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## The Collaborative Innovation and Improvement Network (COIIN): Effect on donor yield, waitlist mortality, transplant rates, and offer acceptance

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## KEYWORDS

clinical research/practice, kidney transplantation/nephrology, organ procurement and allocation, Organ Procurement and Transplantation Network (OPTN), Scientific Registry for Transplant Recipients (SRTR)

## 1 | INTRODUCTION

The Organ Procurement and Transplantation Network (OPTN) and Centers for Medicare & Medicaid Services (CMS) monitor 1-year

posttransplant outcomes for quality assurance.<sup>1</sup> Although posttransplant outcomes may improve after CMS regulatory intervention,<sup>2</sup> regulatory review may limit access to transplant due to an incorrect perception that performing transplants with high predicted risk leads

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Abbreviations: CMS, Centers for Medicare & Medicaid Services; COIIN, Collaborative Innovation and Improvement Network; DSA, donation service area; EPTS, estimated posttransplant survival; KDPI, Kidney Donor Profile Index; KDRI, Kidney Donor Risk Index; MI, multiple imputation; MPSC, Membership and Professional Standards Committee; OAR, offer acceptance ratio; OPTN, Organ Procurement and Transplantation Network; PMH, practice model hospital; SRTR, Scientific Registry of Transplant Recipients; TRR, transplant rate ratio; UNOS, United Network for Organ Sharing; WMRR, waitlist mortality rate ratio.

to poor posttransplant evaluations.<sup>3</sup> Limited access may produce negative consequences because even kidneys from marginal donors can confer a survival benefit.<sup>4,5</sup> United Network for Organ Sharing (UNOS, the OPTN contractor) thus implemented the Collaborative Innovation and Improvement Network (COIIN) to increase transplants of kidneys with a kidney donor profile index (KDPI) >50% by reducing risk aversion through a collaborative approach to performance improvement.

COIIN was a 3-year study split into 3 phases: design, implementation, and evaluation. During the design phase, practice model hospitals (PMHs) with high acceptance rates and favorable graft survival were identified as high performers. Interviews and on-site visits by UNOS staff provided insight into effective practices, which served as the foundation for the intervention guide for participating transplant programs.

The intervention guide focused on 3 specific areas: waitlist management, organ offers and acceptance, and care coordination. Each focus area involved at least 2 concepts related to higher acceptance and use of moderate- to high-KDPI kidneys. These were actionable, effective practices (i.e., interventions) identified by the PMHs. Programs participating in COIIN could then test the concepts to determine whether the interventions were effective for them. Examples of interventions include a retrospective review of organ offers and educating staff and patients about KDPI with a consistent message. The intervention guide also included considerations related to success (e.g., staffing and technology needs), potential process measures for monitoring progress, and vignettes from PMHs about how they implemented specific practices or improvements.

COIIN provided several levels of support for implementing the intervention guide. Each cohort had its own collaborative website that included the intervention guide, a calendar of upcoming events, resources provided by UNOS staff or uploaded by participants, discussion boards for collaboration among cohort participants, and data dashboards with updated outcome and process measures (e.g., transplant volume, use of moderate- to high-KDPI kidneys, and unadjusted organ and offer acceptance rates). COIIN participants held monthly collaborative conference calls to discuss ongoing improvement efforts, and UNOS staff organized and facilitated webinars presented by subject matter experts during the intervention. Other key components of the COIIN intervention included kick-off meetings for each cohort and site visits focused on identifying opportunities for improvement and developing collective goals. During the in-person kick-off meeting, participating programs met other participants, attended plenary sessions on quality improvement methodology, and learned about the intervention guide to apply it to opportunities for improvement identified during the site visits.

COIIN was split into 2 cohorts (cohorts A and B) to more widely disseminate the effective practices and increase the pool of participating programs. After an application process, both cohorts were selected based on multiple factors, including geographic location, transplant volume, performance, and perceived improvement capacity. For cohort A, 19 programs, including 5 PMHs, were selected and enrolled of 44 applicants. Participating programs and partnering organ procurement organizations were engaged to identify and test opportunities for improvement during cohort A from each intervention guide area. Based on feedback from cohort A, the COIIN intervention was slightly modified before the start of cohort B. For example, the intervention guide was modified to include notations for the most tested interventions, and a panel discussion of 5 cohort A volunteers was added to the cohort B kick-off meeting. Cohort B started at the conclusion of cohort A and enrolled 39 programs of 47 applicants; 20 of the 39 had reapplied after not being selected for cohort A. Programs enrolled in cohort B, including 1 PMH, continued to refine collaborative improvement approaches and methodologies throughout the evaluation phase based on feedback from cohort A.

This study investigated the performance of COIIN programs compared with non-COIIN programs on specific measures of interest: kidney yield, deceased donor transplant rates, waitlist mortality rates, and offer acceptance.

## 2 | 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 OPTN, and has been described elsewhere.<sup>6</sup> The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors.

## 2.1 | Analysis framework

Two analyses estimated the effect of COIIN on each measure of interest: kidney yield, deceased donor transplant rate, waitlist mortality rate, and offer acceptance. First, difference-in-differences (DID) analyses estimated the effect of COIIN on cohorts A and B (Table 1). Second, smoothing splines estimated the temporal trend in each measure of interest for the COIIN and non-COIIN groups. The DID analyses provided an easily interpretable summary for the effect of COIIN, whereas the temporal trends provided insight into the changes over time because COIIN likely did not instantly improve the measures of interest.

The DID analysis framework was similar for each measure despite different models. The analysis compared the changes over time within a group with the changes in other groups. Group assignments were (1) programs in cohort A, (2) programs in cohort B, and (3) programs not participating in COIIN. We assessed each measure of interest over 4 distinct periods: period 1 established a baseline comparison for each group (January 1, 2016, to December 31, 2016); period 2 was the active intervention for cohort A (January 1, 2017, to September 30, 2017); period 3 was the active intervention for cohort B (October 1, 2017, to June 30, 2018); and period 4 was the 9 months after the end of cohort B. In practice, the DID analysis required an interaction between group assignment and time period in each model.

We hypothesized 2 possible effects of COIIN: an "immediate effect" observed during the active intervention and a "delayed effect" after the **TABLE 1** Comparisons of interest for each of the time periods in the analyses of kidney yield, deceased donor transplant, waitlist mortality, and offer acceptance rates

			Baseline	Immediate e	effect	Delayed effec	t
Time period	Description	Dates	comparisons	Cohort A	Cohort B	Cohort A	Cohort B
Period 1	Baseline period	January 1, 2016- December 31, 2016	Yes	Yes	No	No	No
Period 2	Implementation phase for cohort A	January 1, 2017- September 30, 2017	No	Yes	Yes	Yes	No
Period 3	Implementation phase for cohort B	October 1, 2017-June 30, 2018	No	No	Yes	Yes	Yes
Period 4	Post-COIIN follow-up	July 1, 2018-March 31, 2019	No	No	No	No	Yes

Immediate effects indicate whether COIIN improved a measure of interest during the active intervention; delayed effects indicate whether COIIN improved a measure of interest immediately following the active intervention. The Baseline Comparisons, Immediate Effect, and Delayed Effect columns show the periods used to estimate an effect.

COIIN, Collaborative Innovation and Improvement Network.

end of the active intervention. Table 1 summarizes the comparisons for each effect. For each comparison, the control group was programs not in COIIN. Cohort B was not an appropriate control group for cohort A because a large proportion of its programs applied for but were not accepted into cohort A. By applying for cohort A, the cohort B programs signified an intent to improve use before their active intervention.

## 2.2 | Kidney yield

Kidney yield was the number of transplanted kidneys from donors from whom any organ was recovered. We used kidney yield because, unlike the kidney discard rate, it does not depend on the decision to recover a kidney.

A donor was designated as belonging to cohort A or B if at least 1 local program in the recovering donation service area (DSA) participated in the respective cohort. Thus, a DSA could belong to both cohort A and cohort B. The effect of COIIN on kidney yield was analyzed at the DSA level because donors are not associated with any transplant hospital, and kidney yield is influenced by offer acceptance practices.<sup>7</sup>

Descriptive statistics compared donors recovered in DSAs with (1) no programs in COIIN, (2) programs in cohort A but not in cohort B, (3) programs in cohort B but not in cohort A, and (4) programs in both cohorts A and B. Means and standard deviations summarized continuous variables, and frequencies and percentages summarized categorical variables. The analysis used donors recovered between January 1, 2016, and March 31, 2019.

Ordinal logistic regressions estimated the effect of COIIN on the number of kidneys transplanted per donor. Because COIIN focused on improving the use of moderate- to high-KDPI kidneys, the regressions were stratified by donor KDPI of 50%. The regressions adjusted for donor factors included in the SRTR donor yield models (see Supplementary Materials for a complete list) and for temporal trends in yield through a linear effect for calendar time. Splines estimated the effects of all other continuous risk factors to account for potential nonlinearity. Sensitivity analyses separately estimated the nonlinear temporal trends within each group.

# 2.3 | Deceased donor transplant and waitlist mortality rates

Descriptive statistics compared candidates at COIIN programs (separately for cohorts A and B) with candidates at non-COIIN programs. Means and standard deviations summarized continuous variables, and frequencies and percentages summarized categorical variables. The analysis used a period-prevalent cohort of candidates on the waiting list between January 1, 2016, and March 31, 2019.

Cox proportional hazards models estimated the effect of COIIN on the cause-specific hazards of deceased donor transplant and waitlist mortality. The models adjusted for several candidate factors at listing and days on the waiting list at the beginning of the cohort (see Supplementary Materials for a complete list). Calendar time was the time scale, and the baseline hazard therefore identified temporal trends in deceased donor transplant rates and waitlist mortality rates. Sensitivity analyses stratified the effect of COIIN by candidate estimated posttransplant survival (EPTS) <50% versus  $\geq$ 50% and separately estimated the nonlinear trends for each group (see Supplementary Materials for details).

COIIN participants were heavily selected, and some selection factors were associated with transplant rate. A sensitivity analysis matched on candidate and program differences to partly account for the selection process. See Supplementary Materials for a detailed description of the matching analysis methodology.

## 2.4 | Offer acceptance

Descriptive statistics compared deceased donor offers to COIIN programs (separately for cohorts A and B) with offers to non-COIIN programs. Means and standard deviations summarized continuous variables, and frequencies and percentages summarized categorical variables. The offer acceptance analysis used offers from deceased donors recovered between January 1, 2016, and March 31, 2019.

Following the process for the SRTR offer acceptance models,<sup>7</sup> initial logistic regressions adjusted for donor, candidate, and

1078

Donor characteristic	No COIIN program	Cohort A	Cohort B	Cohorts A and B
Number of donors				
Period 1	2968	932	3268	2803
Period 2	2240	718	2589	2187
Period 3	2220	753	2603	2286
Period 4	2327	775	2739	2401
KDPI	54.4 (29.4)	50.1 (28.4)	53.5 (29.3)	56.2 (29.8)
Donor age	40.5 (17.3)	38.9 (16.5)	39.8 (16.9)	40.8 (17.6)
erum creatinine	1.6 (1.7)	1.4 (1.5)	1.6 (1.7)	1.7 (1.9)
Missing serum creatinine	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OCD donors	1588 (16.3)	755 (23.8)	2093 (18.7)	1871 (19.3)
PHS increased risk	2554 (26.2)	1013 (31.9)	2817 (25.2)	2506 (25.9)
Cause of death				
Anoxia	3845 (39.4)	1562 (49.2)	4615 (41.2)	4269 (44.1)
Stroke	2750 (28.2)	703 (22.1)	3110 (27.8)	2638 (27.3)
Trauma	2772 (28.4)	846 (26.6)	3181 (28.4)	2483 (25.7)
Other	388 (4.0)	67 (2.1)	293 (2.6)	287 (3.0)
Mechanism of death				
Asphyxiation	462 (4.7)	239 (7.5)	725 (6.5)	580 (6.0)
Cardiovascular	1624 (16.6)	641 (20.2)	1984 (17.7)	1956 (20.2)
Drug intoxication	1349 (13.8)	534 (16.8)	1247 (11.1)	1275 (13.2)
Gun injury	864 (8.9)	266 (8.4)	941 (8.4)	740 (7.6)
Injury	1867 (19.1)	538 (16.9)	2232 (19.9)	1703 (17.6)
Stroke	2819 (28.9)	726 (22.8)	3143 (28.1)	2720 (28.1)
Other	770 (7.9)	234 (7.4)	927 (8.3)	703 (7.3)
Current other drug use	3204 (32.8)	1185 (37.3)	3517 (31.4)	2980 (30.8)

Means and standard deviations summarized continuous variables; frequencies and percentages summarized categorical variables.

COIIN, Collaborative Innovation and Improvement Network; DCD, donation after circulatory death; DSA, donation service area; KDPI, kidney donor profile index; PHS, Public Health Service.

donor-candidate risk factors after stratifying by donor kidney donor risk index (KDRI). The effects of continuous variables were estimated with linear splines to account for potential nonlinearity. Variable selection followed a 2-step process. Within each stratum, an initial model was estimated, and variables with a Wald test statistic <0.2 or standard error of the parameter estimate >2 were removed due to potential instability. A second model without these covariates was then estimated for each stratum. Afterward, the linear predictors from each stratum were determined.

After the initial stratified logistic regressions, an unstratified logistic regression estimated the effect of COIIN (i.e., the DID analysis), and accounted for candidate and donor risk factors through an offset equal to the linear predictors from the second set of stratified logistic regressions. This unstratified logistic regression also adjusted for the Membership and Professional Standards Committee (MPSC) operational rule, a separate OPTN initiative to increase the use of high-risk donors by reducing the likelihood of regulatory review related to high-risk donors. Finally, a linear effect for calendar time accounted for temporal trends in offer acceptance.

## 2.5 | Missing data

Missing data were multiply imputed (MI) with 10 iterations for the kidney yield, deceased donor transplant rate, and waitlist mortality rate analyses. The MI was completed separately for each analysis and used the outcome variables and risk factors from the corresponding models; for example, the outcome variables for the deceased donor transplant rate analysis were the natural-log of days at risk and an indicator of whether the candidate underwent deceased donor transplant. Rubin's rules estimated the variance of the COIIN effect across the 10 iterations of MI.<sup>8</sup>

**TABLE 2** Characteristics of donors recovered between January 1, 2016, and March 31, 2019, in a DSA with no program actively participating in COIIN, a program actively participating in cohort A, and a program actively participating in cohort B



FIGURE 1 Adjusted odds ratios for kidney vield for the different COIIN groups stratified by donor KDPI below and above 50% (top and bottom panels, respectively). The left panels show the relative differences between groups during the first period (i.e., before the COIIN intervention). The middle-left panels show the relative differences between periods 1 and 2 for each group. The middle-right panels show the relative differences between periods 2 and 3. The right panels show the relative differences between periods 3 and 4. Periods 2 and 3 were the active intervention for cohorts A and B, respectively. COIIN, Collaborative Innovation and Improvement Network; KDPI, kidney donor profile index

MI did not account for missingness in the offer acceptance analysis because the large number of offers (~5 000 000) would require prohibitive computational resources. Instead, continuous variables with missing values were imputed with the median, and an indicator for missingness was included in the regression.

All analyses were completed in R v3.4.3.<sup>9</sup> The survival package estimated the Cox proportional hazards models,<sup>10</sup> the mgcv package estimated the kidney yield models,<sup>11</sup> the mice package completed the multiple imputation,<sup>12</sup> and the dplyr package helped with data management and cleaning.<sup>13</sup>

## 3 | RESULTS

## 3.1 | Kidney yield

Donors recovered in DSAs with programs in cohorts A and B had higher KDPI results and serum creatinine levels (Table 2). The groups also differed in prevalence of donation after circulatory death, Public Health Service increased risk, and current other drug use. Changes over time in kidney yield were similar in DSAs with programs in cohort A or B and DSAs with no programs in COIIN (Figure 1). During the study period, kidney yield increased for lowand high-KDPI donors, but the increase was similar regardless of whether a program in the DSA participated in COIIN (Figures S1 and S2).

## 3.2 | Transplant and waitlist mortality rates

Most candidates were listed at programs not participating in COIIN (Table 3). The unadjusted deceased donor transplant rate differed during period 1: rates were higher for programs not in COIIN than for programs in cohort A or B. In contrast, the unadjusted living donor transplant rate was higher for programs in cohort A than for programs not in COIIN or in cohort B. The unadjusted waitlist mortality rate also differed during period 1: the rate was higher for programs in cohort B than for the other 2 groups. The proportion of Asian race was higher and of white race lower for candidates at programs in cohort B. Otherwise, candidate characteristics were similar between groups.

The adjusted transplant rate was significantly higher during period 1 for non-COIIN programs (transplant rate ratio [TRR]: cohort A vs non-COIIN,  $_{0.89}$ 0.94 $_{1.00}$ ; cohort B vs non-COIIN,  $_{0.92}$ 0.96 $_{1.00}$ ), and similar for programs in cohort A and cohort B (TRR: cohort A vs cohort B,  $_{0.93}$ 0.99 $_{1.05}$ ) (Figure 2). From period 1 to period 2 (i.e., after cohort A started), adjusted transplant rates increased for cohorts A and B compared with non-COIIN programs (TRR: cohort A,  $_{1.08}$ 1.17 $_{1.27}$ ; cohort B,  $_{1.01}$ 1.07 $_{1.14}$ ). Importantly, the increase was larger for cohort A than for cohort B (TRR:  $_{1.00}$ 1.10 $_{1.20}$ ). From period 2 to period 3 (i.e., after cohort B started), changes in adjusted transplant rates were similar in cohorts A and B compared with non-COIIN programs (TRR: cohort B,  $_{0.93}$ 1.01 $_{1.09}$ ). From period 3 to period 4, adjusted transplant rates increased for

WEY ET AL.

Variable	Not in COIIN	Cohort A	Cohort B		
Candidates	143 056	27 861	53 467		
Deceased donor transplant rate <sup>a</sup>					
Period 1	12.8	11.9	11.7		
Period 2	13.3	14.3	12.9		
Period 3	13.7	14.6	13.4		
Period 4	14.8	16.7	13.6		
Living donor transpla	ant rate <sup>a</sup>				
Period 1	5.0	6.3	4.8		
Period 2	5.0	6.8	5.1		
Period 3	5.8	7.7	5.8		
Period 4	6.0	8.1	6.0		
Waitlist mortality rat	e <sup>a</sup>				
Period 1	5.4	5.3	6.1		
Period 2	5.5	5.4	6.0		
Period 3	5.7	5.6	6.0		
Period 4	5.2	4.9	5.5		
Male	88 739 (62.0)	16 683 (59.9)	32 391 (60.6)		
Blood type					
А	43 490 (30.4)	8886 (31.9)	15 948 (29.8)		
В	22 470 (15.7)	4200 (15.1)	8606 (16.1)		
AB	4593 (3.2)	923 (3.3)	1813 (3.4)		
0	72 503 (50.7)	13 852 (49.7)	27 100 (50.7)		
Race					
White	84 618 (59.2)	16 929 (60.8)	30 499 (57.0)		
Black	45 196 (31.6)	8114 (29.1)	16 285 (30.5)		
Asian	10 949 (7.7)	2266 (8.1)	5815 (10.9)		
Other	2293 (1.6)	552 (2.0)	868 (1.6)		
Type of diabetes					
None	80 369 (56.2)	16 444 (59.0)	29 579 (55.3)		
Type 1	5188 (3.6)	1115 (4.0)	1872 (3.5)		
Type 2	56 145 (39.2)	10 055 (36.1)	21 358 (39.9)		
Other/unknown	1240 (0.9)	163 (0.6)	581 (1.1)		
Missing	114 (0.1)	84 (0.3)	77 (0.1)		
Age	52.5 (12.9)	52.7 (13.2)	52.2 (12.7)		
Years of ESRD	3.0 (5.3)	3.1 (5.7)	3.0 (5.4)		

**TABLE 3** Descriptive statistics for candidates in the transplant and waitlist mortality rate analyses, candidates on the list between January 1, 2016, and March 31, 2019

Means and standard deviations summarized continuous variables; frequencies and percentages summarized categorical variables.

COIIN, Collaborative Innovation and Improvement Network; ESRD, end-stage renal disease.

<sup>a</sup>Transplants or deaths per 100 person-years.

cohort A but decreased for cohort B compared with non-COIIN programs (TRR: cohort A,  $_{0.99}$ 1.07 $_{1.16}$ ; cohort B,  $_{0.88}$ 0.94 $_{1.01}$ ). The pattern of associations was similar for candidates below and above EPTS of 50% (Figure S3). Furthermore, transplant rates typically increased regardless of COIIN status but increased more for cohort A during period 2 (Figures S4 and S5). Thus, COIIN may have increased the transplant rate for programs in cohort A but may not have for programs in cohort B. Furthermore, this effect was observed during the active intervention period and was maintained but did not increase, afterward.

As illustrated in Figure 3, adjusted waitlist mortality rates were higher for cohort B during period 1 than for cohort A or non-COIIN programs (waitlist mortality rate ratio [WMRR]: cohort A vs non-COIIN,  $_{0.93}0.98_{1.03}$ ; cohort B vs non-COIIN,  $_{1.01}1.06_{1.10}$ ; cohort A vs cohort B,  $_{0.87}0.92_{0.98}$ ). Cohorts A and B did not differ significantly over the study period compared with non-COIIN programs;



**FIGURE 2** Adjusted transplant rate ratios for the different COIIN groups. The left panels show the relative differences between groups during the first period (i.e., before the COIIN intervention). The middle-left panels show the relative differences between periods 1 and 2 for each group. The middle-right panels show the relative differences between periods 2 and 3 for each group. The right panels show the relative differences between periods 3 and 4. Periods 2 and 3 were the active intervention for cohorts A and B, respectively. COIIN, Collaborative Innovation and Improvement Network



**FIGURE 3** Adjusted waitlist mortality rate ratios for the different COIIN groups. The left panels show the relative differences between groups during the first period (i.e., before the COIIN intervention). The middle-left panels show the relative differences between periods 1 and 2 for each group. The middle-right panels show the relative differences between periods 2 and 3 for each group. The right panels show the relative differences between periods 2 and 3 for each group. The right panels show the relative differences between periods 2 and 3 more the active intervention for cohorts A and B, respectively. COIIN, Collaborative Innovation and Improvement Network

a nonsignificant decrease occurred in cohort B from period 2 to period 3 (WMRR;  $_{0.89}$ 0.95 $_{1.01}$ ), mostly driven by candidates with EPTS  $\geq$  50% (Figure S6). The nonlinear trends for each group over time had similar qualitative interpretations. Thus, COIIN did not significantly affect waitlist mortality rates.

## 3.3 | Offer acceptance

Unadjusted acceptance rates were notably lower for cohort B compared with cohort A and non-COIIN programs (Table 4). However, cohort B received offers at a higher average offer number (i.e., later in the match run, which had lower acceptance rates).<sup>7,14</sup> Otherwise, offer characteristics did not differ meaningfully between non-COIIN programs, cohort A, and cohort B.

The adjusted acceptance rate during period 1 was higher for cohort B than for cohort A or non-COIIN programs (offer acceptance ratio [OAR]: cohort B vs non-COIIN, 1.031.081.14; cohort B vs cohort A,  $_{1.08}$ 1.16 $_{1.25}$ ), and lower for cohort A than for non-COIIN programs (OAR: 0.880.930.99) (Figure 4). From period 1 to period 2, the adjusted acceptance rate increased for cohort A compared with non-COIIN programs (OAR, 1081.18, 29); the change for cohort B was similar to the non-COIIN programs (OAR: 0931.00107). From period 2 to period 3, changes to the adjusted acceptance rate were similar for cohorts A and B compared with non-COIIN programs (OAR: cohort A, 0.880.97106; cohort B, 0.931.00108). From period 3 to period 4, the adjusted acceptance rate increased for cohort A compared with non-COIIN programs but decreased for cohort B (OAR: cohort A, 1.021.121.23; cohort B, 0.820.880.95). Interestingly, for donors with KDPI <50%, acceptance for cohort B increased significantly from period 2 to period 3 but decreased from period 3 to period 4 (Figures S9 and S10). In contrast, acceptance increased consistently in cohort A over the study period regardless of donor KDPI (Figures S9

Variable	Not in COIIN	Cohort A	Cohort B
Number of offers	3 252 999	592 338	1 213 283
Unadjusted acceptance rate			
Overall	27 762 (0.85%)	5374 (0.91%)	9749 (0.80%)
Period 1	8181 (0.83%)	1461 (0.75%)	2826 (0.81%)
Period 2	6236 (0.85%)	1277 (0.90%)	2270 (0.81%)
Period 3	6416 (0.86%)	1243 (0.90%)	2305 (0.78%)
Period 4	6929 (0.88%)	1393 (1.18%)	2348 (0.81%)
Offer number <sup>a</sup>			
Period 1	1148 (1404)	1055 (1436)	1245 (1455)
Period 2	1486 (2081)	1382 (2051)	1541 (2065)
Period 3	1393 (2074)	1370 (2188)	1484 (2091)
Period 4	1329 (1904)	1187 (2008)	1411 (1968)
PHS increased infectious risk			
Yes	649 082 (20)	120 580 (20)	246 476 (20)
Duration of dialysis, y			
0	331 944 (10)	79 616 (13)	130 991 (11)
0-1	230 222 (7)	46 283 (8)	84 384 (7)
1-2	402 036 (12)	76 098 (13)	138 458 (11)
2-3	465 098 (14)	85 932 (15)	154 592 (13)
3-4	464 612 (14)	83 130 (14)	157 206 (13)
4-6	722 615 (22)	119 748 (20)	266 658 (22)
6-8	371 626 (11)	54 438 (9)	155 405 (13)
8-10	131 504 (4)	16 946 (3)	66 515 (5)
>10	133 342 (4)	30 147 (5)	59 074 (5)
KDRI	1.49 (0.39)	1.50 (0.40)	1.46 (0.37)
EPTS	2.17 (0.71)	2.19 (0.68)	2.19 (0.70)
Candidate age	55 (13)	56 (12)	55 (12)
Candidate BMI			
<18.5	48 889 (2)	8050 (1)	16 591 (1)

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18.5-25 633 404 (19) 117 147 (20) 240 056 (20) 25-30 1 076 936 (33) 199 847 (34) 419 148 (35) 30-35 928 713 (29) 165 314 (28) 336 294 (28) >35 561 485 (17) 101 454 (17) 198 651 (16) Primary diagnosis Congenital 32 538 (1) 5334 (1) 10 595 (1) Diabetes 1 233 845 (38) 201 807 (34) 469 912 (39) Glomerulonephritis 531 871 (16) 102 336 (17) 196 962 (16) 314 704 (26) Hypertension 785 509 (24) 152 767 (26) Other 663 386 (20) 128 495 (22) 217 595 (18) Candidate CPRA 2 291 947 (70) 0 420 762 (71) 883 190 (73) 0.01-0.50 240 807 (20) 719 271 (22) 126 075 (21) 0.51-0.70 114 272 (4) 22 322 (4) 43 036 (4)

(Continues)

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<u>1084</u> <u>AIT</u>	WEY ET AL.
TABLE 1 (Continued)	

Variable	Not in COIIN	Cohort A	Cohort B
0.71-0.90	66 778 (2)	11 202 (2)	25 274 (2)
>0.90	60 731 (2)	11 977 (2)	20 976 (2)

Means and standard deviations summarized continuous variables; frequencies and percentages summarized categorical variables. BMI, body mass index; COIIN, Collaborative Innovation and Improvement Network; CPRA, calculated panel-reactive antibody; EPTS, estimated posttransplant survival; KDRI, kidney donor risk index; PHS, Public Health Service.

<sup>a</sup>Offer number is the location of the offer in the match run; high offer numbers are later and low offer numbers are early in the match run.

to S11). Thus, COIIN may have improved the offer acceptance rate of programs in cohort A but not cohort B. Furthermore, the effect of COIIN on cohort A was immediate and sustained.

## 4 | DISCUSSION

Although COIIN did not have an effect on overall kidney yield, it may have improved deceased donor transplant rates and offer acceptance practices for programs in cohort A but not programs in cohort B. Because offer acceptance practices were a potential determinant of transplant rates, the simultaneous improvement in both transplant rate and offer acceptance practices strengthened the evidence of improved use for programs in cohort A. In contrast, COIIN did not improve utilization for cohort B because neither transplant rates nor offer acceptance improved in period 3 or period 4.

Specific components in the COIIN intervention guide were designed to improve transplant rates and offer acceptance practices. At the conclusion of cohort B implementation, UNOS staff administered a survey to both cohorts to identify which interventions programs chose to work on throughout COIIN participation. Three of the 6 most commonly tested interventions were from the organ offer acceptance section of the intervention guide. These interventions aimed to revise and define acceptance criteria, perform a retrospective review of organ offers, and refine and adhere to listing criteria based on the patient population. The survey also found that revising and defining acceptance criteria was the most effective, easiest to test, and most sustainable intervention.

COIIN had no significant effect on waitlist mortality rates. Waitlist management was 1 of 3 focus areas of the intervention guide and included referring patients for transplant evaluation, evaluating and selecting candidates for listing, and reevaluating waitlisted candidates. Although waitlist mortality was the primary outcome measure of this focus area, the waitlist management interventions were also key to improving transplant rates and offer acceptance. For example, as a subcomponent of effective waitlist management, programs with high KDPI consent rates and high turndown rates could revisit their high-KDPI consent practices, eliminating offers that would be turned down and increasing acceptance rates. Conversely, programs with low consent rates but high acceptance rates for high-KDPI kidneys could try to increase consent rates and possibly improve transplant rates.

COIIN was not a randomized study, and programs were selected with regard to potentially informative characteristics, including not being under active OPTN MPSC review. Because programs under CMS review decreased transplant volume,<sup>15</sup> and CMS reviews only a subset of programs reviewed by the MPSC,<sup>1,16</sup> COIIN likely selected programs on a factor related to transplant rate and offer acceptance. As a sensitivity analysis, we estimated the difference in transplant rate between candidates in COIIN and matched controls



**FIGURE 4** Adjusted offer acceptance ratios for the different COIIN groups. The left panels show the relative differences between groups during the first period (i.e., before the COIIN intervention). The middle-left panels show the relative differences between periods 1 and 2 for each group. The middle-right panels show the relative differences between periods 2 and 3 for each group. The right panels show the relative differences between periods 3 and 4. Periods 2 and 3 were the active intervention for cohorts A and B, respectively. COIIN, Collaborative Innovation and Improvement Network

not in COIIN, matching on candidate characteristics, baseline program-specific transplant rate, and initial program-specific posttransplant evaluation (see Supplementary Materials for details). While the baseline differences attenuated, the qualitative interpretation of the matching analysis was similar: transplant rates for cohorts A and B increased from period 1 to period 2 (i.e., the intervention period for cohort A) and remained constant from period 2 to period 3. Thus, the effect of COIIN for cohort A was likely not confounded by baseline differences in transplant rate or posttransplant evaluations, although the procedure for selecting programs for participation in COIIN could have caused residual confounding through other mechanisms.

Two general reasons may explain the improved use in cohort A but not in cohort B: (1) differences in the selection process and (2) differences in COIIN implementation. Regarding the former, cohort A was more selected than cohort B, including more PMHs and possibly more programs with better resources to implement COIIN interventions. Furthermore, many cohort B programs originally applied for cohort A and may have started improvement efforts before COIIN participation. This is particularly possible because applying to COIIN required programs to identify at least 2 people who would be engaged in the COIIN project. Thus, these programs demonstrated an interest in quality improvement and may have started efforts to increase transplants of moderate- to high-KDPI kidneys before the start of cohort B. Regarding the latter reason, the monthly conference calls for cohort B were less focused because it included nearly twice as many programs as cohort A. For example, cohort B discussed generally broad themes (e.g., "We are reviewing our waiting list and looking at areas to prioritize to activate patients"), whereas cohort A covered specific, practical items (e.g., "Do you break your waiting list up by alphabet when assigning it to a coordinator?"). Regardless, the specific reasons cohort A but not cohort B improved use are critical for the broader implementation of COIIN. Thus, future collaborative improvement initiatives could, for example, track the program staff who attend monthly meetings, enabling a more detailed investigation into the determinants of effectiveness; for example, the COIIN interventions could be more effective if surgical or medical directors, rather than primary program administrators, attended the meetings.

The analysis was limited in ways beyond the informative selection process and the potential presence of unmeasured confounders. For example, the MPSC agreed to exempt participating COIIN programs from MPSC review for kidney outcomes during the participating year, dependent on engagement in the COIIN Alternate Improvement Process designed for programs trending unfavorably on key outcome and process measures. The MPSC also agreed to take COIIN participation into consideration if a program was flagged for kidney outcomes based on transplants performed during COIIN participation. Because of the perception of risk aversion caused by posttransplant outcome review,<sup>1</sup> the effect of COIIN may have conflated the modified MPSC posttransplant review with the intervention guide, the sharing of best practices, and other initiatives critical to the success of collaborative improvement.<sup>17</sup> COIIN was a promising intervention for improving transplant rates and offer acceptance practices. However, more research is necessary to ensure that broader implementation aligns more with cohort A than with cohort B. In addition, further monitoring of posttransplant outcomes is required.

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#### DISCLOSURE

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

## DATA AVAILABILITY STATEMENT

Data are available from SRTR (SRTR.org).

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#### REFERENCES

- Kasiske BL, Salkowski N, Wey A, Israni AK, Snyder JJ. Potential implications of recent and proposed changes in the regulatory oversight of solid organ transplantation in the United States. Am J Transplant. 2016;16(12):3371-3377.
- Hamilton TE. Regulatory oversight in transplantation: are the patients really better off? Curr Opin Organ Transplant. 2013;18(2):203-209.
- Snyder JJ, Salkowski N, Wey A, et al. Effects of high-risk kidneys on Scientific Registry of Transplant Recipients program quality reports. Am J Transplant. 2016;16(9):2646-2653.
- Massie AB, Luo X, Chow EKH, Alejo JL, Desai NM, Segev DL. Survival benefit of primary deceased donor transplantation with high-KDPI kidneys. *Am J Transplant*. 2014;14(10):2310-2316.
- Wey A, Salkowski N, Kremers WK, et al. A kidney offer acceptance decision tool to inform the decision to accept an offer or wait for a better kidney. Am J Transplant. 2018;18(4):897-906.
- Leppke S, Leighton T, Zaun D, et al. Scientific registry of transplant recipients: collecting, analyzing, and reporting data on transplantation in the United States. *Transplant Rev.* 2013;27(2):50-56.
- Wey A, Salkowski N, Kasiske BL, Israni AK, Snyder JJ. Influence of kidney offer acceptance behavior on metrics of allocation efficiency. *Clin Transplant*. 2017;31(9):e13057. https://doi.org/10.1111/ ctr.13057.
- Marshall A, Altman DG, Holder RL, Royston P. Combining estimates of interest in prognostic modelling studies after multiple imputation: current practice and guidelines. BMC Med Res Methodol. 2009;9:57.
- R Core Team. A Language and Environment for Statistical Computing. Vienna, Austria, 2017. https://www.gbif.org/en/tool/81287/r-alanguage-and-environment-for-statistical-computing. Accessed August 19, 2019.

- 1086 A
- 10. Therneau T. A Package for Survival Analysis S. 2015. https://CRAN.R-project.org/package=survival. Accessed August 19, 2019.
- Wood S, Scheipl F. gamm4: Generalized Additive Mixed Models Using 'mgcv' and 'Ime4' 2017. https://cran.r-project.org/web/packages/ gamm4/gamm4.pdf. Accessed August 10, 2019.
- 12. van Buuren S, Groothuis-Oudshoorn K. mice: multivariate imputation by chained equations in R. J Stat Software. 2011;45(3):1-67.
- Wickham H, Francois R, Henry L, et al. *dplyr: A Grammar of Data* Manipulation. 2017. Available at: https://rdrr.io/cran/dplyr/. Accessed August 19, 2019.
- Wey A, Pyke J, Schladt DP, et al. Offer acceptance practices and geographic variability in allocation model for end-stage liver disease at transplant. *Liver Transpl.* 2018;24(4):478-487.
- Schold JD, Buccini LD, Srinivas TR, et al. The association of center performance evaluations kidney transplant volume in the United States. Am J Transplant. 2013;13(1):67-75.
- Salkowski N, Wey A, Snyder JJ, Orlowski JP, Israni AK, Kasiske BL. The clinical relevance of Organ Procurement and Transplantation Network screening criteria for program performance review in the United States. *Clin Transplant*. 2016;30(9):1066-1073.

 Nembhard IM. Learning and improving in quality improvement collaboratives: which collaborative features do participants value most? *Health Serv Res.* 2009;44(2pt1);359-378.

## SUPPORTING INFORMATION

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

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