# Final Report

OPTN Ad Hoc Multi-Organ Transplantation Committee

Descriptive Data Request

# Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation 6-Month Monitoring Report

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# **Executive Summary**

SHK and SLuK Registrations:

- 1. The proportion of multiple organ registrations among all registrations listed for a heart or lung decreased after implementation of the safety net policy.
- 2. Despite this decrease, the proportion of multiple organ registrations that met eligibility criteria for Simultaneous Heart Kidney (SHK) transplant increased post-policy, while that for Simultaneous Lung Kidney (SLuK) transplant remained similar post-policy. The primary reason for SHK eligibility was meeting the chronic kidney disease (CKD) subcriteria. The primary reason for SLuK eligibility will be revisited when sample size allows.
- 3. In both policy eras, the primary reason for removal from the waiting list for registrations ever listed for SHK and SLuK was deceased donor transplant.

Kidney-After-Heart and Kidney-After-Lung (Safety Net) Registrations:

- 4. The number of kidney-after-heart safety net registrations waiting at the end of each month increased over time. Trends for Kidney-After-Lung registrations will be revisited when sample size allows.
- 5. Removals for deceased donor transplant increased post-safety-net-policy for both Kidney-After-Heart and Kidney-After-Lung registrations.

Heart-Kidney, Lung-Kidney, and Safety Net Transplants:

- 6. The proportion of multi-organ transplants among all heart or lung transplants decreased post-policy. However, the proportion of transplants that met SHK or SLuK eligibility criteria at transplant increased post-policy. The majority of eligible heart-kidney and lung-kidney transplants qualified through the CKD subcriteria.
- 7. The distribution of heart statuses for SHK recipients remained similar pre- and post-policy. SLuK recipients tended to have higher CAS scores at transplant post-policy, although sample size is small.
- 8. The proportion of SHK recipients experiencing delayed graft function remained similar pre- and post-policy. No SLuK recipients experienced delayed graft function post-policy.
- 9. All kidney safety net recipients were eligible for safety net at the time of their transplant. The majority of these recipients did not experience delayed kidney graft function.
- 10. The proportion of kidneys being transplanted into heart or lung recipients remained similar pre- and post-policy.

# **Background/Purpose**

The OPTN implemented a policy to establish eligibility criteria for simultaneous heart-kidney and lung-kidney allocation and to create a safety net for kidney after heart and kidney after lung allocation. The OPTN previously established eligibility criteria and safety net policies for simultaneous liver-kidney allocation and through this policy sought to implement similar criteria for heart-kidney and lung-kidney candidates.

The Ad Hoc Multi-Organ Transplantation (MOT) Committee established eligibility criteria for simultaneous heart-kidney and lung-kidney allocation that adds requirements based on kidney function. The goal was to restrict required offers of multiple organs to candidates who have clinical justification to receive the kidney along with the heart or lung, thereby promoting access to transplantation for kidney-alone candidates. Additionally, the Committee established a "safety net," which gives some priority in kidney allocation to heart and lung recipients who meet medical criteria for a kidney transplant within one year of their heart or lung transplant. Taken together, the proposed eligibility criteria and safety net are intended to improve equity in transplant opportunities for multi-organ and single-organ candidates.

# Strategic Plan Goal or Committee Project Addressed

Increase equity in access to transplants

# **Committee Request**

The monitoring reports using pre vs. post comparisons will be presented to the Committee after approximately 6 months, 1 year and 2 years. Metrics include:

#### Waiting List:

- Volume of heart-kidney and lung-kidney registrations by eligibility criteria and subcriteria and heart status for heart-kidney registrations
- Waiting list mortality for heart-kidney and lung-kidney candidates who are eligible and not eligible for the kidney with the heart or lung
- Volume of kidney after heart and kidney after lung registrations (safety net) by eligibility criteria
- Waiting list mortality for heart and lung candidates that need a kidney following the thoracic transplant by safety net eligibility

#### Transplant:

- Volume of heart-kidney and lung-kidney transplants by eligibility criteria and subcriteria and heart status for heart-kidney transplants or lung composite allocation score for lung-kidney transplants
- Volume of kidney after heart and kidney after lung transplants (safety net) by eligibility criteria
- Percent of deceased donor kidneys being transplanted in heart and lung recipients
- Percent of recipients with delayed Kidney graft function for multi-organ transplants and safety net
- Kidney graft survival for kidney alone, heart-kidney and lung-kidney recipients
- Heart graft survival for heart alone and heart-kidney recipients
- Lung graft survival for lung alone and lung-kidney recipients

Due to the OPTN data lag or insufficient sample size, survival analyses and waiting list mortality rates were not available for the 6 month monitoring report. These analyses will be available in future monitoring iterations as data allow.

#### **Data Source**

OPTN data as of July 26, 2024 were used for this analysis. Candidate information was submitted through OPTN Waiting List and on the Transplant Candidate Registration (TCR) form. Recipient and transplant data were submitted on the Transplant Recipient Registration (TRR) form. Donor data were submitted in OPTN Donor Data and Matching System (Donornet) and on the Deceased Donor Registration (DDR) form. Data are subject to change based on future submission or correction.

#### Cohort

This six month monitoring report reviews the impact of the implementation of kidney after heart or lung safety net policy on June 29, 2023 and the implementation of the simultaneous heart-kidney (SHK) and simultaneous lung-kidney (SLuK) eligibility policy on September 28, 2023. Due to the differing implementation dates two different policy era cohorts are defined below for each policy.

The cohort used for percent of deceased donor kidney transplanted in kidney after thoracic recipients and SHK and SLuK recipients was defined based on whether the deceased donor kidney transplant date was between September 28, 2022 - June 28, 2023 (pre-policy) and June 29, 2023 - March 28, 2024 (post-policy).

#### Simultaneous Heart-Kidney and Simultaneous Lung-Kidney

When evaluating the impact of the SHK and SLuK eligibility policy this report includes cohorts of single and multiple organ registrations and transplants that include a registration or transplant for heart or lung. Heart-lung registrations and transplants are excluded from this analysis.

- Pre-Policy: March 29, 2023 to September 27, 2023
- Post-Policy: September 28, 2023 to March 28, 2024

OPTN Waiting List additions consist of heart or lung registrations listed between March 29, 2023 - September 27, 2023 (pre-policy) and September 28, 2023 - March 28, 2024 (post-policy). SHK and SLuK registration eligibility is based on eligibility at listing.

OPTN Waiting List removals consist of heart or lung registrations ever listed for an SHK or SLuK transplant removed between March 29, 2023 - September 27, 2023 (pre-policy) and September 28, 2023 - March 28, 2024 (post-policy). SHK and SLuK registration eligibility is based on eligibility at removal or transplant.

Transplant cohorts were defined based on deceased donor transplants between March 29, 2023 - September 27, 2023 (pre-policy) and September 28, 2023 - March 28, 2024 (post-policy).

#### Kidney after Lung or Heart Transplant Safety Net

When evaluating the impact of the kidney after lung or heart transplant safety net policies this report includes cohorts of kidney registrations or transplants who also received a heart or lung transplant and who were added to the kidney OPTN Waiting List prior to the one-year anniversary of their most recent heart or lung transplant date. They include both kidney registrations added prior to their heart or lung transplant as well as following their heart or lung transplant.

- Pre-Policy: September 28, 2022 to June 28, 2023
- Post-Policy: June 29, 2023 to March 28, 2024

The cohort consist of OPTN Waiting List kidney registrations ever waiting between September 28, 2022 - June 28, 2023 (pre-policy) and June 29, 2023 - March 28, 2024 (post-policy).

OPTN Waiting List removals consist of kidney registrations removed between September 28, 2022 - June 28, 2023 (pre-policy) and June 29, 2023 - March 28, 2024 (post-policy).

Transplant cohorts are defined based on deceased donor kidney transplants between June 29, 2023 - March 28, 2024 (post-policy). For the safety net policy the transplant cohort is evaluated in the post-policy era only.

#### Methods

Counts and percentages were used to summarize categorical variables or characteristics and stratified by thoracic organ of interest when appropriate and as sample size allowed.

Kidney delayed graft function (DGF) is defined as the need for dialysis within one week of kidney transplant.

#### Simultaneous Heart-Kidney and Simultaneous Lung-Kidney

Eligibility for SHK and SLuK differs based on the policy era.

**Heart:** Heart registration-level eligibility assumes that the transplant hospital was located at or within 500 nautical miles (NM) of the donor hospital. This assumption holds across both policy-eras. Eligibility for a SHK transplant is defined as follows:

• Pre-Policy (March 29, 2023 - September 27, 2023) - Heart status 1, 2, 3 or any active pediatric heart status and transplant hospital was located at or within 500 NM from the donor hospital.

• Post-Policy (September 28, 2023 - March 28, 2024) - Heart status 1, 2, 3, 4, 5 or any active pediatric heart status, the candidates met either of the kidney criteria out outlined in **Table 1** and transplant hospital was located at or within 500 NM from the donor hospital.

Table 1. Medical Eligibility Criteria for Heart-Kidney Allocation

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	At least one of the following:
measured or estimated glomerular filtration rate (GFR) less than or equal to 60 mL/min for greater than 90 consecutive days	<ul> <li>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.</li> <li>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.</li> <li>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.</li> </ul>
Sustained acute kidney injury	At least <i>one</i> of the following, or a combination of <i>both</i> 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 and a kidney from the same donor.

**Lung:** Lung registration-level eligibility based on Composite Allocation Score (CAS) is unable to be determined because CAS depends on the distance between the donor and transplant hospital, which varies by match run. Therefore, the eligibility of lung candidates on the OPTN Waiting List reported is solely based on kidney eligibility criteria in **Table 2**. However, eligibility for an SLuK transplant recipients is defined as follows:

- Pre-Policy (March 29, 2023 September 27, 2023) CAS of 25 or above
- Post-Policy (September 28, 2023 March 28, 2024) CAS of 25 or above or age at listing less than 18 years of age and also met either of the kidney criteria out outlined in **Table 2**.

Table 2. Medical Eligibility Criteria for Lung-Kidney Allocation

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	At least one of the following:
measured or estimated glomerular filtration rate (GFR) less than or equal to 60 mL/min for greater than 90 consecutive days	<ul> <li>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.</li> <li>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.</li> <li>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.</li> </ul>
Sustained acute kidney injury	At least <i>one</i> of the following, or a combination of <i>both</i> 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 lung and a kidney from the same donor.

#### Kidney after Lung or Heart Transplant Safety Net

Safety net eligibility for an kidney after lung or heart transplant implemented on June 29, 2023 is defined as follows: Prior heart or lung recipients would qualify for the safety net if they:

- Are registered on the kidney waiting list prior to the one year anniversary of their most recent heart or lung transplant
- Meet at least one of the following criteria on a date that is at least 60 days but not more than 365 days after the candidate's heart or lung transplant date:
  - Measured or estimated creatinine clearance or glomerular filtration rate less than or equal to 20  $\,$  mmL/min
  - On dialysis

As safety net eligibility can change over time, registration eligibility is shown based on snap shot data providing kidney after thoracic eligibility for any kidney after thoracic registrations waiting at the end of every month included within the monitoring time frame.

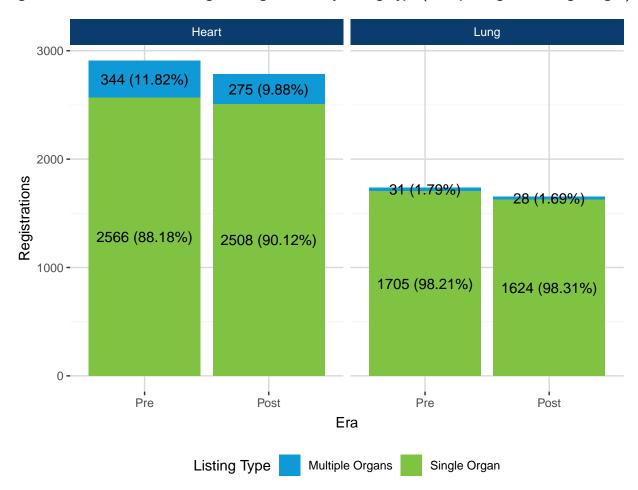
# **Results - OPTN Waiting List**

#### Heart-Kidney and Lung-Kidney Registrations March 29, 2023 to March 28, 2024

This section evaluates the characteristics and eligibility of multiple organ registrations at listing based on the multiple organ combination they were listed for during the pre-policy era from March 29, 2023 to September 27, 2023 and post-policy era from September 28, 2023 to March 28, 2024. All combinations contain either a heart or lung registration.

Figure 1 shows the proportion of thoracic OPTN Waiting List registration additions that were listed for multiple organs beyond a heart or a lung. The figure is stratified by thoracic organ. Overall the proportion of multiple organ registrations out of all registrations listed for a heart or lung decreased post-policy era.

Figure 1. Thoracic OPTN Waiting List Registrations by Listing Type (Multiple Organs vs. Single Organ)



The following tables (3-5) and figures (2-4) evaluate the characteristics and eligibility of heart-kidney registrations at listing stratified by those listed in the pre-policy era from March 29, 2023 to September 27, 2023 and those listed in the post-policy era from September 28, 2023 to March 28, 2024.

Figure 2 and Table 3 show the proportion of heart registrations by registration type. In the post-policy era the number and proportion of heart-kidney and heart other MOT combinations decreased.

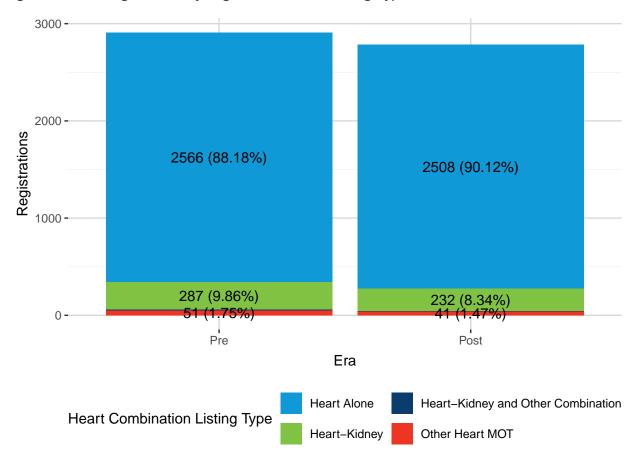


Figure 2. Heart Registrations by Organ Combination Listing Type

\*Heart combination listing types containing <1% of registrations were not labelled, but appear in the corresponding table.

Table 3. Heart Registrations by Organ Combination Listing Type

	Policy Era		
Organ Combination Listing Type	Pre	Post	
Heart Alone	2,566 (88.18%)	2,508 (90.12%)	
Heart-Kidney	287 (9.86%)	232 (8.34%)	
Heart-Kidney and Other Combination	6 (0.21%)	2 (0.07%)	
Other Heart MOT	51 (1.75%)	41 (1.47%)	
Total	2,910 (100.00%)	2,783 (100.00%)	

Figure 3 and Table 4 show all heart-kidney OPTN waiting list registrations based on whether the registration met eligibility criteria for an SHK transplant at listing. Eligibility criteria changed from pre- to post-policy as highlighted in the methods section above. Although there was a decrease in heart-kidney registrations in the post-policy era, the proportion of SHK eligible registrations increased by almost 40% in the post-policy era with the shift in eligibility criteria.

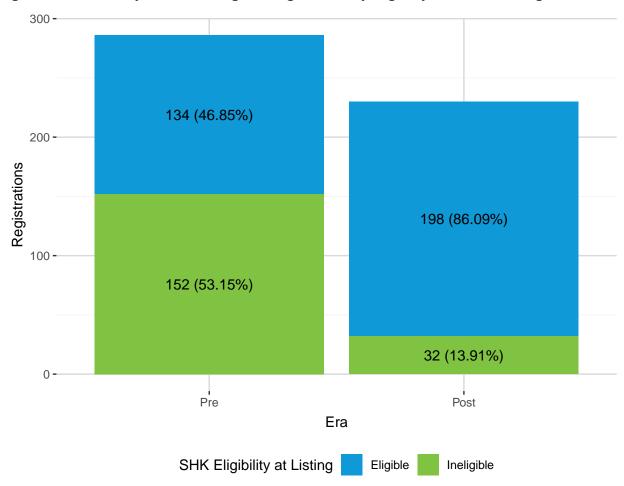


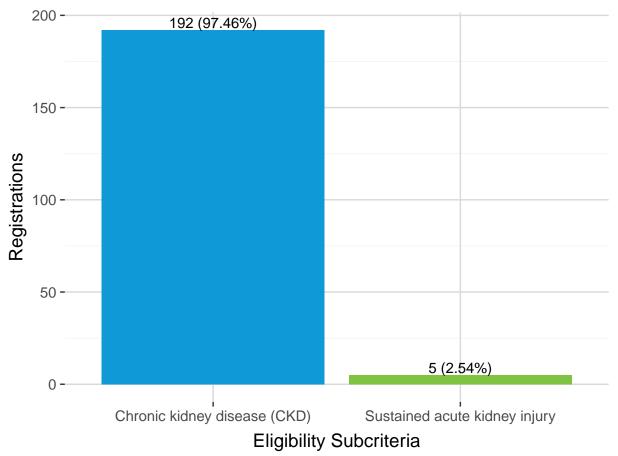
Figure 3. Heart-Kidney OPTN Waiting List Registrations by Eligibility Criteria At Listing

Table 4. Heart-Kidney OPTN Waiting List Registrations by Eligibility Criteria At Listing

	Policy Era		
SHK Eligibility at Listing	Pre	Post	
Eligible	134 (46.85%)	198 (86.09%)	
Ineligible	152 (53.15%)	32 (13.91%)	
Total	286 (100.00%)	230 (100.00%)	

Figure 4 and Table 5 show all heart-kidney OPTN Waiting List registrations that were eligible for SHK transplants at listing based on the kidney subcriteria met (**Table 1**) in the post-policy era. Almost all heart-kidney registrations in the post-policy era qualified for eligibility through the chronic kidney disease subcriteria.

Figure 4. Heart-Kidney Eligible Waiting List Registrations by Kidney Subcriteria in the Post-Policy Era



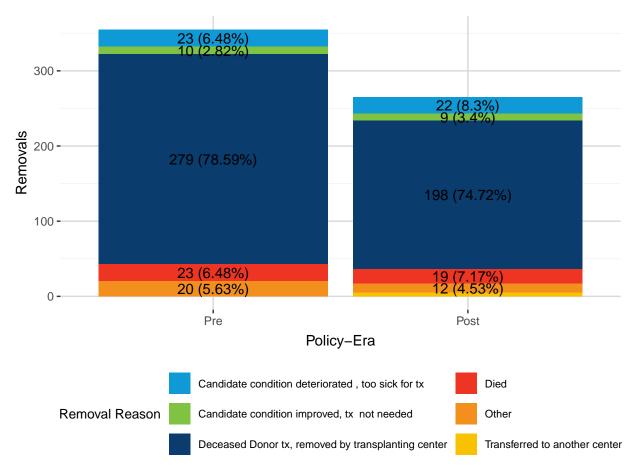
\*Pediatrics were not included due to small sample size

Table 5. Heart-Kidney Eligible Waiting List Registrations by Kidney Subcriteria in the Post-Policy Era

	Policy Era
SHK Eligibility Criteria	Post
Chronic kidney disease (CKD)	192 (96.97%)
Pediatric	1 (0.51%)
Sustained acute kidney injury	5 (2.53%)
Total	198 (100.00%)

Figure 5 and Table 6 below deviate from the cohorts above, containing registrations ever listed for a heart and kidney at the same time **removed** in the pre- and post-policy eras by removal reason. Removal reasons with less than 4 observations in an era were grouped into the "Other" removal reason for Figure 5 but are expanded upon in Table 6 below. In both eras the majority of ever heart-kidney registrations removed from the OPTN Waiting List were removed for the reason of deceased donor transplant. The proportion of ever heart-kidney registration removed for reasons of death or too sick increased slightly in the post-policy era.

Figure 5. OPTN Waiting List Removals by Removal Reason for Heart Registrations Ever Listed for Heart-Kidney



\*Removal reasons with <4 events were grouped into Other, but appear in the corresponding table.

Table 6. OPTN Waiting List Removals by Removal Reason for Heart Registrations Ever Listed for Heart-Kidney

	Policy Era	
Removal Reason	Pre	Post
Deceased Donor tx, removed by transplanting center Candidate condition deteriorated , too sick for tx Died Other Candidate condition improved, tx not needed	279 (78.59%) 23 (6.48%) 23 (6.48%) 12 (3.38%) 10 (2.82%)	198 (74.72%) 22 (8.30%) 19 (7.17%) 8 (3.02%) 9 (3.40%)
Transferred to another center Refused transplant Transplant at another center (multi-listed) Unable to contact candidate Patient died during TX procedure	3 (0.85%) 3 (0.85%) 2 (0.56%) 0 (0.00%) 0 (0.00%)	5 (1.89%) 0 (0.00%) 1 (0.38%) 2 (0.75%) 1 (0.38%)
Total	355 (100.00%)	265 (100.00%)

The following tables (7 & 8) and figures (6 & 7) evaluate the characteristics and eligibility of lung-kidney registrations at listing stratified by those listed in the pre-policy era from March 29, 2023 to September 27, 2023 and those listed in the post-policy era from September 28, 2023 to March 28, 2024.

Figure 6 and Table 7 show the proportion of lung registrations by registration type. In the post-policy era the number and proportion of lung-kidney registrations remained relatively consistent to what was seen in the pre-policy era.

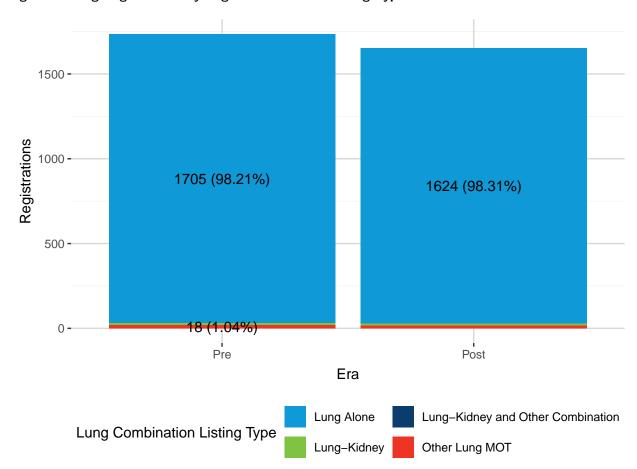


Figure 6. Lung Registrations by Organ Combination Listing Type

Table 7. Lung Registrations by Organ Combination Listing Type

	Policy Era		
Organ Combination Listing Type	Pre	Post	
Lung Alone	1,705 (98.21%)	1,624 (98.31%)	
Lung-Kidney	13 (0.75%)	12 (0.73%)	
Lung-Kidney and Other Combination	0 (0.00%)	1 (0.06%)	
Other Lung MOT	18 (1.04%)	15 (0.91%)	
Total	1,736 (100.00%)	1,652 (100.00%)	

<sup>\*</sup>Lung combination listings with <1% events were not labelled here, but appear in the corresponding table.

Figure 7 and Table 8 show all lung-kidney OPTN Waiting List registrations based on whether the registration met eligibility criteria for an SLuK at listing. Eligibility criteria changed from pre- to post-policy as highlighted in the methods section above. Pre-policy lung registration-level eligibility is unknown as eligibility is based solely on Composite Allocation Score (CAS) and is unable to be determined for registrations because CAS depends on the distance between the donor and transplant hospital, which varies by match run. Registration-level eligibility in the post-policy era assumes the registration has a CAS of 25 or above and is soley based on whether the registration meets kidney criteria highlighted in table 2. In the post-policy era, the majority of registrations were eligible for a SLuK transplant at listing assuming their CAS was 25 or above. Due to the small number of registrations the breakdown of the kidney subcriteria for eligible lung-kidney registrations is not shown.

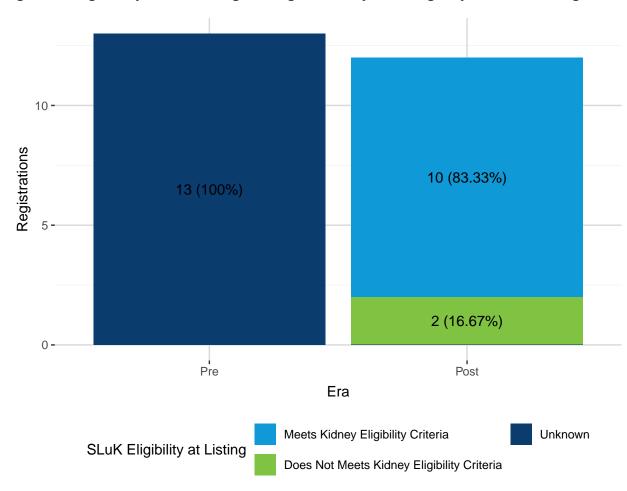
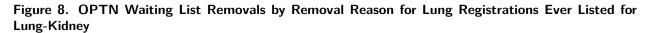


Figure 7. Lung-Kidney OPTN Waiting List Registrations by SLuK Eligibility Criteria at Listing

Table 8. Lung-Kidney Waiting List Registrations by SLuK Eligibility Criteria at Listing

	Policy Era		
SLuK Eligibility at Listing	Pre	Post	
Meets Kidney Eligibility Criteria	0 (0.00%)	10 (83.33%)	
Does Not Meets Kidney Eligibility Criteria	0 (0.00%)	2 (16.67%)	
Unknown	13 (100.00%)	0 (0.00%)	
Total	13 (100.00%)	12 (100.00%)	

Figure 8 and Table 9 below deviate from the cohorts above, containing registrations ever listed for a lung and kidney at the same time **removed** in the pre- and post-policy era by removal reason. In both eras the majority of ever lung-kidney registrations removed from the OPTN Waiting List were removed for the reason of deceased donor transplant. The number of ever lung-kidney registrations removed for reasons of death or too sick decreased in the post-policy era.



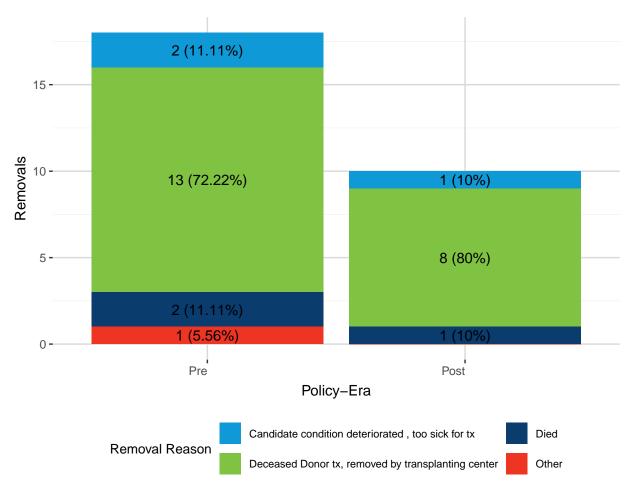


Table 9. OPTN Waiting List Removals by Removal Reason for Lung Registrations Ever Listed for Lung-Kidney

	Policy Era		
Removal Reason	Pre	Post	
Deceased Donor tx, removed by transplanting center Candidate condition deteriorated , too sick for tx Died Other Total	13 (72.22%) 2 (11.11%) 2 (11.11%) 1 (5.56%) 18 (100.00%)	8 (80.00%) 1 (10.00%) 1 (10.00%) 0 (0.00%) 10 (100.00%)	

# Kidney After Heart and Kidney After Lung Registrations (Safety Net)

This section contains information and trends on kidney registrations who have received a heart or lung transplant and were added to the kidney OPTN Waiting List prior to the one-year anniversary of their most recent heart or lung transplant date. It includes both kidney registrations added prior to their heart or lung transplant as well as following their heart or lung transplant. As safety net eligibility can change over time, registration eligibility is shown based on snap shot data providing kidney after thoracic eligibility for any kidney after thoracic registrations waiting at the end of every month included within the monitoring time frame for figures 9-11 and tables 10-12. Eligibility for the safety net policy as defined in the methods section above is shown for the post-policy eras. In order to show trends in registrations over time, that definition is applied to the pre- and post-policy era data below. It is critical to remember that prior to implementation of the safety net policy on June 29, 2023 the safety net option was not available. Thus, the information in the pre-policy section of the plots below reflect registrations that could have been eligible or ineligible for safety net had this policy been in place during that time.

Figure 9 and Table 10 provide the number of kidney after heart transplant registrations on the OPTN Waiting List at the end of each month based on their eligibility for a safety net transplant at that time. Kidney after lung transplant registration trends are not shown due to small sample size (a range of 0-3 total registrations were seen each month).

The number of kidney after heart registrations waiting at the end of each month increased over time, with the increase becoming much more significant following the implementation of the safety net policy on June 28, 2023 shown by the dotted line. The number of eligible candidates saw a similar trend. At the end of each month in the post-policy era, the number of eligible kidney after heart registrations on the OPTN Waiting List exceeded the number of ineligible registrations.

Figure 9. Kidney After Heart Transplant Registrations Waiting at the End of each Month by Safety Net Eligibility



Dotted line represents implemention of safety net policy for kidney after heart.

\*\*Pre-policy eligibility is based on whether registrations would have met the post-policy eligibility criteria

Table 10. Kidney After Heart Transplant Registrations Waiting at the End of each Month by Safety Net Eligibility

Month-Year	Eligible	Ineligible	Total
10-2022 11-2022	1 (20%) 1 (16.67%)	4 (80%) 5 (83.33%)	5 (100%) 6 (100%)
12-2022	3 (60%)	2 (40%)	5 (100%)
01-2023	2 (40%)	3 (60%)	5 (100%)
02-2023	2 (40%)	3 (60%)	5 (100%)
03-2023	2 (50%)	2 (50%)	4 (100%)
04-2023	2 (20%)	8 (80%)	10 (100%)
05-2023	2 (18.18%)	9 (81.82%)	11 (100%)
06-2023	6 (46.15%)	7 (53.85%)	13 (100%)
07-2023	9 (56.25%)	7 (43.75%)	16 (100%)
08-2023	11 (61.11%)	7 (38.89%)	18 (100%)
09-2023	14 (63.64%)	8 (36.36%)	22 (100%)
10-2023	13 (61.9%)	8 (38.1%)	21 (100%)
11-2023	15 (65.22%)	8 (34.78%)	23 (100%)
12-2023	18 (66.67%)	9 (33.33%)	27 (100%)
01-2024	22 (66.67%)	11 (33.33%)	33 (100%)
02-2024	25 (60.98%)	16 (39.02%)	41 (100%)
03-2024	33 (63.46%)	19 (36.54%)	52 (100%)

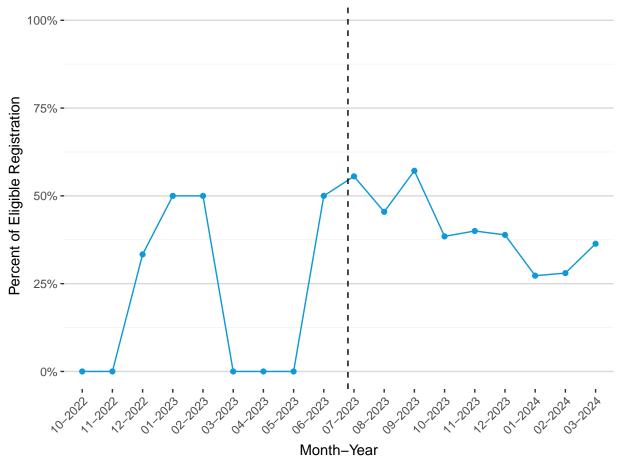
Figure 10, Figure 11 and Table 11 provide the proportion of eligible kidney after heart transplant registrations on the OPTN Waiting List at the end of each month based on safety net subcriteria. Due to the small number of kidney after lung transplant registrations the breakdown for eligibility subcriteria for those registrations is not provided at this time.

Kidney after heart registrations eligible for the safety net policy must meet at least one of the following criteria on a date that is at least 60 days but not more than 365 days after the candidate's heart transplant date:

- Measured or estimated creatinine clearance (CrCL) or glomerular filtration rate (eGFR) less than or equal to 20 mmL/min
- On dialysis

Figure 10 shows the proportion of eligible kidney after heart registrations on the OPTN Waiting List at the end of each month for those who qualify for the safety net through the dialysis subcriteria. After the implementation of the safety net policy, the proportion of eligible registrations on dialysis increased.

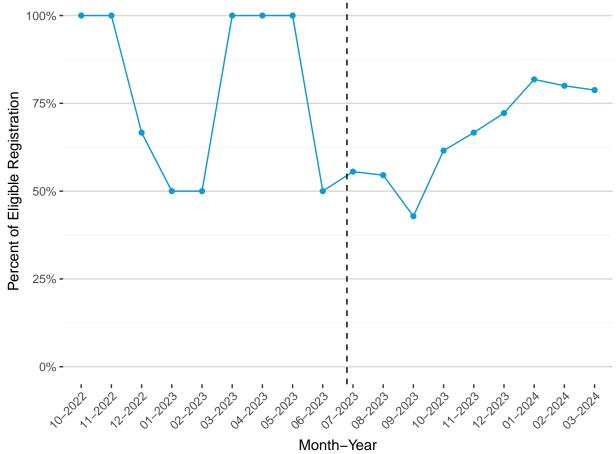
Figure 10. Percent of Eligible Kidney After Heart Registrations Waiting at the End of each Month On Dialysis



Dotted line represents implemention of safety net policy for kidney after heart transplants.

Figure 11 shows the proportion of eligible kidney after heart registrations on the OPTN Waiting List at the end of each month for those who qualify for the safety net through the CrCL or eGFR subcriteria. After the implementation of the safety net policy the proportion of eligible candidates waiting at the end of each month who qualified for the safety net policy through having eGFR or CrCL < 20 mmL/min has steadily climbed over time with a more consistent upward trend than observed in the pre-policy era.

Figure 11. Percent of Eligible Kidney After Heart Registrations Waiting at the End of each Month with eGFR <=20 mmL/min or CrCL <=20 mmL/min



Dotted line represents implemention of safety net policy for kidney after heart transplants.

Table 11 shows the proportion of eligible kidney after heart transplant registrations on the OPTN Waiting List at the end of each month based on the subcriteria they qualify through for the safety net policy. After implementation the greatest proportion of eligible candidates waiting at the end of each month most consistently qualified for the safety net through having an eGFR or  $CrCL \le 20$ .

Table 11. Eligible Kidney After Heart Registrations Waiting at the End of each Month by Safety Net Eligibility Criteria

	Heart			
Month-Year	Dialysis and eGFR or CrCL <=20 mmL/min	Dialysis	eGFR or CrCL <=20 mmL/min	Total Eligible
10-2022	0 (0%)	0 (0%)	1 (100%)	1 (100%)
11-2022	0 (0%)	0 (0%)	1 (100%)	1 (100%)
12-2022	0 (0%)	1 (33.33%)	2 (66.67%)	3 (100%)
01-2023	0 (0%)	1 (50%)	1 (50%)	2 (100%)
02-2023	0 (0%)	1 (50%)	1 (50%)	2 (100%)
03-2023	0 (0%)	0 (0%)	2 (100%)	2 (100%)
04-2023	0 (0%)	0 (0%)	2 (100%)	2 (100%)
05-2023	0 (0%)	0 (0%)	2 (100%)	2 (100%)
06-2023	0 (0%)	3 (50%)	3 (50%)	6 (100%)
07-2023	1 (11.11%)	4 (44.44%)	4 (44.44%)	9 (100%)
08-2023	0 (0%)	5 (45.45%)	6 (54.55%)	11 (100%)
09-2023	0 (0%)	8 (57.14%)	6 (42.86%)	14 (100%)
10-2023	0 (0%)	5 (38.46%)	8 (61.54%)	13 (100%)
11-2023	1 (6.67%)	5 (33.33%)	9 (60%)	15 (100%)
12-2023	2 (11.11%)	5 (27.78%)	11 (61.11%)	18 (100%)
01-2024	2 (9.09%)	4 (18.18%)	16 (72.73%)	22 (100%)
02-2024	2 (8%)	5 (20%)	18 (72%)	25 (100%)
03-2024	5 (15.15%)	7 (21.21%)	21 (63.64%)	33 (100%)

Table 12 shows the number of ineligible kidney after heart safety net registrations on the OPTN Waiting List at the end of each month based on the reason for ineligibility (whether it was due to the time frame constraint or not meeting qualifying subcriteria). Once again due to small numbers lung after kidney registrations are excluded at this time.

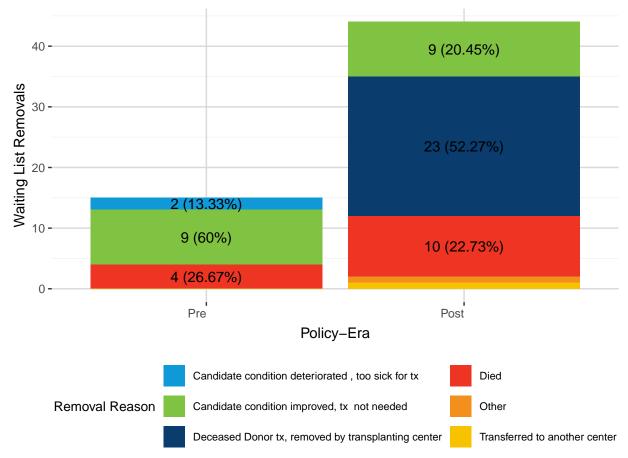
After the implementation of the policy up until February 2024, the majority of ineligible kidney after heart transplant candidates waiting at the end of each month were ineligible due to the fact that they did not meet the qualifying subcriteria, not due to the time frame constraints of the policy.

Table 12. Ineligible Kidney After Heart Transplant Registrations Waiting at the End of each Month by Ineligibility Reason

Policy Era	Month-Year	Ineligible	Ineligible (<60 Days since Thoracic Transplant)	Total
Pre	10-2022	2 (50%)	2 (50%)	4 (100%)
Pre	11-2022	3 (60%)	2 (40%)	5 (100%)
Pre	12-2022	2 (100%)	0 (0%)	2 (100%)
Pre	01-2023	2 (66.67%)	1 (33.33%)	3 (100%)
Pre	02-2023	2 (66.67%)	1 (33.33%)	3 (100%)
Pre	03-2023	2 (100%)	0 (0%)	2 (100%)
Pre	04-2023	4 (50%)	4 (50%)	8 (100%)
Pre	05-2023	5 (55.56%)	4 (44.44%)	9 (100%)
Post	06-2023	4 (57.14%)	3 (42.86%)	7 (100%)
Post	07-2023	4 (57.14%)	3 (42.86%)	7 (100%)
Post	08-2023	5 (71.43%)	2 (28.57%)	7 (100%)
Post	09-2023	5 (62.5%)	3 (37.5%)	8 (100%)
Post	10-2023	5 (62.5%)	3 (37.5%)	8 (100%)
Post	11-2023	7 (87.5%)	1 (12.5%)	8 (100%)
Post	12-2023	8 (88.89%)	1 (11.11%)	9 (100%)
Post	01-2024	8 (72.73%)	3 (27.27%)	11 (100%)
Post	02-2024	8 (50%)	8 (50%)	16 (100%)
Post	03-2024	9 (47.37%)	10 (52.63%)	19 (100%)

Figure 12 and Table 13 below deviate from the cohorts above, containing registrations for kidney after heart transplant **removed** in the pre- and post-policy by removal reason. Kidney after lung removals are not shown below due to the small sample size, however all four removals for kidney after lung registrations in the post-policy era were for deceased donor transplant. Heart saw an increase in kidney after registrations removed from the OPTN Waiting List in the post-policy era. This was largely driven by the increase in removals due to deceased donor transplants.

Figure 12. Kidney After Heart Transplant Registrations Removed from the OPTN Waiting List by Removal Reason



\*Removal Reasons with <5% events were not labelled here, but appear in the corresponding table.

Table 13. Kidney After Heart Transplant Registrations Removed from the OPTN Waiting List by Removal Reason

Removal Reason	Pre	Post
Deceased Donor tx, removed by transplanting center	0 (0.00%)	23 (52.27%)
Died	4 (26.67%)	10 (22.73%)
Candidate condition improved, tx not needed	9 (60.00%)	9 (20.45%)
Candidate condition deteriorated , too sick for tx	2 (13.33%)	0 (0.00%)
Other	0 (0.00%)	1 (2.27%)
Transferred to another center	0 (0.00%)	1 (2.27%)
Total	15 (100.00%)	44 (100.00%)

# **Results - Transplants**

# Heart-Kidney and Lung-Kidney Transplants

This section evaluates the characteristics and eligibility of multiple organ transplant based on the multiple organ combination they received during the pre-policy era from March 29, 2023 to September 27, 2023 and post-policy era from September 28, 2023 to March 28, 2024. All combinations contain either a heart or lung transplant.

Figure 13 shows the proportion of thoracic transplants that were MOT. The figure is stratified by thoracic organ. Overall the proportion of MOT out of all heart or lung transplants decreased post-policy.

Figure 13. Thoracic Transplants by Transplant Type (Multiple Organ vs. Single Organ)



The following tables (14-18) and figures (14-18) evaluate the characteristics and eligibility of heart MOT at transplant (with a focus on SHK transplants) stratified by those transplanted in the pre-policy era from March 29, 2023 to September 27, 2023 and those transplanted in the post-policy era from September 28, 2023 to March 28, 2024.

Figure 14 and Table 14 show the proportion of heart transplants by MOT type. In the post-policy era the number and proportion of heart-kidney and heart-kidney and other multiple organ transplants decreased.

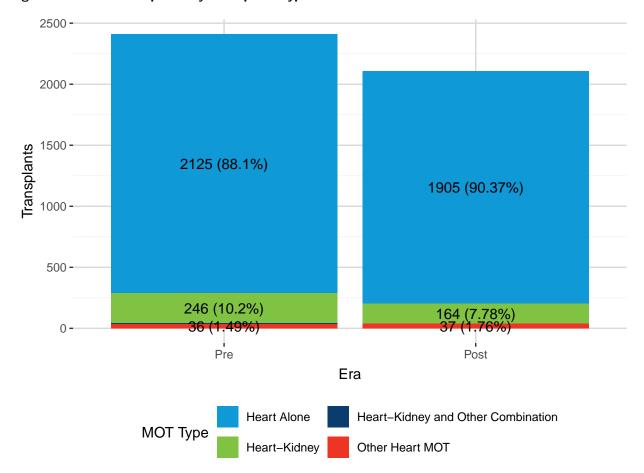


Figure 14. Heart Transplants by Transplant Type

Table 14. Heart Transplants by Transplant Type

	Policy Era	
Transplant Type	Pre	Post
Heart Alone	2,125 (88.10%)	1,905 (90.37%)
Heart-Kidney	246 (10.20%)	164 (7.78%)
Heart-Kidney and Other Combination	5 (0.21%)	2 (0.09%)
Other Heart MOT	36 (1.49%)	37 (1.76%)
Total	2,412 (100.00%)	2,108 (100.00%)

<sup>\*</sup>Heart MOT types containing <1% of transplants were not labelled, but appear in the corresponding table.

Figure 15 and Table 15 show all SHK transplants based on whether the recipient met eligibility criteria for an SHK transplant at transplant. Eligibility criteria changed from pre- to post-policy as highlighted in the methods section above. Although there was a decrease in SHK transplants in the post-policy era, the proportion of SHK recipients who were eligible at transplant increased by almost 13% post-policy with the shift in eligibility criteria.



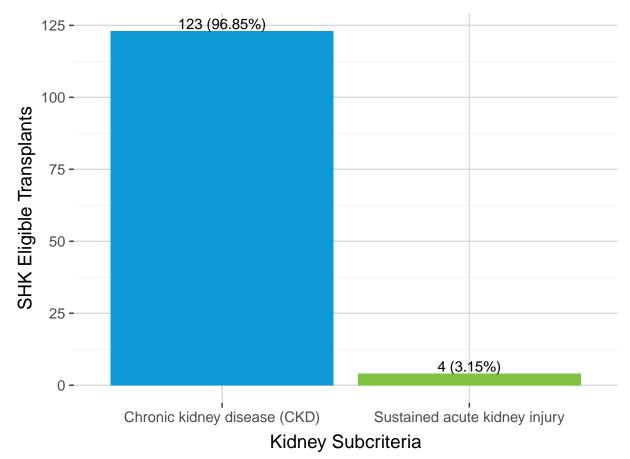
Figure 15. Heart-Kidney Transplants by Eligibility At Transplant

Table 15. Heart-Kidney Transplants by Eligibility At Transplant

	Policy Era		
SHK Eligibility at Transplant	Pre	Post	
Eligible	160 (65.04%)	128 (78.05%)	
Ineligible	86 (34.96%)	36 (21.95%)	
Total	246 (100.00%)	164 (100.00%)	

Figure 16 and Table 16 show all eligible SHK transplants based on the kidney subcriteria met (**Table 1**) in the post-policy era. Almost all eligible heart-kidney transplants in the post-policy era qualified through the chronic kidney disease subcriteria, similar to results seen with eligible SHK listings.

Figure 16. Heart-Kidney Eligible Transplants by Kidney Criteria At Transplant in the Post Era



\*Pediatric group is not shown here due to the small sample size.

Table 16. Heart-Kidney Eligible Transplants by Kidney Criteria At Transplant in the Post Era

SHK Eligibility Criteria at Transplant	Post-Policy Era
Chronic kidney disease (CKD) Sustained acute kidney injury	123 (96.85%) 4 (3.15%)
Total	127 (100.00%)

Figure 17 and Table 17 show all SHK transplants (eligible and ineligible) based the heart status of the candidates at transplant. Despite the decrease in SHK transplants, the distribution of heart statuses for SHK recipients at transplant remained consistent in the post-policy era.

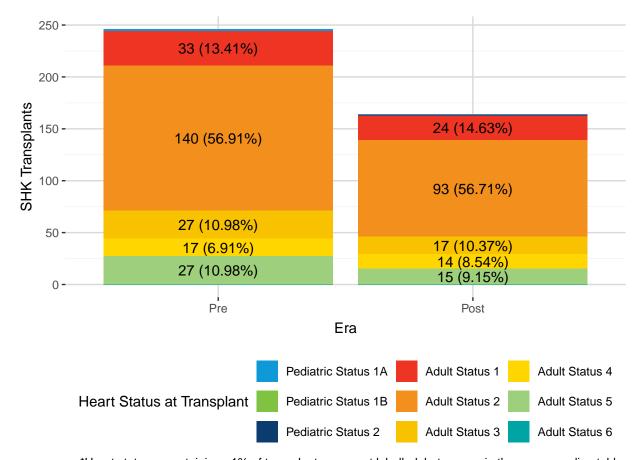


Figure 17. Heart-Kidney Transplants by Heart Status

\*Heart statuses containing <1% of transplants were not labelled, but appear in the corresponding table. No SHK transplants for recipients in pediatric statuses 1b or 2 or adult status 6 occurred in either policy era.

Table 17. Heart-Kidney Transplants by Heart Status

	Policy Era	
Heart Status at Transplant	Pre	Post
Pediatric Status 1A	2 (0.81%)	1 (0.61%)
Pediatric Status 1B	0 (0.00%)	0 (0.00%)
Pediatric Status 2	0 (0.00%)	0 (0.00%)
Adult Status 1	33 (13.41%)	24 (14.63%)
Adult Status 2	140 (56.91%)	93 (56.71%)
Adult Status 3	27 (10.98%)	17 (10.37%)
Adult Status 4	17 (6.91%)	14 (8.54%)
Adult Status 5	27 (10.98%)	15 (9.15%)
Adult Status 6	0 (0.00%)	0 (0.00%)
Total	246 (100.00%)	164 (100.00%)

Figure 18 and Table 18 show all SHK transplants (eligible and ineligible) based the event of delayed kidney graft function. The proportion of SHK recipients experiencing delayed kidney graft function remained consistent post-policy compared to pre-policy trends.

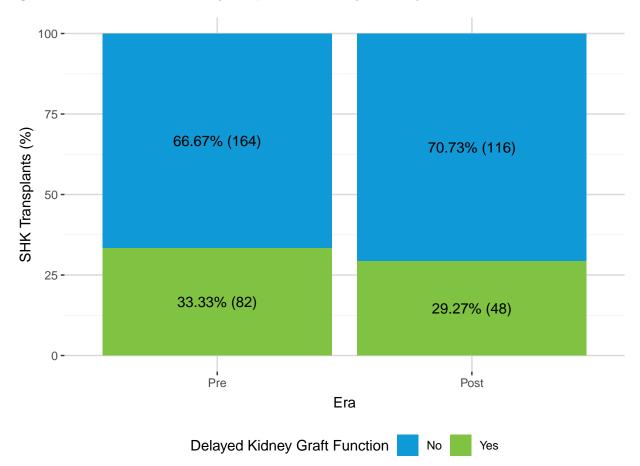


Figure 18. Percent of Heart-Kidney Recipients with Delayed Kidney Graft Function

Table 18. Percent of Heart-Kidney Recipients with Delayed Kidney Graft Function

	Policy Era	
Delayed Kidney Graft Function	Pre	Post
No	66.67% (164)	70.73% (116)
Yes	33.33% (82)	29.27% (48)
Total	100.00% (246)	100.00% (164)

<sup>\*</sup>Delayed kidney graft function is defined as the need for dialysis within one week of kidney transplant.

The following tables (19-22) and figures (19-22) evaluate the characteristics and eligibility of lung MOT recipients at transplant (with specific focus on SLuK transplants) stratified by those transplanted in the pre-policy era from March 29, 2023 to September 27, 2023 and those transplanted in the post-policy era from September 28, 2023 to March 28, 2024.

Figure 19 and Table 19 show the proportion of lung transplants by MOT type. In the post-policy era the number and proportion of all lung MOT types, with the exception of 'lung-kidney and other organ transplants', decreased.

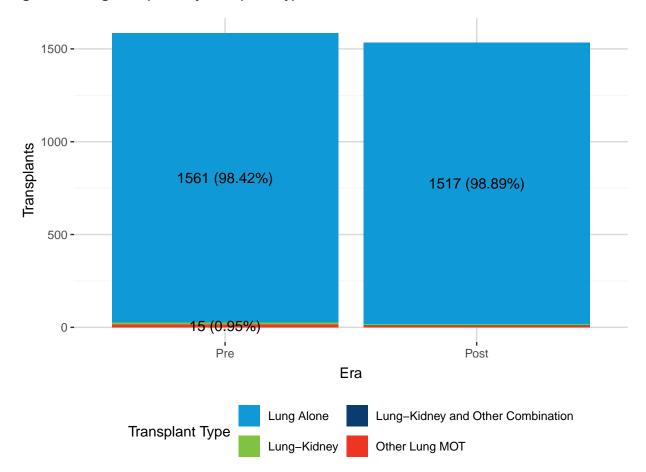


Figure 19. Lung Transplants by Transplant Type

Table 19. Lung Transplants by Transplant Type

	Policy Era	
Organ Combination Transplant	Pre	Post
Lung Alone Lung-Kidney Lung-Kidney and Other Combination Other Lung MOT Total	1,561 (98.42%) 10 (0.63%) 0 (0.00%) 15 (0.95%) 1,586 (100.00%)	1,517 (98.89%) 8 (0.52%) 1 (0.07%) 8 (0.52%) 1,534 (100.00%)

<sup>\*</sup>Lung transplant types containing <0.75% of transplants were not labelled, but appear in the corresponding table.

Figure 20 and Table 20 show all SLuK transplants based on whether the recipient met eligibility criteria for an SLuK transplant at the time of transplant. Eligibility criteria changed from pre- to post-policy as highlighted in the methods section above. Although there was a decrease in SLuK transplants, all SLuK recipients were eligible at transplant in the post-policy era. All but one SLuK recipient in the post-policy era was eligible for the SLuK transplant through the chronic kidney disease subcriteria outlined in **Table 2**.

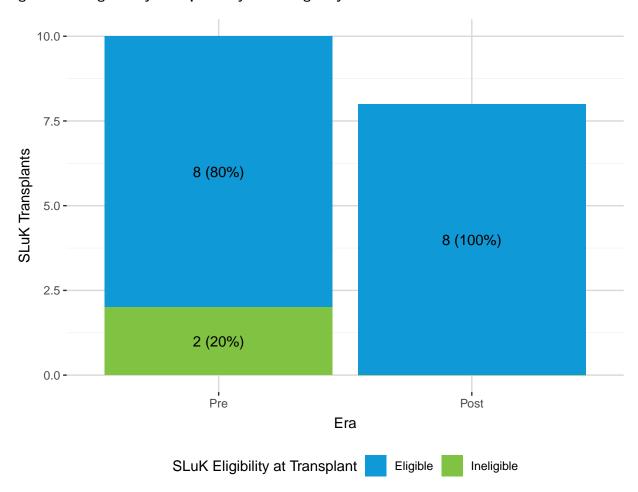


Figure 20. Lung-Kidney Transplants by SLuK Eligibility Criteria

Table 20. Lung-Kidney Transplants by SLuK Eligibility Criteria

	Policy Era	
SLuK Eligibility at Transplant	Pre	Post
Eligible	8 (80.00%)	8 (100.00%)
Ineligible	2 (20.00%)	0 (0.00%)
Total	10 (100.00%)	8 (100.00%)

Figure 21 and Table 21 show all SLuK transplants by lung CAS of recipients at transplant. SLuK recipients tended to have higher CAS at transplant post-policy, although due to small numbers firm conclusions are difficult to discern at this time.

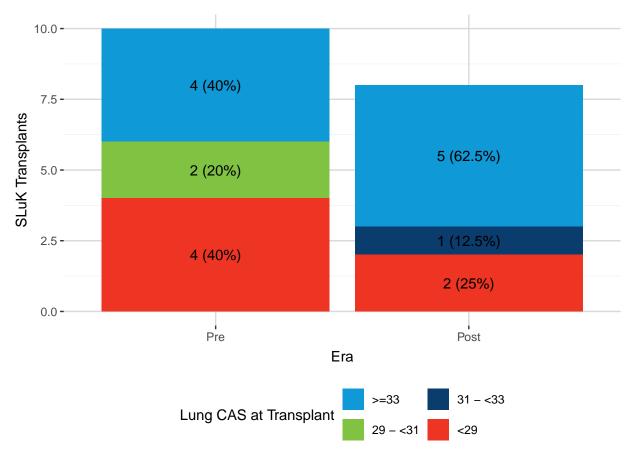


Figure 21. Lung-Kidney Transplants by Lung Composite Allocation Score

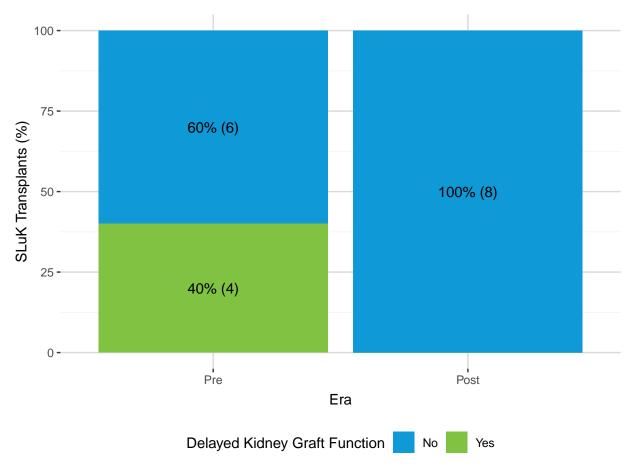
There were no SLuK transplants for recipients with CAS 31–<33 in the pre-policy era or CAS 29–<31 in the post-policy.

Table 21. Lung-Kidney Transplants by Lung Composite Allocation Score

	Policy Era	
SLuK Eligibility at Transplant	Pre	Post
>=33	4 (40.00%)	5 (62.50%)
29 - <31	2 (20.00%)	0 (0.00%)
31 - <33	0 (0.00%)	1 (12.50%)
<29	4 (40.00%)	2 (25.00%)
Total	10 (100.00%)	8 (100.00%)

Figure 22 and Table 22 show all SLuK transplants (eligible and ineligible) based the event of delayed kidney graft function. No SLuK recipients had delayed kidney graft function in the post-policy era.

Figure 22. Percent of Lung-Kidney Recipients with Delayed Kidney Graft Function



<sup>\*</sup>Delayed kidney graft function (DGF) is defined as the need for dialysis within one week of kidney transplant.

Table 22. Percent of Lung-Kidney Recipients with Delayed Kidney Graft Function

	Policy Era	
Delayed Kidney Graft Function	Pre	Post
No	60.00% (6)	100.00% (8)
Yes	40.00% (4)	0.00% (0)
Total	100.00% (10)	100.00% (8)

# **Kidney After Heart or Lung Transplants (Safety Net)**

This section evaluates the characteristics of kidney transplant recipients within one year of their heart or lung transplants and their safety net eligibility based on whether their kidney was transplanted during the post-policy era from June 29, 2023 to March 28, 2024. Eligibility for the safety net policy as defined in the methods section above is shown for the post-policy era. It is critical to remember that prior to implementation of the safety net policy on June 29, 2023 the safety net option was not available for those waiting in the pre-policy era. Two SHK recipients in the post-policy era who had previously received a heart alone transplants are excluded from the figures below as the allocation of their kidneys was driven primarily by their heart-kidney eligibility not kidney safety net eligibility. These transplants were included in the SHK transplant section above.

Figure 23 and Table 23 show the number of safety net transplants for kidney recipients who had previously received a heart or lung transplant in the year prior to their kidney transplant kidney transplant that occurred in the post-policy era by their eligibility for a safety net kidney. All kidney safety net transplants in the post-policy era were eligible for the safety net at time of transplant.

Figure 23. Kidney Transplants after Thoracic Transplants by Safety Net Eligibility Status in the Post-Policy Era

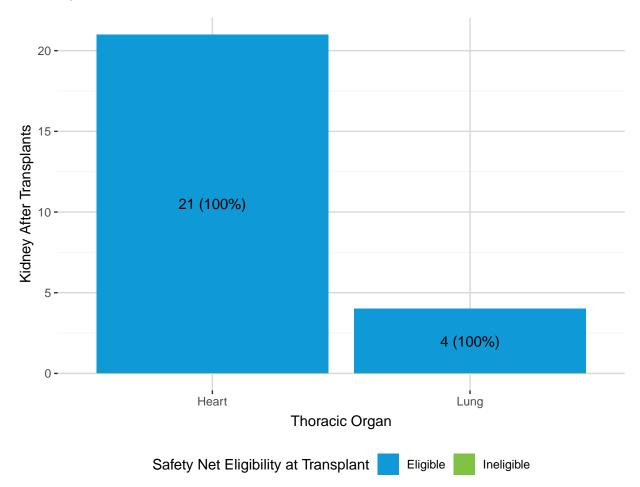
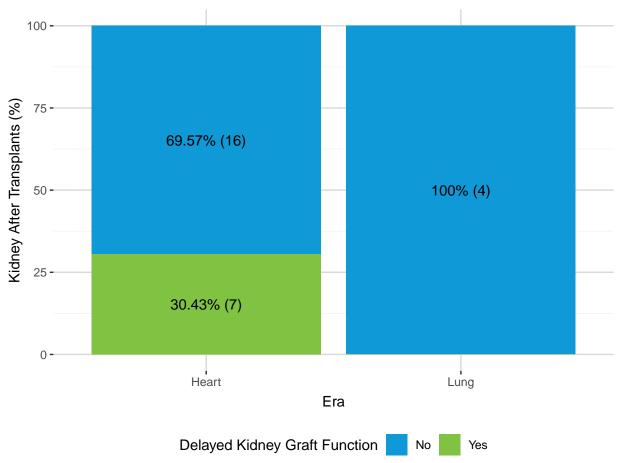


Table 23. Kidney Transplants after Thoracic Transplants by Safety Net Eligibility Status in the Post-Policy Era

	Thoracic Organ	
Safety Net Eligibility	Heart	Lung
Eligible	21 (100.00%)	4 (100.00%)
Ineligible	0 (0.00%)	0 (0.00%)
Total	21 (100.00%)	4 (100.00%)

Figure 24 and Table 24 show all kidney safety net transplants based on the event of delayed kidney graft function. The majority of kidney safety net transplants for recipients that received either heart or lung transplants in the year prior did not experience delayed kidney graft function.

Figure 24. Percent of Kidney Recipients After Thoracic Transplant with Delayed Kidney Graft Function by Thoracic Organ in the Post-Policy Era



<sup>\*</sup>Delayed kidney graft function is defined as the need for dialysis within one week of kidney transplant.

Table 24. Percent of Safety Net Recipients with Delayed Kidney Graft Function by Thoracic Organ in the Post-Policy Era

	Thoracic Organ	
Delayed Kidney Graft Function	Heart	Lung
No	16 (69.57%)	4 (100.00%)
Yes	7 (30.43%)	0 (0.00%)
Total	23 (100.00%)	4 (100.00%)

## **Kidney Deceased Donor Transplants**

Figure 25 and Table 25 show all deceased donor kidney transplants that occured in the pre-policy era from September 28, 2022 to June 28, 2023 and post-policy era from June 29, 2023 to March 28, 2024 based on whether the kidney transplant was a heart or lung safety net kidney transplant, simultaneous heart-kidney transplant, simultaneous lung-kidney transplant or another type of kidney transplant. The proportion of kidneys being transplanted into heart or lung recipients remained relatively consistent between pre- and post-policy eras.

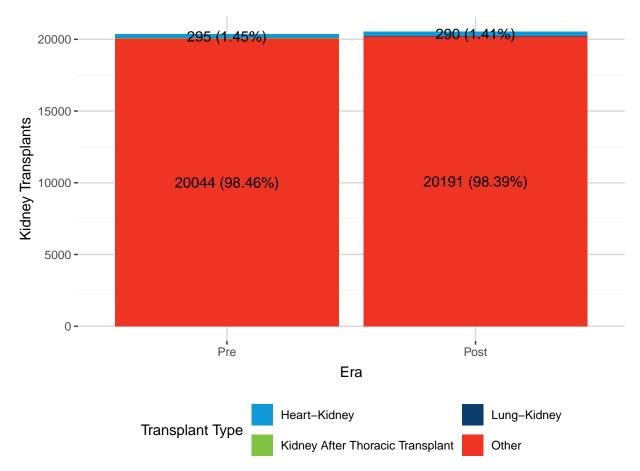


Figure 25. Percent of Kidneys being Transplanted in Heart and Lung Recipients

Table 25. Percent of Kidneys being Transplanted in Heart and Lung Recipients

	Policy Era	
Transplant Type	Pre	Post
Heart-Kidney	295 (1.45%)	290 (1.41%)
Kidney After Thoracic Transplant	0 (0.00%)	27 (0.13%)
Lung-Kidney	19 (0.09%)	14 (0.07%)
Other	20,044 (98.46%)	20,191 (98.39%)
Total	20,358 (100.00%)	20,522 (100.00%)

<sup>\*</sup>Transplant types containing <1% of transplants were not labelled, but appear in the corresponding table.