

Check for updates

# Effect of the ASCENT Intervention to Increase Knowledge of Kidney Allocation **Policy Changes Among Dialysis Providers**



Wairimu Magua<sup>1</sup>, Mohua Basu<sup>1</sup>, Stephen O. Pastan<sup>2</sup>, Joyce J. Kim<sup>1</sup>, Kayla Smith<sup>1</sup>, Jennifer Gander<sup>3</sup>, Sumit Mohan<sup>4,5</sup>, Cam Escoffery<sup>6</sup>, Laura C. Plantinga<sup>2,7</sup>, Taylor Melanson<sup>1</sup>, Michael D. Garber<sup>7</sup> and Rachel E. Patzer<sup>1,2,7</sup>

<sup>1</sup>Department of Surgery, Division of Transplantation, Emory University School of Medicine, Atlanta, Georgia, USA; <sup>2</sup>Department of Medicine, Renal Medicine, Emory University School of Medicine, Atlanta, Georgia, USA; <sup>3</sup>Center for Research and Evaluation, Kaiser Permanente Georgia, Atlanta, Georgia, USA; <sup>4</sup>Department of Medicine, Division of Nephrology, College of Physicians and Surgeons, Columbia University, New York, New York, USA; <sup>5</sup>Department of Epidemiology, Mailman School of Public Health, Columbia University, New York, New York, USA; <sup>6</sup>Department of Behavioral Sciences and Health Education, Rollins School of Public Health, Emory University, Atlanta, Georgia, USA; and <sup>7</sup>Department of Epidemiology, Rollins School of Public Health, Emory University School of Medicine, Atlanta, Georgia, USA

Introduction: The Allocation System Changes for Equity in Kidney Transplantation (ASCENT) trial was a cluster-randomized pragmatic, effectiveness-implementation study designed to test whether a multicomponent educational intervention targeting leadership, clinic staff, and patients in dialysis facilities improved knowledge and awareness of the 2014 Kidney Allocation System (KAS) change.

Methods: Participants included 690 dialysis facility medical directors, nephrologists, social workers, and other staff within 655 US dialysis facilities, with 51% (n = 334) in the intervention group and 49% (n = 321) in the control group. Intervention activities included a webinar targeting medical directors and facility staff, an approximately 10-minute educational video targeting dialysis staff, an approximately 10-minute educational video targeting patients, and a facility-specific audit and feedback report of transplant performance. The control group received a standard United Network for Organ Sharing brochure. Provider knowledge was a secondary outcome of the ASCENT trial and the primary outcome of this study; knowledge was assessed as a cumulative score on a 5-point Likert scale (higher score = greater knowledge). Intention-to-treat analysis was used.

Results: At baseline, nonintervention providers had a higher mean knowledge score (mean  $\pm$  SD, 2.45  $\pm$ 1.43) than intervention providers (mean  $\pm$  SD, 2.31  $\pm$  1.46). After 3 months, the average knowledge score was slightly higher in the intervention (mean  $\pm$  SD, 3.14  $\pm$  1.28) versus nonintervention providers (mean  $\pm$ SD, 3.07  $\pm$  1.24), and the estimated mean difference in knowledge scores between the groups at follow-up minus the mean difference at baseline was 0.25 (95% confidence interval [CI], 0.11–0.48; P = 0.039). The effect size (0.41) was low to moderate.

**Conclusion:** Dialysis facility provider education could help extend the impact of a national policy change in organ allocation.

Kidney Int Rep (2020) 5, 1422-1431; https://doi.org/10.1016/j.ekir.2020.06.027

KEYWORDS: dialysis; effectiveness-implementation trial; health system intervention; kidney allocation system; kidney transplantation; pragmatic trial

© 2020 Published by Elsevier, Inc., on behalf of the International Society of Nephrology. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

#### See Commentary on Page 1385

n 2014, the United Network for Organ Sharing implemented a major change to how deceased donor kidneys are allocated to patients with an overhaul of the KAS policy. The policy change was intended in part to increase patient access to kidney transplantation and in part to reduce racial disparities in transplantation.<sup>1</sup> In the previous policy, time on the waitlist begun when the patient was deemed transplant-eligible and was added to the waitlist. In the new KAS, patient waiting time, an important determinant of receiving an organ, now includes time spent on dialysis. In 2016, hemodialysis was the initial renal replacement therapy

Correspondence: Rachel Patzer, Department of Surgery, Division of Transplantation, Emory University School of Medicine, 101 Woodruff Circle, 5105 WMB, Atlanta, Georgia 30322, USA. E-mail: rpatzer@emory.edu

Received 14 February 2020; revised 29 May 2020; accepted 23 June 2020; published online 2 July 2020

for 87.3% of patients with incident end-stage renal disease (ESRD).<sup>2</sup> Therefore, dialysis facilities remain an important point of access to renal transplantation. However, the extent to which dialysis providers are educated about the impact of KAS on patient waitlisting and access to transplantation is largely unknown.

It is essential that clinical providers who are responsible for referring patients for kidney transplantation are aware of the change in the policy because patients who have been on dialysis for multiple years would likely go to the top of the waiting list and receive a transplant more quickly than in the past. This is particularly important for minority patients, such as African American patients with ESRD, who typically have longer times on dialysis and substantial racial disparities in transplant access.<sup>3–5</sup> Lags in access to transplantation implies barriers to its associated benefits, including (i) better long-term survival,<sup>6,7</sup> (ii) superior quality of life,<sup>6-9</sup> (iii) a lower risk of cardiovascular events,<sup>6</sup> and (iv) substantial health care cost savings to the health care system,<sup>10,11</sup> among other benefits. Despite changes in the KAS designed to increase transplant access and reduce racial disparities, Kim et al.<sup>12</sup> found that 81% of dialysis providers in facilities with low waitlisting were unaware of existing racial disparities in waitlisting.

The Centers for Medicare and Medicaid Services, as a part of conditions for coverage for patients with ESRD, requires that education on kidney transplantation be provided to the approximately 500,000 patients in the >7000 US dialysis facilities.<sup>13–15</sup> However, evidence suggests that dialysis providers, including nephrologists, social workers, clinic managers, and/or nurses, have limited knowledge of transplantation. For example, research has shown that 52% of staff had insufficient knowledge to answer most patient questions about transplantation.<sup>16</sup> Inadequate care provider education on transplantation, <sup>12,16</sup> provider beliefs,<sup>17,18</sup> and provider's differential provision of patient education on transplantation<sup>19</sup> may preclude patient education and contribute to disparities in transplantation.

Previous research suggests that system-level interventions targeting dialysis facilities can improve care at the regional and national levels.<sup>20–23</sup> Evidence also suggests that audit and feedback reports combined with multicomponent and multilevel educational interventions in dialysis facilities can reduce racial disparities in transplant access.<sup>24–26</sup> In this study, we assess the effectiveness of a multicomponent educational intervention on changes in knowledge of the impact new KAS on transplantation among dialysis facility providers in US dialysis facilities with low waitlisting. The outcome of the present analysis, provider knowledge, is a secondary outcome in the ASCENT trial. Increasing provider knowledge on KAS and transplantation is a requisite step toward increasing the quality of patient education on transplantation, increasing access to transplantation, and reducing inequities in kidney transplantation. We hypothesized that providers in dialysis facilities allocated to the multicomponent educational intervention group would have a greater knowledge of transplantation and KAS compared with those in dialysis facilities receiving standard educational brochures. Our results may inform the reach of the KAS policy among providers as related to renal transplantation knowledge and access.

# METHODS

## Study Design

The ASCENT study<sup>27</sup> was a cluster-randomized,<sup>28,29</sup> pragmatic, effectiveness-implementation study designed to test whether a multicomponent educational intervention targeting medical directors and facility leadership, clinical staff, and patients with ESRD in US dialysis facilities with low waitlisting increased patient waitlisting and reduced waitlisting disparities at 1 year. Data collection for these longer-term endpoints at the patient level is ongoing. The ASCENT study was also designed to evaluate an earlier secondary endpoint-whether the multicomponent educational intervention increased dialysis facility provider knowledge, the focus of this work. Participant enrollment, allocation, and follow-up are presented in Figure 1.<sup>29</sup> Following e-mailed consent for participation, the baseline survey was administered to dialysis facility providers from October to December 2016, with a follow-up survey administered about 3 months after each facility completed the baseline survey. Educational materials were made available within a few days of baseline survey completion. The study was approved by the Emory University Institutional Review Board (IRB#81580; trial registration: ClinicalTrials.gov identifier NCT02879812).

## Eligibility, Settings, and Participants

Among all US dialysis facilities in 2014 (n = 7822), we excluded those with <11 patients (n = 1324) and <4 African American patients (n = 1519). Facilities that ranked in the lowest national tertile for proportion of patients waitlisted (<15.2%) were defined as low waitlisting and considered eligible (n = 1529; Figure 2).<sup>30</sup> Eight hundred twelve facilities did not respond to the request to participate via e-mail and 62 facilities had erroneous contact information, leaving 655 dialysis facilities with low waitlisting (42.8%) consenting to participate in the study before randomization. A total of 334 (51%) and 321 (49%) dialysis facilities were randomly allocated to the intervention and waitlist control groups, respectively (Figure 1).

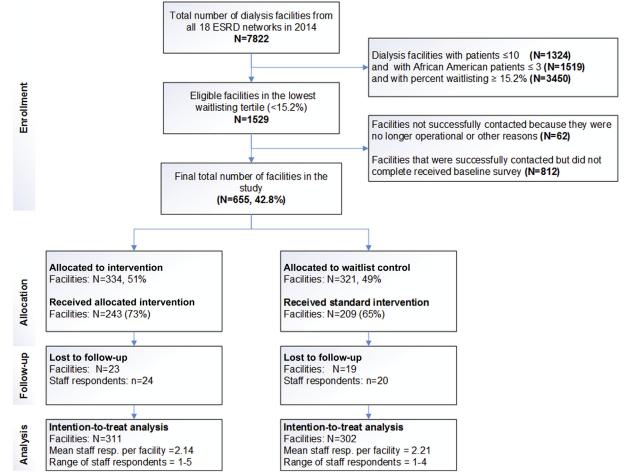


Figure 1. Flow diagram illustrating the number of dialysis facilities that (i) met the inclusion/exclusion criteria during enrollment, (ii) were allocated to the study groups, (iii) participated during follow-up, and (iv) were included as part of the analytic sample. ESRD, end-stage renal disease.

## Recruitment

ESRD Network 6 leadership led the recruitment process by sending the baseline and follow-up surveys to eligible dialysis facility medical directors or nurse managers.<sup>27</sup> Dialysis facility providers were aware at the time of the survey that their identifiable data were blinded to network leaders. ASCENT research staff sent e-mails and made calls to invite facilities that did not

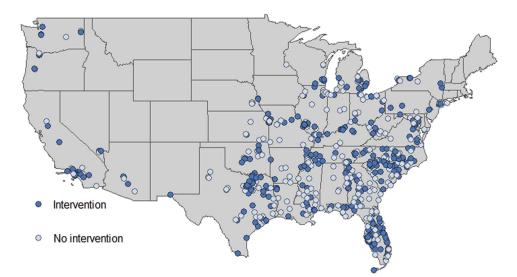


Figure 2. Dialysis facility locations were overlaid on cartographic boundaries provided by the US Census Bureau (public domain) and implemented using the USAboundaries R package.<sup>30</sup>

respond to the initial or follow-up e-mails to participate. We tested whether the distribution of participating dialysis facilities differed from nonparticipating facilities based on cluster level characteristics: profit status (profit vs. nonprofit), census region (Northeast, South, Midwest, or West), and percent of families considered to be below the national poverty level (< 20%, 10% - 20%, or > 20%).

#### Randomization and Intervention

A random number generator was used to assigned facilities to the group (cluster/dialysis facility). The assignment sequence remained concealed until assignment was complete. To minimize spillover, we assigned facilities with the same medical director or nurse manager to the same group. There were no other deviations from the random assignment protocol.

Facilities in the intervention group received a webinar targeting medical directors and other dialysis facility staff, an approximately 10-minute educational video targeting dialysis staff, and a facility-specific audit and feedback report of their transplant performance as hard copies and by e-mail within 2 weeks after the baseline surveys were completed.<sup>27</sup> The interventions were developed by a multidisciplinary advisory board described in detail elsewhere.<sup>27</sup> All intervention group educational materials were made available online for unlimited access (www. ascenttotransplant.org). Given the nature of the intervention, providers were not blinded. The power of our study was based on the original ASCENT trial primary outcome.<sup>27</sup> The control group received a standard United Network for Organ Sharing brochure.

The outcome variable, measured using 5 items on a survey, was designed *a priori* to be a secondary outcome of the trial: staff knowledge of KAS and transplantation. This survey was developed by a multidisciplinary stakeholder group as previously described<sup>27</sup> and was used to quantify knowledge of KAS and transplantation using a cumulative knowledge score (0 = least knowledge, 5 = highest level of knowledge). The survey items can be found in Section S1 of the Supplementary Table S1.

#### Analytical Methods

As part of the pragmatic trial design, we applied a provider-level, intention-to-treat analysis<sup>31</sup> and used linear mixed-effects models to estimate the treatment effect of the intervention with 95% CIs using R soft-ware's robustlmm,<sup>32</sup> lme4,<sup>33</sup> and lmerTest<sup>34</sup> packages. To address potential baseline differences in outcome, we estimated the treatment effect as the mean difference in knowledge between the intervention and control group at follow-up minus the mean difference in

knowledge between the study groups at baseline. We adjusted for the following individual-level covariates: dialysis care provider, sex, race, care role, and length of time in role. We examined the proportion of model variability attributable to facilities, geographic areas (ZIP codes), and ESRD networks each via a random effect. Dialysis facilities were nested within ZIP codes, which were nested in ESRD networks. We obtained restricted maximum likelihood model estimates.<sup>33</sup> P < 0.05 was considered statistically significant. The estimated effect size was defined as the treatment effect divided by the dispersion between dialysis facilities.

In an exploratory stratified analysis, we investigated the potential differential gain in intervention effects using facility characteristics that may influence health outcomes and contribute to waitlisting disparities: facility size, <sup>35</sup> profit status (profit vs. nonprofit), <sup>19</sup> number of social workers, <sup>36</sup> geographic region (Northeast, South, Midwest, or West), <sup>37</sup> level of ZIP code poverty, <sup>38</sup> and percent of patients in the facilities with identified comorbidities. <sup>39</sup> The facility-level characteristics not included in the study data were obtained by linking to United States Renal Data System facilitylevel data, US census data, and Dialysis Facility Report data.

Missing data patterns were investigated using R software's VIM package.<sup>40</sup> For primary analyses, multiple imputation was implemented using the MICE package in R.<sup>41</sup> We imputed missing values using the classification and regression trees method in MICE, a nonparametric approach that can be applied to data with complex distributions. We imputed both missing covariate and response variables, creating 10 datasets over 50 iterations. and subsequently applied our analytic model to the pooled dataset.<sup>42</sup> In a sensitivity analysis, we performed a complete case analysis to investigate possible bias in model estimates.

#### RESULTS

The number of respondents per facility ranged between 1 and 5. Of the 655 facilities, 94% and 82% had 1 respondent at baseline and follow-up, respectively. We included data from facilities with  $\geq$ 1 participant. Baseline facility-level characteristics were similarly distributed across study groups by profit status, census region, percentage of families below the national poverty level, numbers of patient and staff, and distributions of comorbid conditions (Table 1). Based on cluster-level characteristics, the facilities that were eligible for study inclusion but did not respond to the invitation to participate (n = 812) were similarly distributed to those that participated in the study

included in the ASCENT study	/ by study g	roup, Octob	er 2016.
Baseline characteristics	Baseline participation, $N = 655$	Control group, n = 321 (49%)	Intervention group, $n = 334$ (51%)
Profit status, <i>n</i> (%)			
For-profit	64 (9.8)	29 (9.0)	35 (10.5)
Nonprofit	591 (90.2)	292 (91.0)	299 (89.5)
Census region, n (%)	. ,	. ,	. ,
Northeast	27 (4.1)	13 (4.0)	14 (4.2)
South	424 (64.7)	223 (69.5)	231 (69.2)
Midwest	120 (18.3)	66 (20.6)	54 (16.2)
West	54 (8.2)	19 (5.9)	35 (10.5)
Percentage of families considered to be below the national poverty level (based on ZIP code US Census data), n (%)			
<5	52 (7.9)	22 (6.9)	30 (9.0)
5–10	137 (20.9)	73 (22.7)	64 (19.2)
10–15	174 (26.6)	85 (26.5)	89 (26.6)
15–20	127 (19.4)	60 (18.7)	67 (20.1)
>20	154 (23.5)	80 (24.9)	74 (22.2)
Missing	11 (1.7)	1 (0.3)	10 (3.0)
Patients, n (%)			
≤50	187 (28.5)	92 (28.7)	95 (28.4)
51–70	157 (24.0)	76 (23.7)	81 (24.3)
71–95	147 (22.4)	73 (22.7)	74 (22.2)
<95	148 (22.6)	73 (22.7)	75 (22.5)
Missing	16 (2.4)	7 (2.2)	9 (2.7)
Staff, <i>n</i> (%)			
≤10	170 (26.0)	87 (27.1)	83 (24.9)
11–15	215 (32.8)	97 (30.2)	118 (35.3)
16–20	124 (18.9)	66 (20.6)	58 (17.4)
>20	123 (18.8)	61 (19.0)	62 (18.6)
Missing	23 (3.5)	10 (3.1)	13 (3.9)
Percent of patients with comorbidities, o	quartiles		
Diabetes, n (%)			
<50	149 (22.7)	71 (22.1)	78 (23.4)
50–55.34	166 (25.3)	83 (25.9)	83 (24.9)
55.34–61.32	160 (24.4)	74 (23.1)	86 (25.7)
>61.32	159 (24.3)	85 (26.5)	74 (22.2)
Missing	21 (3.2)	8 (2.5)	13 (3.9)
Hypertension, n (%)			
<84.71	158 (24.1)	72 (22.4)	86 (25.7)
84.71-89.19	164 (25.0)	90 (28.0)	74 (22.2)
89.19–92.86	156 (23.8)	70 (21.8)	86 (25.7)
>92.86	156 (23.8)	81 (25.2)	75 (22.5)
Missing	21 (3.2)	8 (2.5)	13 (3.9)
Congestive heart failure, n (%)			
<22.50	155 (23.7)	71 (22.1)	84 (25.1)
22.50–29.17	161 (24.6)	85 (26.5)	76 (22.8)
29.17–36.84	157 (24.0)	80 (24.9)	77 (23.1)
>36.84	160 (24.4)	77 (24.0)	83 (24.9)
Missing	22 (3.4)	8 (2.5)	14 (4.2)
Chronic obstructive pulmonary disease, n (%)			
<5.33	148 (22.6)	71 (22.1)	77 (23.1)
5.33–9.00	149 (22.7)	78 (24.3)	71 (21.3)
9.00–13.31	150 (22.9)	75 (23.4)	75 (22.5)
>13.31	155 (23.7)	75 (23.4)	80 (24.0)
Missing	53 (8.1)	22 (6.9)	31 (9.3)
Capcor $p(0/2)$			

Table 1.	Baseline char	acteristics amoi	ng US dialysis facilities
included	in the ASCEN	T study by study	y group, October 2016.

(Continued)

Table 1. (Continued) Baseline characteristics among US dialysis
facilities included in the ASCENT study by study group,
October 2016.

Baseline characteristics	Baseline participation, $N = 655$	Control group, <i>n</i> = 321 (49%)	Intervention group, $n = 334$ (51%)
<3.7740	152 (23.2)	67 (20.9)	85 (25.4)
3.77-6.25	135 (20.6)	74 (23.1	61 (18.3)
6.25-9.09	153 (23.4)	74 (23.1)	79 (23.7)
>9.09	143 (21.8)	69 (21.5)	74 (22.2)
Missing	72 (11.0)	37 (11.5)	35 (10.5)
Insurance type, mean (SD)			
Medicare	43.7 (35.0)	45.4 (37.3)	42.2 (32.7)
Medicaid	30.9 (26.3)	30.8 (26.4)	31.0 (26.2)
Employer-based	22.0 (19.9)	22.5 (20.7)	21.5 (19.2)
Other insurance	6.5 (11.0)	6.3 (8.3)	6.7 (13.2)
Uninsured	10.4 (11.6)	10.7 (11.7)	10.1 (11.5)

ASCENT, Allocation System Changes for Equity in Kidney Transplantation.

(*n* = 655) by profit status and by percent of families considered to be below the national poverty level, and differently distributed by census region ( $\chi^2$  = 32.6, *P* < 0.001).

Among the 690 providers who completed the baseline survey (Table 2), 17.2% were medical directors, 49.1% were nurse managers, 17.4% were facility administrators, and 13.2% were social workers. Most participants (73.6%) were female. Approximately 62.1% of participants in the intervention group were white, and 11.8% were African American, compared with 58.2% and 13.5% in the control group. Almost half of participants (48.3%) had been in their professional role for 1–5 years. All provider baseline characteristics were similarly distributed across study groups by sex, race, provider role, and length of time in the role (Table 2).

Approximately 55% of the sample had no missing information; 28% had missing provider role variable, and 3% of the sample had missing race information. Approximately  $\leq 3\%$  of the sample had  $\geq 3$  variables with missing values. The missing data were assumed to be missing at random.

Among 655 facilities, a total of 23 (7%) facilities (n = 24 staff respondents) in the intervention and 19 (6%) facilities (n = 20 staff respondents) in the control groups were considered lost to follow-up. In the follow-up survey (n = 613 facilities), providers from 73% and 65% of the dialysis facilities in the intervention and control group, respectively, reported to have received the allocated intervention. The remaining providers may have not received the intervention or may have received the intervention but remained unaware or nonadherent. However, using intention-to-treat analysis served to maintain the balance in our original allocation and yield conservative treatment effects.<sup>31</sup>

Cancer. n(%)

**Table 2.** Characteristics of providers who completed the baselinesurvey from 655 dialysis facilities in all 18 ESRD Networks by studygroup, October 2016

Baseline characteristics,	Baseline participation,	Control group,	Intervention group,
п (%)	N = 690	n = 342 (49.6%)	n = 348 (50.4%)
Sex			
Male	147 (21.3)	74 (21.6)	73 (21.0)
Female	508 (73.6)	245 (71.6)	263 (75.6)
Missing	35 (5.1)	23 (6.7)	12 (3.4)
Race			
White	415 (60.1)	199 (58.2)	216 (62.1)
African American	87 (12.6)	46 (13.5)	41 (11.8)
Hispanic	42 (6.1)	19 (5.6)	23 (6.6)
Asian	58 (8.4)	27 (7.9)	31 (8.9)
Other	20 (2.9)	12 (3.5)	8 (2.3)
Missing	68 (9.9)	39 (11.4)	29 (8.3)
Professional role			
Medical director	119 (17.2)	59 (17.3)	60 (17.2)
Nurse manager	339 (49.1)	175 (51.2)	164 (47.1)
Facility administrator	120 (17.4)	59 (17.3)	61 (17.5)
Social worker	91 (13.2)	40 (11.7)	51 (14.7)
Other staff	21 (3.0)	9 (2.6)	12 (3.4)
Length of time in role, yr			
<1	108 (15.7)	51 (14.9)	57 (16.4)
1–5	333 (48.3)	170 (49.7)	163 (46.8)
5–10	120 (17.4)	52 (15.2)	68 (19.5)
≥10	129 (18.7)	69 (20.2)	60 (17.2)

ESRD, end-stage renal disease.

At baseline, the control group had a higher crude average knowledge score (mean  $\pm$  SD, 2.45  $\pm$  1.43) than the intervention group (mean  $\pm$  SD, 2.31  $\pm$  1.46). Investigating baseline differences using both adjusted and unadjusted linear mixed effects models, we found no statistically significant difference in baseline cumulative knowledge scores by study group. At followup, the intervention group had a higher crude average knowledge score (mean  $\pm$  SD, 3.14  $\pm$  1.28) than the control group (mean  $\pm$  SD, 3.07  $\pm$  1.24). The primary analysis model estimates obtained from using multiple imputation pooling 10 datasets over 50 iterations showed that the mean change of the knowledge score over time in the intervention group compared with the model-estimated mean change of the knowledge score over time in the control group was 0.25 (95% CI, 0.11-0.48; P = 0.039; Table 3), with a low to moderate effect size of 0.41.

In the sensitivity analysis using complete case model estimates with robust standard errors, we found the increase in knowledge score from baseline to follow-up among intervention providers minus the increase of the knowledge score from baseline to follow-up among control providers to be slightly higher at 0.33 (95% CI, 0.04–0.62; P = 0.025; Supplementary Table S2) than primary analysis model estimates (Table 3). The direction of the model parameter estimates in the imputed

**Table 3.** Mean difference in staff knowledge gap between the dialysis facility intervention (50.4%) and control group (49.6%) at follow-up minus mean difference of knowledge gap at baseline using multiple imputation pooling 10 datasets over 50 iterations for providers from 655 dialysis in all 18 ESRD Networks in the lowest national tertile (<15.2%), October 2016 to May 2017

Description	Estimate	95% CI	P Value	
Estimated treatment effect <sup>a</sup>	0.25	0.11-0.48	0.039	
Intervention vs. control group <sup>b</sup>	-0.16	-0.36 to 0.03	0.104	
Follow-up vs. baseline <sup>b</sup>	0.63	0.47-0.80	< 0.001	
Covariates: sex, role, length of time in role, race				
Male vs. female	-0.07	-0.33 to 0.18	0.562	
Provider role vs. medical director				
Nurse manager	-1.00	-1.30 to -0.69	< 0.001	
Facility administrator	-0.92	-1.23 to $-0.61$	< 0.001	
Social worker	-0.48	-0.82 to -0.13	0.008	
Other	-0.98	-1.40 to $-0.57$	< 0.001	
Length of time in role vs. shortest length of time in role (<1 yr)				
1 to <5	0.22	0.04-0.40	0.016	
5 to <10	0.12	-0.10 to $0.34$	0.282	
≥10	0.35	0.12-0.58	0.003	
Race vs. white				
African American	-0.43	-0.64 to $-0.22$	< 0.001	
Hispanic	-0.56	$-0.85\ \text{to}\ -0.27$	< 0.001	
Asian	-0.33	$-0.61\ \text{to}\ -0.05$	0.023	
Other	-0.04	-0.40 to $0.32$	0.819	

CI, confidence interval; ESRD, end-stage renal disease.

<sup>a</sup>The treatment effect is defined as the mean difference in knowledge between the intervention and the control group at follow-up minus the mean difference in knowledge between the intervention and control group at baseline.

<sup>b</sup>The lower-order terms are a result of the treatment effect, which is modeled as an interaction of time and study group.

data was the same as that in the complete case analysis. Medical directors had higher knowledge overall at any point compared with providers in other roles regardless of study group. Of the total model variability, about 20% was attributable to the dialysis facilities. We found no variability attributable to geographic regions or ESRD networks.

In an exploratory stratified analysis, we examined the facility characteristics associated with a greater impact of the intervention, measured as a comparison of the difference in the average cumulative provider knowledge score between the intervention and control groups at follow-up and at baseline. A higher intervention impact was associated with facilities in which <50% (lowest quartile) of patients had diabetes (mean difference in knowledge, 0.89 [95% CI, 0.33– 1.42]; P = 0.001), with facilities that had >20 (largest quartile) staff members (mean difference in knowledge, 0.63 [95% CI, 0.70–1.11], P = 0.017) and with nonprofit facilities (mean difference in knowledge, 1.28 [95% CI, 0.64–1.89]; P < 0.001).

#### DISCUSSION

This study provides evidence of the effectiveness of a pragmatic, multicomponent educational intervention in

increasing knowledge of KAS and transplantation among nephrologists, social workers, nurses, and clinic managers working in dialysis facilities with historically low waitlisting performance. While the estimated effect on knowledge change was low to moderate, when applied to a large number of facilities across the country, even small effects can have impact on improving knowledge and awareness about changes in kidney allocation policies on a population level.

Under the oversight of the Centers for Medicare and Medicaid Services, ESRD Networks develop and evaluate adherence to standards that govern quality of care in facilities and assignment of patients to other renal replacement modalities, including transplantation.<sup>43</sup> Evidence indicates that multicomponent provider education interventions can improve the quality of care of patients with ESRD in dialysis facilities.<sup>44,45</sup> These gains may be understood through the theory of reasoned action, which postulates that attitude is a mediating mechanism between knowledge and action.<sup>46–49</sup> Previous studies have shown that the engagement of institutional leaders in quality improvement initiatives increases the level of engagement and enhances the attitude and compliance of physicians and staff in those initiatives.<sup>50,51</sup>

ESRD networks, dialysis facilities, UNOS, transplant center outreach staff, and/or Centers for Medicare and Medicaid Services could use this freely available multicomponent educational intervention to improve knowledge of KAS and transplantation among dialysis providers as a first step to improve patient education and transplantation access. Furthermore, such interventions may extend the reach of the new KAS policy. The results of this study are particularly relevant because comprehensive patient education on transplantation is predicated on the level of provider knowledge of KAS and transplantation. Our study examined 655 dialysis facilities in which an average of approximately 60 patients with ESRD were treated. If the ASCENT intervention were applied to all facilities, providers in these facilities could translate this knowledge to the approximately 40,000 patients with ESRD within these facilities. While additional resources for successful implementation may be required, we demonstrated that combining pragmatic techniques such as leveraging leadership engagement,<sup>16,50,51</sup> encouraging staff to watch videos during "lunch and learn" sessions as part of quality improvement initiatives, and offering continuing medical education credit as an incentive for participation can support successful implementation of such complex educational interventions compared to a single intervention component.<sup>52</sup> Future research on the cost-effectiveness of such a multicomponent intervention may be worthwhile to further inform implementation strategies.

Our study targeted facilities with the lowest waitlisting in the nation, which are the facilities that most need to improve patient interest and knowledge of transplantation and to increase provider knowledge on their role at every step of the care process leading up to transplantation. Research indicates that patients who receive comprehensive education on transplantation are more likely to complete transplantation evaluation,<sup>53</sup> a requisite step for waitlisting. Furthermore, existing racial disparities in waitlisting<sup>38</sup> may in part be attributable to the lower likelihood of racial minorities to receive adequate patient education.<sup>54</sup>

There has been a longstanding recognition of the need for provider education interventions to improve quality of care and to reduce disparities in care processes and outcomes since the Institute of Medicine's Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care.<sup>55</sup> Extant research suggests that provider educational interventions can improve care processes and health outcomes of patients.<sup>56</sup> However, passive interventions such as printed material and traditional continuous medical education alone tend to be less effective in increasing knowledge or in changing the behavior of physicians compared with interactive interventions.<sup>57</sup> Our intervention encouraged interaction through questions and answers during the webinar and used visual illustrations of content during the video presentations and webinar session, and may explain why we observed an effect of the intervention.

Our study results also suggest that medical directors, regardless of group or time (baseline or follow-up) had higher cumulative knowledge scores than providers in other roles. Combined evidence suggests that facility leaders can potentially serve as champions in the sustained implementation of quality improvement programs.<sup>50,51</sup> Our exploratory stratified analysis also suggests that the intervention was most effective in dialysis facilities characterized by lower diabetes burden, more staff members, and nonprofit facilities. Future studies are needed to investigate institutional strategies such as incentives that promote consistent provider engagement in quality initiatives.

There are several potential limitations of this study. We analyzed the secondary outcome for the ASCENT trial because the primary outcome data are not yet available, and our original power calculation was for the primary outcome.<sup>27</sup> Nonetheless, our study shows a low to moderate effect size of 0.41 with improvement in knowledge among both the control and intervention groups, indicating that any provider education is an improvement of the status quo. It is possible that the

effect size may have been smaller with a larger size of respondents. Nevertheless, extant meta-analysis suggests that educational and behavioral interventions with low effect sizes can be meaningful.<sup>58,59</sup> Future patient-level data for the primary outcome of the ASCENT trial (waitlisting) will be available to determine if provider change in knowledge was associated with a population-level impact on access to transplantation and in reduced disparities on the patient level.

The outcome as measured in this study is not continuous. However, resulting departures from normality do not much impact fixed effects and variance component estimators obtained using linear mixed effects models, and they can be corrected by using robust standard errors.<sup>60</sup> We showed in our sensitivity analysis that model estimates remain comparable before and after robust standard errors are applied to correct for departures from normality. Our results may only apply to US dialysis facilities with low waitlisting. The generalizability of the study was improved given that facilities were well distributed across the country and by numerous facility attributes related to facility level random allocation. Also, the proportion of missing data was large. However, the use of multiple imputation has been shown to reduce bias in missing at random data even when the proportion of missing data is large.<sup>61</sup> Furthermore, selection bias resulting from differential nonresponse between the intervention and nonintervention groups is mitigated by multiple imputation.<sup>62,63</sup>

The study also relied on self-reported survey data from providers. We provided anonymity of responses to network leaders to mitigate any social desirability bias. Over 25% of respondents did not recall receiving the intervention; results of a process evaluation study to examine delivery, common implementation approaches, and reactions to inform understanding of the effectiveness of intervention are ongoing. It is possible that the impact of an intervention such as ours may be attenuated by high provider turnover. However, evidence-based long-term quality improvement interventions have been shown to increase health care professional morale and reduce turnover.<sup>64</sup>

In this effectiveness-implementation trial, we found that the ASCENT intervention increased dialysis provider knowledge of the KAS policy change and transplantation. The need for long-term education interventions designed to increase the knowledge of KAS and transplantation among dialysis providers remains. This study is poised to inform such sustainable and pragmatic intervention designs and implementation. Our study demonstrates that a pragmatic education intervention may be useful in extending the reach of a national policy change through provider education. The educational intervention we tested in this study is brief, freely available, and accessible. Centers for Medicare and Medicaid Services, United Network for Organ Sharing, transplant center outreach staff, ESRD Networks, and/or individual nephrology clinics and dialysis facilities may find these interventions valuable to implement in practice.

# DISCLOSURE

All the authors declared no competing interests.

#### ACKNOWLEDGEMENTS

Some of the data reported were supplied by the US Renal Data System. Interpretation and reporting of these data are the authors' responsibility and should not be seen as official policy or interpretation of the US government.

We thank members of the Dissemination Advisory Board who helped develop the intervention and create educational materials: Alex Berlin, Teri Browne, John Burkart, Susan Caponi, Diana Clynes, Eric Gibney, Gary Green, Sean Kalloo, Jenna Krisher, Janice Lea, Carol Lyden, William M. McClellan, Laura Mulloy, Gary Renville, Leighann Sauls and Nicole Turgeon. Thank you also to the ESRD Executive Directors and staff of the 18 ESRD Networks, who helped with implementing the intervention. We thank Reem Hamoda, Mari Palta, and Harold Franch for insights that enhanced the manuscript.

This work was supported by National Institute on Minority Health and Health Disparities Grant No. R01MD010290. The full trial protocol is available in *Kidney International Reports*. ClinicalTrials.gov identifier: NCT02879812.

#### SUPPLEMENTARY MATERIAL

#### Supplementary File (PDF)

**Table S1.** Survey items that constitute the cumulative knowledge of the new kidney allocation system policy change (scores range from 0 = least knowledge to 5 = highest level of knowledge) measured at baseline and at 3-month follow-up among providers in 655 dialysis facilities in the lowest waitlisting tertile in all 18 ESRD Networks.

**Table S2.** A comparison of model estimates using naïve standard errors and estimates using robust standard errors intended to correct departures from model normality assumptions. The treatment effect is the mean difference in knowledge gap between the dialysis facility intervention (50.4%) and control groups (49.6%) at follow-up minus the mean difference of knowledge gap at base-line among providers in 655 dialysis in all 18 ESRD Networks in the lowest national tertile (<15.2%), October 2016 to May 2017.

**CONSORT** Checklist.

# REFERENCES

- Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. J Am Soc Nephrol. 2014;25:1842–1848.
- United States Renal Data System. 2018 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2018.
- Navaneethan SD, Singh S. A systematic review of barriers in access to renal transplantation among African Americans in the United States. *Clin Transplant*. 2006;20:769–775.
- Stolzmann KL, Bautista LE, Gangnon RE, et al. Trends in kidney transplantation rates and disparities. J Natl Med Assoc. 2007;99:923–932.
- Joshi S, Gaynor JJ, Bayers S, et al. Disparities among blacks, Hispanics, and whites in time from starting dialysis to kidney transplant waitlisting. *Transplantation*. 2013;95:309–318.
- Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *Am J Transplant*. 2011;11:2093–2109.
- Neipp M, Karavul B, Jackobs S, et al. Quality of life in adult transplant recipients more than 15 years after kidney transplantation. *Transplantation*. 2006;81:1640–1644.
- 8. Simmons RG, Abress L. Quality-of-life issues for end-stage renal disease patients. *Am J Kidney Dis.* 1990;15:201–208.
- 9. Ogutmen B, Yildirim A, Sever MS, et al. Health-related quality of life after kidney transplantation in comparison intermittent hemodialysis, peritoneal dialysis, and normal controls. *Transplant Proc.* 2006;38:419–421.
- Loubeau PR, Loubeau JM, Jantzen R. The economics of kidney transplantation versus hemodialysis. *Prog Transplant*. 2001;11:291–297.
- Yen EF, Hardinger K, Brennan DC, et al. Cost-effectiveness of extending Medicare coverage of immunosuppressive medications to the life of a kidney transplant. *Am J Transplant*. 2004;4:1703–1708.
- Kim JJ, Basu M, Plantinga L, et al. Awareness of racial disparities in kidney transplantation among health care providers in dialysis facilities. *Clin J Am Soc Nephrol.* 2018;13: 772–781.
- Centers for Medicare and Medicaid Service. Dialysis facilities compare 2018. Available at: https://www.medicare.gov/ dialysisfacilitycompare/. Accessed July 7, 2020.
- Saran R, Robinson B, Abbott KC, et al. US Renal Data System 2016 annual data report: epidemiology of kidney disease in the United States. *Am J Kidney Dis.* 2017;69(3 suppl 1):A7–A8.
- Electronic Code of Federal Regulations. 42 CFR 494 conditions for coverage for end-stage renal disease facilities. 73 FR 20475, October 1, 2011. Available at: https://www.gpo.gov/ fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part4 94. Accessed July 7, 2020.
- Waterman AD, Goalby C, Hyland SS, et al. Transplant education practices and attitudes in dialysis centers: dialysis leadership weighs in. J Nephrol Therapeutic. 2012;4(suppl):007.
- Ayanian JZ, Cleary PD, Keogh JH, et al. Physicians' beliefs about racial differences in referral for renal transplantation. *Am J Kidney Dis.* 2004;43:350–357.

- Boulware LE, Meoni LA, Fink NE, et al. Preferences, knowledge, communication and patient-physician discussion of living kidney transplantation in African American families. *Am J Transplant*. 2005;5:1503–1512.
- Kucirka LM, Grams ME, Balhara KS, et al. Disparities in provision of transplant information affect access to kidney transplantation. *Am J Transplant*. 2012;12:351–357.
- Mason J, Khunti K, Stone M, et al. Educational interventions in kidney disease care: a systematic review of randomized trials. *Am J Kidney Dis.* 2008;51:933–951.
- 21. Foy R, Eccles MP, Jamtvedt G, et al. What do we know about how to do audit and feedback? Pitfalls in applying evidence from a systematic review. *BMC Health Serv Res.* 2005;5:50.
- McClellan WM, Krisher JO. Collecting and using patient and treatment center data to improve care: adequacy of hemodialysis and end-stage renal disease surveillance. *Kidney Int.* 2000;57(suppl 74):S7–S13.
- Mohan S, Mutell R, Patzer RE, et al. Kidney transplantation and the intensity of poverty in the contiguous United States. *Transplantation*. 2014;98:640–645.
- 24. Hamoda RE, Gander JC, McPherson LJ, et al. Process evaluation of the RaDIANT community study: a dialysis facilitylevel intervention to increase referral for kidney transplantation. *BMC Nephrol.* 2018;19:13.
- 25. Patzer RE, Gander J, Sauls L, et al. The RaDIANT community study protocol: community-based participatory research for reducing disparities in access to kidney transplantation. *BMC Nephrol.* 2014;15:171.
- Patzer RE, Paul S, Plantinga L, et al. A randomized trial to reduce disparities in referral for transplant evaluation. *J Am Soc Nephrol.* 2017;28:935–942.
- Patzer RE, Smith K, Basu M, et al. The ASCENT (Allocation System Changes for Equity in Kidney Transplantation) study: a randomized effectiveness-implementation study to improve kidney transplant waitlisting and reduce racial disparity. *Kidney Int Rep.* 2017;2:433–441.
- 28. Donner A, Klar N. *Design and Analysis of Cluster Randomization Trials in Health Research*. London, UK: Arnold; 2000.
- Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extension to cluster randomised trials. *BMJ*. 2004;328: 702–708.
- Mullen L, Bratt J. USAboundaries: historical and contemporary boundaries of the United States of America. *Journal of Open Source Software*. 2018;3:314.
- **31.** Gupta SK. Intention-to-treat concept: a review. *Perspect Clin Res.* 2011;2:109.
- Koller M. robustImm: an R package for robust estimation of linear mixed-effects models. J Stat Software. 2016;75:1–24.
- Bates D, Mächler M, Bolker B, Walker S. Fitting linear mixedeffects models using Ime4. *arXiv preprint.* arXiv:1406.5823. Accessed July 7, 2020.
- 34. Kuznetsova A, Brockhoff PB, Christensen RHB. ImerTest package: tests in linear mixed effects models. *J Stat Software*. 2017;82:1–26.
- **35.** Frankenfield DL, Sugarman JR, Presley RJ, et al. Impact of facility size and profit status on intermediate outcomes in chronic dialysis patients. *Am J Kidney Dis.* 2000;36:318–326.

- **36.** Auslander G, Dobrof J, Epstein I. Comparing social work's role in renal dialysis in Israel and the United States: the practice-based research potential of available clinical information. *Soc Work Health Care.* 2001;33:129–151.
- Erickson KF, Tan KB, Winkelmayer WC, et al. Variation in nephrologist visits to patients on hemodialysis across dialysis facilities and geographic locations. *Clin J Am Soc Nephrol.* 2013;8:987–994.
- **38.** Patzer RE, Amaral S, Wasse H, et al. Neighborhood poverty and racial disparities in kidney transplant waitlisting. *J Am Soc Nephrol.* 2009;20:1333–1340.
- **39.** Goodkin DA, Bragg-Gresham JL, Koenig KG, et al. Association of comorbid conditions and mortality in hemodialysis patients in Europe, Japan, and the United States: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *J Am Soc Nephrol.* 2003;14:3270–3277.
- Kowarik A, Templ M. Imputation with the R Package VIM. J Stat Software. 2016;74:1–16.
- Buuren SV, Groothuis-Oudshoorn K. mice: multivariate imputation by chained equations in R. *J Stat Software*. 2010;45:1–67.
- **42.** Burgette LF, Reiter JP. Multiple imputation for missing data via sequential regression trees. *Am J Epidemiol.* 2010;172: 1070–1076.
- Wish JB, Meyer KB. ESRD Networks: past, present, and challenges for the future. *Clin J Am Soc Nephrol*. 2012;7:1907–1914.
- 44. McClellan WM, Hodgin E, Pastan S, et al. A randomized evaluation of two health care quality improvement program (HCQIP) interventions to improve the adequacy of hemodialysis care of ESRD patients: feedback alone versus intensive intervention. J Am Soc Nephrol. 2004;15:754–760.
- 45. Goldman RS. Continuous quality improvement in ESRD: the role of networks, the United States Renal Data System, and facility-specific reports. *Am J Kidney Dis.* 1998;32(6 suppl 4): S182–S189.
- Ajzen I, Fishbein M. Attitude-behavior relations: a theoretical analysis and review of empirical research. *Psychol Bull.* 1977;84:888.
- Khanna R, Kavookjian J, Scott VG, et al. Using the theory of reasoned action to determine physicians' intention to measure body mass index in children and adolescents. *Res Social Adm Pharm*. 2009;5:170–181.
- Roberto AJ, Krieger JL, Katz ML, et al. Predicting pediatricians' communication with parents about the human papillomavirus (HPV) vaccine: an application of the theory of reasoned action. *Health Commun.* 2011;26:303–312.
- Sharp LK, Lipsky MS. The short-term impact of a continuing medical education program on providers' attitudes toward treating diabetes. *Diabetes Care*. 1999;22:1929–1932.
- Weiner BJ, Shortell SM, Alexander J. Promoting clinical involvement in hospital quality improvement efforts: the

effects of top management, board, and physician leadership. *Health Serv Res.* 1997;32:491–510.

- Berner ES, Baker CS, Funkhouser E, et al. Do local opinion leaders augment hospital quality improvement efforts? A randomized trial to promote adherence to unstable angina guidelines. *Med Care.* 2003;41:420–431.
- 52. Campbell AJ, Robertson MC. Rethinking individual and community fall prevention strategies: a meta-regression comparing single and multifactorial interventions. *Age Ageing.* 2007;36:656–662.
- Kutner NG, Zhang R, Huang Y, Johansen KL. Impact of race on predialysis discussions and kidney transplant preemptive wait-listing. *Am J Nephrol.* 2012;35:305–311.
- Waterman AD, Peiper JD, Hyland SS, et al. Modifiable patient characteristics and racial disparities in evaluation completion and living donor transplant. *Clin J Am Soc Nephrol.* 2013;8: 995–1002.
- 55. Institute of Medicine Committee on Understanding and Eliminating Racial and Ethnic Disparaties in Health Care. In: Smedley AD, Stith AY, Nelson AR, eds. Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Washington, DC: National Academies Press; 2003:666.
- 56. Beach MC, Gary TL, Price EG, et al. Improving health care quality for racial/ethnic minorities: a systematic review of the best evidence regarding provider and organization interventions. *BMC Public Health*. 2006;6:104.
- Sohn W, Ismail AI, Tellez M. Efficacy of educational interventions targeting primary care providers' practice behaviors: an overview of published systematic reviews. *J Public Health Dent.* 2004;64:164–172.
- Glass GV. Primary, secondary, and meta-analysis of research. Educational Researcher. 1976;5:3–8.
- Lipsey MW, Wilson DB. The efficacy of psychological, educational, and behavioral treatment: confirmation from meta-analysis. *Am Psychol.* 1993;48:1181–1209.
- Verbeke G, Lesaffre E. The effect of misspecifying the random-effects distribution in linear mixed models for longitudinal data. *Computational Statistics and Data Analysis*. 1997;23:541–556.
- **61.** Madley-Dowd P, Hughes R, Tilling K, Heron J. The proportion of missing data should not be used to guide decisions on multiple imputation. *J Clin Epidemiol.* 2019;110:63–73.
- 62. Haneuse S. Distinguishing selection bias and confounding bias in comparative effectiveness research. *Med Care.* 2016;54:e23.
- Rubin DB. Multiple imputation after 18+ years. J Am Stat Assoc. 1996;91:473–489.
- **64.** Meredith LS, Batorsky B, Cefalu M, et al. Long-term impact of evidence-based quality improvement for facilitating medical home implementation on primary care health professional morale. *BMC Fam Pract.* 2018;19:149.