Final Report

OPTN Kidney Transplantation Committee

Descriptive Data Request

37

Allocation of Dual and En Bloc Kidneys Two Year Post-Implementation Monitoring Report

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Executive Summary

After policy implementation:

- There was a decrease in the number of dual kidney transplants performed overall, however transplant
 counts did increase in the last year of post policy implementation in comparison to the first year following
 implementation. (Figure 3 & Table 1).
- A higher proportion of dual kidney recipients were aged 65+ years (Figure 5 & Table 3).
- Cold ischemic time for dual kidney transplants decreased (Figure 8 & Table 6).
- One year graft and patient survival rates for dual kidney recipients decreased similar to the trends seen in single kidney recipients during the time but did not significantly differ from pre-policy graft and patient survival rates (Figure 10 & Table 8, Figure 11 & Table 9).
- Dual kidney grafts were rarely split and transplanted singly (**Table 13**).
- Just under half of dual kidneys were allocated out of single kidney classifications, rather than dual kidney (Table 15).
- The number of en bloc kidney transplants performed dropped in the first year of implementation but has since increased to pre-policy transplant levels (Table 16 & Figure 15).
- The proportion of en bloc kidney transplants for recipients aged 18-34 and 35-49 years notably increased, while it decreased for those aged 50-64 and 65+ years (**Figure 18**).
- The proportion of en bloc kidney transplants to recipients with EPTS 0-20% increased (Figure 19 & Table 20).
- One year graft and patient survival rates for en bloc kidney recipients did not significantly differ from pre-policy graft and patient survival rates (Figure 22 & Table 23, Figure 23 & Table 24).
- The proportion of donors weighing less than 18 kg with donations leading to En-Bloc transplants increased (**Figure 24**).

Background

Policies dictating the allocation of dual and en bloc kidneys were implemented on September 5, 2019. These policies were developed by the OPTN Kidney Transplantation Committee in order to increase utilization of high KDPI deceased donor kidneys. A summary of deceased donor kidney allocation, and how dual and en bloc kidney offers fit into it, is provided in **Figure 1** and **Figure 2**. The data in this report was collected before and after the removal of DSA and region from kidney allocation which was implemented on March 15, 2021, and Figure 1 reflects policy prior to this change and Figure 2 reflects the policy under circle allocation.

Donors with KDPI of at least 35% can be offered as dual. For donors with KDPI 35-85%, kidneys must be offered singly to all candidates on the match before being offered as dual. For donors with KDPI 86-100%, after being offered singly for mandatory national shares, kidneys are offered first singly then as dual at the local, regional, and national level at implementation. After March 15, 2022, KDPI 86-100% kidneys were offered singly then dual to candidates within 250 nautical miles of the donor hospital before being offered singly then dual to candidates more than 250 nautical miles away.

Any donor weighing less than 18 kilograms must first be offered as en bloc, following the same algorithm as donors with KDPI 0-20%, before kidneys from this donor may be offered singly. KDPI is masked from en bloc offers.

Centers must opt in at the registration level to receive offers for dual or en bloc kidneys. Once accepted, centers have the discretion to split dual or en bloc kidneys and transplant a single kidney into their patient. The remaining kidney must be reallocated according to released organ policy.

Figure 1: Summary of Deceased Donor Kidney Allocation Sequences Prior to March 15, 2021

Sequence A*	Sequence B	Sequence C	Sequence D
KDPI 0-20%	KDPI 21-34%	KDPI 35-85%	KDPI 86-100%
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 safety net
Local pediatrics	Local pediatrics	Local safety net	Local Single
Local top 20% EPTS	Local safety net	Local	Local Dual (Opt-in)
0-ABDRmm (all)	Local adults	Regional	Regional Single
Local (all)	Regional pediatrics	National	Regional Dual (Opt-in)
Regional pediatrics	Regional adults	Local Dual (Opt-in)	National Single
Regional (top 20%)	National pediatrics	Regional Dual (Opt-in)	National Dual (Opt-in)
Regional (all)	National adults	National Dual (Opt-in)	
National pediatrics			
National (top 20%)			
National (all)			

^{*}En Bloc is a replication of Sequence A for centers that have opted in to receive en bloc offers [Sequence E].

Figure 2: Summary of Deceased Donor Kidney Allocation Sequences Beginning March 15, 2021

Sequence A*	Sequence B	Sequence C	Sequence D
KDPI 0 – 20%	KDPI 21 – 34%	KDPI 35 – 85%	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 KAL Safety Net Inside Circle (All) National Pediatrics National (All)	100% Highly Sensitized Inside Circle Prior Living Donor Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ABDRmm Inside Circle KAL Safety Net Inside Circle (All) National (All) Inside Circle (dual) National (dual)	100% Highly Sensitized Inside Circle Medically Urgent 98% - 99% Highly Sensitized 0-ADBRmm Inside Circle KAL Safety Net Inside Circle Inside Circle (dual) National National (dual)

^{*}En Bloc [Sequence E] is a replication of Sequence A for candidates that have opted in to receive en bloc offers KDPI: Kidney Donor Profile Index, EPTS: Estimated Post-Transplant Kidney Survival, KAL: Kidney After Liver

Strategic Goal

Increase the number of transplants

Committee Request

In order to assess the effectiveness of the dual and en bloc kidney allocation policies, the Committee requested the following data be evaluated at six, twelve, and twenty-four months:

- Dual
 - The number (and percent) of transplants (single vs. dual), overall, and by select recipient and donor demographics.
 - How many kidneys allocated as dual are subsequently split, and if split, what happens to the second kidney (transplanted at same center, different center, or discarded)?
 - The number (and percent) of deceased donor kidney transplant programs performing dual transplants.
 - Descriptive statistics on cold ischemia of dual kidney transplants (and if split) pre- and post-policy implementation.
 - The number (and percent) of KDPI 85+ kidneys recovered that are utilized (single vs. dual) vs. discarded.
 - Survival outcomes (patient and graft)
- En Bloc
 - The number (and percent) of transplants (single vs. en-bloc), overall, and by both recipient and donor demographics, including but not limited to donor weight, KDPI (for singles), and recipient age.
 - How many kidneys allocated as en bloc are subsequently split?
 - The number (and percent) of deceased donor kidney transplant programs performing en-bloc transplants.
 - Descriptive statistics on cold ischemic time of kidneys transplanted en-bloc (and split).
 - The number (and percent) of kidneys recovered en-bloc that are utilized vs. discarded, overall and by demographics, including but not limited to donor age, donor weight, and KDPI (for singles).

Data and Methods

Data Sources:

This report uses data obtained from Waitlist, the Transplant Candidate Registration (TCR), the Transplant Recipient Registration (TRR), and the Deceased Donor Registration (DDR), as well as Potential Transplant Recipient (PTR) data.

Cohort:

To account for variation in volume due to the relatively small portion of deceased donor kidney transplants that are either dual or en bloc, trends in volume are presented in one year intervals from September 5, 2015 to September 4, 2021. Donor and recipient demographics are compared pre- and post-policy using the following cohorts:

- Pre-Policy: September 5, 2017 September 4, 2019
- Post-Policy: September 5, 2019 September 4, 2021

Data are current as of March 11, 2022 and are subject to change based on future submission or correction.

Analyses of donor potential and utilization are restricted to deceased donors who could be allocated as dual or en bloc under current policy, regardless of when the donor was recovered. That is, this report looks at changes in utilization for donors with KDPI 35-100% to examine the effects of the dual kidney policy and donors weighing less than 18 kilograms to examine the effects of the en bloc policy.

Utilization rate is defined as the ratio of the number of organs transplanted and the total possible number of organs recovered. Discard rate is defined as the ratio of the number of organs discarded and the number of organs recovered for the purpose of transplantation.

To assess opt-in practices, this report looks at a snapshot of active kidney registrations on the waiting list on the last day of each month in the post-policy period (September 2019 - August 2021). This report looks at dual and en bloc opt in at both the registration and center level.

Match run records were used to determine if kidneys were accepted out of a dual classification or en bloc match run but were split and transplanted separately. This does not necessarily mean the kidneys were recovered as dual or en bloc.

A one year unadjusted Kaplan Meier patient and graft survival analysis was performed for recipients transplanted between September 5, 2017 - December 31, 2020. The pre-policy cohort included recipients that received a single, dual, or en bloc kidney transplants from September 5, 2017 through September 4, 2019 and the post-policy cohort included recipients from September 5, 2019 through December 31, 2020. The cohort was limited to transplants before October 31, 2020 in order to allow sufficient time for complete follow up.

Results

Dual

Transplants

Figure 3 and **Table 1** show the number of dual kidney transplants performed from September 5, 2015 to September 4, 2021. While there was an increase in dual kidney transplants from September 2015 to September 2019, there was a decrease in volume in one-year post-policy period. During two-year pre-policy, 252 dual kidney transplants occurred, accounting for 0.83% of all deceased donor kidney transplants. For the two-year post-policy, 198 dual kidney transplants occurred, accounting for 0.55% of all deceased donor kidney transplants, a reduction of both percentage and volume compared to one-year pre-policy.

Figure 3: Dual Kidney Transplants, September 5, 2015 - September 4, 2021

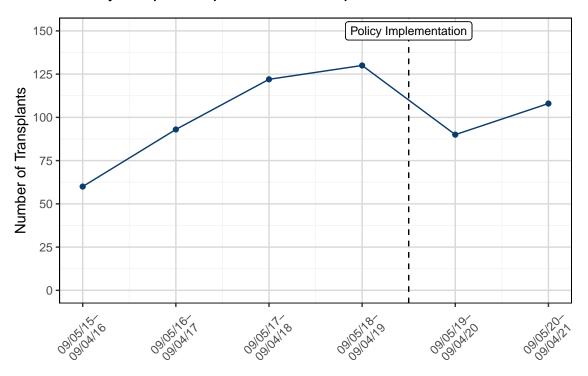


Table 1: Dual Kidney Transplants, March 5, 2015 - September 4, 2021

Date	DD KI Transplants	Dual Transplants	% Dual
09/05/15-09/04/16	12844	60	0.47
09/05/16-09/04/17	13993	93	0.66
09/05/17-09/04/18	14417	122	0.85
09/05/18-09/04/19	15900	130	0.82
09/05/19-09/04/20	17211	90	0.52
09/05/20-09/04/21	18784	108	0.57

Figure 4 and **Table 2** show dual kidney transplants from September 5, 2017 to September 4, 2021 by KDPI and policy era. Ten dual kidney transplants, two pre-policy and eight post-policy, utilized organs from donors with KDPI less than 35%. Lower count and proportion of dual kidney transplants utilized organs from donors with KDPI 35-85% in post-policy (131(52%) pre-policy to 78(39%) post-policy). The proportion of transplanted kidneys recovered from donors with KDPI 86-100% increased from 47% pre-policy to 57% post-policy, but a lower count in post-policy.

Figure 4: Dual Kidney Transplants by KDPI and Policy Era, September 5, 2017 - September 4, 2021

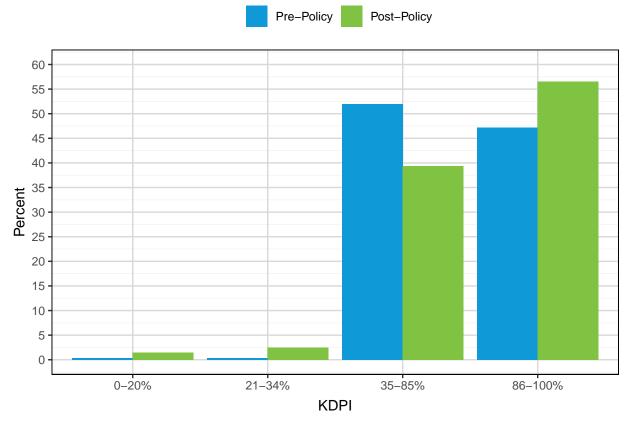


Table 2: Dual Kidney Transplants by KDPI and Policy Era, September 5, 2017 - September 4, 2021

	Pre-	Policy	Post	-Policy
KDPI	N	%	N	%
	IV	/0	IN	
0-20%	1	0.4	3	1.52
21-34%	1	0.4	5	2.53
35-85%	131	51.98	78	39.39
86-100%	119	47.22	112	56.57

Figure 5 and Table 3 show dual kidney transplants from September 5, 2017 - September 4, 2021 by recipient age at transplant and policy era. No dual kidney transplants were performed in recipients younger than 18 years old. The proportion of dual kidney transplants to recipients aged 18-34 and 35-49 years remained stable at around 2% and 6% post-policy respectively, whereas the proportion of dual kidney recipients aged 50-64 years decreased from 42% to 39%. The proportion of dual kidney recipients aged 65 years and older increased from 49% to 54% after policy implementation.

Figure 5: Dual Kidney Transplants by Recipient Age and Policy Era, September 5, 2017 - September 4, 2021

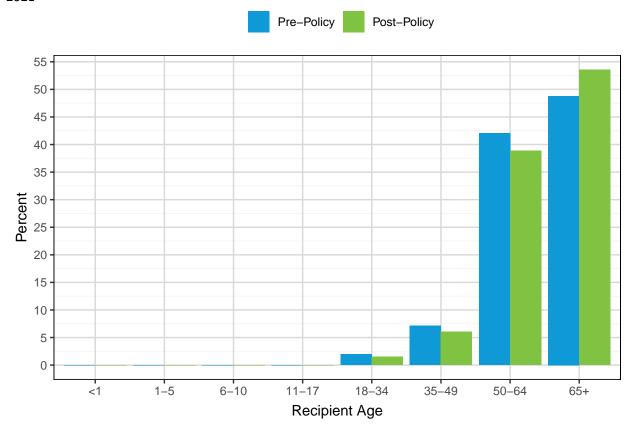


Table 3: Dual Kidney Transplants by Recipient Age and Policy Era, September 5, 2017 - September 4, 2021

	Pre-Policy		Post-	Policy
Recipient Age	N	%	N	%
<1	0	0	0	0
1-5	0	0	0	0
6-10	0	0	0	0
11-17	0	0	0	0
18-34	5	2	3	2
35-49	18	7	12	6
50-64	106	42	77	39
65+	123	49	106	54

Figure 6 and **Table 4** show dual kidney transplants from September 5, 2017 to September 4, 2021 by recipient EPTS at transplant and policy era. The proportion of dual kidney recipients with EPTS 0-20% at transplant remained stable at around 4-5% as well as those with with EPTS 21-100% at around 95-96% for both pre- and post-policy.

Figure 6: Dual Kidney Transplants by EPTS and Policy Era, September 5, 2017 - September 4, 2021

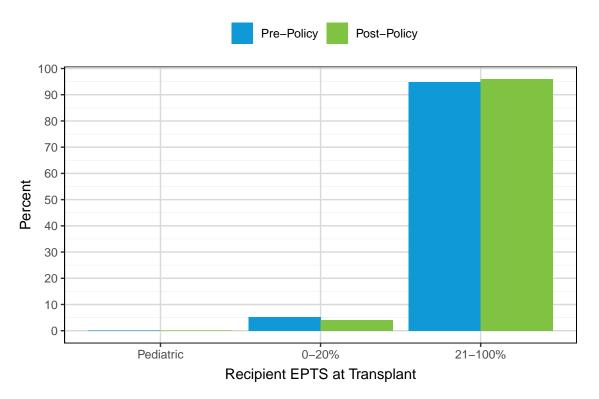


Table 4: Dual Kidney Transplants by EPTS and Policy Era, September 5, 2017 - September 4, 2021

	Pre-F	Policy	Post-Policy		
Recipient EPTS at Transplant	N	%	N	%	
Pediatric	0	0	0	0	
0-20%	13	5	8	4	
21-100%	239	95	190	96	

Figure 7 and **Table 5** show dual kidney transplants from September 5, 2017 - September 4, 2021 by CPRA at transplant and policy era. The majority (pre-policy: 74%, post-policy: 77%) of dual kidney transplants both pre- and post-policy went to recipients with CPRA 0% at transplant. There was a small decrease in proportion for recipients with CPRA 1-19% at transplant from 10% pre-policy to 8% post-policy. The proportion of recipients with CPRA 20-79% remained consistent from 13% pre-policy to 12% post-policy. The proportion of dual kidney transplants to highly sensitized recipients with CPRA 80%-97% and 98-100% did not change after policy implementation, remaining at around 2%.

Figure 7: Dual Kidney Transplants by CPRA and Policy Era, September 5, 2017 - September 4, 2021

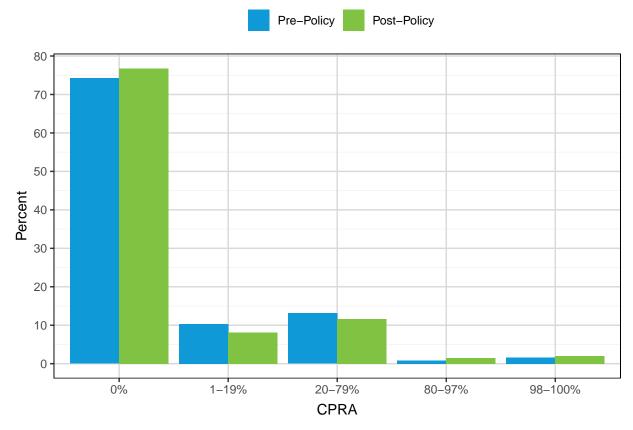


Table 5: Dual Kidney Transplants by CPRA and Policy Era, September 5, 2017 - September 4, 2021

	Pre-F	Pre-Policy		-Policy
CPRA	N	%	N	%
0%	187	74	152	77
1-19%	26	10	16	8
20-79%	33	13	23	12
80-97%	2	1	3	2
98-100%	4	2	4	2

Figure 8 and **Table 6** show the distribution of cold ischemic time for dual kidney transplants from September 5, 2017 - September 4, 2021 by policy era. There was a small decrease in cold ischemic time after policy implementation, with the median decreasing from around 22 hours pre-policy to around 20 hours post-policy.

Figure 8: Distribution of Cold Ischemic Time for Dual Kidney Transplants by Policy Era, September 5, 2017 - September 4, 2021

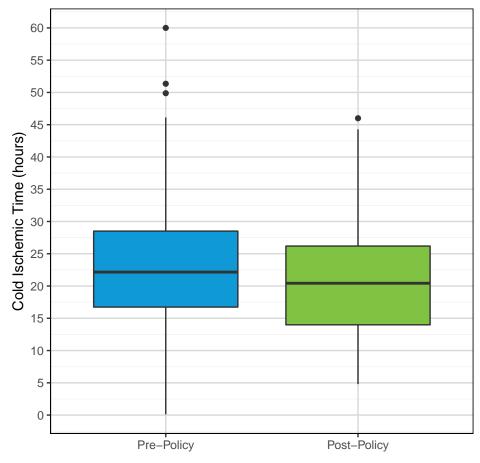


Table 6: Distribution of Cold Ischemic Time for Dual Kidney Transplants by Policy Era, September 5, 2017 - September 4, 2021

Era	N	Missing	Min	25th %-tile	Median	75th %-tile	Max
Pre-Policy Post-Policy		_	0.12 4.80	16.735 13.990	22.16 20.43	28.5100 26.1925	60 46

Figure 9 and **Table 7** show the distribution of cold ischemic time for single kidney transplants from September 5, 2017 - September 4, 2021 by policy era and KDPI above 35%. Cold ischemic time increased slightly for donors with KDPI 35%-85% from a median of about 17 hours in the pre-policy era to around 19 hours in the post-policy era. Whereas, for high KDPI 86%-100% median cold ischemic time decreased from around 20 hours pre-policy to around 18 hours post-policy. Overall, cold ischemic time increased slightly for all single kidney donors with KDPI above 35% in the post-policy.

Figure 9: Distribution of Cold Ischemic Time for Single Kidney Transplants by KDPI and Policy Era, September 5, 2017 - September 4, 2021

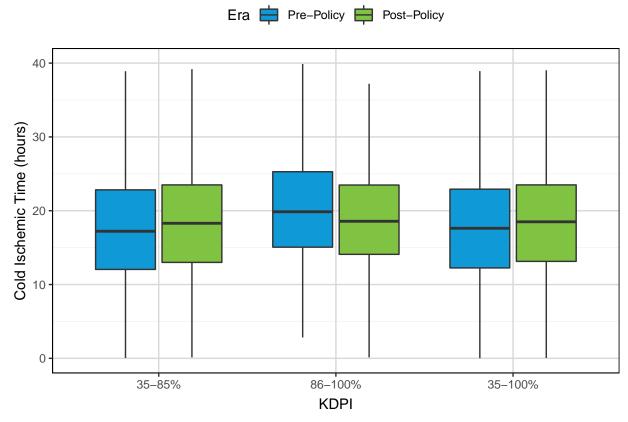


Table 7: Distribution of Cold Ischemic Time for Single Kidney Transplants by KDPI and Policy Era, September 5, 2017 - September 4, 2021

KDPI	Era	N	Missing	Min	25th %-tile	Median	75th %-tile	Max
35-85%	Pre-Policy	5167	15	0.05	12.20	17.42	23.20	93.62
	Post-Policy	6270	44	0.13	13.04	18.48	23.88	71.00
86-100%	Pre-Policy	531	2	2.83	15.18	20.28	25.87	47.73
	Post-Policy	694	6	0.13	14.19	18.65	23.78	55.00
35-100%	Pre-Policy	5620	16	0.02	12.38	17.93	23.35	70.08
	Post-Policy	7149	63	0.06	13.30	18.67	23.83	70.06

Post-Transplant Outcomes

Figure 10 and **Table 8** show the graft survival analysis for for single kidney and dual transplant recipients from September 5, 2017 to December 31, 2020. Both dual and single kidney transplant recipients saw a decrease in the estimate graft survival at 1 year post-transplant from pre to post policy. The decrease in post-transplant graft survival for dual kidney recipients from pre- to post-policy era was not statistically significant at one year post-transplant however.

Figure 10: One-Year Post-Transplant Graft Survival for Deceased Donor Kidney Transplants by Procedure Type and Policy Era, September 5, 2017 - December 31, 2020



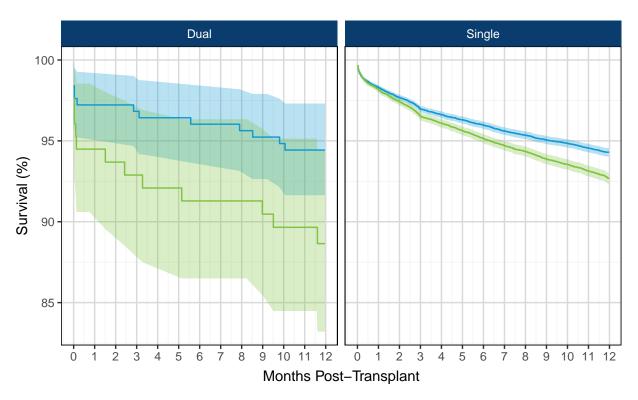
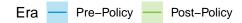


Table 8: One-Year Post-Transplant Graft Survival for Deceased Donor Kidney Transplants by Procedure Type and Policy Era, September 5, 2017 - December 31, 2020

		Pre-Policy		Post-Policy
Procedure	N	1-year Survival [95% CI]	N	1-year Survival [95% CI]
Dual Single	252 29668	94.43 [91.64, 97.31] 94.28 [94.01, 94.54]	127 22701	88.65 [83.20, 94.45] 92.66 [92.31, 93.00]

Figure 11 and **Table 9** show the patient survival analysis for for single kidney and dual transplant recipients from September 5, 2017 to December 31, 2020. Both dual and single kidney transplant recipients saw a decrease in the estimate patient survival at 1 year post-transplant from pre to post policy. The decrease in post-transplant patient survival for dual kidney recipients from pre- to post-policy era was not statistically significant at one year post-transplant however.

Figure 11: One-Year Post-Transplant Patient Survival for Deceased Donor Kidney Transplants by Procedure Type and Policy Era, September 5, 2017 - December 31, 2020



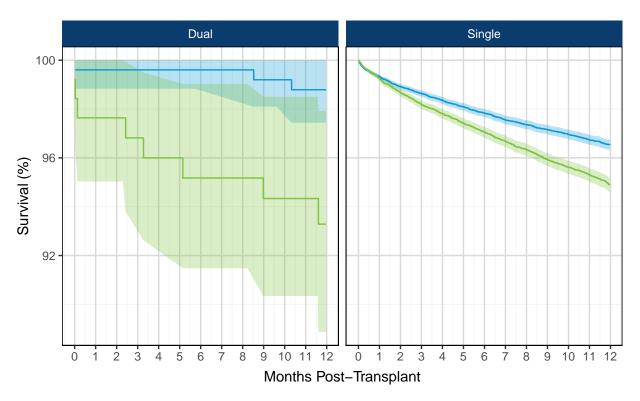


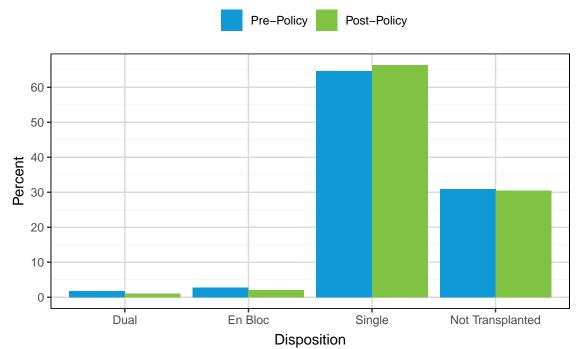
Table 9: One-Year Post-Transplant Patient Survival for Deceased Donor Kidney Transplants by Procedure Type and Policy Era, September 5, 2017 - December 31, 2020

	Pre-Policy			Post-Policy
Procedure	N	1-year Survival [95% CI]	N	1-year Survival [95% CI]
Dual Single	252 29668	98.79 [97.44, 100.00] 96.53 [96.32, 96.74]	127 22701	93.29 [88.87, 97.92] 94.88 [94.59, 95.18]

Donors

Figure 12 and **Table 10** show the data of 32197 of deceased donors with KPDI 35-100% recovered from September 5, 2017 - September 4, 2021 by disposition and policy era. There was a slight change in the proportion of these donors used in dual kidney and single kidney transplants (1.73% pre-policy to 1.07% post-policy and 76.39% pre-policy to 77.81% post-policy, respectively).

Figure 12: KDPI 35-100% Deceased Donors by Disposition and Policy Era, September 5, 2017 - September 4, 2021



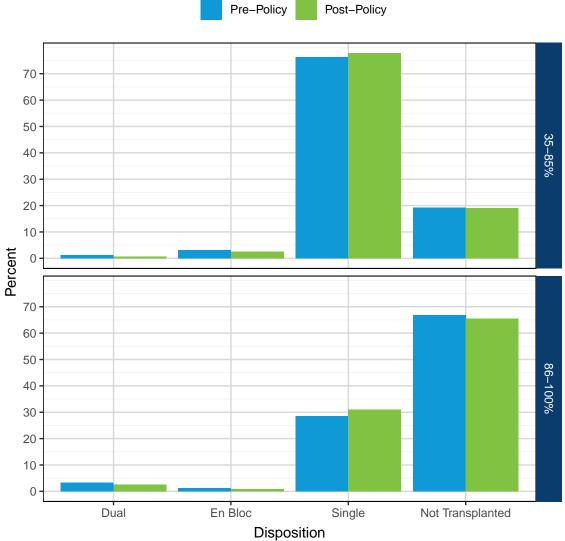
Note: Single implies at least one kidney was transplanted whereas not transplanted implies neither kidney was utilized.

Table 10: KDPI 35-100% Deceased Donors by KDPI, Disposition, and Policy Era, September 5, 2017 - September 4, 2021

		Pre-l	Pre-Policy		Policy
KDPI	Disposition	N	%	N	%
35-85% 86-100%	Dual En Bloc Single Not Transplanted Dual	131 346 8319 2094 119	1.2 3.18 76.39 19.23 3.37	78 339 10428 2557 112	0.58 2.53 77.81 19.08 2.56
35-100%	En Bloc Single Not Transplanted	46 1008 2358 250	1.3 28.55 66.78 1.73	41 1360 2861	0.94 31.09 65.41 1.07
33-100/0	En Bloc	392	2.72	380	2.14
	Single Not Transplanted	9327 4452	64.68 30.87	11788 5418	66.31 30.48

Figure 13 shows donor disposition stratified by KDPI. There was decrease in the proportion of KDPI 35-85% donors and KDPI 86-100% donors utilized in dual kidney transplants (1.2% pre-policy to 0.58% post-policy and 3.37% pre-policy to 2.56% post-policy, respectively).

Figure 13: KDPI 35-100% Deceased Donors by KDPI, Disposition, and Policy Era, September 5, 2017 - September 4, 2021



Note: Single implies at least one kidney was transplanted whereas not transplanted implies neither kidney was utilized.

Table 11 describes kidney utilization for KDPI 35-100% deceased donors recovered September 5, 2017 - September 4, 2021 by KDPI and policy era. There were minimal changes seen in discard (0.28 pre-policy to 0.31 post-policy) and utilization (0.64 in both eras) rate for KDPI 35-100% donors. Similar trends in results were observed for KDPI 35-85% and 86-100% deceased donors.

Table 11: Kidney Utilization for KDPI 35-100% Deceased Donors by KDPI and Policy Era, September 5, 2017 - September 4, 2021

KDPI	Era	N	N Recovered	N Transplanted	Discard Rate (95% CI)	Utilization Rate (95% CI)
35-85%	Pre-Policy	10890	20416	16438	0.19 (0.19-0.2)	0.75 (0.75-0.76)
	Post-Policy	13402	25659	20245	0.21 (0.21-0.22)	0.76 (0.75-0.76)
86-100%	Pre-Policy	3531	5229	1972	0.62 (0.61-0.64)	0.28 (0.27-0.29)
	Post-Policy	4374	7119	2493	0.65 (0.64-0.66)	0.28 (0.28-0.29)
35-100%	Pre-Policy	14421	25645	18410	0.28 (0.28-0.29)	0.64 (0.63-0.64)
	Post-Policy	17776	32778	22738	0.31 (0.3-0.31)	0.64 (0.63-0.64)

Center Opt In

Figure 14 and **Table 12** show monthly trends for center and registration opt in to receive dual kidney offers on the last day of the month post-policy implementation. At the end of August 2021, 157 centers had at least on registration opted in, accounting for 64.34% of centers with at least one active registration. 46.84% of all active kidney registrations had opted to receive dual kidney offers. Over this same twelve month period 46 centers performed dual kidney transplants, accounting for 19.41% of centers with at least one deceased donor kidney transplant.

Figure 14: Center and Registration Opt in to Receive Dual Kidney Offers on the Last Day of the Month, September 2019 - August 2021

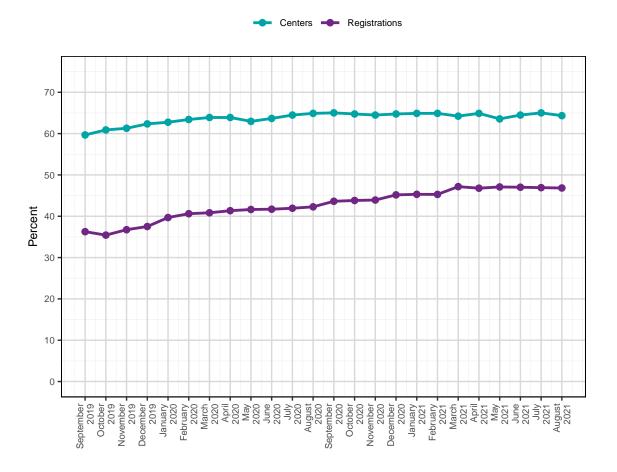


Table 12: Center and Registration Opt in to Receive Dual Kidney Offers on the Last Day of the Month, September 2019 - August 2021

	Centers		ſ	Registratio	ns	
Date	N	N Dual	% Dual	N	N Dual	% Dual
September 2019	248	148	59.68	65151	23626	36.26
October 2019	248	151	60.89	65393	23172	35.43
November 2019	248	152	61.29	65509	24071	36.74
December 2019	247	154	62.35	65340	24511	37.51
January 2020	247	155	62.75	64780	25707	39.68
February 2020	246	156	63.41	64267	26102	40.61
March 2020	241	154	63.9	61484	25109	40.84
April 2020	241	154	63.9	60990	25215	41.34
May 2020	243	153	62.96	61477	25594	41.63
June 2020	245	156	63.67	61195	25521	41.7
July 2020	245	158	64.49	60540	25387	41.93
August 2020	245	159	64.9	60117	25415	42.28
September 2020	243	158	65.02	59826	26098	43.62
October 2020	244	158	64.75	59587	26109	43.82
November 2020	245	158	64.49	59208	26007	43.92
December 2020	244	158	64.75	58699	26516	45.17
January 2021	245	159	64.9	57927	26246	45.31
February 2021	245	159	64.9	57494	26035	45.28
March 2021	246	158	64.23	57238	27000	47.17
April 2021	245	159	64.9	57083	26708	46.79
May 2021	247	157	63.56	57083	26881	47.09
June 2021	245	158	64.49	57037	26820	47.02
July 2021	243	158	65.02	56509	26515	46.92
August 2021	244	157	64.34	56242	26343	46.84

Splits

Table 13 shows dual kidney splits for match runs completed between September 5, 2017 and September 4, 2021. During this time, 16 donors were accepted for dual kidney transplants but later transplanted singly. For 12 of these donors, the second kidney was reallocated and transplanted to another candidate, six at the same center as the original acceptor and an additional six at the centers in same DSA. The other four were not transplanted.

Table 13: Dual Kidney Splits from September 5, 2017 - September 4, 2021

	Ν
Splits	16
Not Transplanted	4
Transplanted in the Same DSA	12
Transplanted at the Same Center	6

Table 14 shows cold ischemic time for dual kidneys recovered September 5, 2017 to September 4, 2021 that were eventually split by acceptor. Median cold ischemic time was around 25 hours for the original acceptor and around 24 hours for the recipient of the reallocated kidney.

Table 14: Cold Ischemic Time for Split Dual Kidney Grafts by Acceptor, September 5, 2017 - September 4, 2021

Acceptor	Median CIT
Original	25.55
Reallocation	24.61

Classifications

Table 15 shows the dual kidney transplants by match run classification for transplants between September 5, 2017 to September 4, 2021. Almost half (44%) of dual kidney transplants were allocated off of a single kidney classification.

Table 15: Dual Kidney Transplants by Classification, September 5, 2017 - September 4, 2021

Classification	N	%
Dual	110	55.56
Single	88	44.44

En Bloc

Transplants

Figure 15 and **Table 16** show the number of en bloc kidney transplants performed from September 5, 2015 to September 4, 2021. From September 2016 to September 2017, roughly 190 en bloc kidney transplants occurred every year. In the year preceding policy implementation, the number of en bloc kidney transplants rose to 210, accounting for 1.32% of all deceased donor kidney transplants that occurred during that time. This dropped to 178 in one year after policy implementation, accounting for 1.03% of all deceased donor kidney transplants that occurred during that time. En bloc kidney transplants have since rose again to 208, 1.11% of all deceased donor kidney transplants between September 2020 to September 2021.

Figure 15: En Bloc Kidney Transplants, March 5, 2015 - September 4, 2021

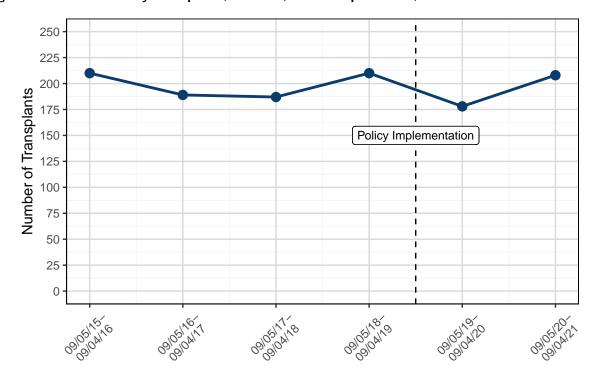


Table 16: En Bloc Kidney Transplants, March 5, 2015 - September 4, 2021

Date	DD KI Transplants	En Bloc Transplants	% En Bloc
09/05/15-09/04/16	12844	210	1.64
09/05/16-09/04/17	13993	189	1.35
09/05/17-09/04/18	14417	187	1.30
09/05/18-09/04/19	15900	210	1.32
09/05/19-09/04/20	17211	178	1.03
09/05/20-09/04/21	18784	208	1.11

Figure 16 and **Table 17** show en bloc kidney transplants from September 5, 2017 to September 4, 2021 by KDPI and policy era. Eleven en bloc kidney transplants, five pre-policy and six post-policy, utilized organs from donors with KDPI less than 35%. Post-policy, there was no change in the count and proportion of en bloc kidney transplants utilized organs from donors with KDPI 35-85% (87.15% pre-policy to 87.82% post-policy) as well as donors with KDPI 86-100% (11.59% pre- to 10.62% post-policy).

Figure 16: En Bloc Kidney Transplants by KDPI and Policy Era, September 5, 2017 - September 4, 2021

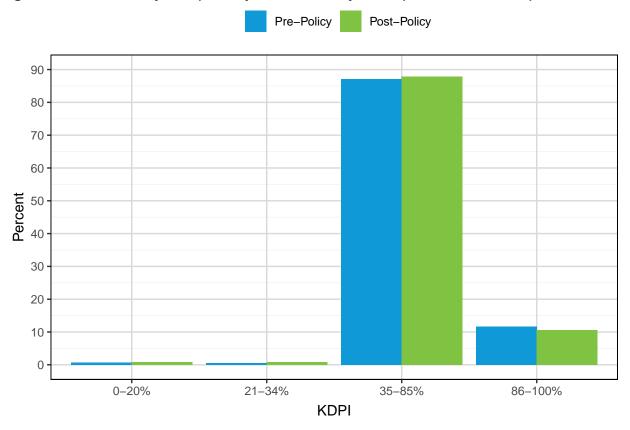
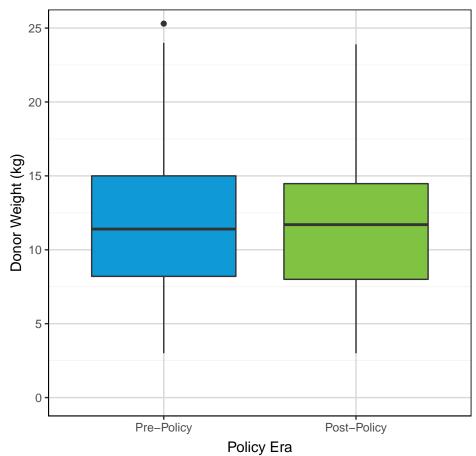


Table 17: En Bloc Kidney Transplants by KDPI and Policy Era, September 5, 2017 - September 4, 2021

	Pre-	Pre-Policy		-Policy
KDPI	N	%	N	%
0-20%	3	0.76	3	0.78
21-34%	2	0.5	3	0.78
35-85%	346	87.15	339	87.82
86-100%	46	11.59	41	10.62

Figure 17 and **Table 18** show the distribution of donor weight in kilograms for en bloc kidney transplants performed between September 5, 2017 and September 4, 2021. The median donor weight did not change post-implementation (11.4 kg for pre-policy and 11.7 for post-policy).

Figure 17: Distribution of Donor Weight for En Bloc Kidney Transplants by Policy Era, September 5, 2017 - September 4, 2021



Note: View restricted to donor weight < 25 kg

Table 18: Distribution of Donor Weight for En Bloc Kidney Transplants by Policy Era, September 5, 2017 - September 4, 2021

Era	N	Missing	Min	25th %-tile	Median	75th %-tile	Max
Pre-Policy	397	0	3	8.2	11.4	15.000	137.0
Post-Policy	386	0	3	8.0	11.7	14.475	93.7

Figure 18 and Table 19 show en bloc kidney transplants performed between September 5, 2017 and September 4, 2021 by recipient age at transplant and policy era. The proportion for en bloc transplants to recipients aged 1-5 years remained stable (0.76% pre-policy to 1.04% post-policy). Similarly, there was a small increase for recipients aged 6-10 years (0% pre-policy to 0.52% post-policy), although this change of was attributed to two transplants. There was a large increase in the proportion of en bloc transplants to recipients aged 18-34 and 35-49 years, growing from 14.11% and 23.93% pre-policy to 40.16% and 36.53% post-policy, respectively. The contrary happened for those aged 50-64 and 65+ years, decreasing from 40.55% and 20.4% pre-policy to 16.58% and 4.92% post-policy, respectively.

Figure 18: En Bloc Kidney Transplants by Recipient Age and Policy Era, September 5, 2017 - September 4, 2021

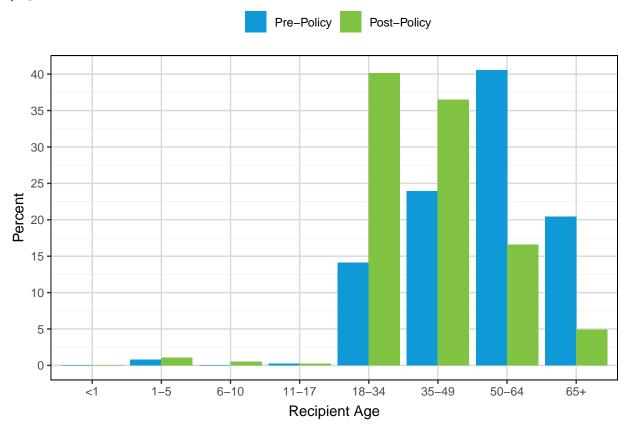


Table 19: En Bloc Kidney Transplants by Recipient Age and Policy Era, September 5, 2017 - September 4, 2021

	Pre-	Pre-Policy		-Policy
Recipient Age	N	%	N	%
<1	0	0	0	0
1-5	3	0.76	4	1.04
6-10	0	0	2	0.52
11-17	1	0.25	1	0.26
18-34	56	14.11	155	40.16
35-49	95	23.93	141	36.53
50-64	161	40.55	64	16.58
65+	81	20.4	19	4.92

Figure 19 and **Table 20** show en bloc kidney transplants performed between September 5, 2017 and September 4, 2021 by recipient EPTS at transplant and policy era. The proportion of en bloc kidney transplants to recipients with EPTS 0-20% significantly increased from 26% pre-policy to 77% post-policy. On the other hand, the proportion for en bloc transplant recipients with EPTS 21-100% decreased from 73% pre-policy to 21% post-policy.

Figure 19: En Bloc Kidney Transplants by EPTS and Policy Era, September 5, 2017 - September 4, 2021

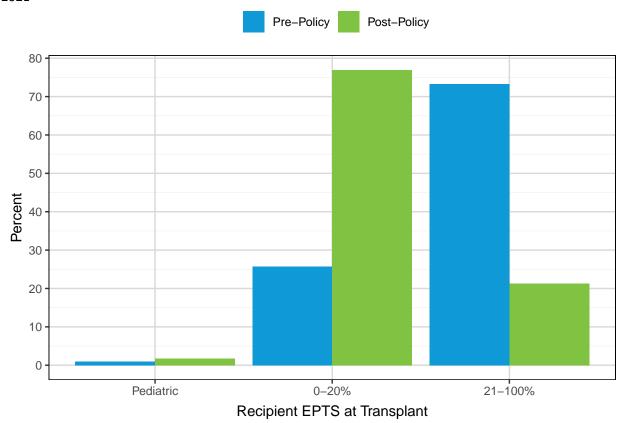


Table 20: En Bloc Kidney Transplants by EPTS and Policy Era, September 5, 2017 - September 4, 2021

	Pre-Policy		Post-	Policy
EPTS	N	%	N	%
Pediatric	4	1	7	2
0-20%	102	26	297	77
21-100%	291	73	82	21

Figure 20 and Table 21 show en bloc kidney transplants from September 5, 2017 to September 4, 2021 by CPRA at transplant and policy era. The majority of en bloc kidney transplants both pre- (63%) and post-policy (71%) went to recipients with CPRA 0% at transplant. The proportion for recipients with a CPRA 80-97% decreased from 10% pre-policy to 4% post-policy. The proportion of en bloc kidney transplants to highly sensitized recipients (CPRA 98-100%) increased slightly from 2% pre-policy to 3% post-policy.

Figure 20: En Bloc Kidney Transplants by CPRA and Policy Era, September 5, 2017 - September 4, 2021

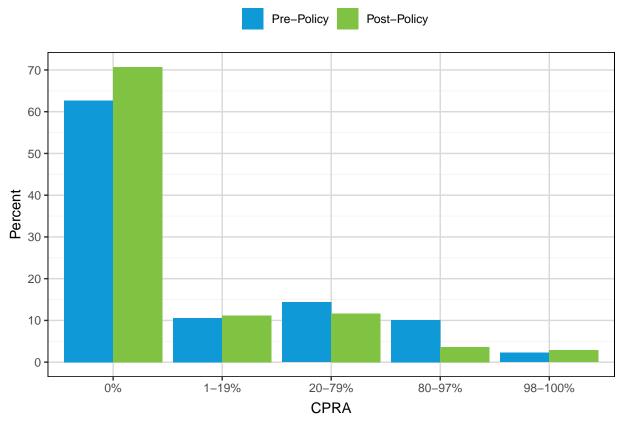


Table 21: En Bloc Kidney Transplants by CPRA and Policy Era, September 5, 2017 - September 4, 2021

	Pre-F	Pre-Policy		Policy
CPRA	N	%	N	%
0%	249	63	273	71
1-19%	42	11	43	11
20-79%	57	14	45	12
80-97%	40	10	14	4
98-100%	9	2	11	3

Figure 21 and **Table 22** show the distribution of cold ischemic time for en bloc kidney transplants from September 5, 2017 to September 4, 2021 by policy era. There was little change in median cold time after policy change (16.41 hours pre-policy to 17.56 hours post-policy), though the 75th percentile increased from 22.24 hours pre-policy to 23.85 hours post-policy.

Figure 21: Distribution of Cold Ischemic Time for En Bloc Kidney Transplants by Policy Era, September 5, 2017 - September 4, 2021

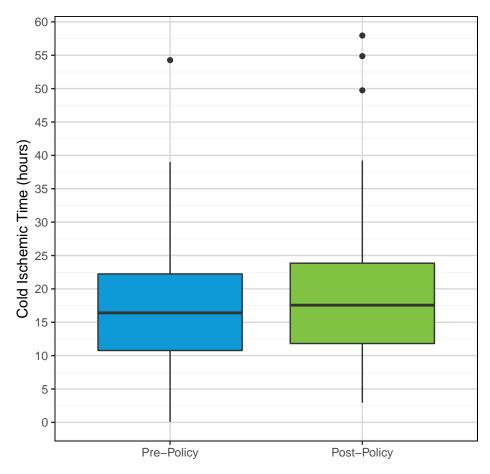


Table 22: Distribution of Cold Ischemic Time for En Bloc Kidney Transplants by Policy, September 5, 2017 - September 4, 2021

Era	N	Missing	Min	25th %-tile	Median	75th %-tile	Max
Pre-Policy	397	1	0.07	10.77	16.41	22.24	54.27
Post-Policy	386	3	2.95	11.81	17.56	23.85	57.96

Table 23: shows the counts of kidney transplants from donors under 18 kg, by age group and era, from September 5, 2017 to September 4, 2021. There were 4 pediatric en bloc kidney recipients in pre-policy and 6 in post-policy period. Single kidney transplants from donors under 18 kg decreased for adult recipients after policy implementation, from 214 recipients pre-policy to 114 post-policy. There was 4 dual and 331 en bloc adult transplants in the pre-policy and 2 dual and 346 en bloc adult transplants post-policy for donors under 18kg. No dual transplants occurred in the either era for pediatric candidates. However en bloc transplants for pediatric candidates increased from 4 in the pre-policy to 7 in the post-policy.

Table 23: Kidney Transplants for Donors <18 kg by Procedure Type, Age Group and Era, September 5, 2017 - September 4, 2021

		Procedure Type		
Recipient Age	Era	Dual	En-Bloc	Single
Pediatric	Pre-Policy	0	4	4
	Post-Policy	0	7	6
Adult	Pre-Policy	4	331	214
	Post-Policy	2	346	114

Table 24: shows the counts for kidney transplants from donors 18-25 kg by procedure type, recipient age, and era from September 5, 2017 to September 4, 2021. No pediatric recipients received dual or en bloc kidneys transplants from donors 18-25 kg over the study period, however pediatric single kidney transplants from donors 18-25kg did increase from 3 pre-policy to 8 post-policy. The number of adult dual and en bloc transplants from donors 18-25 kg saw a slight decrease (pre-policy 1 and 24 to post-policy 0 and 20, respectively). The count of adults receiving single kidney transplants from donors 18-25 kg increased from 214 recipients pre-policy to 217 post-policy.

Table 24: Kidney Transplants for Donors 18-25 kg by Procedure Type, Age Group and Era, September 5, 2017 - September 4, 2021

		Procedure Type		
Recipient Age	Era	Dual	En-Bloc	Single
Pediatric	Pre-Policy	0	0	3
	Post-Policy	0	0	8
Adult	Pre-Policy	1	24	214
	Post-Policy	0	20	217

Post-Transplant Outcomes

Figure 22 and **Table 25** show the graft survival analysis for for single kidney and en bloc transplant recipients from September 5, 2017 to December 31, 2020. Single kidney transplant recipients saw a decrease in the estimate graft survival at 1 year post-transplant from pre to post policy. However their was no significant change to graft survival for en bloc kidney transplant recipients.

Figure 22: One-Year Post-Transplant Graft Survival for Deceased Donor Kidney Transplants by Procedure Type and Policy Era, September 5, 2017 - December 31, 2020



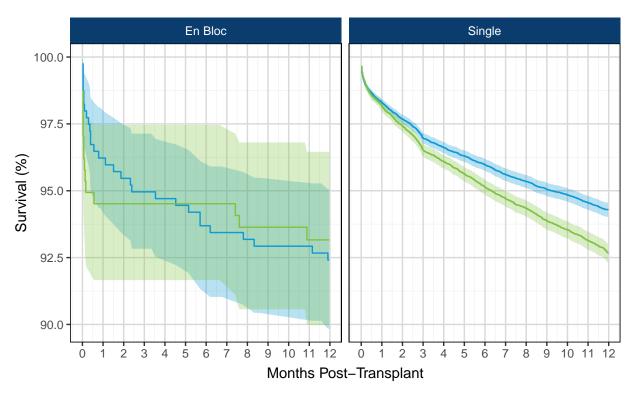
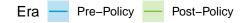


Table 25: One-Year Post-Transplant Graft Survival for Deceased Donor Kidney Transplants by Procedure Type and Policy Era, September 5, 2017 - December 31, 2020

		Pre-Policy		Post-Policy
Procedure	N	N 1-year Survival [95% CI]		1-year Survival [95% CI]
En Bloc Single	397 29668	92.41 [89.84, 95.06] 94.28 [94.01, 94.54]	237 22701	93.16 [89.98, 96.46] 92.66 [92.31, 93.00]

Figure 23 and **Table 26** show the patient survival analysis for for single kidney and en bloc transplant recipients from September 5, 2017 to December 31, 2020. Single and en bloc kidney transplant recipients saw a decrease in the estimate patient survival at 1 year post-transplant from pre to post policy. However the decrease was not significant for en bloc kidney transplant recipients.

Figure 23: One-Year Post-Transplant Patient Survival for Deceased Donor Kidney Transplants by Procedure Type and Policy Era, September 5, 2017 - December 31, 2020



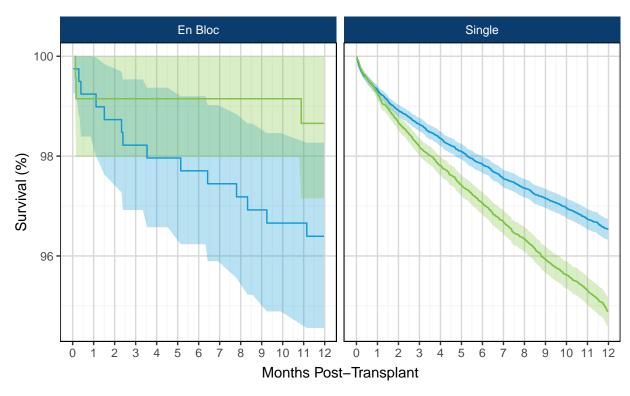


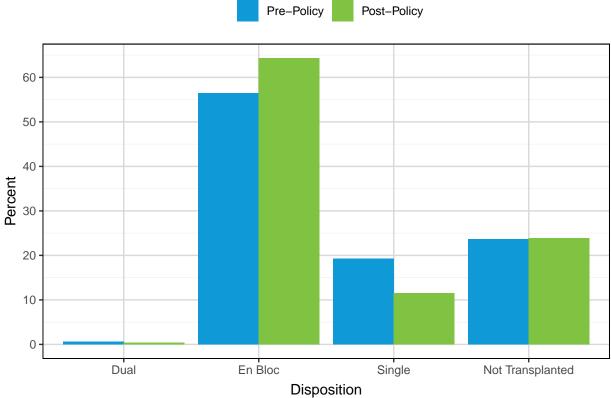
Table 26: One-Year Post-Transplant Patient Survival for Deceased Donor Kidney Transplants by Procedure Type and Policy Era, September 5, 2017 - December 31, 2020

		Pre-Policy		Post-Policy
Procedure	N	N 1-year Survival [95% CI]		1-year Survival [95% CI]
En Bloc Single	397 29668	96.39 [94.56, 98.27] 96.53 [96.32, 96.74]	237 22701	98.66 [97.15, 100.00] 94.88 [94.59, 95.18]

Donors

Figure 24 and Table 27 show deceased donors weighing less than 18 kilograms recovered from September 5, 2017 to September 4, 2021 by disposition and policy era. While there an increase in the proportion of these donors used in en bloc transplants (56.49% pre-policy to 64.3% post-policy), the proportion of these donors with at least one kidney transplanted alone decreased from 19.22% pre- to 11.48% post-policy. The proportion of not transplanted saw little change from 23.61% to 23.86% after policy implementation.

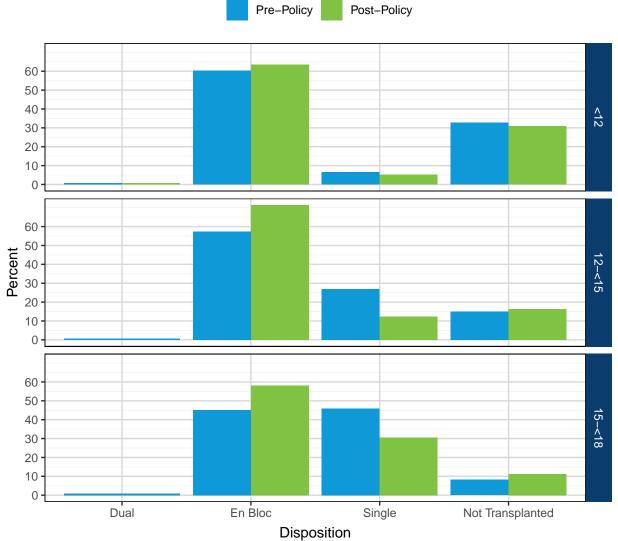
Figure 24: Deceased Donors < 18 kg by Disposition and Policy Era, September 5, 2017 - September 4, 2021



Note: Single implies at least one kidney was transplanted whereas not transplanted implies neither kidney was utilized.

Figure 25 and Table 27 shows deceased donors recovered September 5, 2019 to September 4, 2021 by weight, disposition, and policy era. After policy implementation, the proportion of donors with en bloc kidney transplanted increased for donors weighing less than 12 kg, donors weighing 12 to less than 15 kg and for donors weighing 15 to less than 18 kg, while single kidney transplants decreased for all donor <18kg. The proportion of donors with neither kidney transplanted remained relatively consistent across policy eras for the weight groups shown.

Figure 25: Deceased Donors by Weight, Disposition, and Policy Era, September 5, 2017 - September 4, 2021



Note: Single implies at least one kidney was transplanted whereas not transplanted implies neither kidney was utilized.

Table 27: Deceased Donors by Weight, Disposition, and Policy Era, September 5, 2017 - September 4, 2021

		Pre-	Policy	Post	-Policy
Donor Weight (kg)	Disposition	N	%	N	%
<12	Dual En Bloc Single Not Transplanted	2 203 22 110	0.59 60.24 6.53 32.64	2 204 17 99	0.62 63.35 5.28 30.75
12-<15	Dual En Bloc Single Not Transplanted	1 77 36 20	0.75 57.46 26.87 14.93	0 92 16 21	0 71.32 12.4 16.28
15-<18	Dual En Bloc Single Not Transplanted	1 55 56 10	0.82 45.08 45.9 8.2	0 57 30 11	0 58.16 30.61 11.22
<18	Dual En Bloc Single Not Transplanted	4 335 114 140	0.67 56.49 19.22 23.61	2 353 63 131	0.36 64.3 11.48 23.86

Table 28 describes kidney utilization for deceased donors weighing less than 18 kilograms recovered September 5, 2017 to September 4, 2021 by weight and policy era. The discard rate for these donors increased from 0.15 to 0.18 after policy implementation, however the utilization rate also increased from 0.76 to 0.77.

Table 28: Kidney Utilization for Deceased Donors < 18kg by Policy Era, September 5, 2017 - September 4, 2021

Donor Weight (kg)	Era	N	N Recovered	N Trans- planted	Discard Rate (95% CI)	Utilization Rate (95% CI)
<12	Pre-Policy	337	578	454	0.21 (0.18-0.25)	0.67 (0.64-0.71)
	Post- Policy	322	584	451	0.23 (0.19-0.26)	0.7 (0.66-0.74)
12-<15	Pre-Policy	134	246	229	0.07 (0.04-0.11)	0.85 (0.81-0.89)
	Post- Policy	129	257	217	0.16 (0.11-0.21)	0.84 (0.79-0.88)
15-<18	Pre-Policy	122	240	223	0.07 (0.04-0.11)	0.91 (0.87-0.94)
	Post- Policy	98	193	176	0.09 (0.05-0.14)	0.9 (0.84-0.94)
<18	Pre-Policy	593	1064	906	0.15 (0.13-0.17)	0.76 (0.74-0.79)
	Post- Policy	549	1034	844	0.18 (0.16-0.21)	0.77 (0.74-0.79)

Table 29: shows the kidney utilization for deceased donors' weight between 18-25 kg by policy era, between September 5, 2017 and September 4, 2021. During post-implementation the number of kidney recovered decreased from 300 to 293, however the number of kidneys transplated increased from 277 to 280, respectively. The discard rate dropped from 0.08 pre-policy to 0.04 post-policy. For the utilization rate it increased from 0.91 pre-policy to 0.93 post-policy.

Table 29: Kidney Utilization for Deceased Donors Between 18-25 kg by Policy Era, September 5, 2017 - September 4, 2021

Era	N	N KI Recovered	N KI Txed	Discard Rate	Utilization Rate
Pre-Policy	153	300	277	0.08	0.91
Post-Policy	150	293	280	0.04	0.93

Center Opt In

Figure 26 and **Table 30** show trends for center and registration opt in to receive en bloc kidney offers on the last day of the month post-policy implementation. At the end of August 2021, 180 centers had at least on registration opted in, accounting for 73.77% of centers with at least one active registration. 59.35% of all active kidney registrations had opted to receive en bloc kidney offers. Over this same twelve month period 90 centers performed en bloc kidney transplants, accounting for 37.97% of centers with at least one deceased donor kidney transplant.

Figure 26: Center and Registration Opt in to Receive En Bloc Kidney Offers on the Last Day of the Month, September 2019 - August 2021

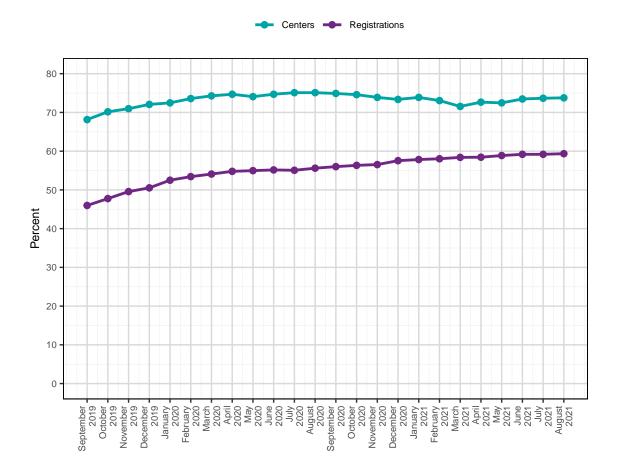


Table 30: Center and Registration Opt in to Receive En Bloc Kidney Offers on the Last Day of the Month, September 2019 - August 2021

		Center	S	Registrations		
Date	N	N En Bloc	% En Bloc	N	N En Bloc	% En Bloc
September 2019	248	169	68.15	65151	29958	45.98
October 2019	248	174	70.16	65393	31230	47.76
November 2019	248	176	70.97	65509	32468	49.56
December 2019	247	178	72.06	65340	33015	50.53
January 2020	247	179	72.47	64780	34011	52.5
February 2020	246	181	73.58	64267	34334	53.42
March 2020	241	179	74.27	61484	33258	54.09
April 2020	241	180	74.69	60990	33417	54.79
May 2020	243	180	74.07	61477	33795	54.97
June 2020	245	183	74.69	61195	33753	55.16
July 2020	245	184	75.1	60540	33335	55.06
August 2020	245	184	75.1	60117	33429	55.61
September 2020	243	182	74.9	59826	33505	56
October 2020	244	182	74.59	59587	33568	56.33
November 2020	245	181	73.88	59208	33476	56.54
December 2020	244	179	73.36	58699	33777	57.54
January 2021	245	181	73.88	57927	33502	57.83
February 2021	245	179	73.06	57494	33368	58.04
March 2021	246	176	71.54	57238	33425	58.4
April 2021	245	178	72.65	57083	33358	58.44
May 2021	247	179	72.47	57083	33604	58.87
June 2021	245	180	73.47	57037	33756	59.18
July 2021	243	179	73.66	56509	33446	59.19
August 2021	244	180	73.77	56242	33377	59.35

Splits

Table 31 shows en bloc kidney splits for match runs completed between September 5, 2019 and September 4, 2021. During this time, 65 donors were accepted for en bloc kidney transplants but later transplanted singly. For 59 of these donors, the second kidney was reallocated and transplanted to another candidate, 46 at the same center as the original acceptor and 13 at the centers in the same DSA.

Table 31: En Bloc Kidney Splits from September 5, 2017 - September 4, 2021

	N
Splits	65
Not Transplanted	6
Transplanted in the Same DSA	59
Transplanted at the Same Center	46

Table 32 shows cold ischemic time for en bloc kidneys recovered September 5, 2019 to September 4, 2021 that were eventually split by acceptor. Median cold ischemic time was 14.90 hours for the original acceptor and 18.84 hours for the recipient of the reallocated kidney.

Table 32: Cold Ischemic Time for Split En Bloc Kidney Grafts by Acceptor, September 5, 2017 - September 4, 2021

Acceptor	Median CIT
Original	14.90
Reallocation	18.84

Conclusion

There was a decrease in the number of dual kidney transplants one year after the implementation of the new allocation policy in September 2019. The transplant counts have increased to in the last year of monitoring but overall the number of dual kidney transplants has decreased from two years pre-policy to two years post-policy. After policy implementation a higher proportion of dual kidney recipients were aged 65+ years. Cold ischemic time decreased for dual kidney transplants, though this is likely attributable to these organs being allocated earlier in the match to a single kidney classification rather than a dual classification. There was little change in the type of recipients who received dual kidney transplants in terms of EPTS and CPRA. The proportion of donors used for dual kidney transplants had higher KDPI post-policy. There were no notable changes in utilization of kidneys from donors with KDPI 35-100%, the donors with the potential to be allocated as dual. Though many centers opted in to receive offers, few performed any dual kidney transplants.

En bloc kidney transplants decreased one year after the new policy was implemented, however have since increased. While there was no significant increase in the number of pediatric candidates receiving en bloc kidney transplants, there was a substantial increase in the proportion of en bloc transplants going to younger adult and low EPTS recipients. KDPI for donors used in en bloc transplants increased. Discard rates increased, however so did utilization rates for donors weighing less than 18 kilograms. As with dual kidneys, many centers opted into receiving offers for en bloc kidneys, but few performed any transplants. As previously mentioned,