

6 Month Waiting Time Modification/ 1 Year Race-Neutral eGFR Calculations Monitoring Report

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Executive Summary

There were no large changes to the makeup of the OPTN kidney waiting list with the move to race-neutral eGFR calculations. There was a decrease of candidates qualifying for waiting time by maintenance dialysis from 61.44% in the pre-policy era to 55.43% in the post-policy era and a corresponding increase in those qualifying as of tiebreaker (or registration) date. This suggests a shift to candidates using lab values, such as eGFR, to qualify for waiting time over maintenance dialysis. More data is needed to determine whether this is an impact of these policies or indicative of a larger trend. Transplants stratified by race/ethnicity were similarly distributed across the eras and there was an increase in the percent of Black kidney candidates transplanted pre-dialysis from 11.7% pre-policy and 13.9% post-policy. Deaths of Black, non-Hispanic candidates on the waiting list decreased from 4.99 per 100 patient years in the pre-policy era to 4.42 per 100 patient years in the post-policy era. It is important to note that waiting list mortality declined for all other groups as well, so the decrease we see may not be attributable to this policy.

Between January 5, 2023 and July 5, 2023, there were 6103 complete waiting time modifications and 338 incomplete modifications. The median time awarded to registrations with a modification was 1.7 years. As of July 5, 2023, 491 candidates with a waiting time modification received a deceased donor transplant and 15 received a living donor transplant. As of July 5, 2023, the OPTN received attestations from 12 of the 232 active kidney programs. More time and data are needed to assess the true impact of this policy change as programs have until January 3, 2024 to complete the review of their list and submit attestations.

Background/Purpose

This report monitors the impact of two policy changes: Establish OPTN Requirement for Race-Neutral eGFR Calculations and Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations. Details regarding the changes that occurred for each policy change are below.

Establish OPTN Requirement for Race-Neutral eGFR Calculations

The policy's purpose was to prohibit the use of Estimated Glomerular Filtration Rate (eGFR) calculations that include a race-based variable in OPTN policy. The new policy defines GFR within OPTN Policy so that any eGFR calculation used must not contain a race-based variable. This requirement for race-neutral calculations was intended to increase equity in access to transplantation for Black kidney candidates.

As outlined in the monitoring plan in the board briefing report, the Committee will monitor metrics as they relate to using race-neutral eGFR calculations. This includes, but is not limited to:

- Count and percent of Black kidney candidates listed pre-dialysis
- Number of kidney transplants to Black candidates, broken out by transplants performed pre-dialysis versus post-dialysis
- eGFR at listing for Black kidney candidates qualifying by eGFR
- Waiting list mortality for Black kidney candidates
- Time waiting from listing until transplant for Black kidney candidates
- Probability of transplant within one year for Black kidney candidates

These metrics will be reviewed at approximately six months, one year, and two years post-implementation. Waiting list mortality, time waiting to transplant, and probability of transplant within one year for Black kidney candidates will be provided only at one and two years post-implementation. This policy was implemented on July 27, 2022.

Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations

The policy's purpose was to provide a pathway for waiting time modifications for Black kidney candidates that were registered on the kidney transplant waiting list who had been affected by race-inclusive eGFR calculations. This pathway provides programs a 365 day time frame to review their waiting lists and request eGFR waiting time modifications for registered Black kidney candidates impacted by race-inclusive eGFR calculations. All designated kidney transplant programs must submit an attestation to the OPTN by January 3, 2024 affirming that the program has completed both of the following: (i) notification to all candidates registered at the transplant program of their eligibility for a waiting time modification according to this policy, and (ii) submission of eGFR waiting time modifications for all eligible candidates registered at the transplant program.

As outlined in the monitoring plan in the board briefing report, the Committee will monitor metrics as they relate to using waiting time modifications. This includes, but is not limited to:

- Number of modifications by complete vs. incomplete status
- The distribution of the amount of waiting time awarded to modified registrations
- Number of modified registrations by registration year and month
- Summary of demographics of candidates with modified registrations

This policy will be evaluated at approximately six months and one year post-implementation. This policy was implemented on January 5, 2023.

Relevant OPTN policies regarding waiting time are below.

OPTN Policy 8.3.A Waiting Time for Candidates Registered at Age 18 Years or Older

If a kidney candidate is 18 years or older on the date the candidate is registered for a kidney, then the candidate's waiting time is based on the earliest of the following:

1. The candidate's registration date with a glomerular filtration rate (GFR) or measured or estimated creatinine clearance (CrCl) less than or equal to 20 mL/min.
2. The date after registration that a candidate's GFR or measured or estimated CrCl becomes less than or equal to 20 mL/min.
3. The date that the candidate began regularly administered dialysis as an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

OPTN Policy 8.3.B Waiting Time for Candidates Registered prior to Age 18

If a kidney candidate is less than 18 years old at the time of registration on the waiting list, then the candidate's waiting time is based on the earlier of the following:

1. The date that the candidate registered on the waiting list regardless of clinical criteria.
2. The date that the candidate began regularly administered dialysis as an ESRD patient in a hospital based, independent non-hospital based, or home setting.

Strategic Plan Goal or Committee Project Addressed

Improve equity in access to transplants.

Data and Methods

These analyses use data from the OPTN waiting list, the Transplant Candidate Registration (TCR) form, the Transplant Recipient Registration (TRR) form, and Waiting Time Modifications received by the Organ Center.

Analyses are based on OPTN data as of November 10, 2023 and are subject to change based on future data submission or correction. We were unable to provide time from listing to transplant for Black kidney candidates due to limitations with the data. Due to the long waiting time for kidney candidates, 50% of the cohort had not yet received a transplant for the 1 year monitoring report. This metric will be re-evaluated on the two year report.

In this report, pre-dialysis in the waitlist additions cohort is defined as the candidate being listed on the waiting list before dialysis was initiated. Post-dialysis is defined as the candidate being listed on the waiting list after the initiation of dialysis. For the transplant cohort, pre-dialysis is defined as the candidate being transplanted before dialysis was initiated. Post-dialysis is defined as the candidate being transplanted after the initiation of dialysis. Registrations with missing or unknown dialysis dates were grouped in the pre-dialysis category.

The OPTN only collects an eGFR value for a kidney registration if that value is less than or equal to 20 mL/min. Not every registration has an eGFR entered at listing, so the metric shown in this report is the first entered eGFR for that registration. This does not include the modified eGFR if the registration received a modification through the eGFR waiting time modification policy.

Cohort: Establish OPTN Requirement for Race-Neutral eGFR Calculations

Registrations added to the kidney waiting list between July 27, 2021 and July 26, 2022 (pre) or between July 27, 2022 and July 26, 2023 (post) were evaluated. These data were stratified by race/ethnicity, whether the registrations were pre-dialysis or post-dialysis, and waiting time qualifying source. Candidates qualifying for waiting time by tiebreaker date (registration date) are defined as having a qualifying lab value prior to their registration date. In these cases, the registration date is used to begin a candidate's waiting time. Qualifying lab values include an eGFR less than or equal to 20 mL/min or CrCl less than or equal to 20 mL/min.

Kidney recipients transplanted between July 27, 2021 and July 26, 2022 (pre) or between July 27, 2022 and July 26, 2023 (post) were evaluated. These data were stratified by race/ethnicity and whether the transplants were done pre-dialysis or post-dialysis. Waiting list mortality rates were defined as the number of deaths on the waiting list divided by the total amount of time on the waiting list (active or inactive) for registrations ever waiting between July 27, 2021 and July 26, 2023. These results are presented as deaths per 100 patient years. Deaths were defined as:

- Removals from the waiting list due to death
- Death within 14 days of waiting list removal as reported to the OPTN or identified via verified external sources.

Probability of a deceased donor kidney transplant within 6 months for Black/African American kidney registrations used a 6 month cohort to allow for sufficient follow-up time for each era. For this analysis a competing risks approach was taken to calculate cumulative incidence. Registrations added to the kidney waiting list between January 26, 2022 and July 26, 2022 (pre) or between July 27, 2022 and January 27, 2023 (post) were evaluated.

Cohort: Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations

All modifications and attestations received by the Organ Center from January 5, 2023 to July 5, 2023 and corresponding waitlist registrations were analyzed.

Results

Establish OPTN Requirement for Race-Neutral eGFR Calculations

Table 1 shows kidney registrations added to the waiting list stratified by the candidate's race/ethnicity at listing. Race/ethnicity was similarly distributed across eras. Pre-policy 29.40% of kidney waitlist additions were Black, non-Hispanic candidates and post-policy 30.12% of kidney waitlist additions were Black, non-Hispanic.

Table 1. Overall Kidney Waitlist Additions by Race/Ethnicity

Race/Ethnicity	Policy Era	
	Pre	Post
Amer Ind/Alaska Native, Non-Hispanic	333 (0.76%)	361 (0.79%)
Asian, Non-Hispanic	3,532 (8.08%)	3,377 (7.37%)
Black, Non-Hispanic	12,843 (29.40%)	13,807 (30.12%)
Hispanic/Latino	8,555 (19.58%)	9,286 (20.26%)
Multiracial, Non-Hispanic	336 (0.77%)	382 (0.83%)
Native Hawaiian/other Pacific Islander, Non-Hispanic	212 (0.49%)	212 (0.46%)
White, Non-Hispanic	17,876 (40.92%)	18,420 (40.18%)
Total	43,687 (100.00%)	45,845 (100.00%)

Figure 1 shows the count and percent of Black kidney waitlist additions stratified by whether the candidate was listed pre-dialysis. The percent of Black candidates listed pre-dialysis remained steady from the pre-policy era (26.3%) to the post-policy era (28.4%).

Figure 1. Black Kidney Waitlist Additions by Whether Candidate Was Listed Pre-Dialysis

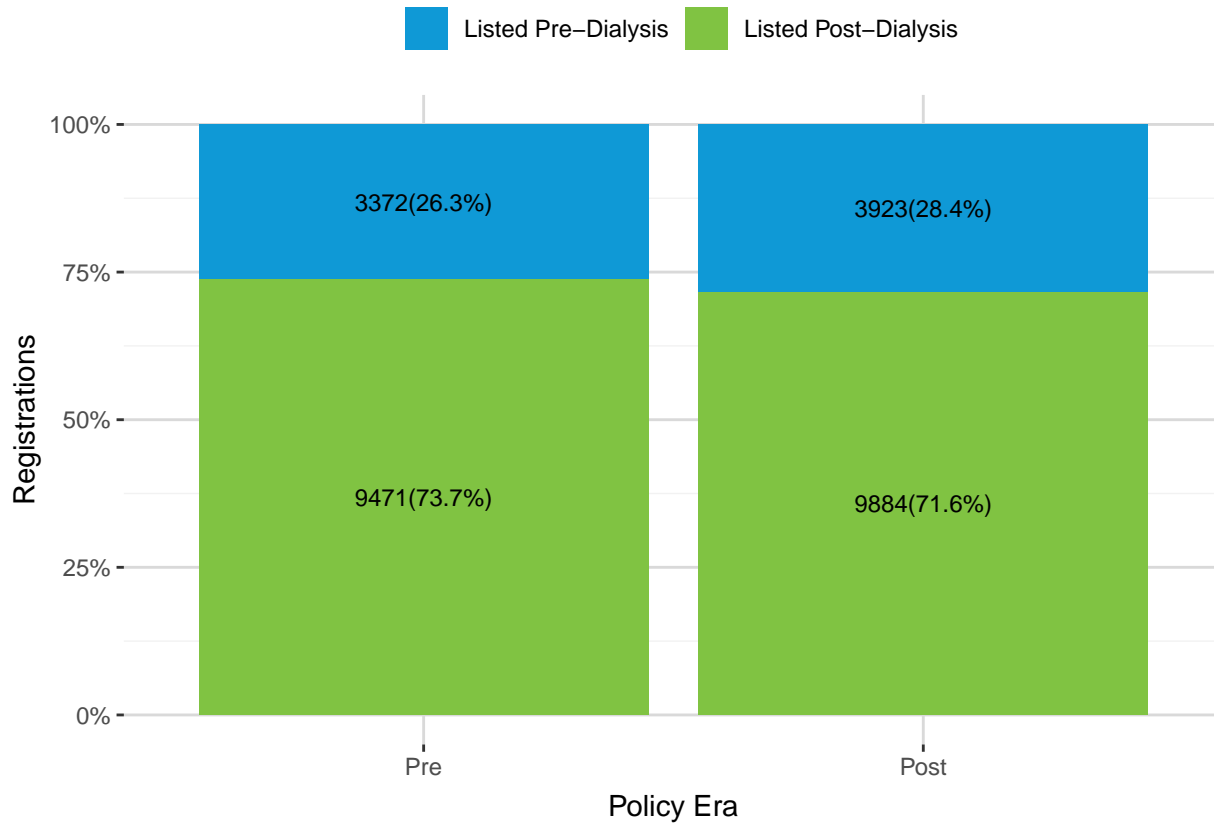


Table 2 shows Black kidney waitlist additions stratified by the candidate's waiting time qualifying source. Candidates qualifying for waiting time by tiebreaker date (registration date) are defined as having a qualifying lab value prior to their registration date. In these cases, the registration date is used to begin a candidate's waiting time. Qualifying lab values include an eGFR less than or equal to 20 mL/min or CrCl less than or equal to 20 mL/min. Maintenance dialysis had a drop from 61.44% of waitlist additions in the pre-policy era to 55.43% in the post-policy era. There was a corresponding increase in those qualifying as of tiebreaker (or registration) date from 36.25% pre-policy to 42.33% post-policy. This suggests that there may be a shift of Black kidney candidates qualifying using lab values over maintenance dialysis with these new policies. More monitoring is needed to determine if this is a temporary shift or a trend that will occur more often.

Table 2. Overall Black Kidney Waitlist Additions by Waiting Time Qualifying Source

Qualifying Source	Policy Era	
	Pre	Post
Does Not Qualify	129 (1.00%)	154 (1.12%)
GFR 20 or Lower	73 (0.57%)	76 (0.55%)
Maintenance Dialysis	7,891 (61.44%)	7,653 (55.43%)
Pediatric Policy	94 (0.73%)	79 (0.57%)
Qualify As Of Tiebreaker Date	4,656 (36.25%)	5,845 (42.33%)
Total	12,843 (100.00%)	13,807 (100.00%)

Figure 2 shows the distribution of the first entered eGFR for all Black kidney waitlist additions qualifying for waiting time with an eGFR of 20 or lower, or by tiebreaker date (registration date). The eGFR values are similarly distributed across eras. It is important to note that the OPTN does not collect eGFR values if they are above 20 mL/min.

Figure 2. Distribution of First Entered eGFR for Black Kidney Waitlist Additions Qualifying by an eGFR of 20 or Lower, or by Tiebreaker Date

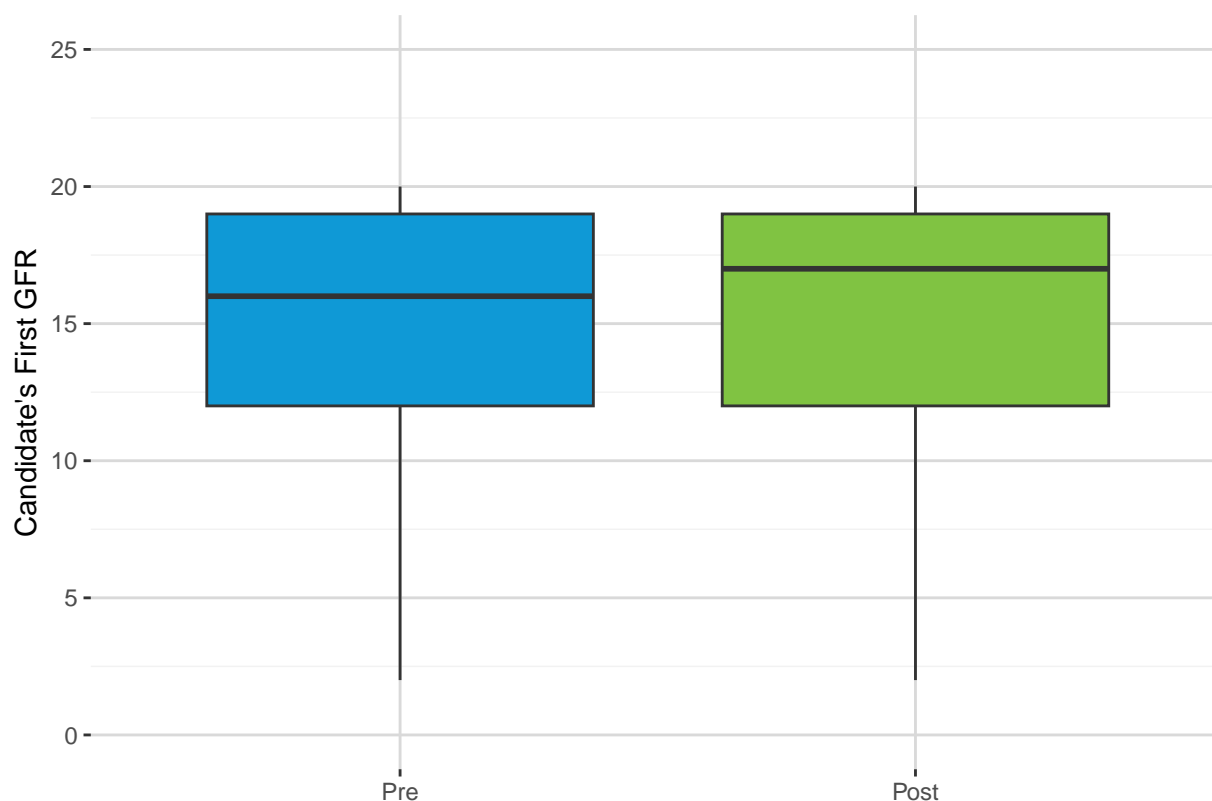


Table 3 shows the distribution of the first entered eGFR for all Black kidney waitlist additions qualifying for waiting time with an eGFR of 20 or lower. The median stayed the same in both eras, but the number of registrations for Black candidates qualifying by an eGFR of 20 or lower was small, so the true distribution may be hard to interpret.

Table 3. Distribution of First Entered eGFR for Black Kidney Waitlist Additions Qualifying by an eGFR of 20 or Lower

Era	Count	Missing	eGFR				
			Minimum	25th Percentile	Median	75th Percentile	Maximum
Pre	73	0	4	13.800	18.00	19	20
Post	76	0	4	14.225	18.15	19	20

Table 4 shows overall kidney transplants stratified by race/ethnicity. Race/ethnicity was similarly distributed across the eras. Pre-policy 28.49% of kidney transplants were to Black candidates and post-policy 29.48% of kidney transplants were to Black candidates.

Table 4. Overall Kidney Transplants by Race/Ethnicity

Race/Ethnicity	Policy Era	
	Pre	Post
Amer Ind/Alaska Native, Non-Hispanic	181 (0.74%)	198 (0.74%)
Asian, Non-Hispanic	1,879 (7.69%)	2,107 (7.85%)
Black, Non-Hispanic	6,961 (28.49%)	7,910 (29.48%)
Hispanic/Latino	4,970 (20.34%)	5,418 (20.19%)
Multiracial, Non-Hispanic	196 (0.80%)	248 (0.92%)
Native Hawaiian/other Pacific Islander, Non-Hispanic	104 (0.43%)	123 (0.46%)
White, Non-Hispanic	10,144 (41.51%)	10,831 (40.36%)
Total	24,435 (100.00%)	26,835 (100.00%)

Figure 3 shows the count and percent of transplants to Black kidney candidates by whether the transplant was performed pre-dialysis. The percent of Black candidates transplanted pre-dialysis increased from 11.7% (n=815) in the pre-policy era to 13.9% (n=1099) in the post-policy era.

Figure 3. Transplants to Black Kidney Candidates Pre-Dialysis vs. Post-Dialysis

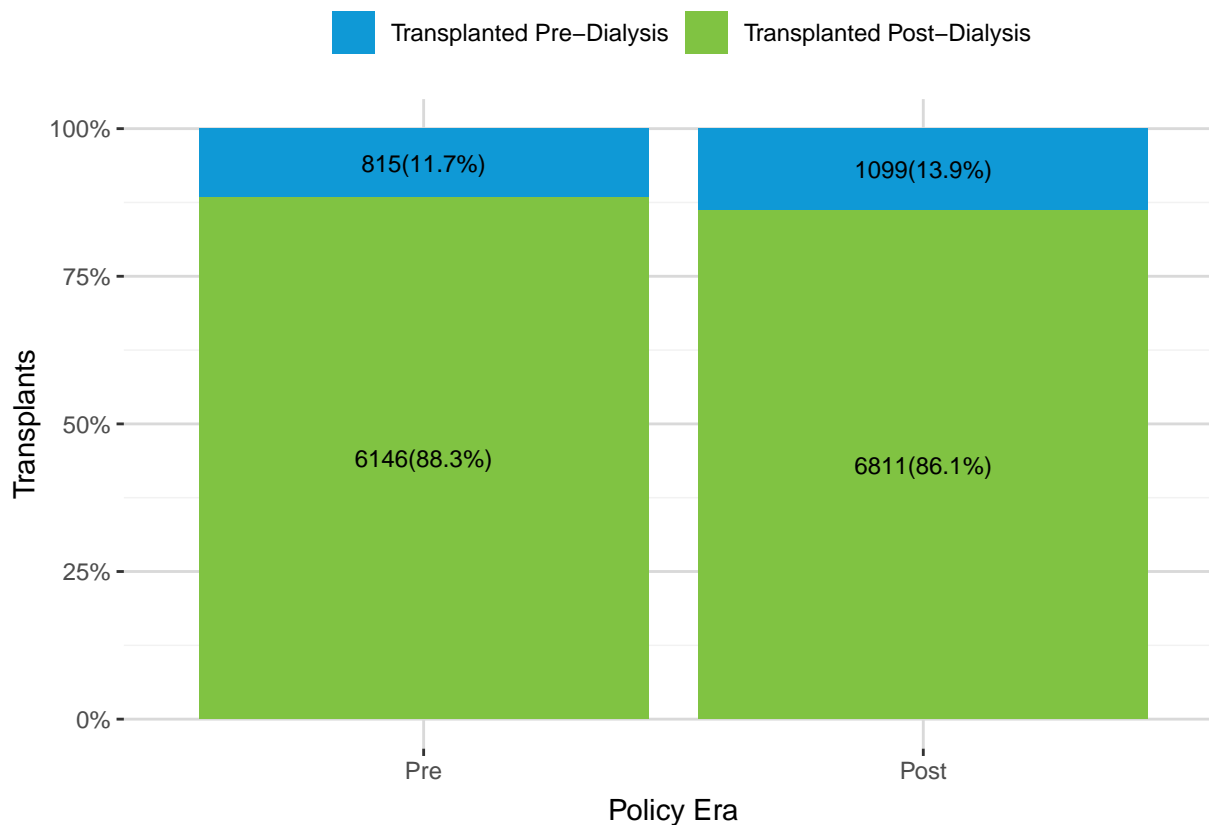


Figure 4 and 5 below show the numbers of deaths per 100 patient years for kidney registrations ever waiting from July 27, 2021 - July 26, 2023 stratified by policy era and by race/ethnicity. Deaths decreased for Black, non-Hispanic candidates from 4.99 per 100 patient years in the pre-policy era to 4.42 per 100 patient years in the post-policy era. It is important to note that waiting list mortality declined for all other groups as well, so the decrease we see may not be attributable to this policy.

Figure 4. Deaths per 100 Patient Years for Kidney Registrations Ever Waiting July 27, 2021 - July 26, 2023 by Policy Era and Race/Ethnicity

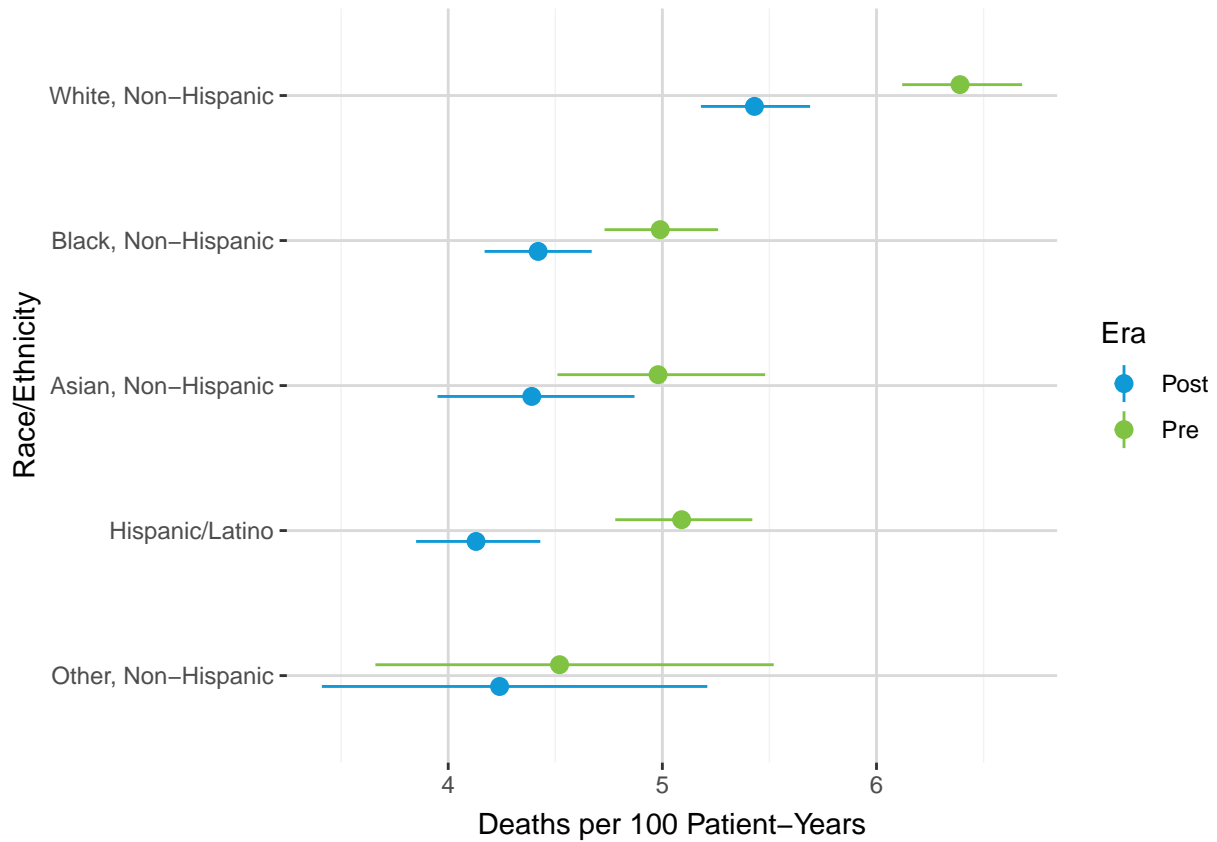


Table 5. Deaths per 100 Patient Years for Kidney Registrations Ever Waiting July 27, 2021 - July 26, 2023 by Policy Era and Race/Ethnicity

Race/Ethnicity	Era	N Patients	N Events	Total Patient-Years	Deaths per 100 Patient-Years	95% Confidence Interval	
						Lower CL	Upper CL
White, Non-Hispanic	Pre	47274	2052	32089.18	6.39	6.12	6.68
	Post	47678	1723	31730.26	5.43	5.18	5.69
Black, Non-Hispanic	Pre	38876	1393	27936.18	4.99	4.73	5.26
	Post	39062	1210	27397.52	4.42	4.17	4.67
Asian, Non-Hispanic	Pre	11274	414	8319.14	4.98	4.51	5.48
	Post	11201	362	8245.50	4.39	3.95	4.87
Hispanic/Latino	Pre	26965	981	19276.80	5.09	4.78	5.42
	Post	27704	810	19596.32	4.13	3.85	4.43
Other, Non-Hispanic	Pre	3003	96	2125.68	4.52	3.66	5.52
	Post	3050	90	2122.73	4.24	3.41	5.21

Table 6 shows the probability of a deceased donor transplant within 6 months for Black/African American kidney registrations. The probability of a deceased donor transplant increased slightly from 17.88% in the pre-policy era to 18.75% in the post-policy era.

Table 6. Probability of a Deceased Donor Transplant Within 6 Months for Black/African American Kidney Registrations

Era	Registrations	Prob. TX within 6 Months	95% CI
Pre	6667	17.88%	(16.97%, 18.81%)
Post	6704	18.75%	(17.83%, 19.69%)

Note:

Three registration removed for missing values

Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations

As of July 5, 2023 the OPTN received 12 attestations from kidney programs confirming that they sent the required patient notifications, reviewed their lists, and submitted all needed eGFR waiting time modifications. There are currently 232 active kidney programs and pediatric programs are required to submit an attestation. There were a total of 6103 completed eGFR waiting time modifications between January 5, 2023 and July 5, 2023 and 338 incomplete modifications. Reasons an eGFR waiting time modification may be marked incomplete include, but are not limited to, errors in submitted documentation such as missing dates or lab values or the candidate not being eligible due to policy requirements. The incomplete modification number changes as proper documentation is received. 52 registrations received more than one eGFR waiting time modification and all of their gained waiting time for any completed modification is added together counted in the median time awarded numbers below. As of July 5, 2023, 491 candidates with an eGFR waiting time modification received a deceased donor transplant and 15 received a living donor transplant.

Figure 5 and table 7 show the distribution of waiting time awarded to candidates with a complete waiting time modification. The median time awarded to registrations with a complete waiting time modification was 1.7 years, with 75% of registrations receiving 2.8 years or less.

Figure 5. Distribution of Waiting Time Awarded

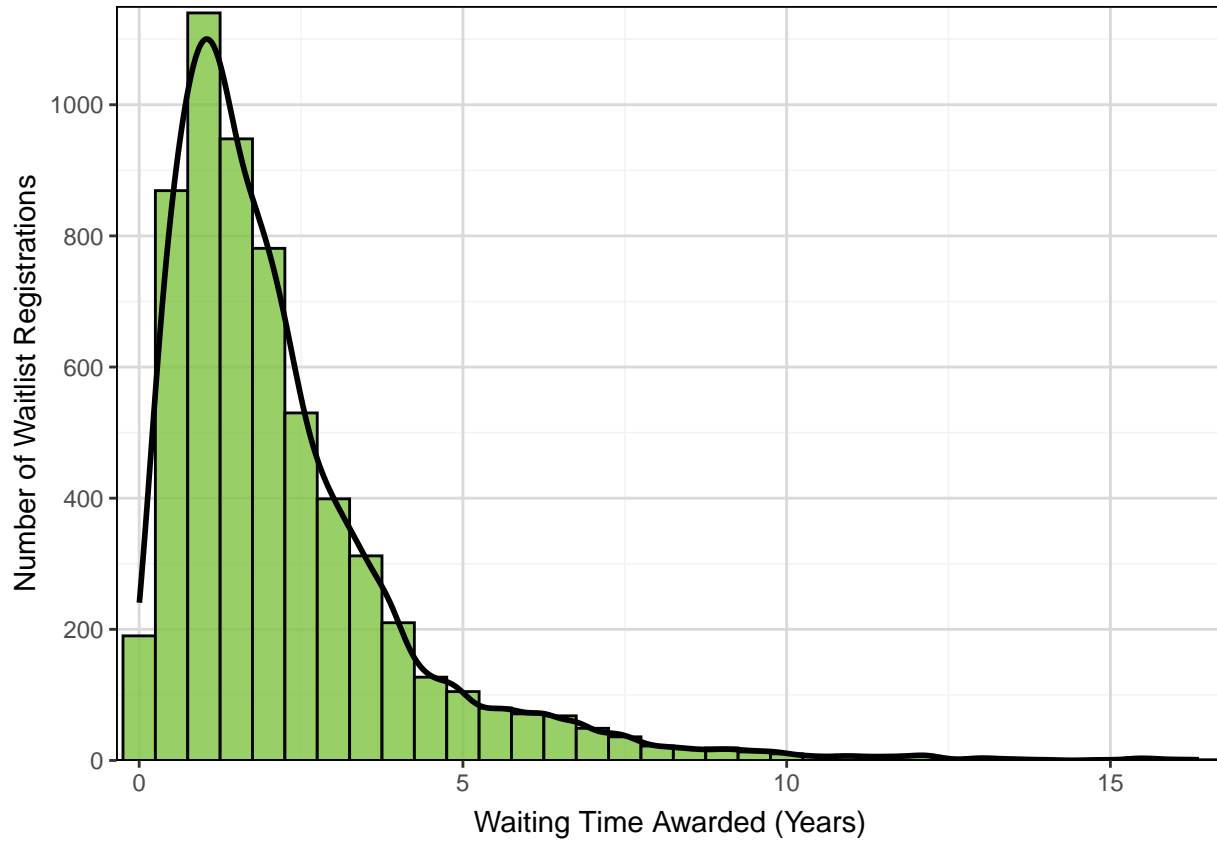


Table 7. Distribution of Waiting Time Awarded

Count	Waiting Time Awarded (Years)				
	Minimum	25th Percentile	Median	75th Percentile	Maximum
6047	0	0.9	1.7	2.8	16.4

Figure 6 shows the number of modified registrations grouped by the registration year. The majority of modified registrations were listed in either 2022 (31.09%) or 2021 (21.27%).

Figure 6. Number of Modified Registrations by Registration Year

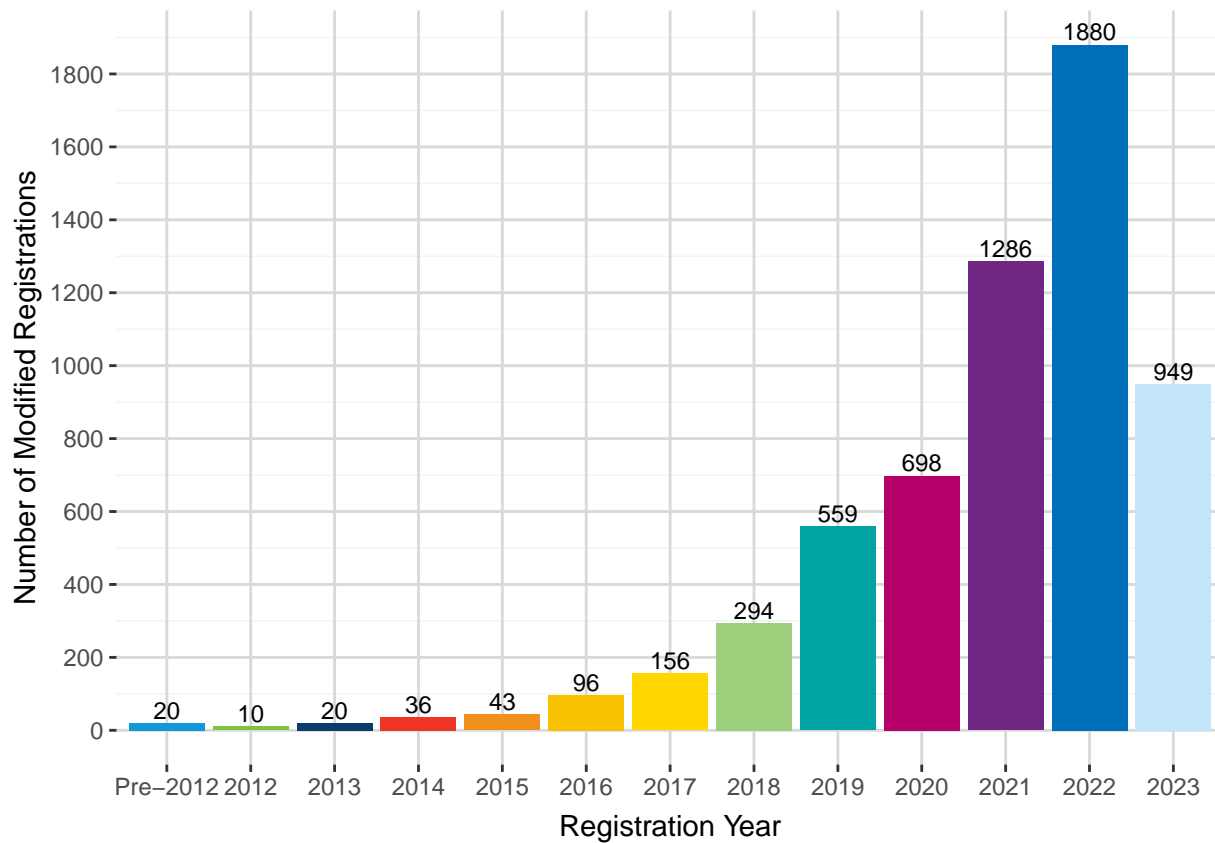


Table 8. Number of Modified Registrations by Registration Year

Registration Year	n (%)
Pre-2012	20 (0.33%)
2012	10 (0.17%)
2013	20 (0.33%)
2014	36 (0.60%)
2015	43 (0.71%)
2016	96 (1.59%)
2017	156 (2.58%)
2018	294 (4.86%)
2019	559 (9.24%)
2020	698 (11.54%)
2021	1,286 (21.27%)
2022	1,880 (31.09%)
2023	949 (15.69%)
Total	6,047 (100.00%)

Figure 7 shows modified registrations by the registrant's blood type. The majority of modified registrations were candidates with blood type O (54.54%). The distribution of blood type for modified registrations was similar to all registrations waiting for a kidney from January 5, 2023 to July 5, 2023 where blood type O made up 53.43%, though there were some slight differences in blood type A and B. For all registrations waiting for a kidney from January 5, 2023 to July 5, 2023, a slightly higher percent were blood type A at 27.80% (compared to 22.08% for the modified registrations) and a slightly lower percent were blood type B at 16.00% (compared to 20.51% for the modified registrations).

Figure 7. Modified Registrations by Blood Type

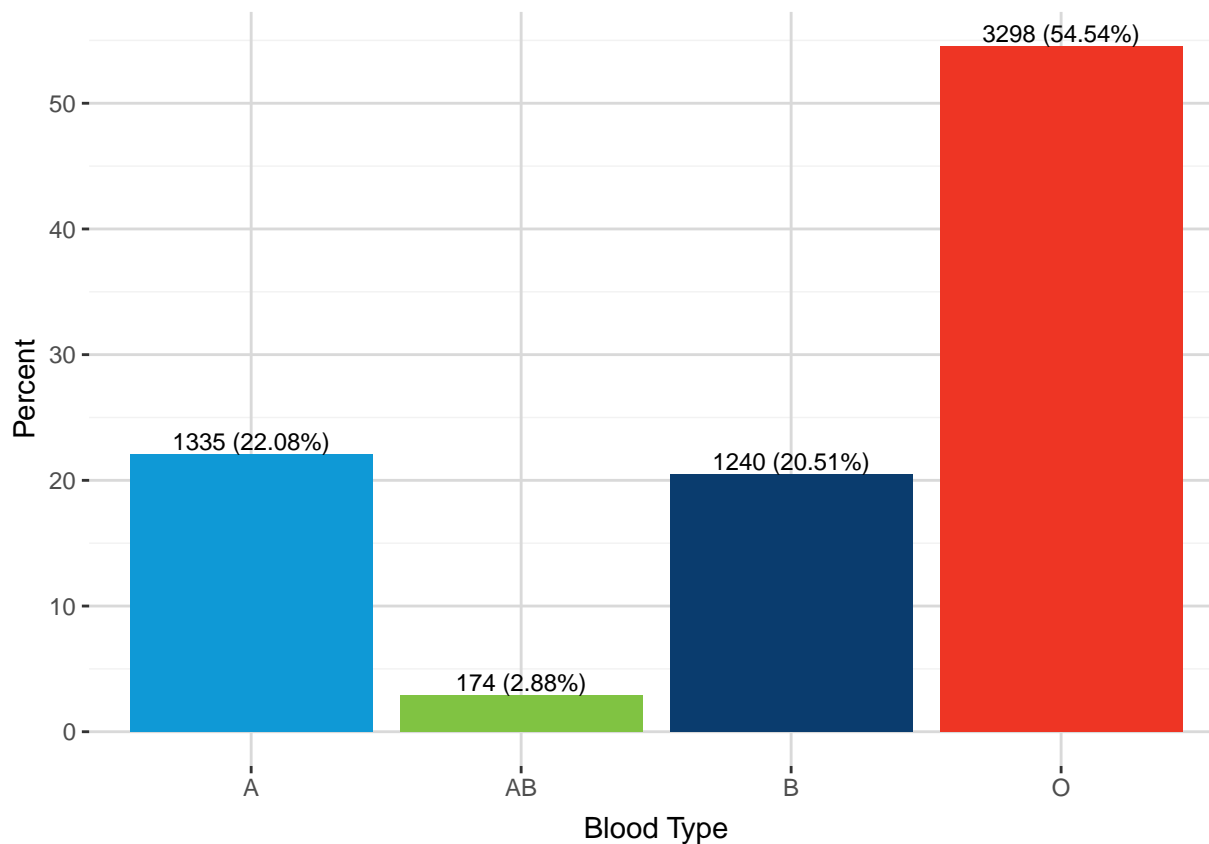


Figure 8 shows modified registrations by the registrant's birth sex. The majority of modified registrations were male candidates (57.57%). This is slightly lower when compared to all registrations waiting for a kidney from January 5, 2023 to July 5, 2023 where 61.98% were male.

Figure 8. Modified Registrations by Birth Sex

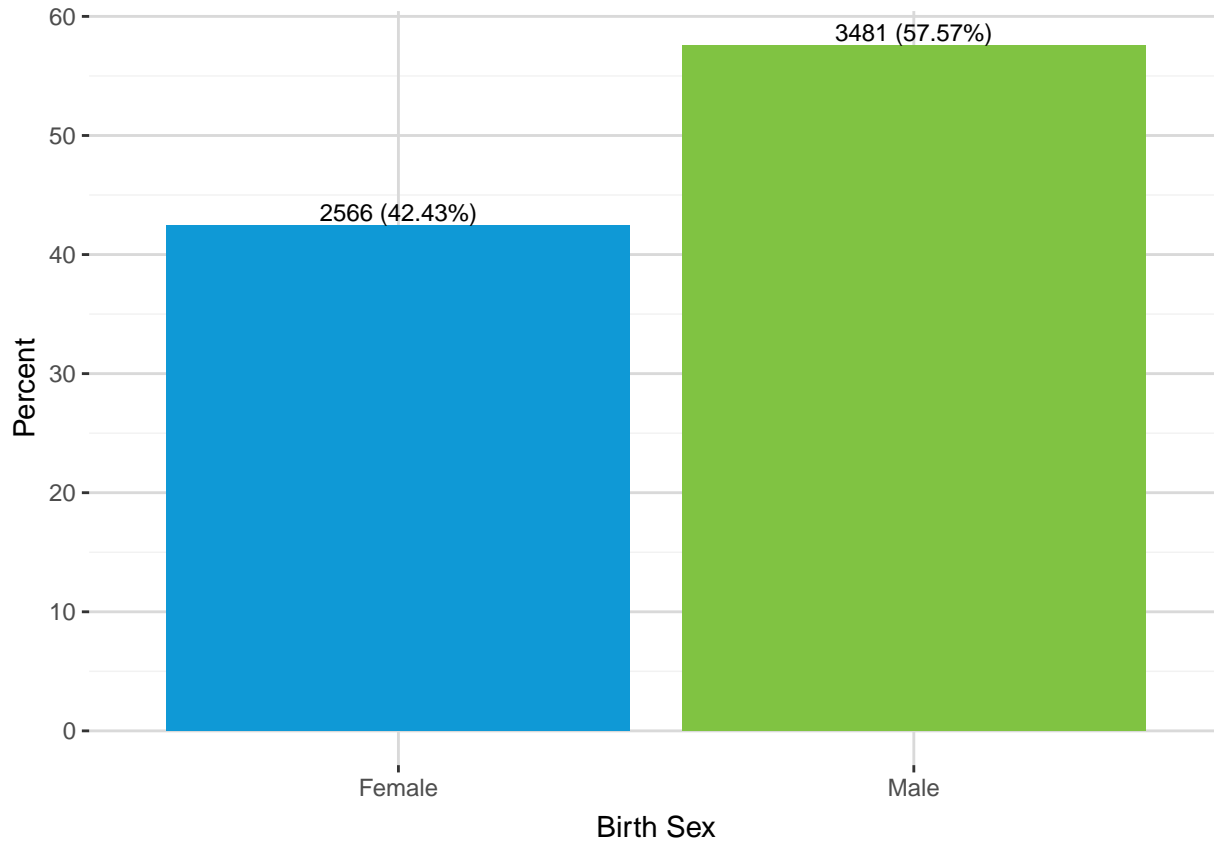


Figure 9 shows modified registrations by the candidate's age at listing. The majority of candidates with a modified registration were 50-64 years old at listing (49.3%). This distribution is similar to all registrations waiting for a kidney from January 5, 2023 to July 5, 2023, but there are some differences. In all registrations waiting for a kidney from January 5, 2023 to July 5, 2023, 1.95% were less than 18 years old which is slightly higher than in the modified registrations group and 42.98% were 50-64 years old, which is lower than in the modifications group.

Figure 9. Modified Registrations by Candidate's Age at Listing

