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

OPTN Ad Hoc Multi-Organ Transplantation Committee
MOT Committee Project Map

April 2021
- ExCom proposal – establish Ad Hoc MOT Committee

January 2022 Public Comment
- Eligibility criteria and safety net for heart-kidney and lung-kidney

January 2023 Public Comment
- Kidney/Pancreas CD
- Prioritization between kidney MOT and SOT candidates

August 2023 Public Comment
- Eligibility criteria and safety net for heart-lung, lung-liver, liver-heart

January 2024 Public Comment
- Match run prioritization for OPOs

August 2024 Public Comment
- MOT considerations for heart, VCA CD
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

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
<table>
<thead>
<tr>
<th>Conditions</th>
<th>Reporting Requirements</th>
</tr>
</thead>
</table>
| **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

<table>
<thead>
<tr>
<th>Sequence A</th>
<th>Sequence B</th>
<th>Sequence C</th>
<th>Sequence D</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>KDPI 0-20% (and en bloc)</strong></td>
<td><strong>KDPI 20-34%</strong></td>
<td><strong>KDPI 35-85%</strong></td>
<td><strong>KDPI 86-100%</strong></td>
</tr>
<tr>
<td>100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics</td>
<td>100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent</td>
<td>100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Pediatrics Inside Circle Medically Urgent</td>
<td>100% Highly Sensitized Inside Circle Medically Urgent 98%-99% Highly Sensitized 0-ABDRmm</td>
</tr>
<tr>
<td>98%-99% Highly Sensitized 0-ABDRmm Inside Circle Top 20% EPTS</td>
<td>98%-99% Highly Sensitized 0-ABDRmm</td>
<td>98%-99% Highly Sensitized 0-ABDRmm</td>
<td>Inside Circle Safety Net</td>
</tr>
<tr>
<td>0-ABDRmm (ALL) Inside Circle (All) National Pediatrics National (Top 20%) National (All)</td>
<td>Inside Circle Safety Net</td>
<td>Inside Circle Safety Net</td>
<td>Inside Circle (All) National (All) Inside Circle (dual) National (dual)</td>
</tr>
</tbody>
</table>

Inside Circle Safety Net

OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK
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

* 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.

August 10, 2017, to May 31, 2021
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?