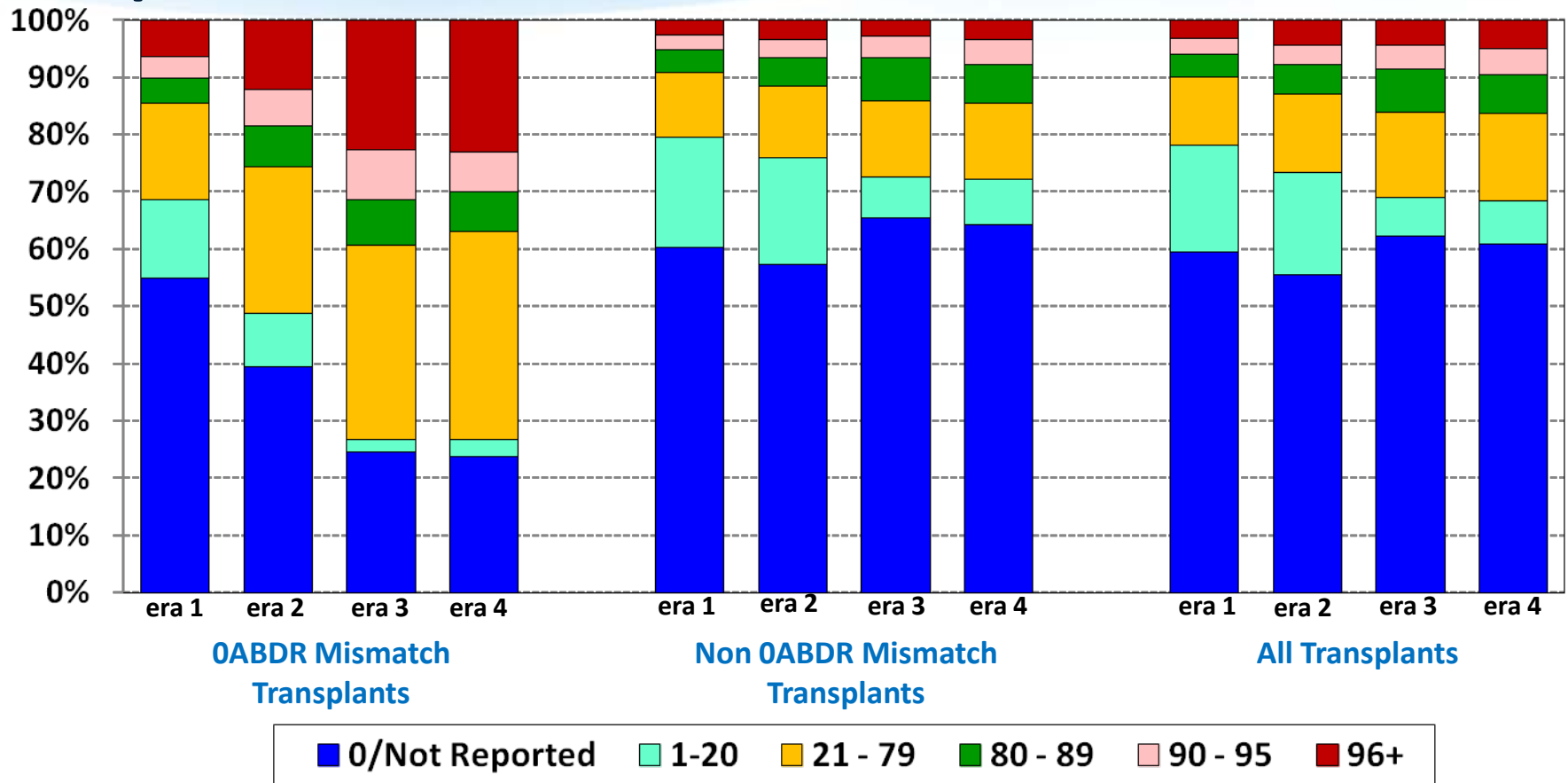


OABDR Mismatch

Non OABDR Mismatch

The number of OABDR mismatch offers refused due to a positive crossmatch remained similar through the recent years. Mandatory non local sharing of OABDR mismatched kidneys was eliminated for 0-20% PRA adults on January 21, 2009. For moderately and broadly sensitized registrations, percentage of OABDR mismatch offers refused due to a positive crossmatch didn't change significantly after CPRA implementation.

PRA/CPRA distribution of deceased donor transplant recipients*



■ 0/Not Reported ■ 1-20 ■ 21 - 79 ■ 80 - 89 ■ 90 - 95 ■ 96+

Mandatory non local sharing of OABDR mismatched kidneys was eliminated for 0-20% PRA adults on January 21, 2009.

Total number of OABDR mismatch transplants: era 1 = 1,671; era 2 = 1,179; era 3 = 928; era 4 = 1,013

era 1 = 04/01/2007 – 06/30/2008; era 2 = 07/01/2008 – 09/30/2009;
era 3 = 10/01/2009 – 12/31/2010; era 4 = 01/01/2011 – 03/31/2012

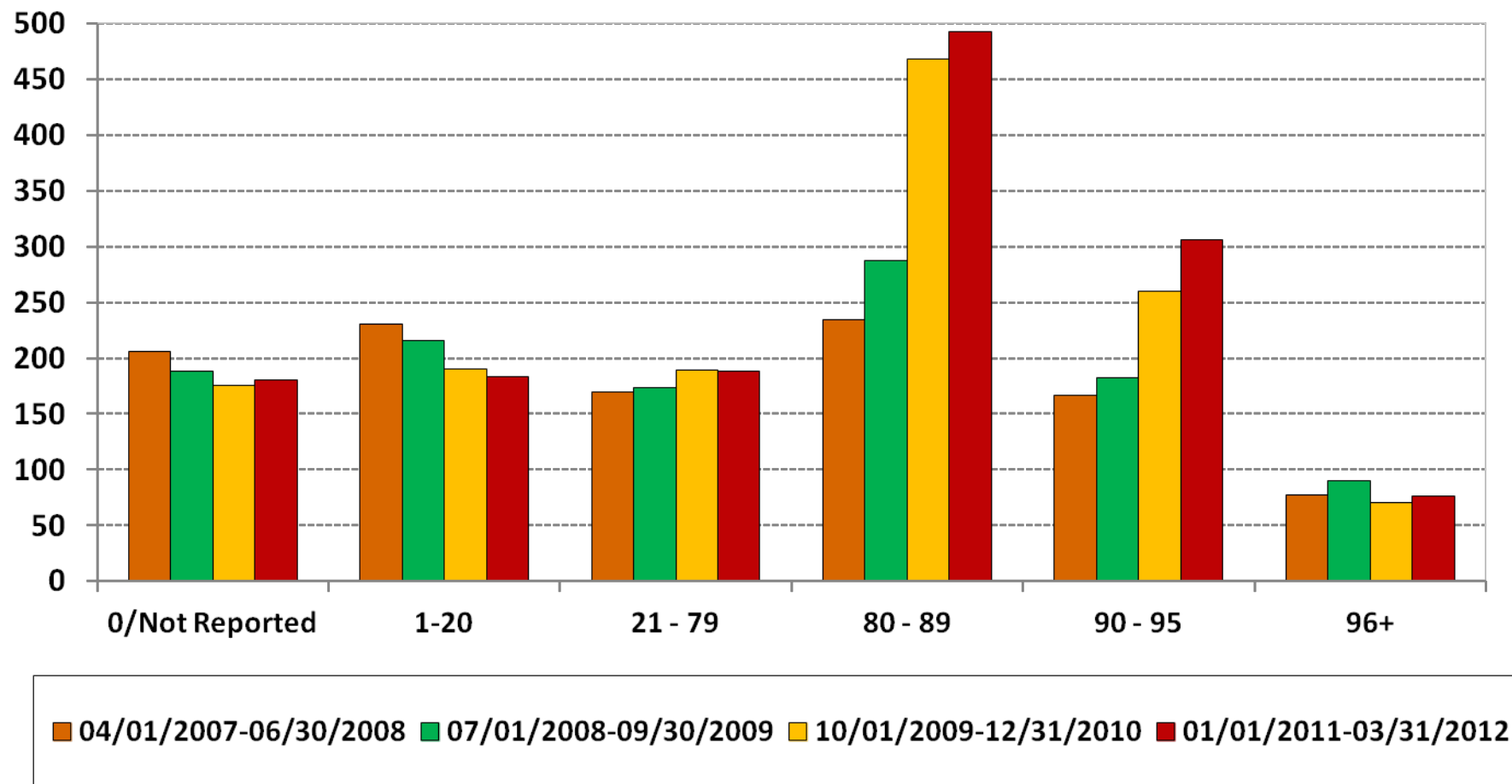
* Based on adult kidney alone transplants

Transplant rates per 1,000 active patient years

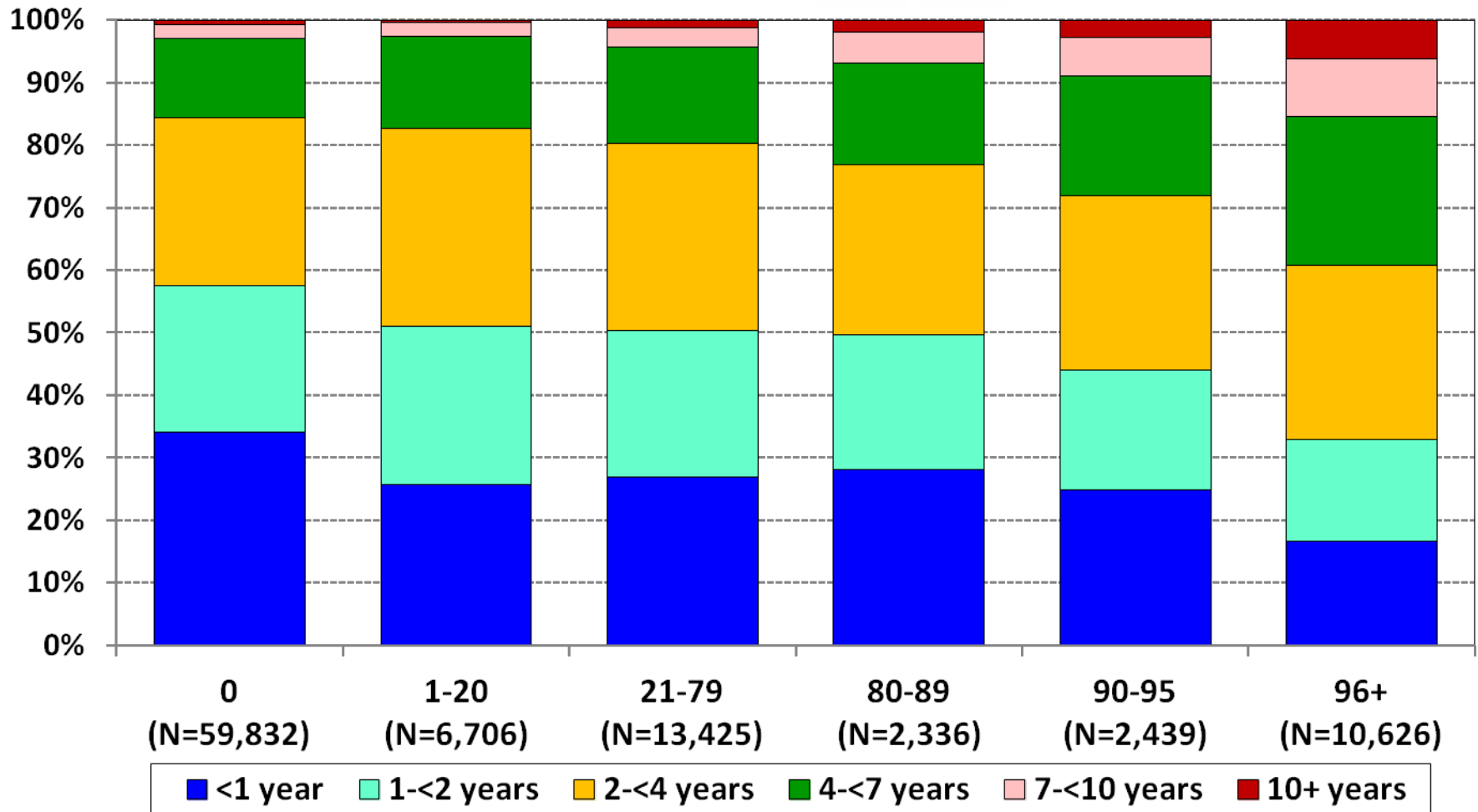
Data and Methods

- Transplant rates (expressed by transplants per 1,000 active patient-years) were calculated by dividing the number of all deceased donor kidney transplants within an interval by the number of active years patients spent waiting, and then multiplying by 1,000
- Transplant rates were calculated taking into account CPRA changes on the waiting list

Transplant rate per 1,000 active patient-years



Accumulated waiting time for registrations waiting on 07/13/2012*



Kaplan-Meier 6, 12, 18 month Graft Survival Rates by PRA/CPRA Groups: No Significant Change

Months	PRA/CPRA Group (%)							
	0/Not Reported		1 - 20		21 - 79		80+	
	10/2007 - 9/2009	10/2009 - 3/2010	10/2007 - 9/2009	10/2009 - 3/2010	10/2007 - 9/2009	10/2009 - 3/2010	10/2007 - 9/2009	10/2009 - 3/2010
6	94.2	94.2	94.2	95.0	93.8	94.4	93.7	92.4
12	91.8	91.3	91.6	92.0	91.7	91.7	91.1	90.3
18	89.6	88.1	89.6	88.3	89.4	87.0	88.5	87.6