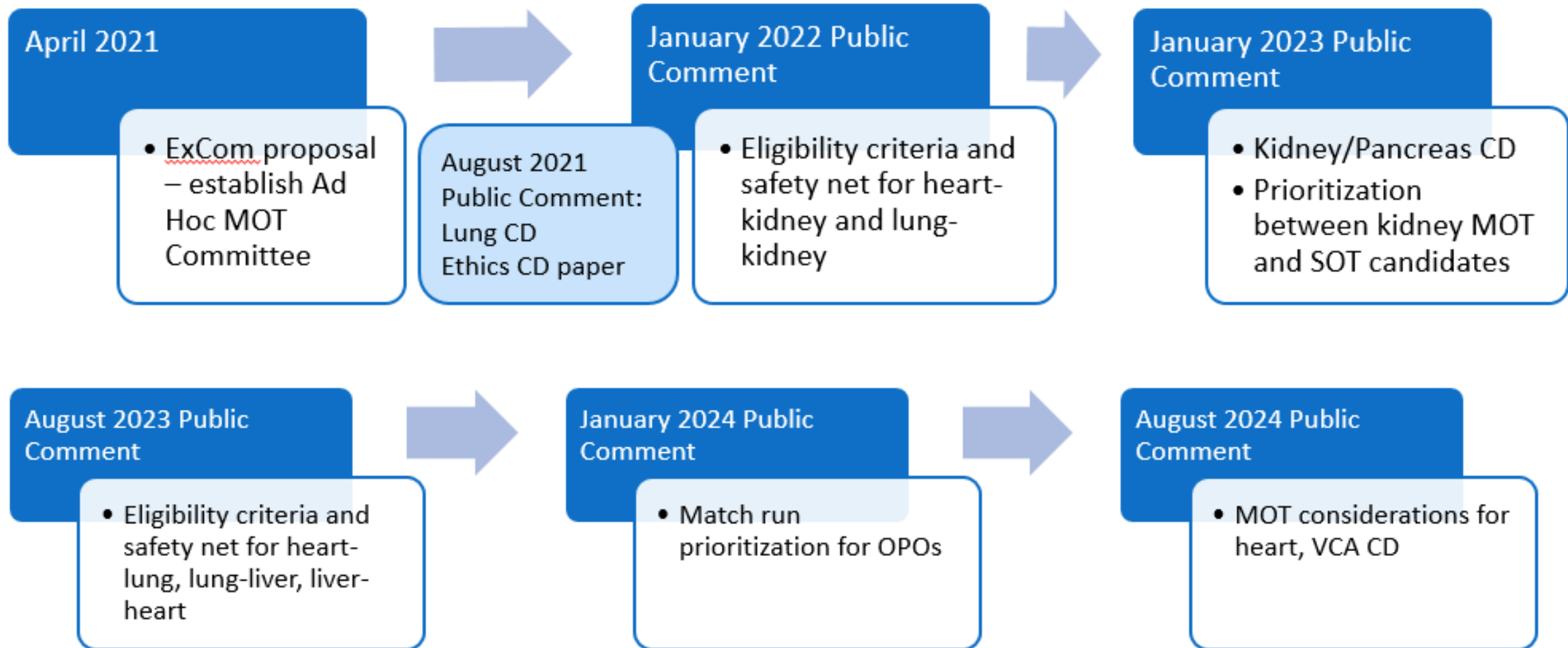


Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation

OPTN Ad Hoc Multi-Organ Transplantation Committee

MOT Committee Project Map



Project Map Builds on Previous OPTN Work

- Clarification of multi-organ policy was approved by the Board in June 2021
- Implementation date: February 10, 2022
- Establishes when OPOs must offer liver or kidney along with heart or lung
- Based on heart or lung status and distance from donor hospital

<https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/clarify-multi-organ-allocation-policy/>

Purpose of Proposal

- Set eligibility criteria and safety net for heart-kidney and lung-kidney allocation based on kidney function
- Eligibility criteria ensures clinical justification for allocating multiple organs to one candidate
- Safety net protects access to kidneys for heart and lung recipients with kidney failure

Proposal

- **Eligibility criteria for simultaneous heart-kidney and lung-kidney allocation**
 - Uses same medical criteria as simultaneous liver-kidney (SLK) allocation for chronic kidney disease and sustained acute kidney injury diagnoses
 - Retains 500 nautical mile (nm) distance threshold established in recently approved policy
 - Does not apply to pediatric candidates – they are eligible if registered for both organs
- **Safety net for kidney-after-heart and kidney-after-lung allocation**
 - Uses same criteria as kidney-after-liver safety net
 - Gives the same priority in kidney allocation to qualifying heart and lung recipients as prior liver recipients

If the candidate's transplant nephrologist confirms a diagnosis of:

Then the transplant program must report to the OPTN and document in the candidate's medical record:

Chronic kidney disease (CKD)
with a measured or estimated glomerular filtration rate (GFR) less than or equal to 60 mL/min for greater than 90 consecutive days

At least *one* of the following:

- That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.
- At the time of registration on the kidney waiting list, that the candidate's most recent measured or estimated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min.
- On a date after registration on the kidney waiting list, that the candidate's measured or estimated CrCl or GFR is less than or equal to 30 mL/min.

Sustained acute kidney injury

At least *one* of the following, or a combination of *both* of the following, for the last 6 weeks:

- That the candidate has been on dialysis at least once every 7 days.
- That the candidate has a measured or estimated CrCl or GFR less than or equal to 25 mL/min at least once every 7 days.

If the candidate's eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a [heart or lung] and a kidney from the same donor.

Safety Net

- Prior heart and lung recipients registered for a kidney would receive safety net priority if:
 - The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent heart or lung transplant date
 - On a date that is at least 60 days but not more than 365 days after the candidate's heart or lung transplant date, at least *one* of the following criteria is met:
 - The candidate has a measured or estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 mL/min
 - The candidate is on dialysis

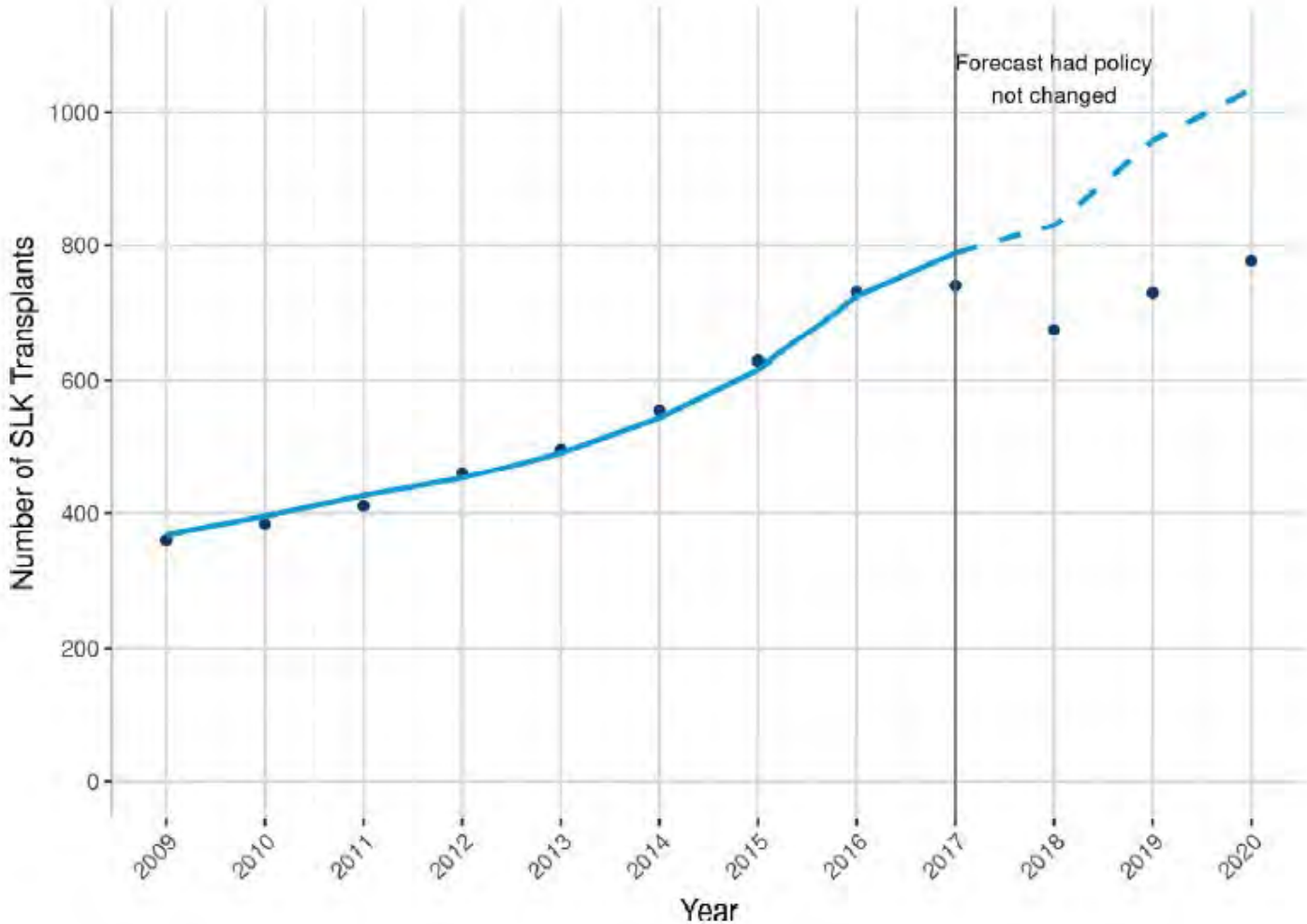
Safety Net Priority in Kidney Allocation

Sequence A KDPI 0-20% (and Ten bloc)	Sequence B KDPI 20-34%	Sequence C KDPI 35-85%	Sequence D KDPI 86-100%
100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent 98%-99% Highly Sensitized 0-ABDRmm Inside Circle Top 20% EPTS 0-ABDRmm (ALL) Inside Circle (All) National Pediatrics National (Top 20%) National (All)	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent 98%-99% Highly Sensitized 0-ABDRmm Inside Circle Safety Net Inside Circle (All) National (All)	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Medically Urgent 98%-99% Highly Sensitized 0-ABDRmm Inside Circle Safety Net Inside Circle (All) National (All) Inside Circle (dual) National (dual)	100% Highly Sensitized Inside Circle Medically Urgent 98%-99% Highly Sensitized 0-ABDRmm Inside Circle Safety Net Inside Circle (All) Inside Circle (dual) National (All) National (dual)

Rationale

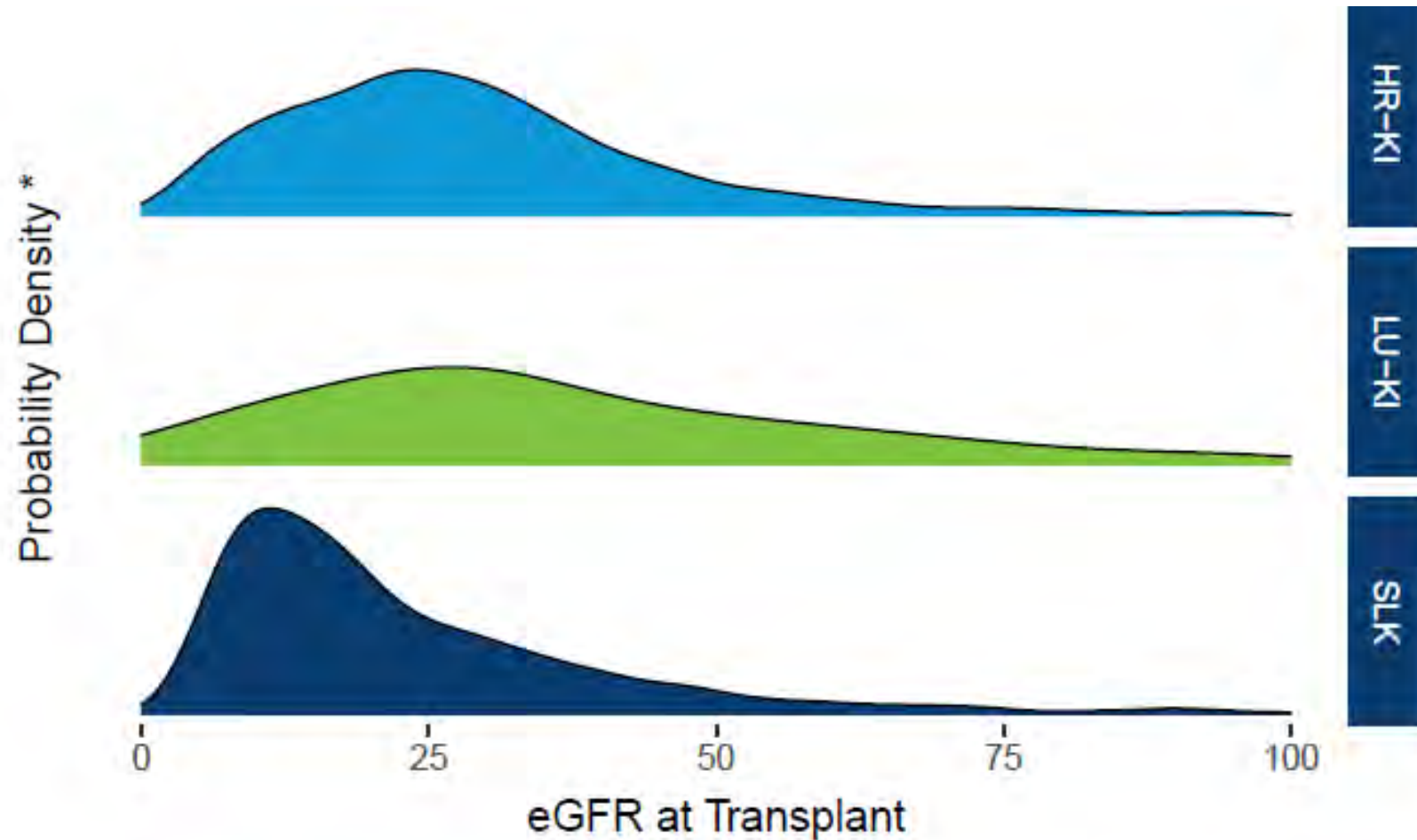
- Eligibility criteria based on kidney function that is consistent across multi-organ combinations is clinically appropriate and equitable
- Data on heart-kidney and lung-kidney transplantation support following the approach used for liver-kidney transplantation
- Safety net will “catch” patients who don’t meet eligibility criteria but need a kidney shortly after transplant
- Criteria can be adjusted as more data are gathered

SLK Transplants vs. Forecast Without Policy



Wilk et al. (2021) "Developing simultaneous liver-kidney transplant medical eligibility criteria while providing a safety net," *American Journal of Transplantation*

eGFR at Transplant - SHK and SLuK vs. SLK



August 10, 2017,
to May 31, 2021

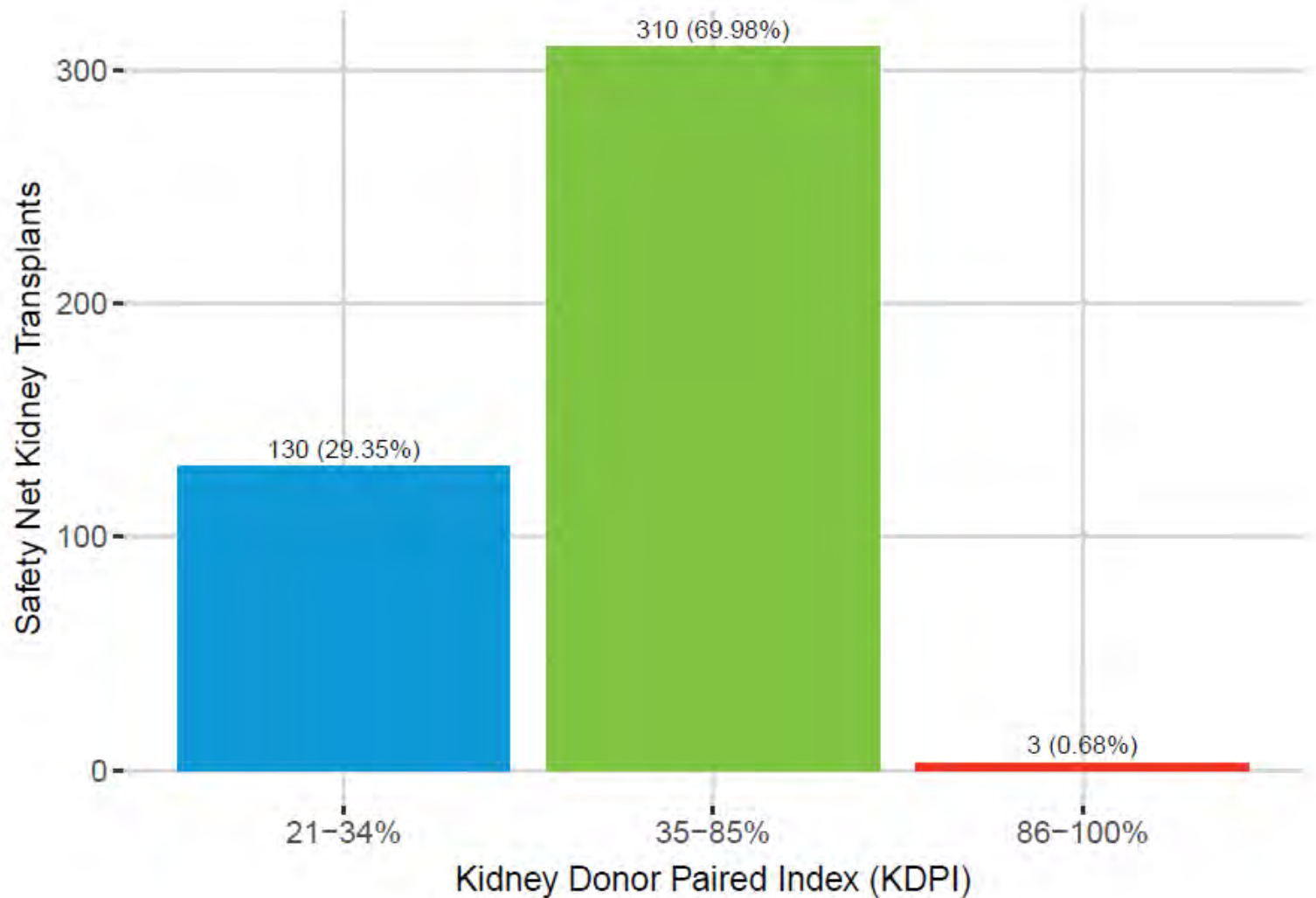
* High probability density values mean that a high percentage of the population lies at or around the corresponding x-axis value, and vice versa. 6 heart-kidney recipients, 1 lung-kidney recipient, and 50 liver-kidney recipients had an eGFR at transplant over 100.

Liver Safety Net Provides Good Kidney Offers

Median days between kidney registration and transplant:*

109 days

*Does not include safety net patients who did not receive a kidney (Wilk 2021)



Member Actions

- Transplant hospitals would need to submit additional data to indicate if candidates meet eligibility criteria or safety net priority
- OPOs would need to become familiar with changes to required shares, which would be displayed on match runs

What do you think?

- Is it appropriate to use eligibility criteria for heart-kidney and lung-kidney allocation similar to the criteria in use for liver-kidney allocation?
- For heart-kidney candidates with chronic kidney disease, is ≤ 30 mL/min the appropriate eGFR threshold for SHK?
- Should Status 4 heart candidates on dialysis be included in the SHK eligibility criteria?
- Is 500 nm from the donor hospital an appropriate distance threshold for heart-kidney allocation?