Simultaneous Liver Kidney (SLK) Allocation Project

June 2, 2015

SLK Project

The problem

- SLK allocation not based on standard medical criteria; only based on geographic proximity of donor and candidate
- Inconsistent allocation practices across the country mean candidates not being treated equitably

Different Perspectives on the Problem

- OPO community: Need consistent rules
- Liver community: Inconsistency in regional allocation is counter to goal the regional ‘Share 35’ liver policy seeks to achieve
- Kidney community: Need to ensure a balance of fairness/utility in allocation of kidneys

Important Historical Background

2006-2007— Societies hold consensus conference on the issue

2009— Kidney and Liver Committees sponsor public comment proposal

2010—Committees decided not to move forward due to complex IT programming associated with proposal (mostly due to kidney allocation variances) and development of new KAS

2014—KAS is implemented, removing all variances

Recent Outreach/Collaboration

OPO, Liver, MAC, Ops and Safety, Ethics Committees

OPTN Regions

AST

ASTS

NKF

AUA

2015 SLK Recommendations

2 main policy elements

Medical eligibility criteria for SLK allocation

“Safety Net”

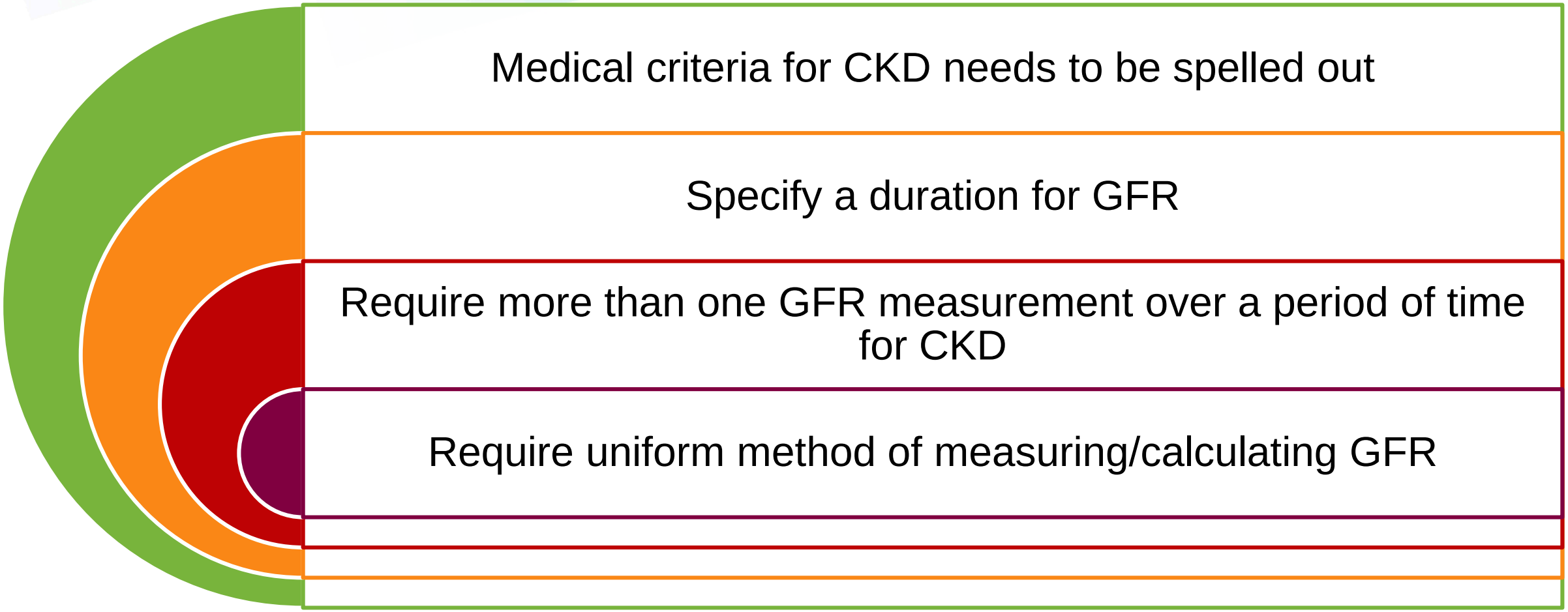
Prioritization on the kidney alone waiting list for liver recipients with post-operative dialysis dependency or significant renal dysfunction

SLK Medical Eligibility Criteria

SLK Medical Eligibility Criteria (as presented for feedback)

Transplant nephrologist must confirm candidate has one of the following:	And tx hospital must document one of the following in the medical record:
1. Chronic kidney disease	1. Dialysis for ESRD 2. eGFR at or below 35 mL/min
2. Sustained acute kidney failure	1. Dialysis for six consecutive weeks 2. eGFR/CrCl at or below 25 mL/min for at least six consecutive weeks (documented every 7 days) 3. Any combination of #1 and #2 above for six consecutive weeks
3. Metabolic disease	Diagnosis of: 1. Hyperoxaluria 2. Atypical HUS from mutations in factor H and possibly factor I 3. Familial non-neuropathic systemic amyloid 4. Methylmalonic aciduria

Regional Feedback



Constituency Group Feedback

AST

- Generally supportive
- Concerned CKD definition does not contain time component; suggested adopting NKF KDOQI criteria (90 days)
- Requested requiring uniform method of measuring/calculating GFR

NKF

- Supports updated criteria, especially having nephrologist confirm candidate diagnosis
- Remain concerned with category #2 being labeled as ‘kidney failure’, would suggest it be re-labeled

AUA

- Generally rejected notion that SLK recipients have better outcomes if receiving both organs from the same donor and would encourage use of living donors in this setting instead of SLK

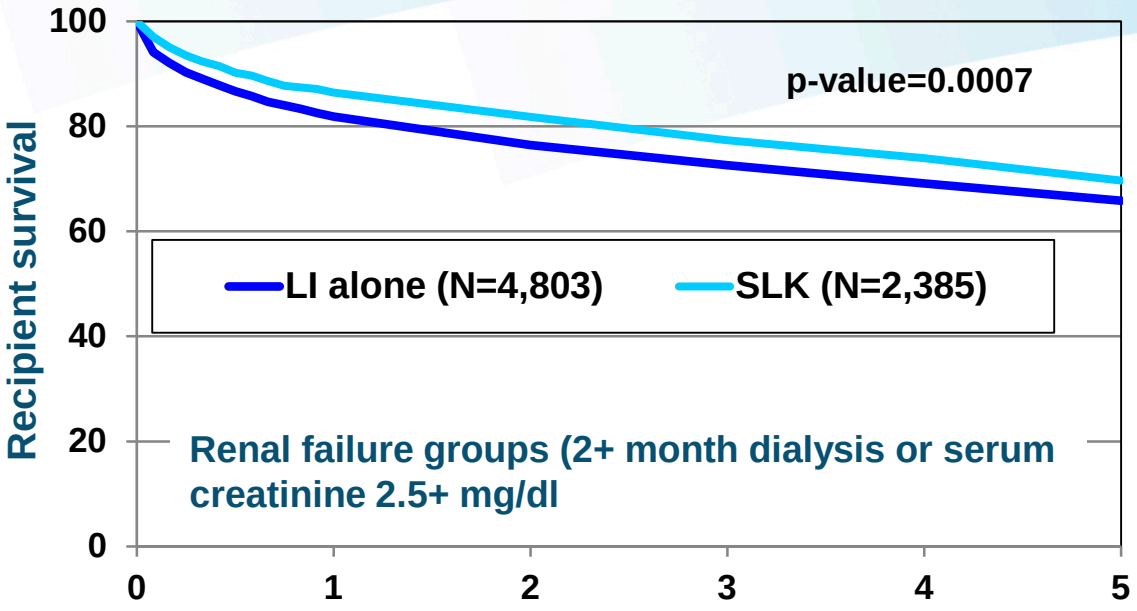
Updated Recommendations

Transplant nephrologist must confirm candidate has one of the following:	And tx hospital must document one of the following in the medical record:
1. Chronic kidney disease with measured or calculated GFR less than or equal to 60 mL/min for greater than 90 days	1. Dialysis for ESRD 2. Most recent eGFR/CrCl is at or below 35 mL/min at the time of registration on kidney waiting list
2. Sustained acute kidney injury	1. Dialysis for six consecutive weeks 2. eGFR/CrCl at or below 25 mL/min for at least six consecutive weeks 3. Any combination of #1 and #2 above for six consecutive weeks
3. Metabolic disease	Diagnosis of: 1. Hyperoxaluria 2. Atypical HUS from mutations in factor H and possibly factor I 3. Familial non-neuropathic systemic amyloid 4. Methylmalonic aciduria

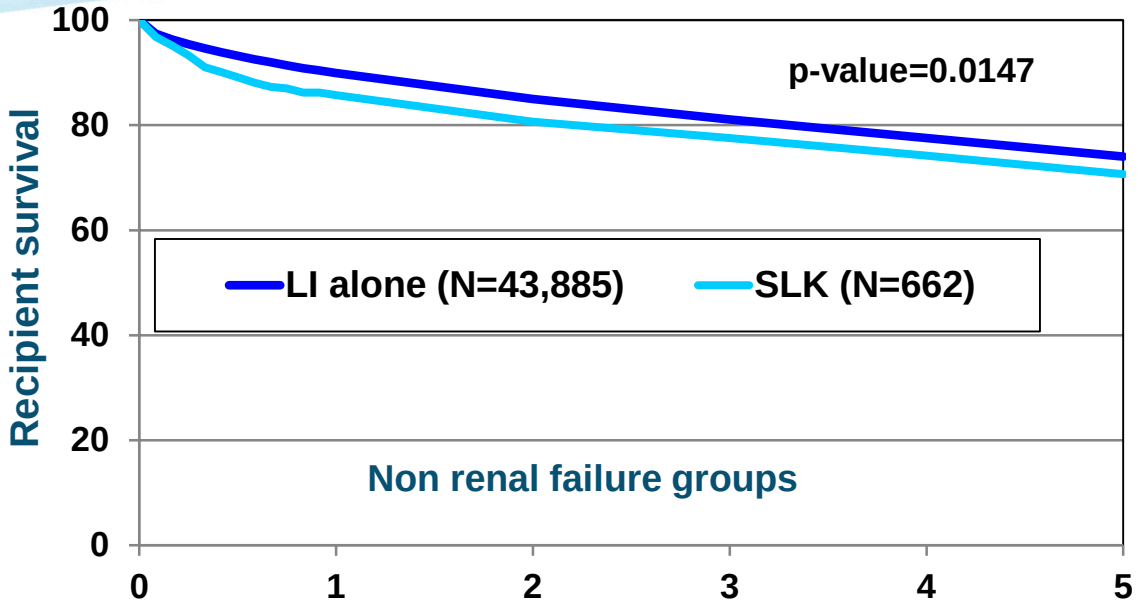
KDOQI criteria

OPTN

Crude survival advantage of receiving a kidney vs. liver alone



	LI Alone	SLK
White	70%	62%
Diabetes	27%	41%
MELD*	36	27
KDPI%	50	40
Age*	55	56
LI CIT*	6.9	6.4



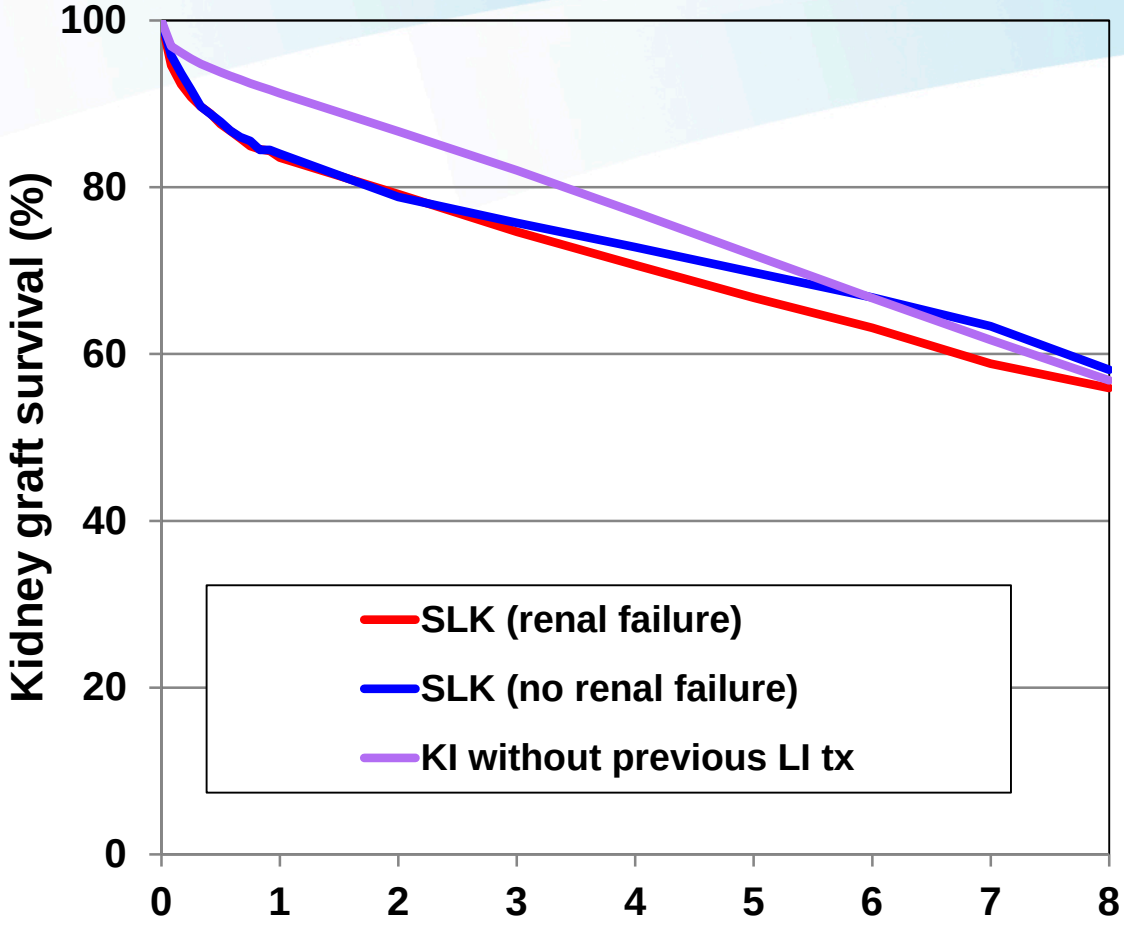
	LI Alone	SLK
White	73%	65%
Diabetes	23%	38%
MELD*	17	28
KDPI%	50	40
Age*	55	57
LI CIT*	6.7	6.5

OPTN | UNOS

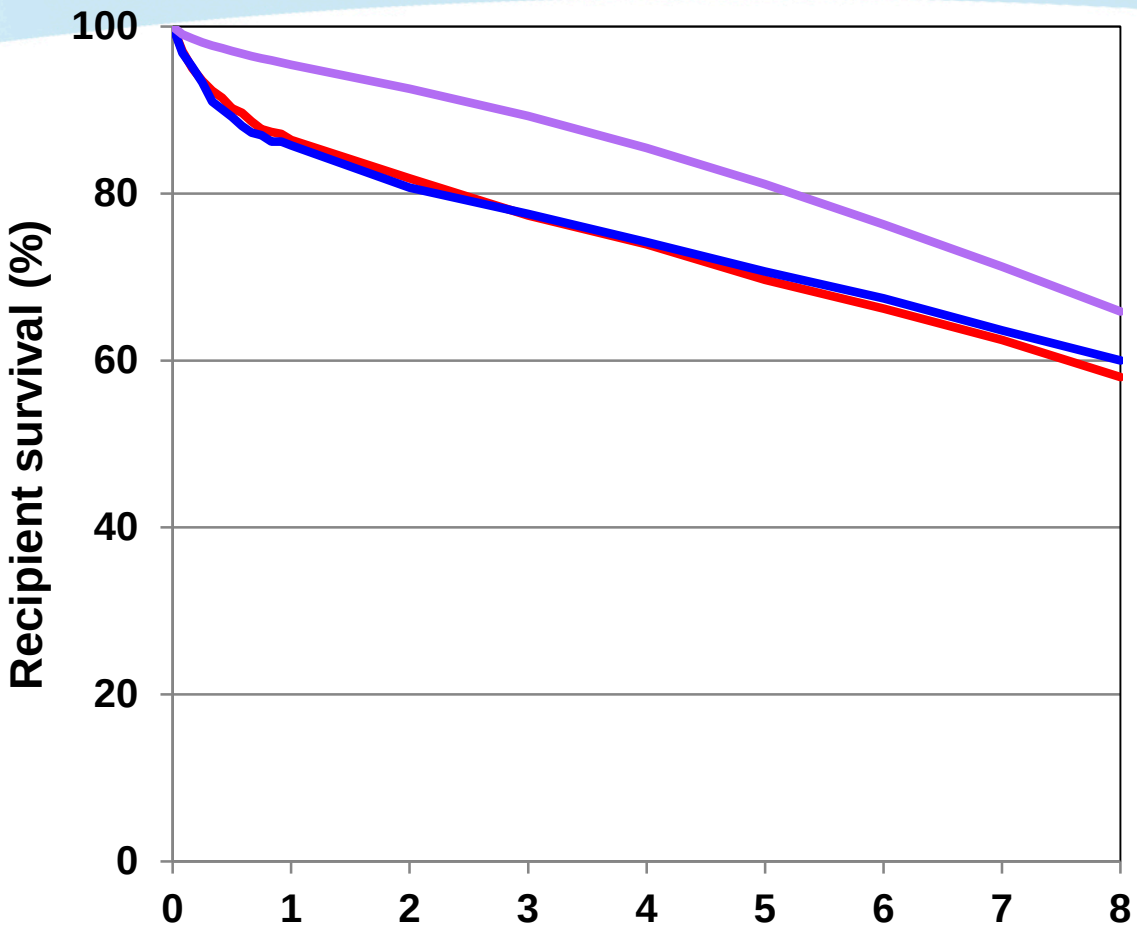
* Medians are shown

Cohort: recipients Mar 31, 2002 – Dec 21, 2012

Kidney graft survival



Recipient survival



	SLK (ren. failure)	SLK (no ren. failure)	KI
White	62%	65%	45%
Age (median)	56	57	54

OPTN | UNOS

Cohort: recipients Mar 31, 2002 – Dec 31, 2012

SLK ‘Safety Net’ Policy

‘Safety Net’ Policy (as presented for feedback)

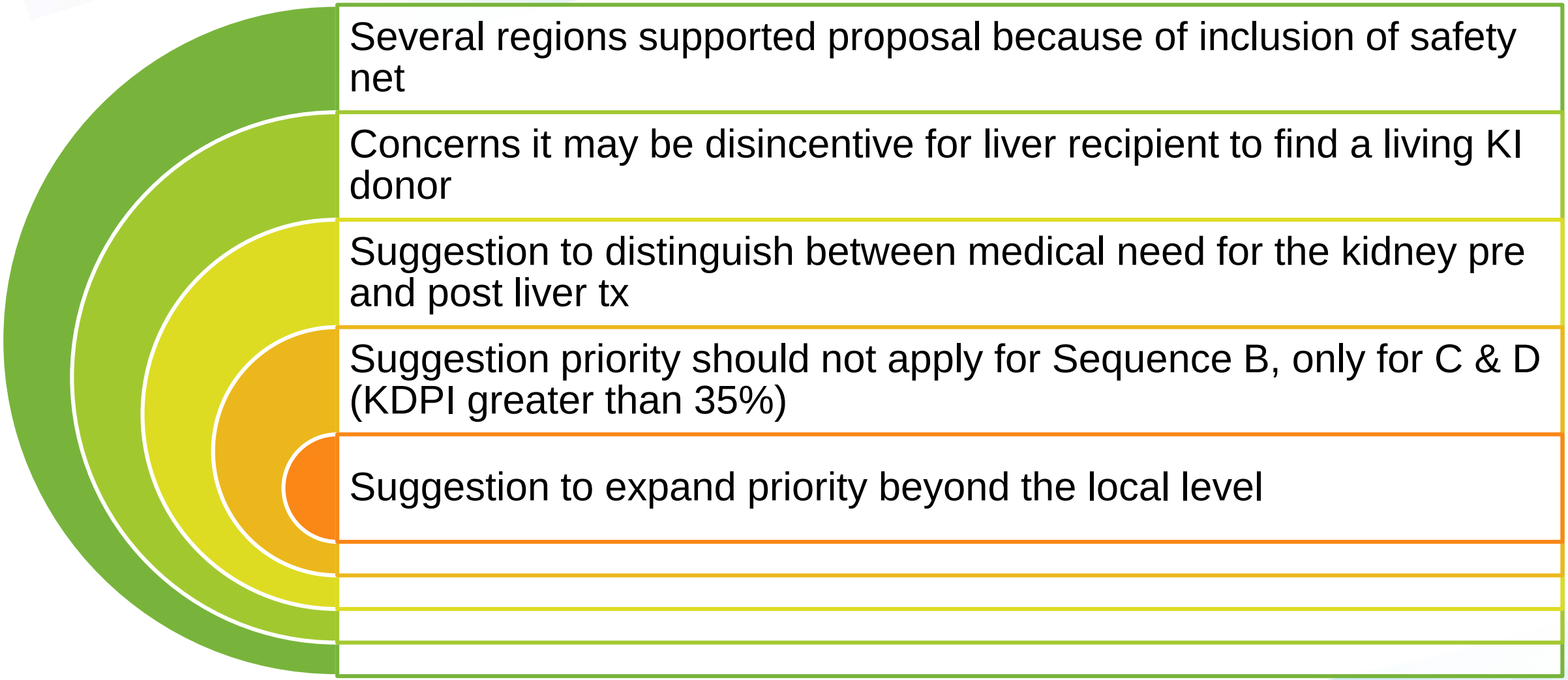
Liver recipients receive additional *match classification* priority on the kidney waiting list if:

- on a date that is 2-12 months after the most recent LI tx, LI recipient *is on kidney waiting list* and is either:
  - on dialysis for ESRD *or*
  - eGFR is at or below 20 mL/min

Once eligible, candidate will continue to receive additional priority until candidate is transplanted under this listing or removed from waiting list for other reason

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

Regional Feedback



Constituency Group Feedback

NKF

- Strongly support
- Appreciative of the changes made since 2009 proposal

AUA

- No comments on ‘safety net’ priority

AST

- Support ‘safety net’ prioritization
- Requested Committee consider no priority for sequence B (KDPI 21-34%) because it could be disincentive for candidate to seek a living donor

Updated ‘Safety Net’ Recommendations

Liver recipients **(except for prior SLK recipients)** receive additional match classification priority on the kidney waiting list if:

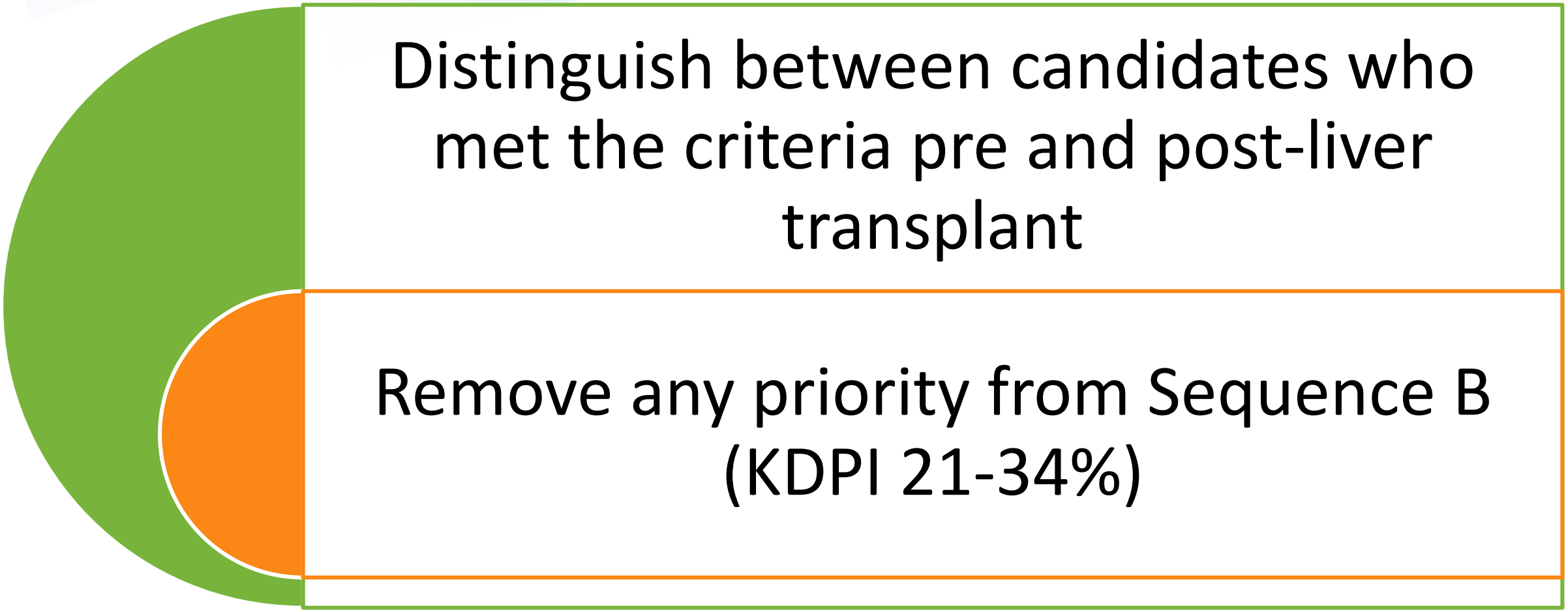
- on a date that is 2-12 months after the most recent LI tx, LI recipient *is on kidney waiting list* and is either:
  - on dialysis for ESRD *or*
  - eGFR is at or below 20 mL/min

All other liver recipients (including recipients of liver tx with other organs) will be eligible for safety net priority

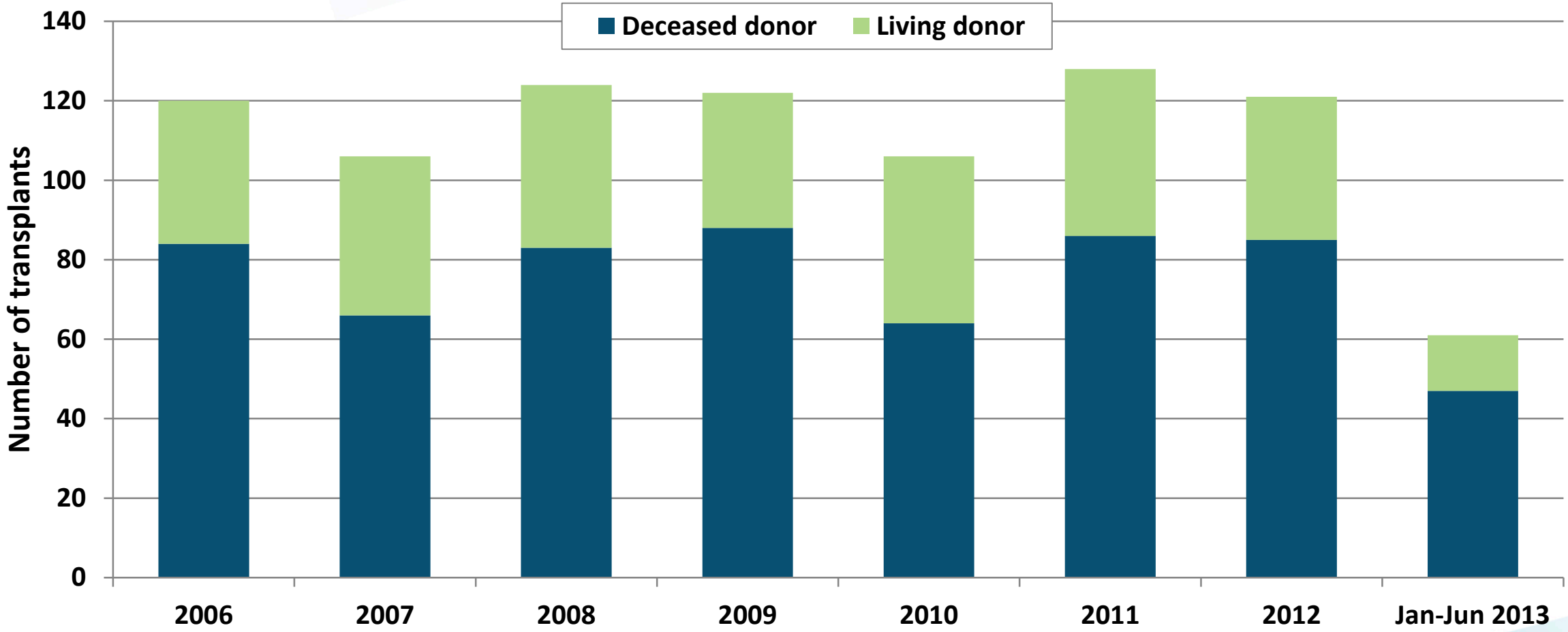
- **SLK recipients will be eligible if kidney graft failure occurred within 90 days of SLK transplant**
- **In this limited instance, priority will be applied**

Once eligible, candidate will continue to receive additional priority until candidate is transplanted under this listing or removed from waiting list for other reason

Considered but no change



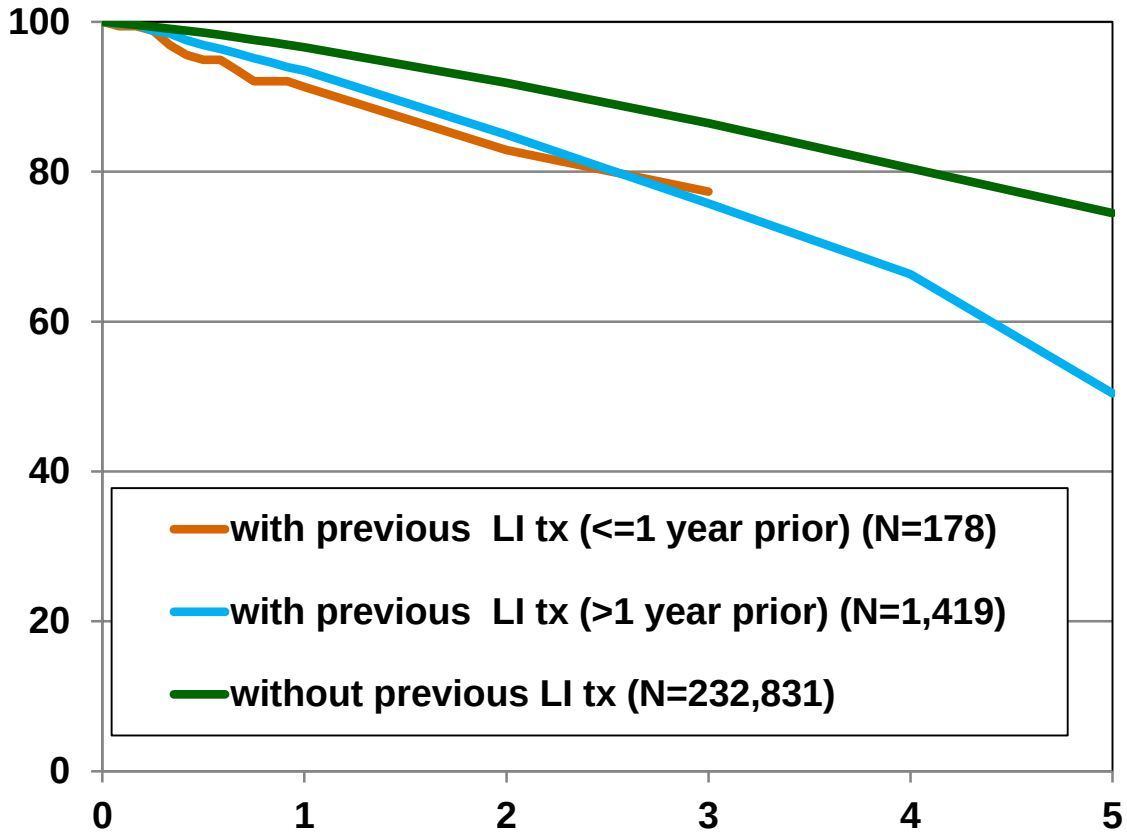
Kidney transplants after liver transplants (2005-6/2013) by kidney donor type



Analyses are based on first deceased and living donor kidney alone transplants that occurred during 2005-6/2013 and followed a liver alone transplant that was still functioning at the time of the subsequent kidney transplant.

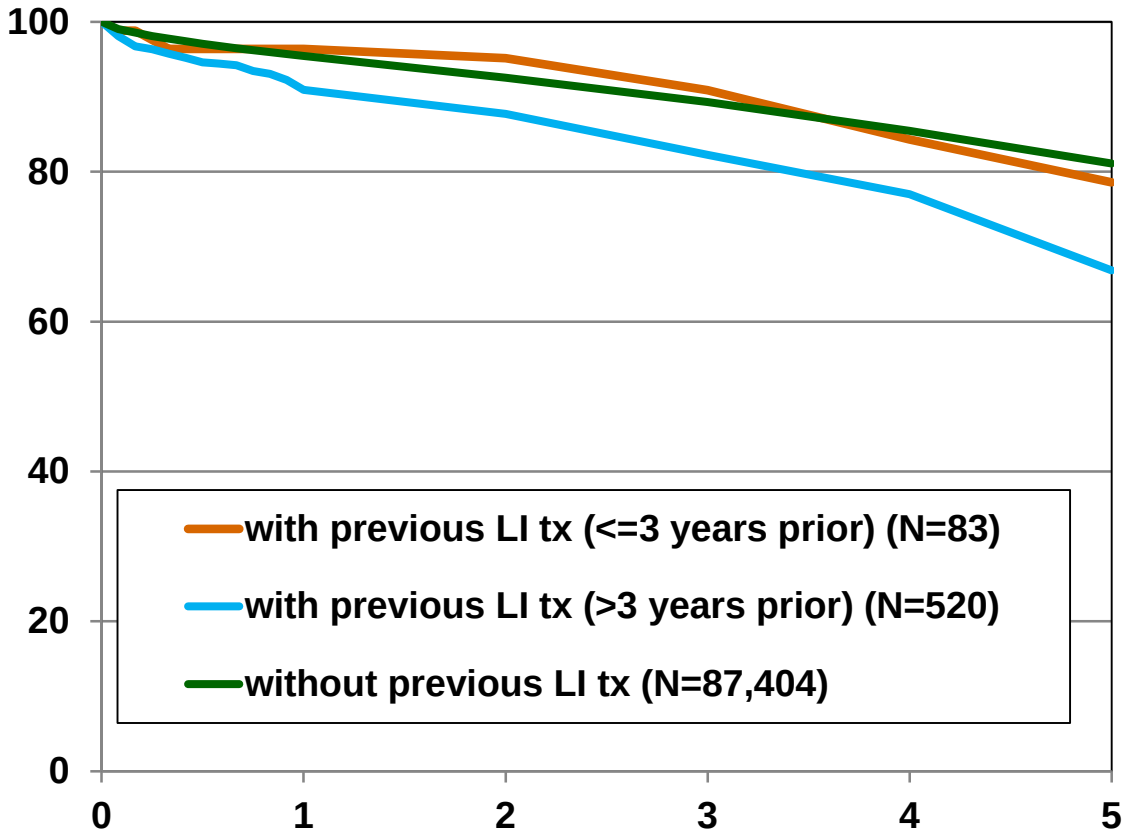
Kidney patient survival: with vs. without prior liver tx

Waiting list survival



	With LI (<=1)	With LI (>1)	W/t LI
White	75%	74%	45%
Age (median)	57	59	53

Recipient survival



	With LI (<=3)	With LI (>3)	W/t LI
White	70%	78%	45%
Age (median)	57	60	54

OPTN | UNOS

Time period: Mar 31, 2002 – Dec 31, 2012

OPTN Strategic Plan Alignment

Current OPTN Strategic Plan	• Increase access to transplants
2015-2018 OPTN Strategic Plan	• Increase equity in access to transplants • Objective: Establish clearer rules for allocation of multiple organs to a single candidate, especially liver-kidney candidates

Next Steps

Explore and discuss application of changes to heart/kidney and lung/kidney allocation

Expand working group composition and scope to discuss order of allocation between multi-organ and single organ candidates

SLK recommendations will be incorporated into larger multi-organ proposal

Board Feedback Requested

- Is the recommended medical eligibility criteria appropriate?
- Is the ‘safety net’ priority appropriately placed on the kidney waiting list?
- Should SLK allocation be expanded to prioritize both local and *regional* SLK candidates who meet the medical eligibility criteria?
- What is the appropriate timing to bring this proposal back to the Board? Should the Committee wait for the larger multi-organ ‘ordering’ project to conclude before bringing proposal back to the Board for a vote?

Extra SLK slides

How will this be operationalized?

Programmed into UNet℠

Transplant nephrologist must confirm candidate has one of the following:	And tx hospital must document one of the following in the medical record:
1. Chronic kidney disease with a measured or calculated GFR less than or equal to 60 mL/min for greater than 90 days	1. Dialysis for ESRD 2. Most recent eGFR/CrCl is at or below 35 mL/min at the time of registration on kidney waiting list
2. Sustained acute kidney non-function	1. Dialysis for six consecutive weeks 2. eGFR/CrCl at or below 25 mL/min for at least six consecutive weeks 3. Any combination of #1 and #2 above for six consecutive weeks
3. Metabolic disease	Diagnosis of: 1. Hyperoxaluria 2. Atypical HUS from mutations in factor H and possibly factor I 3. Familial non-neuropathic systemic amyloid 4. Methylmalonic aciduria

OPTN | UNOS

How will this be monitored?

Transplant nephrologist must confirm candidate has one of the following:	And tx hospital must document one of the following in the medical record:
1. Chronic kidney disease with a measured or calculated GFR less than or equal to 60 mL/min for greater than 90 days	1. Dialysis for ESRD 2. Most recent eGFR/CrCl is at or below 35 mL/min at the time of registration on kidney waiting list
2. Sustained acute kidney non-function	1. Dialysis for six consecutive weeks 2. eGFR/CrCl at or below 25 mL/min for at least six consecutive weeks 3. Any combination of #1 and #2 above for six consecutive weeks
3. Metabolic disease	Diagnosis of: 1. Hyperoxaluria 2. Atypical HUS from mutations in factor H and possibly factor I 3. Familial non-neuropathic systemic amyloid 4. Methylmalonic aciduria

Site monitors will check documentation in medical record

The Impact of the Problem by #'s

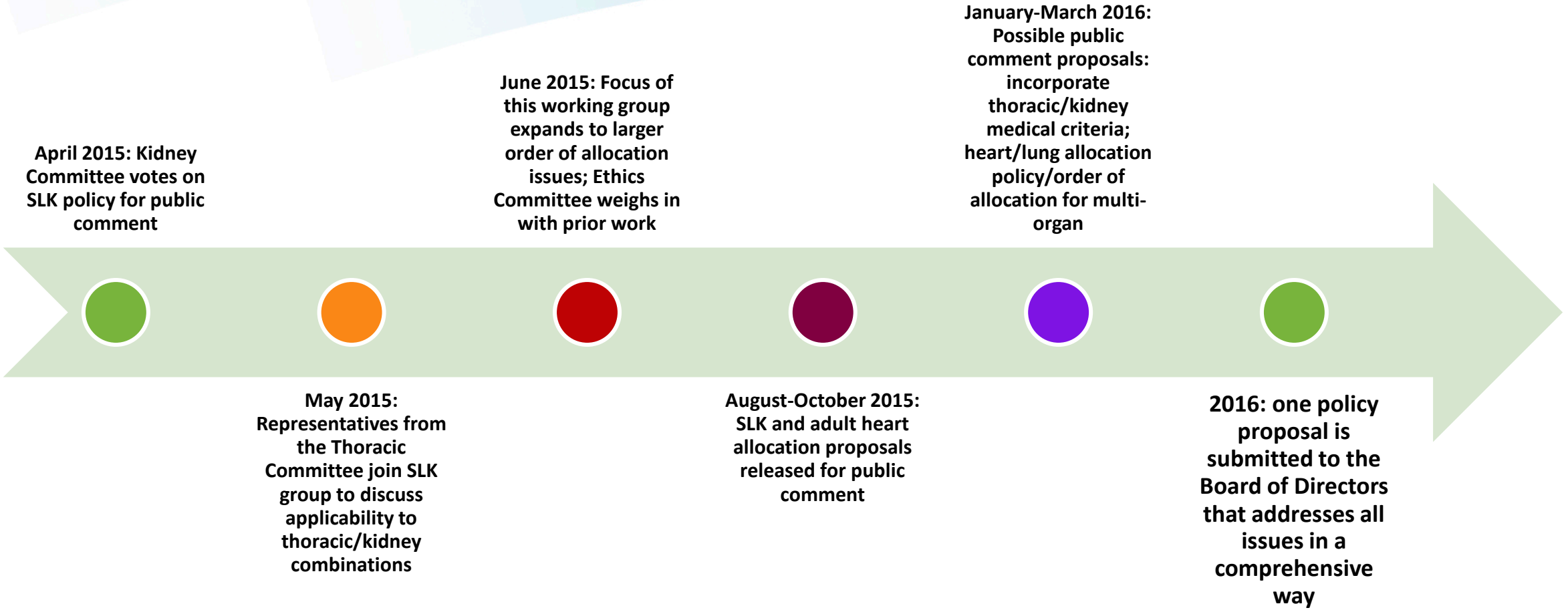
500—the approximate number of SLK transplants per year

50-65—the number of SLK recipients with no pre-tx dialysis

110-120—the number of recipients with <2 months of dialysis

48%--the percentage of kidneys used in SLK transplants that had KDPI < 35% (usually prioritized for peds)

Multi-Organ Project Timeline



OPTN | UNOS