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# Association between changes in Membership and Professional Standards Committee review criteria and use of higher-risk kidneys for transplant

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## Abstract

The Organ Procurement and Transplantation Network's Membership and Professional Standards Committee implemented an operational rule on March 1, 2017, intended to increase the number of kidneys transplanted from donors with kidney donor profile index (KDPI) ≥ 85% into recipients with poor estimated posttransplant survival (≥ 80%). Using data from the Scientific Registry of Transplant Recipients, ordinal and logistic regressions estimated, respectively, differences in kidney yield (number of transplanted kidneys per recovered donor) and offer acceptance practices before and after implementation. We included donors recovered January 1, 2016-February 28, 2018. The odds of higher kidney yield for donors with KDPI ≥ 85% were 27% higher after implementation (odds ratio, $_{1.06}1.27_{1.53}$), but odds were also 20% higher for donors with KDPI < 85% ($_{1.04}1.20_{1.38}$). Thus, kidney yield was higher for all donors, with a slightly larger difference for donors with KDPI ≥ 85%. Additionally, the difference in offer acceptance before and after implementation was similar regardless of KDPI (KDPI < 85%, $_{0.97}1.02_{1.07}$; KDPI ≥ 85%, $_{0.95}1.04_{1.14}$). In the first year after implementation, kidney yield increased for donors with KDPI < and ≥ 85%. Thus, kidney yield from higher KDPI donors may have increased without the operational rule.

**KEYWORDS**

kidney transplantation, kidney yield, Membership and Professional Standards Committee, offer acceptance, Organ Procurement and Transplantation Network, regulatory review

## 1 | INTRODUCTION

The Organ Procurement and Transplantation Network (OPTN) and the Centers for Medicare & Medicaid Services (CMS) monitor kidney transplant program posttransplant outcomes for quality assurance. A perception exists that higher-risk transplants increase the risk of review, and thereby provide an incentive for risk aversion, has caused unnecessary discards of transplantable kidneys.[1] In combination with the decades-long increase in kidney discard rates,[2] the potentially negative consequences of regulatory review motivated policies and/or interventions to reduce the perceived disincentives associated with higher-risk kidneys. Such policies could reduce the number of discards and improve access to transplant, although changes in the underlying donor population explain most of the increase in kidney discard rates.[2]

At its October 2016 meeting, OPTN's Membership and Professional Standards Committee (MPSC) approved an operational

rule for kidney programs intended to reduce the perceived disincentives and risk aversion caused by MPSC review of posttransplant outcomes. The operational rule, implemented on March 1, 2017, required that kidney programs meet the review criteria for all transplants, after excluding transplants of higher-risk donor kidneys into higher-risk recipients.[3,4] Specifically, kidney programs were identified only if *both* of the following conditions were met:

1. The program met the MPSC flagging criteria for every transplant *and*
2. The program met the MPSC flagging criteria after excluding transplants of kidneys from donors with kidney profile donor index (KDPI) ≥ 85% into recipients with poor estimated posttransplant survival (EPTS; ≥ 80%).

The operational rule aimed to increase the number of kidney transplants by removing higher-risk transplants from the algorithm that determined which programs would undergo MPSC review. Importantly, at any program that met conditions (1 and 2), every transplant was reviewed by the MPSC, not only lower-risk transplants. However, because posttransplant evaluations adjusted for the effect of the kidney donor risk index (KDRI), the clinical score underlying the KDPI, kidney transplant programs were typically not identified for regulatory review due to poor outcomes for transplants from donors with KDPI ≥ 85%. Instead, kidney programs were usually identified due to poor outcomes for transplants from all donors.[5] The MPSC pursued the operational rule because transplant community feedback suggested that the perception that high-KDPI kidneys cause MPSC review could hinder utilization, and the operational rule would necessarily reduce the number of programs reviewed by the MPSC.

An evaluation of the operational rule will help contextualize the effect of changing regulatory policy on organ utilization for several reasons. First, differences in the donor population explained most of the increase in the kidney discard rate.[2] Thus, the operational rule may not increase the number of transplants because whether regulatory review caused the residual rise in kidney discard rates is unclear. Second, transplant programs were typically not identified for MPSC review solely due to poor outcomes for higher-risk transplants.[5] We therefore investigated the change in kidney yield (ie, number of transplanted kidneys from donors with any recovered organ) and offer acceptance practices before and up to 1 year after implementation of the operational rule.

## 2 | MATERIALS AND METHODS

This study used SRTR data. The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of the OPTN, and has been described elsewhere.[6] The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors.

Both the kidney yield and the offer acceptance analyses included deceased donors recovered between January 1, 2016, and February 28, 2018. Descriptive statistics summarized the donors and offers before and after implementation of the operational rule on March 1, 2017. Means and standard deviations summarized continuous variables; frequencies and percentages summarized categorical variables.

### 2.1 | Kidney yield

Kidney yield was the number of transplanted kidneys from donors with any recovered organ. In contrast, the kidney discard rate was the percentage of kidneys recovered for the purpose of transplant but not transplanted. We analyzed kidney yield because, unlike the kidney discard rate, it does not depend on the decision to recover a kidney for transplant.

The difference in kidney yield before and after implementation was estimated for donors with KDPI < 85% and ≥ 85%. An ordinal logistic regression estimated these differences through an interaction between donors recovered after implementation and donors with KDPI ≥ 85%. The regression included a linear effect for calendar time to adjust for common temporal trends across every donor. To help further characterize the presence of temporal but secular trends in donor yield, we were particularly interested in whether the difference in kidney yield after implementation was higher for donors with KDPI ≥ 85% than for donors with KDPI < 85%. The logistic regression also adjusted for potentially important donor factors; Appendix S1 provide the specific donor factors included in the regression. Continuous covariates with missing values were imputed with a constant, and an indicator for missingness was included. Splines accounted for the potential non-linear effects of continuous covariates.

To help contextualize the practical importance of the operational rule, the average difference in numbers of transplanted high-KDPI kidneys before and after implementation was estimated in a counterfactual framework. Specifically, the average number of kidneys transplanted from high-KPDI donors recovered after implementation was compared with the average number that would have been transplanted if the donors were recovered before implementation. That is, separate predictive models for donors recovered before and after implementation estimated the total expected kidney yield from every high-KDPI donor recovered after implementation. These separate predictive models used the same donor factors as the primary analysis but did not include the interactions or the calendar time effect.

Sensitivity analyses were investigated due to the fundamental difficulty of measuring the effect of a policy without a meaningful control group. First, splines estimated the temporal change over the study period because any change in kidney yield likely occurred over time rather than suddenly at implementation. Secondly, a separate sensitivity analysis adjusted for the potential effect of the Collaborative Innovation and Improvement Network (COIIN), a

separate OPTN initiative intended to improve utilization of deceased donor kidneys. The analysis included an indicator that identified whether the donor was recovered in a donation service area with a program actively participating in COIIN.

### 2.2 | Offer acceptance

The offer acceptance analysis estimated the probability of an offer of a deceased donor kidney being accepted. Importantly, only offers of kidneys that were eventually accepted were included, because match run data contain no information on when discarded kidneys are no longer offered. Additionally, only offers to kidney-alone or kidney-pancreas candidates were included.

The difference in offer acceptance before and after implementation was estimated for offers from donors with KDPI < 85%, offers from donors with KDPI ≥ 85%, and offers from donors with KDPI ≥ 85% to candidates with a raw EPTS > 2.70. Importantly, a raw EPTS of 2.70 corresponds approximately to an EPTS of 80%. The operational rule should have the largest effect on the last group of offers, which specifically corresponded to the potential transplants the rule targeted. Similar to the kidney yield analysis, the other two groups of offers help contextualize the potential temporal but secular trends in acceptance practices.

Similar to the SRTR process for offer acceptance models, an initial two-step process accounted for the effect of donor, candidate, and donor-candidate covariates after stratifying by donor KDRI < 1.05, 1.05-< 1.75, and ≥ 1.75.[7] The models stratified by KDRI and not KDPI because the underlying KDRI cutoffs change every year. The number of previous offers was parameterized with indicators early in the match run and right-hand linear splines later in the match run, which ensured a non-zero probability of acceptance for each offer. For each strata of KDRI, the first step estimated a logistic regression including every covariate and then removed variables with a Wald test statistic < 0.2 or standard error of the parameter estimate > 2 due to potential instability. The second step estimated a model for each strata of KDRI after removal of covariates with potential instability in the corresponding stratum.

After the two-step process, a separate logistic regression estimated the interaction in acceptance for offers from donors with KDPI ≥ 85% and offers from donors recovered after implementation of the operational rule. Similar to the kidney yield analysis, the regression included a linear effect for calendar time to adjust for common temporal trends in acceptance across every donor and candidate. A separate logistic regression also estimated the difference in acceptance for offers from donors with KDPI ≥ 85% to candidates with raw EPTS > 2.70; that is, the group of offers specifically targeted by the operational rule. The regressions accounted for candidate and donor characteristics through an offset equal to the log-odds from the initial two-step process. Appendix S1 overview the model fitting process and list the specific candidate and donor characteristics.

The final logistic regression did not adjust for potential correlation between offers from the same donor. A donor-level adjustment was difficult to implement because, for example, a random effects model would potentially adjust the probability of acceptance of early offers based on the number of eventual declines, which would violate the temporal availability of information. In other words, the information required to estimate the random effect for a specific donor would not be available for the first offer and instead would be available only after the organ was accepted. Importantly, the models adjusted for offer number, with high offer numbers strongly associated with a lower probability of acceptance.

All analyses were completed in R version 3.4.3. The dplyr package helped with data cleaning and management,[8] and the gamm4 package estimated the ordinal logistic regressions.[9]

## 3 | RESULTS

### 3.1 | Kidney yield

Deceased donors recovered before implementation of the operational rule differed slightly from or were similar to donors recovered afterward (Table 1). Serum creatinine and prevalence of donation after circulatory death were slightly higher after implementation than before, possibly also causing higher KDPI. Prevalence of Public Health Service (PHS) increased risk and current other drug use was slightly higher after than before implementation, but the causes and mechanisms of death were similar.

Kidney yield was higher after implementation regardless of donor KDPI (Table 2). The odds of transplanting more kidneys from donors with KDPI ≥ 85% were 27% higher after compared with before implementation (odds ratio [OR], $_{1.06}1.27_{1.53}$), although odds were also 20% higher for donors with KDPI < 85% (OR, $_{1.04}1.20_{1.38}$). Kidney yield increased more for donors targeted by the operational rule (ie, KDPI ≥ 85%) than for donors unaffected by it, although the difference was small and not statistically significant (OR, $_{0.91}1.06_{1.25}$). Thus, the operational rule may have increased kidney yield for donors with KDPI ≥ 85%, although secular trends may exist as shown by the increased yield for donors with KDPI < 85%. Qualitative interpretations of the results were similar after adjusting for potential effects of COIIN.

Donors with KDPI ≥ 85% recovered after implementation yielded, on average, 0.065 more kidneys than the expected yield had they been recovered before implementation (Table 3), or approximately 7 additional transplanted kidneys for every 100 recovered donors with KDPI ≥ 85%. Alternatively, an additional 137 more kidneys were transplanted after implementation, that is, from March 1, 2017, to February 28, 2018, than expected from the kidney yield of donors recovered before implementation. Thus, the operational rule and/or other secular trends in kidney yield resulted in additional transplanted kidneys from donors with KDPI ≥ 85%.

For donors with KDPI ≥ 85%, kidney yield was constant or decreasing at the start of the study period before increasing at a notable

**TABLE 1** Descriptive statistics for donors recovered during the study period

| Covariates | Before implementation | After implementation |
|---|---|---|
| Number of donors | 11 632 | 10 287 |
| KDPI, mean (SD) | 53.0 (29.4) | 54.0 (29.5) |
| Donor age, y, mean (SD) | 39.7 (17.2) | 40.1 (17.1) |
| Serum creatinine, mg/dL, mean (SD) | 1.5 (1.7) | 1.6 (1.8) |
| Missing serum creatinine | 0 (0.0) | 0 (0.0) |
| DCD donor | 1981 (17.0) | 1887 (18.3) |
| PHS increased risk | 2891 (24.9) | 2734 (26.6) |
| Cause of death | | |
| Anoxia | 4722 (40.6) | 4336 (42.2) |
| Stroke | 3324 (28.6) | 2715 (26.4) |
| Trauma | 3199 (27.5) | 2946 (28.6) |
| Other | 387 (3.3) | 290 (2.8) |
| Mechanism of death | | |
| Asphyxiation | 630 (5.4) | 612 (5.9) |
| Cardiovascular | 2049 (17.6) | 1901 (18.5) |
| Drug intoxication | 1494 (12.8) | 1360 (13.2) |
| Gun injury | 997 (8.6) | 904 (8.8) |
| Injury | 2121 (18.2) | 2020 (19.6) |
| Stroke | 3445 (29.6) | 2752 (26.8) |
| Other | 896 (7.7) | 738 (7.2) |
| Current other drug use | 3608 (31.0) | 3323 (32.3) |

*Note:* The operational rule was implemented on March 1, 2017. Unless otherwise indicated, values are n (%).

Abbreviations: DCD, donation after circulatory death; KDPI, kidney donor profile index; PHS, Public Health Service; SD, standard deviation.

**TABLE 2** Adjusted odds ratios for the difference in kidney yield after versus before implementation of the operational rule

| | Category | Odds Ratio (95% CI) |
|---|---|---|
| Not adjusted for COIIN[*] | KDPI < 85% | 1.20 (1.04-1.38) |
| | KDPI ≥ 85% | 1.27 (1.06-1.53) |
| Adjusted for COIIN[*] | KDPI < 85% | 1.18 (1.02-1.36) |
| | KDPI ≥ 85% | 1.25 (1.05-1.50) |

*Note:* For example, the odds of more kidneys being placed per donor with KDPI ≥ 85% were 27% higher after implementation of the operational rule versus before.

Abbreviations: CI, confidence interval; COIIN, Collaborative Innovation and Improvement Network; KDPI, kidney donor profile index; OPTN, Organ Procurement and Transplantation Network.

[a]COIIN was a separate OPTN initiative intended to increase kidney utilization, and a sensitivity analysis accounted for its effect.

and consistent rate approximately 3 months before implementation (Figure 1). The operational rule may have caused the change in trajectory of kidney yield for donors with KDPI ≥ 85%, although the imperfect alignment with implementation complicates this interpretation. In contrast, kidney yield increased steadily and consistently over the study period for donors with KDPI < 85% (Figure 2). The consistent increase in yield over the study period suggests little impact of the operational rule for donors with KDPI < 85%.

### 3.2 | Offer acceptance

The unadjusted acceptance rate was higher after implementation for offers from deceased donors recovered during the study period (Table 4). Regarding donor characteristics, offers had slightly higher KDRI after implementation, but fewer offers were from donors with PHS increased risk. Regarding candidate characteristics, a higher proportion of offers were made to candidates with calculated panel-reactive antibodies equal to 0 after implementation, while other characteristics were similar.

As illustrated in Table 5, the odds of acceptance were 4% higher after implementation for donors with KDPI ≥ 85% (OR, $_{0.95}1.04_{1.14}$), and 2% higher for donors with KDPI < 85% (OR, $_{0.97}1.02_{1.07}$). As expected, the difference in acceptance for donors with KDPI ≥ 85% was similar to the difference for donors with KDPI < 85% (OR, $_{0.94}1.02_{1.12}$). The operational rule did not meaningfully increase the acceptance of kidneys from donors with KDPI ≥ 85%, and any difference was similar to the change in acceptance of kidneys from donors with KDPI < 85%. Surprisingly, the odds of acceptance were similar before and after implementation for offers with both KDPI ≥ 85% and raw EPTS ≥ 2.70, that is, offers for potential transplants specifically targeted by the operational rule (OR, $_{0.88}0.99_{1.12}$). Thus, the operational rule had no apparent effect on offer acceptance for the donors and candidates it specifically targeted.

## 4 | DISCUSSION

The primary goal of the MPSC operational rule was to improve utilization of kidneys with KDPI ≥ 85% by removing the perceived

**TABLE 3** The change in kidney yield for donors with KDPI ≥ 85% recovered after implementation of the operational rule versus the expected yield had the donors been recovered before implementation

| | Kidneys per 1 Donor | Kidneys per 100 Donors | Total Kidneys |
|---|---|---|---|
| Before implementation | 0.522 | 52.2 | 1094.8 |
| After implementation | 0.588 | 58.8 | 1231.9 |
| Change | 0.065 | 6.5 | 137.1 |

*Note:* For example, 137 more kidneys were transplanted than expected after implementation based on donor characteristics and may therefore be attributable to the operational rule.

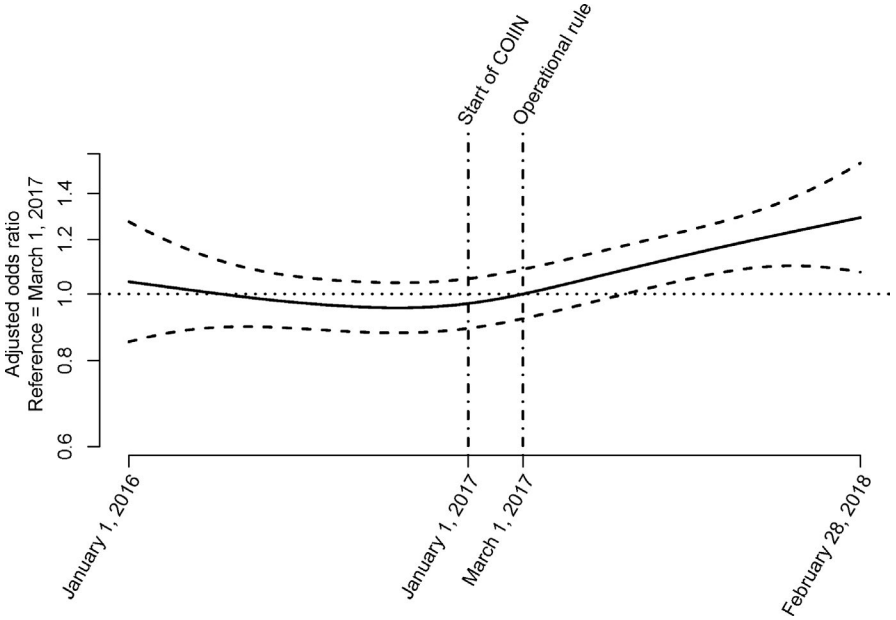


**FIGURE 1** Kidney yield over the study period for donors with KDPI ≥ 85%. COIIN was a separate OPTN initiative intended to increase kidney utilization. COIIN, Collaborative Innovation and Improvement Network; KDPI, kidney donor profile index; OPTN, Organ Procurement and Transplantation Network

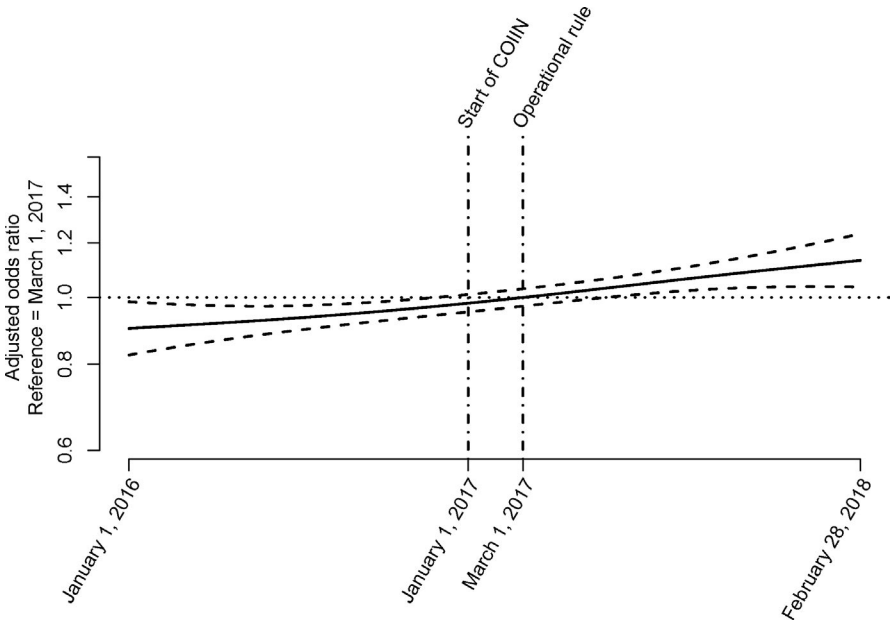


**FIGURE 2** Kidney yield over the study period for donors with KDPI < 85%. COIIN was a separate OPTN initiative intended to increase kidney utilization. COIIN, Collaborative Innovation and Improvement Network; KDPI, kidney donor profile index; OPTN, Organ Procurement and Transplantation Network

disincentive of MPSC review. Kidney yield for such donors increased after implementation of the operational rule. Further, the trajectory of yield for kidneys with KDPI ≥ 85% began increasing about 3 months before implementation, suggesting that the trajectory of yield changed near the time of implementation. However, the lack of a control group significantly restricts the ability to conclusively determine the effectiveness of the operational rule. The higher kidney yield after implementation cannot be precisely attributed either to the operational rule or to temporal changes in utilization, which may have occurred without the operational rule. For example, kidney yield for donors with KDPI < 85% was also higher after implementation, clearly demonstrating presence of temporal trends for kidneys not targeted by the operational rule. If the temporal trends present in kidney yield for donors with KDPI < 85% were unrelated to the operational rule and partially present for donors with KDPI ≥ 85%, then the kidney yield for donors with KDPI ≥ 85% would have increased without the MPSC operational rule.

Higher offer acceptance was the expected mechanism for improving utilization of kidneys from donors with KDPI ≥ 85%. Previous research demonstrated that (a) eventual acceptance of kidneys was lower after severe regulatory action from CMS,[10] and (b) transplant volume was lower after programs were identified for regulatory review by CMS.[11] A reduction in regulatory burden was expected to improve offer acceptance and organ utilization, so the small or non-existent differences in offer acceptance complicate interpretation of the apparent effectiveness of the operational rule.

The operational rule's inability to improve offer acceptance can potentially be explained in several ways. First, MPSC regulatory review may have a smaller effect on program decisions than CMS review, because OPTN, unlike CMS, is not directly responsible for

**TABLE 4** Descriptive statistics for offers of deceased donor kidneys recovered during the study period

| Covariate | Before implementation | After implementation |
|---|---|---|
| Number of offers | 1 779 639 | 1 544 684 |
| Accepted | 14 483 (0.81) | 13 007 (0.84) |
| PHS increased infectious risk | 383 847 (22) | 274 395 (18) |
| KDRI, mean (SD) | 1.46 (0.39) | 1.49 (0.38) |
| Dialysis duration, y | | |
| 0 | 186 259 (10) | 166 404 (11) |
| 0-1 | 126 837 (7) | 108 098 (7) |
| 1-2 | 213 870 (12) | 188 869 (12) |
| 2-3 | 245 939 (14) | 220 258 (14) |
| 3-4 | 242 853 (14) | 218 760 (14) |
| 4-6 | 392 581 (22) | 333 293 (22) |
| 6-8 | 211 921 (12) | 172 824 (11) |
| 8-10 | 79 467 (4) | 653 90 (4) |
| > 10 | 79 912 (4) | 70 788 (5) |
| EPTS, mean (SD) | 2.16 (0.71) | 2.18 (0.70) |
| Candidate age, y, mean (SD) | 55 (13) | 55 (13) |
| Candidate BMI, kg/m$^2$ | | |
| < 18.5 | 26 450 (1) | 22 598 (1) |
| 18.5-25 | 356 621 (20) | 301 166 (19) |
| 25-30 | 596 163 (33) | 521 363 (34) |
| 30-35 | 495 606 (28) | 438 062 (28) |
| > 35 | 301 884 (17) | 259 454 (17) |
| Candidate CPRA, % | | |
| 0 | 1 246 119 (70) | 1 106 077 (72) |
| 0.01-0.50 | 385 950 (22) | 331 108 (21) |
| 0.51-0.70 | 66 086 (4) | 52 372 (3) |
| 0.71-0.90 | 41 236 (2) | 29 405 (2) |
| > 0.90 | 40 248 (2) | 25 722 (2) |

*Note:* The operational rule was implemented on March 1, 2017. Offers were included only for eventually accepted kidneys. Unless otherwise indicated, values are n (%).

Abbreviations: BMI, body mass index; CPRA, calculated panel-reactive antibodies; EPTS, estimated posttransplant survival; KDRI, kidney donor risk index; PHS, Public Health Service; SD, standard deviation.

**TABLE 5** Adjusted odds ratios for the difference in acceptance after versus before implementation of the operational rule

| Category of offers | Odds Ratio (95% CI) |
|---|---|
| KDPI < 85% | 1.02 (0.97-1.07) |
| KDPI ≥ 85% | 1.04 (0.95-1.14) |
| KDPI ≥ 85% and EPTS ≥ 2.70 | 0.99 (0.88-1.12) |

*Note:* For example, the odds of acceptance for kidneys with KDPI ≥ 85% were 4% higher after versus before implementation. A raw EPTS of 2.70 is approximately an EPTS of 80%.

Abbreviations: CI, confidence interval; EPTS, estimated posttransplant survival; KDPI, kidney donor profile index.

reimbursement. Second, transplant programs are accountable to their patients, and the higher graft failure rates for high KDPI kidneys may cause risk aversion. Third, the inability to include offers of eventually discarded kidneys may have obscured or attenuated the effect of the operational rule. For example, acceptance practices in match runs with an accepted offer could remain constant before and after implementation even if the underlying discard rate changed.[12]

The operational rule could also have increased the number of transplants by motivating organ procurement organizations (OPOs) to pursue more marginal donors. Organ yield and offer acceptance may fail to capture such an effect. Unfortunately, information is limited regarding donor potential before the decision to recover an organ, which is the primary reason evaluation of OPO performance remains controversial.[13]

The effectiveness of the operational rule fundamentally depends on its visibility and comprehensibility to kidney transplant programs. If it lacked adequate exposure and explanation, kidney programs may have maintained current utilization practices. Unfortunately, the visibility of the operational rule in the transplant community was not measured. While OPTN posted press releases and discussed the rule at national meetings, the transplant community and, specifically, decision makers receiving deceased donor offers, may not have known about it, which could reduce the effectiveness of the effort and increase the likelihood that the observed differences were caused by secular trends rather than the operational rule. While broader communication could still help increase kidney transplants, evaluations with longer follow-up would likely increase the risk of conflating the effect of the operational rule with secular trends. For example, 2 years of follow-up after implementation, instead of 1 year, would overlap with changes in CMS regulatory review, which would further complicate the interpretation. Regardless, OPTN continues to evaluate the best methods for disseminating information about policy and operational changes to the transplant community with the goal of maintaining the greatest possible clarity and awareness of initiatives such as the MPSC's operational rule.

Unmeasured risk factors likely exist, and they could attenuate the apparent effectiveness of the MPSC operational rule if their prevalence was higher after implementation. Alternatively, unmeasured risk factors would increase the likelihood of incorrect identification for MPSC review, especially for large programs.[14] However, the prevalence of unmeasured risk factors is not known, and transplants with high unmeasured risk factors cannot be removed from program evaluations. Instead, unmeasured risk factors with high prevalence and/or strong effect should be referred to the OPTN organ-specific committees or Data Advisory Committee for consideration for potential inclusion in the OPTN database.

We found mixed evidence of improved organ utilization after implementation of the operational rule: higher kidney yield, but potentially explained by temporal trends, and no association with

offer acceptance. This mixed evidence emphasizes the importance of continuing to monitor posttransplant outcomes, because the possibility of higher organ utilization may be tolerable if posttransplant outcomes do not worsen.

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## CONFLICT OF INTEREST

The authors report no conflicts of interest.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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