

Kidney Allocation System (KAS) Clarifications & Clean Up

*Kidney Transplantation Committee
June 6-7, 2016
Board of Directors Meeting*



How does this proposal support the OPTN Strategic Plan?

- **Primary Goal:** Improve equity in access to transplants
 - Requiring OPOs to follow match run ensures more equitable treatment
 - Furthers original goals of KAS to improve access for difficult-to-match candidates
- **Promote the efficient management of the OPTN:**
 - Improve efficiency of KAS and clarifying policy



What problem will the proposal solve and how?

Problem 1: OPOs currently have the option of using a bypass code to skip 99-100% CPRA and 0-mismatches (in match classifications 1-10) after making a minimum # of offers

Proposed Solution: Change policy and deactivate bypass code so that OPOs must follow match run

What problem will the proposal solve and how?

Problem 2: Policy does not give clear direction on informed consent requirement for kidneys with a KDPI score greater than 85% for multi-organ candidates

Proposed Solution: Require informed consent for multi-organ candidates but expand time frame to obtain consent up until the time of transplant

What problem will the proposal solve and how?

Problem 3: Clerical errors and inconsistencies between KAS policy and Policy 5.9 Released Organs

Proposed Solution: Make clerical changes and resolve inconsistencies

Was this proposal changed in response to public comment?

Mandatory Sharing

Theme 1: Changes may prolong allocation time leading to increase in CIT and discard rate

- **Response:** Other bypass codes available & other efforts addressing organ offer process

Theme 2: Changes should be monitored

- **Response:** Discard rates tracked monthly, Committee can request analysis post-implementation (if needed)

Post-Public Comment Outreach: AST and ASTS
Post-Public Comment Change: None

Was this proposal changed in response to public comment?

Informed Consent for KDPI >85% for Multi-Organ Candidates

- *Theme 1:* Lack of data on risks/outcomes for multi-organ candidates
- *Theme 2:* Maintaining consistency with kidney-alone policy & consent for other high risk designations

Post-Public Comment Change: Expand timeframe for obtaining informed consent

- Multi-organ candidate's circumstances may change from listing to time of transplant
- Allows greatest degree of flexibility for obtaining consent
- Change would be supported by Thoracic and Liver Committees

How will members implement this proposal?

- This proposal does not require additional data collection.
- **OPOs:** OPOs will need to update their internal policies and procedures to address policy and programming changes and educate their staff. The mandatory sharing bypass code will be deactivated and OPOs will have to follow the kidney-alone match run.
- **Transplant hospitals:** Transplant hospitals will need to become familiar with changes to policy. Transplant hospitals will need to obtain written, informed consent from multi-organ candidates prior to transplant for kidneys with a KDPI >85%. These changes will not prohibit a transplant hospital from obtaining consent earlier.



How will the OPTN implement this proposal?

- IT Programming Estimate: Large
- Implementation Date:
 - Mandatory sharing and changes to classification titles: Pending programming
 - All other changes: September 1, 2016



Overall Project Impact

Product

Policy

Impacted Populations:

Transplant Candidates

Total IT Implementation Hours

1,000/12,820

Total Overall Implementation and Maintenance Hours

1,490/19,560

Resolution 7 (page 21)

- **RESOLVED**, that changes to Policies 5.3.C (Informed Consent for Kidneys Based on KDPI Greater than 85%), 8.2.B (Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings), 8.3 (Kidney Allocation Points), 8.5.C (Informed Consent for Kidneys Based on KDPI Greater than 85%), 8.5.D (Sorting Within Each Classification), 8.5.E (Allocation of Kidneys by Blood Type), 8.5.F (Prior Living Organ Donors), 8.5.G (Highly Sensitized Candidates), 8.6 (Double Kidney Allocation), 8.7.B (Choice of Right versus Left Donor Kidney), 8.7.C (National Kidney Offers), and 8.7.D (Kidney-Non-renal Organs Allocated and Not Transplanted), as set forth below, are hereby approved, effective September 1, 2016.
- **FURTHER RESOLVED**, that changes to Policies 8.5.H (Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%) and 8.7.A (Mandatory Sharing), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

Extra Slides

Bypass Code Usage

	1st 6 months Post-KAS (12/4/2014 – 6/3/2015)	2nd 6 months Post-KAS (6/4/2015 – 12/3/2015)
N of candidate registrations bypassed	902	537
% bypassed with CPRA 99-100	52%	61%
% bypassed other 0-ABDR mismatch	48%	39%
N of donors	52	49
N of OPOs using bypass code	22	28
Total number of donors with match runs	3,404	3,583
% of donor match runs with bypass code used	1.5%	1.4%

Note: Only match runs with final acceptance are included.

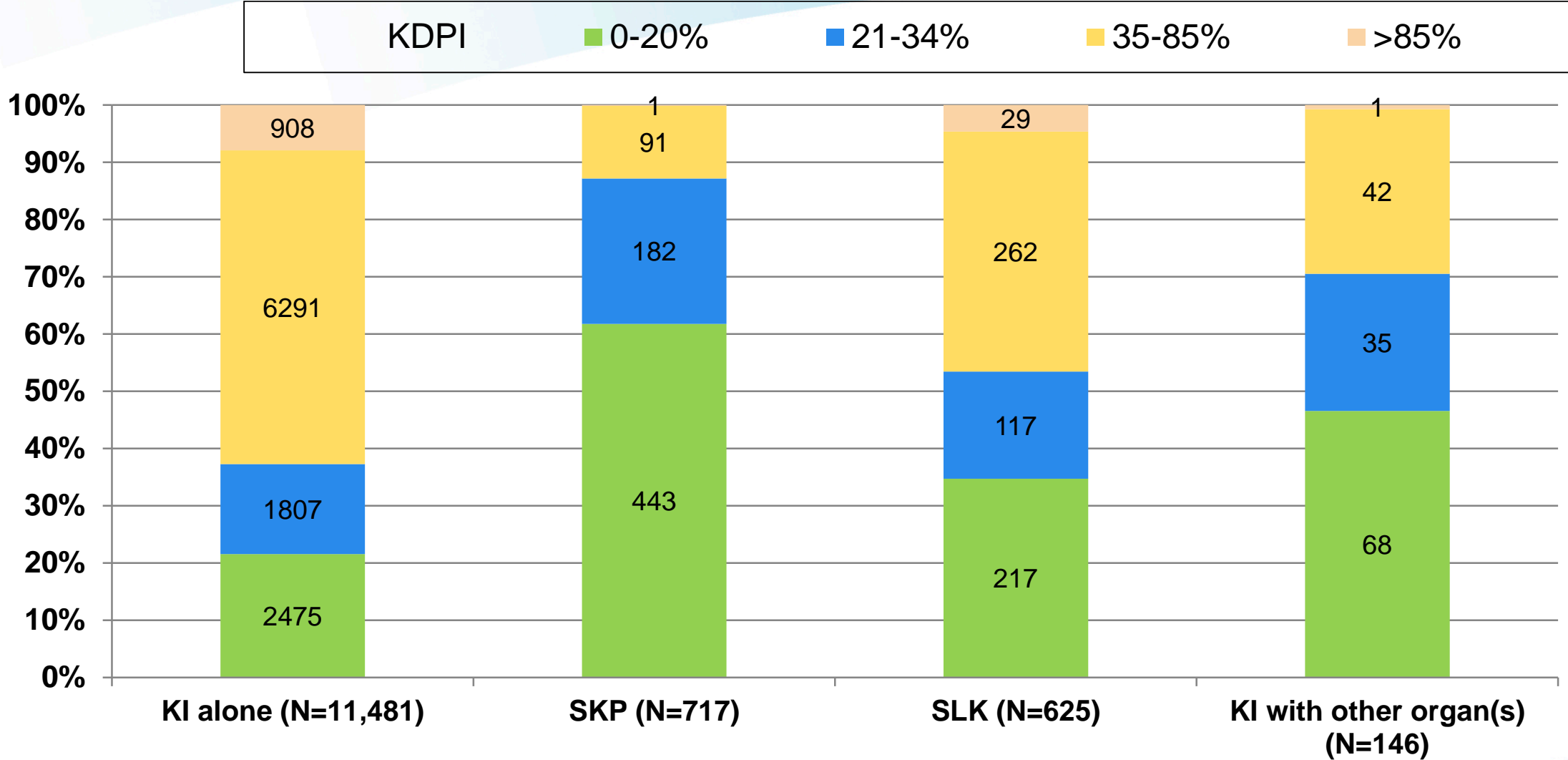
Other Currently Available Bypass Codes

Code	Refusal Reason	Description
861	Operational - OPO	OPO bypassed potential recipient due to transportation logistics, including distance in relation to ischemic time or weather conditions.
862	Donor Medical Urgency	Potential recipient was bypassed due to urgent donor organ placement.
863	Offer not made due to expedited placement attempt	Potential recipient bypassed as a result of offer(s) made during an expedited placement attempt. This includes offers of expanded donor organs, OR time constraints or family time constraints.

N and % of kidney match runs by number of mandatory share registrations on match runs, post-KAS

# mandatory share (non-local CPRA 99-100 or OMM) registrations on match run	KDPI 0-85%				KDPI>85%			
	1 st 6 months (12/4/14-6/3/15)		2 nd 6 months (6/4/15-12/3/15)		1 st 6 months (12/4/14-6/3/15)		2 nd 6 months (6/4/15-12/3/15)	
	N	%	N	%	N	%	N	%
0	1,458	42.2	1,619	45.0	342	61.1	386	65.1
1	700	20.3	710	19.7	99	17.7	103	17.4
2-5	825	23.9	829	23.0	89	15.9	87	14.7
6-10	239	6.9	227	6.3	18	3.2	11	1.9
>10	233	6.7	212	5.9	12	2.1	6	1.0
All	3,455	100.0	3,597	100.0	560	100.0	593	100.0

KDPI distribution among deceased donor kidney transplants in 2015



What problem will the proposal solve?

Clarification

- Inconsistencies between KAS policy and *Policy 5.9 Released Organs*
- **Solution:** Make *Policy 5.9* the prevailing policy

What problem will the proposal solve?

Other Changes

- **Corrections needed for match classification labels**
- **Other clerical changes**

Match Classification Labels

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
16	OPO's region	0-ABDR mismatch, less than 18 years old at time of match , CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
20	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run , CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any

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