Interventions to Improve Blood Pressure Control Among Socioeconomically Disadvantaged Patients With CKD: Kidney Awareness Registry and Education Pilot Randomized Controlled Trial

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Rationale & Objective: Sustainable interventions that enhance chronic kidney disease (CKD) management are not often studied in safety-net primary care, in which populations bear a disproportionate burden of disease and experience translational gaps between research and practice. We tested the feasibility of implementing and the impact of 2 technology-enhanced interventions designed to enhance CKD care delivery.

Study Design: A 2×2 randomized controlled pilot trial.

Setting & Participants: Primary care provider teams (n = 6) and 137 patients with CKD aged 18 to 75 years from 2 safety-net primary care clinics, 2013 to 2015.

Interventions: Primary care provider teams were randomly assigned to access a CKD registry with point-of-care notifications and quarterly feedback or a usual-care registry for 12 months. Patients within provider teams were randomly assigned to participate in a CKD self-management support program or usual care for 12 months.

Outcomes: We examined recruitment, randomization, and participation in each intervention. We also examined the impact of each intervention and their combination on change in systolic blood pressure (SBP), albuminuria, and patient self-reported behavioral measures after 12 months.

Results: Among potentially eligible patients identified using the electronic health record, 24% were eligible for study participation, of whom 35% (n = 137) were enrolled. Mean age was 55 years, 41% were non–English speaking, and 93% were of racial/ethnic minority. Mean baseline estimated glomerular filtration rate was 70.5 (SD = 30.3) mL/min/1.73 m^2; mean baseline SBP was 131 (SD = 21.8) mm Hg. Nearly 90% of clinicians reported that the CKD registry influenced their CKD management. More than 95% of patients randomly assigned to CKD self-management support engaged regularly with the intervention. Estimated changes in SBP over 1 year were nonstatistically different in each of the 3 intervention groups compared with usual care: (usual care: 0.5 [95% CI, −5.2 to 6.3] mm Hg; CKD registry only: −5.4 [95% CI, −12.2 to 1.4] mm Hg; CKD self-management support only: −6.4 [95% CI, −13.7 to 1.0] mm Hg; and CKD registry plus CKD self-management support: −0.5 [−5.5 to 4.5] mm Hg), though differences were larger among those with baseline SBPs > 140/90 mm Hg. Decreases in albuminuria were similarly nonstatistically different in each of the intervention groups compared with usual care. No differences were observed in patient self-reported behaviors.

Limitations: Single health system.

Conclusions: Patient and provider interventions to improve CKD care are feasible to implement in low-income settings with promising results among those with uncontrolled blood pressure.

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Chronic kidney disease (CKD) is common, with an estimated prevalence of 11.5% among the US adult population,[1] with significant variation by sociodemographic factors,[2,3] and causes excess morbidity and mortality.[4,5] Randomized controlled trials have shown that controlling blood pressure,[6] reducing proteinuria using angiotensin-converting enzyme (ACE) inhibitors or angiotensinogen receptor blockers (ARBs),[7-9] and improving glycemic control in people with diabetes[10,11] can delay CKD decline and reduce the morbidity and mortality associated with CKD.[12] However, many people with CKD are not receiving the benefit of these findings. There are a number of possible reasons for this, including low levels of CKD awareness among both providers and patients,[13-15] low confidence among primary care clinicians for delivering CKD care,[16] and low empowerment of patients to live healthy lifestyles, adhere to medication regimens, and avoid nephrotoxic insults.[17,18]

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The Chronic Care Model provides a framework for delivering high-quality chronic disease care and can be incorporated into a Patient-Centered Medical Home.[19] Implementation of single elements of the Chronic Care Model (eg, health care organization, community

resources, patient self-management support [SMS], delivery system redesign, and decision support) can improve care processes for patients with chronic illnesses (ie, decreased hospitalizations among patients with congestive heart failure).[20,21]

Many studies of CKD registries (an example of provider decision support) in the United States with computer-assisted prompts/alerts directed toward individual physicians have similarly increased processes of care (serum laboratory testing and increased ACE-inhibitor/ARB use among patients with CKD) and have not been shown to improve clinical outcomes.[22-25] Interventions that have led to improvements in patient outcomes have incorporated several components of the Chronic Care Model.[26] The North Carolina Improving Performance in Practice program, a state-wide quality improvement program designed to improve health outcomes among patients with diabetes, for example, showed a positive graded association between improved cholesterol levels and implementation of more Chronic Care Model elements, including chronic disease registries, standardized list of items discussed with every patient with diabetes at each visit, comprehensive care protocols for diabetes management, and support systems for patient self-management.[27]

Multicomponent sustainable interventions designed to improve the management of CKD in primary care settings are not common, and to our knowledge, none have been studied in US safety-net delivery systems. In these types of systems, individuals of low socioeconomic status, racial/ethnic minority, and/or limited health literacy/English proficiency experience a disproportionate burden of disease[28,29] and large translational gaps between research and practice.[30] In the Kidney Awareness Registry and Education (KARE) pilot trial, we examined the feasibility of testing a provider-level intervention (ie, CKD registry) and a patient-level intervention (ie, SMS program) that relied on multiple elements of the Chronic Care Model, as well as their combination, to improve blood pressure among low-income patients with CKD.[31,32]

METHODS

Study Design, Population, and Setting

KARE was a 2×2 factorial pilot randomized controlled trial that took place in 2 primary care clinics (1 academic training site and 1 community clinic) in San Francisco's public health care delivery system between 2013 and 2015. The KARE Study had 2 levels of randomization. First, within each clinic, primary care practice teams consisting of several physicians (including trainees), 1 nurse, nurse practitioners, medical assistants, and behaviorists were randomly assigned 1:1 to 1 of 2 arms with a random number generator: access to a CKD registry versus usual-care registry. Second, within 6 months of the provider-level randomization, eligible patients were recruited to a baseline visit and after receiving written informed consent to participate, were randomly assigned within each provider 1:1 to participate in a year-long comprehensive CKD-SMS program delivered as an adjunct to clinical care or usual clinical care (Fig 1), also with a random number generator administered by the study team. The study period lasted 18 months within each clinic. Study participants (providers and patients) and study personnel (study coordinator and health coaches) were aware of the randomization status of providers and patients, but outcome assessors were blinded to randomization.

Six primary care provider teams with 79 providers altogether were recruited to participate in the study. Eligible patients included adults (aged ≥18 years) with CKD, defined by 2 values for estimated glomerular filtration rate (eGFR) of 15 to 60 mL/min/1.73 m^2 or albuminuria (urine dipstick ≥ 1^+ or urinary albumin-creatinine ratio > 30 mg/g) documented in the electronic health record on 2 occasions at least 90 days apart, who had contact with their primary health care team at least once within the past 2 years and spoke English, Spanish, or Cantonese. eGFR using the Modified Diet in Renal Disease Study equation[33] was obtained from the electronic health record.

Patients were excluded from the study if they were kidney transplant recipients, pregnant, or unlikely to

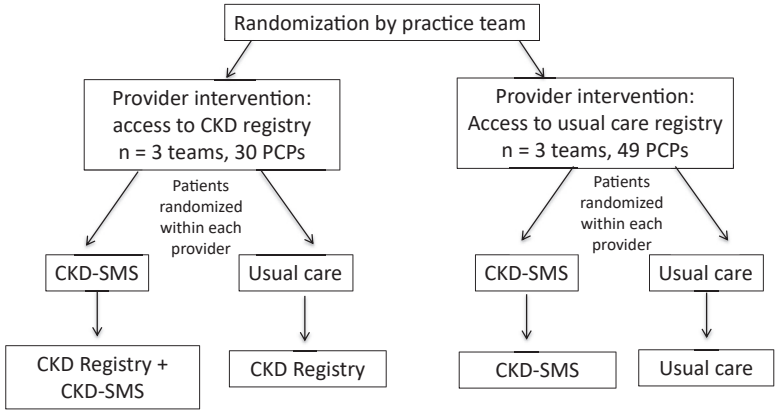

Figure 1. Study design. Academic clinic: May 2013 to November 2014; community clinic: January 2014 to August 2015. Abbreviations: CKD, chronic kidney disease; CKD-SMS, chronic kidney disease self-management support; PCP, primary care provider.

benefit from the SMS program due to hearing or visual impairment, impaired cognition, severe mental illness, or life expectancy of less than 6 months, as determined by the study team or the primary care provider. Approval to conduct this study was granted by the Institutional Review Board at the University of California, San Francisco (#11-07399), and the trial was registered (ClinicalTrials.gov: NCT01530958).

Interventions

The KARE interventions have been previously described in detail and found to be acceptable among providers and patients.[32,34] Briefly, the provider intervention consisted of an electronic health record–enabled CKD registry tool with "in-reach" and "outreach" elements to support team-based management of CKD. At the point of care during each primary care visit, the CKD registry provided primary care teams with data about patient-specific CKD status (eGFR and CKD on problem list), recent ambulatory clinic blood pressure readings, prescription status of pertinent medications (aspirin, ACE inhibitor/ARB, or statin), and date of last albuminuria quantification. The CKD registry also provided immunization status and data pertinent to age-appropriate cancer screening to align with the electronic health–enabled usual-care registry.

To reach patients who did not regularly visit their primary care provider and would thus not benefit from the in-reach component of the CKD registry, the study team research assistant generated quarterly feedback from the electronic registry to practice teams and individual primary care providers that identified patients for outreach. This included lists of patients with CKD who also had blood pressures ≥ 140/90 mm Hg, were not prescribed an ACE inhibitor/ARB, or had persistent albuminuria. Practice teams randomly assigned to the usual-care registry received point-of-care information about age-appropriate cancer screening and immunization status only; they did not receive quarterly feedback.

The patient intervention was a comprehensive CKD-SMS program based on multiple constructs of Social Cognitive Theory: behavioral capability, self-efficacy, expectations, and reinforcement.[35] The CKD-SMS program was delivered over 1 year by 2 full-time bilingual health coaches. The program had 3 distinct elements: (1) language-concordant low-literacy written patient educational materials[36] mailed to patients at months 1, 4, and 8; (2) a language-concordant and culturally tailored automated telephone self-management program with 26 modules delivered every other week that reviewed topics pertinent to kidney health: basics of kidney disease, association of kidney disease with high blood pressure, importance of engagement in healthy lifestyle behaviors (diet, physical activity, smoking cessation, and stress reduction), avoidance of nonsteroidal anti-inflammatory medications, participation and preparation for primary care clinic visits, complementary medication use, medication adherence, and glycemic control; and (3) telephone-based health coaching delivered by lay bilingual health coaches trained in motivational interviewing and action planning.

Outcomes

The primary outcome was change in systolic blood pressure (SBP) after 1 year, ascertained by study personnel at the baseline and 12-month study visits using the Omron digital blood pressure monitor model HEM- 907X, using the average of 3 blood pressure measurements in the right arm after the patient sat quietly for 5 minutes.[37]

Secondary clinical outcomes included changes after 1 year in the proportion of patients with blood pressure control (<140/90 mm Hg) and albuminuria severity (albumin-creatinine ratio), both ascertained at study visits. Secondary behavioral outcomes included changes in patient-reported self-efficacy of chronic disease management, communication with providers, medication adherence, quality of life, and awareness of CKD. Behavioral measures were ascertained at the baseline and 12-month study visits using validated language-concordant instruments, including those validated among similar patients and settings.[38-41]

Covariates

At the baseline visit, patient sociodemographic data (age, sex, race/ethnicity, education, income, and insurance status) were self-reported, as were comorbid condition data (diabetes, coronary artery disease, and hyperlipidemia). Food insecurity and health literacy were ascertained using validated screening questionnaires.[42,43]

Statistical Analyses

This pilot trial had the goal of assessing the feasibility of recruitment, randomization, and implementation of patient- and provider-level interventions and a multilevel combination of those interventions. No sample size was predetermined for this pilot trial; instead, we executed the pilot trial in 2 different primary care clinics (1 academic training clinic and 1 community-based clinic) and recruited all eligible participants, which ultimately determined the sample size. We examined baseline characteristics of KARE participants and losses to follow-up overall and by study arm.

We also tested for differences across the study arms using χ^2 tests for categorical variables and nonparametric Kruskal-Wallis tests for continuous variables. We conducted an intention-to-treat analysis using mixed models to assess the 1-year impact of the CKD registry only, CKD-SMS program only, and CKD registry plus CKD-SMS program compared with usual care for each outcome after an analysis of effect modification for the 2 interventions leveraging the 2×2 factorial design demonstrated nonsignificant interaction for all outcomes. We used the best fitting linear (for continuous outcomes) or logistic (for dichotomous outcomes) mixed model for each outcome

based on the lowest Aikake information criterion, considering random intercepts for person, provider, and team, and a random slope for time (with independent, exchangeable, or unstructured covariance structure). A bootstrap analysis was performed to examine change in albuminuria given the non-normally distributed residuals. Cluster robust standard errors were calculated using the sandwich estimator in the final model for each outcome to account for misspecification. A subgroup analysis of the clinical outcomes was performed among individuals with uncontrolled blood pressure at baseline to determine whether a future trial should focus on this subset of patients.

RESULTS

Recruitment

All primary care provider teams (n = 6) were recruited to participate in the study. We assessed 1,641 primary care patients with possible CKD determined by the electronic health record for eligibility. Among those, only 47% (n = 767) had persistent low eGFRs or elevated albuminuria indicating CKD (Fig 2). On electronic health record review to verify eligibility, many of the patients who were inaccurately identified as having probable CKD in the initial data abstraction had experienced multiple episodes of acute kidney injury with improvement thereafter, had experienced an increase in eGFR over time and no longer met study criteria, had false-positive dipstick albuminuria testing results, or had their albuminuria pharmacologically suppressed before recruitment.

Approximately 16% of patients (n = 264) were not eligible for other reasons, including speaking an ineligible language despite being identified in the electronic health record as speaking English, Spanish, or Cantonese (n = 79); having previously undergone kidney transplantation (n = 6); not having a working telephone (n = 54); and no longer receiving care from a participating clinic (n = 43). Among the 397 (24.2%) eligible patients, 137 were enrolled and randomly assigned (Fig 2). The inability to contact socially vulnerable patients due to inaccurate telephone numbers in the electronic health record (n = 87) was a common reason for not enrolling eligible patients.

Baseline Patient Characteristics

The study population (n = 137) had a mean age of 55 (SD, 12.2) years, consisted of 51.8% women, and was racially/ethnically diverse (42.3% African American, 36.5% Hispanic, 14.6% Asian/Pacific Islander, and 6.6% white). Nearly 35% of patients spoke a language other than English, 23.4% had limited health literacy, and more than one-half self-reported food insecurity. Approximately 59% had diabetes, 54.0% had hyperlipidemia, 48.9% had advanced CKD stages 3 to 4, and 73.0% of patients had micro- or macroalbuminuria (Table 1). Demographic and comorbid condition data were similar across the 4 groups ($P > 0.1$), with the exception of baseline SBP because the median SBP was lowest in the CKD registry plus CKD-SMS program group ($P = 0.02$), and urinary albumin-creatinine ratio because the median urinary albumin-creatinine ratio was lowest in CKD-SMS only group ($P = 0.03$; Table 1). Demographic characteristics captured from the electronic health record were qualitatively similar among potentially eligible individuals who agreed to participate versus those who were contacted but declined (n = 117), though the decliners were statistically more likely to be female and of Asian race/ethnicity and less likely to be Spanish speaking (Table S1).

Retention among study participants was high, with 90% of randomly assigned participants completing the 12-month study visit and no statistically significant difference by study group ($P = 0.2$). The timing of the 12-month follow-up visit ranged from 9.1 to 27.6 months, with a median of 12.7 (interquartile range, 12.3-13.5) months.

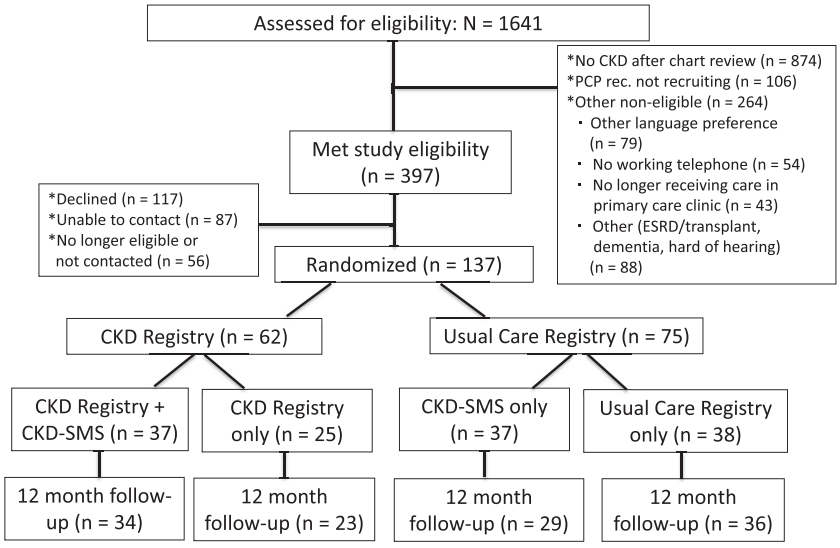

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) diagram. Abbreviations: CKD, chronic kidney disease; CKD-SMS, chronic kidney disease self-management support; ESRD, end-stage renal disease; PCP, primary care provider; rec, recommends.

Table 1. Baseline Characteristics of KARE Participants

Characteristics	All	Usual Care	Intervention Groups			P
			CKD Registry Only	SMS Only	SMS + CKD Registry	
N	n = 137	n = 38	n = 25	n = 37	n = 37	
Age, y	58.0 [50.0-64.0]	56.0 [49.0-64.0]	60.0 [51.0-66.0]	57.0 [50.0-61.0]	56.0 [49.0-63.0]	0.4
Women	71 (51.8%)	18 (47.4%)	14 (56.0%)	16 (43.2%)	23 (62.2%)	0.4
Race/ethnicity						0.3
Caucasian/white	9 (6.6%)	0 (0%)	1 (4.0%)	3 (8.1%)	5 (13.5%)	
Black or African American	58 (42.3%)	21 (55.3%)	8 (32.0%)	17 (45.9%)	12 (32.4%)	
Asian/Pacific Islander	20 (14.6%)	4 (10.5%)	5 (20.0%)	4 (10.8%)	7 (18.9%)	
Hispanic	50 (36.5%)	13 (34.2%)	11 (44.0%)	13 (35.1%)	13 (35.1%)	
Preferred language						0.1
English	90 (65.7%)	27 (71.1%)	15 (60.0%)	28 (76.0%)	20 (54.0%)	
Spanish	40 (29.2%)	10 (26.3%)	10 (40.0%)	8 (21.6%)	12 (32.4%)	
Cantonese	7 (5.1%)	1 (2.6%)	0 (0%)	1 (2.7%)	5 (13.5%)	
Educational attainment						0.8
<High school	46 (33.6%)	14 (36.8%)	9 (36%)	10 (27%)	13 (35.1%)	
High school	41 (29.9%)	8 (21.1%)	8 (32.0%)	11 (29.7%)	14 (37.8%)	
>High school	50 (36.5%)	16 (42.1%)	8 (32.0%)	16 (43.2%)	10 (27%)	
Limited health literacy	32 (23.4%)	8 (21.1%)	8 (32.0%)	5 (13.5%)	11 (29.7%)	0.3
Food insecurity	72 (52.6%)	17 (44.7%)	14 (56.0%)	18 (48.6%)	23 (62.2%)	0.5
Insurance						0.2
None	39 (28.4%)	12 (31.6%)	4 (16.0%)	11 (29.7%)	12 (32.4%)	
Medicaid only	61 (44.5%)	13 (34.2%)	15 (60.0%)	18 (48.6%)	15 (40.5%)	
Medicare only	10 (7.3%)	3 (7.9%)	2 (8.0%)	0 (0.0%)	5 (13.5%)	
Medicare + Medicaid	27 (19.7%)	10 (26.3%)	4 (16.0%)	8 (21.6%)	5 (13.5%)	
Self-reported diabetes[a]	80 (58.4%)	20 (52.6%)	17 (68.0%)	20 (54.1%)	23 (62.2%)	0.6
Self-reported coronary disease[a]	21 (15.3%)	8 (21.1%)	5 (20.0%)	4 (10.8%)	4 (10.8%)	0.7
Self-reported hyperlipidemia[a]	74 (54.0%)	16 (42.1%)	13 (52.0%)	23 (62.2%)	22 (59.5%)	0.4
Baseline systolic blood pressure, mm Hg	129.0 [115.0-142.0]	123.0 [115.0-135.0]	131.0 [113.0-153.0]	137.0 [129.0-147.0]	122.0 [112.0-139.0]	0.02
Estimated glomerular filtration rate, mL/min/1.73 m^2	60.2 [48.5-94.7]	51.8 [45.4-91.3]	60.7 [47.0-97.1]	63.9 [52.1-96.3]	62.5 [51.6-90.9]	0.4
CKD stage						0.2
1-2	70 (51.1%)	14 (36.8%)	14 (56.0%)	20 (54.0%)	22 (59.5%)	
3-4	67 (48.9%)	24 (63.2%)	11 (44.0%)	17 (46.0%)	15 (40.5%)	
Albumin-creatinine ratio, mg/g	86.9 [21.0-561.0]	50.5 [9.0-373]	438.0 [69.0-1481.0]	119.0 [36.0-219.0]	77.5 [14.5-367.5]	0.03
Albumin-creatinine ratio, mg/g[a]						0.03
A1 <30	36 (26.3%)	14 (36.8%)	3 (12%)	8 (21.6%)	11 (29.7%)	
A2 30-300 (microalbuminuria)	57 (41.6%)	12 (31.6%)	8 (32%)	21 (56.8%)	16 (43.2%)	
A3 >300 (macroalbuminuria)	43 (31.4%)	12 (31.6%)	14 (56%)	8 (21.6%)	9 (24.3%)	

Note: Values expressed as median [interquartile range] or number (percent).
Abbreviations: CKD, chronic kidney disease; KARE, Kidney Awareness Registry and Education; SMS, self-management support.
[a]Column and row percentages may not sum to 100% due to missing data.

Uptake of Interventions

Patient uptake of the intervention was favorable. Average call completion of automated telephone modules was 61% across the 50-week program (Fig 3). Among the 74 participants randomly assigned to receive the intervention, nearly 40% were considered high utilizers, with an average call completion rate ≥ 80%. More than 95% of individuals participated in regular telephone calls with their health coach; 77% completed at least 1 action plan. Among the 38% of clinicians randomly assigned to have access to the CKD registry who completed the satisfaction survey, most (88%) reported that point-of-care notifications influenced the way they managed CKD and 74% reported that quarterly feedback enhanced their ability to manage CKD.[34]

Clinical Outcomes

Mean baseline SBP among study participants was 131 (SD, 22.0) mm Hg and mean change at the 12-month

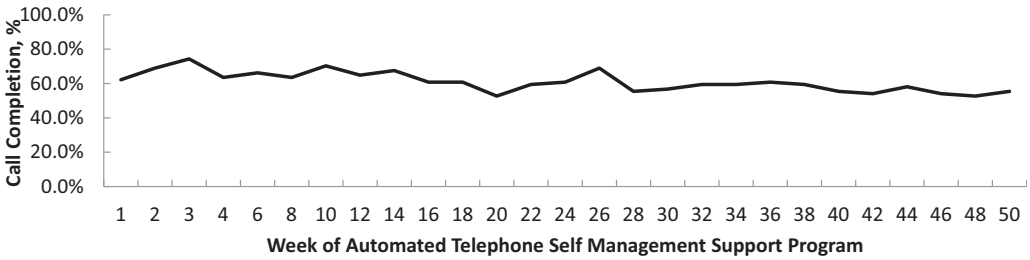

Figure 3. Call completion of automated telephone self-management modules.

follow-up visit was −2.4 (SD, 19.8) mm Hg. Mean estimated change in SBP ranged from −6.37 (95% confidence interval [CI], −13.69 to 0.95) mm Hg (CKD-SMS only) to +0.53 (95% CI, −5.20 to 6.27) mm Hg (usual care) across groups; mean estimated SBP values at baseline and 12 months for each group are shown in Figure 4A.

Compared with patients randomly assigned to usual care, who had little change in SBP, those randomly assigned to intervention groups had nonstatistically larger changes in SBP: −6.0 (95% CI, −14.9 to 2.9) mm Hg for CKD registry; −6.9 (95% CI, −16.2 to 2.4) mm Hg for CKD-SMS program; and −1.0 (95% CI, −8.6 to 6.6) mm Hg for CKD registry plus CKD-SMS program. There was no evidence of effect modification by baseline SBP ($P_{interaction} = 0.16$), but among patients with baseline SBP < 140 mm Hg (n = 91), little difference in changes in SBP was observed across trial groups (range, −1.59 to 3.71 mm Hg) compared with usual care (2.63 mm Hg), whereas among patients with baseline SBPs ≥ 140 mm Hg (n = 46), larger decreases in SBP were observed among those randomly assigned to the intervention groups (range, −20.85 to −9.84 mm Hg) compared with usual care (−4.90 mm Hg; Fig 4B).

Similarly, change in the proportion of patients with blood pressure control was nonstatistically larger among patients randomly assigned to 3 intervention groups

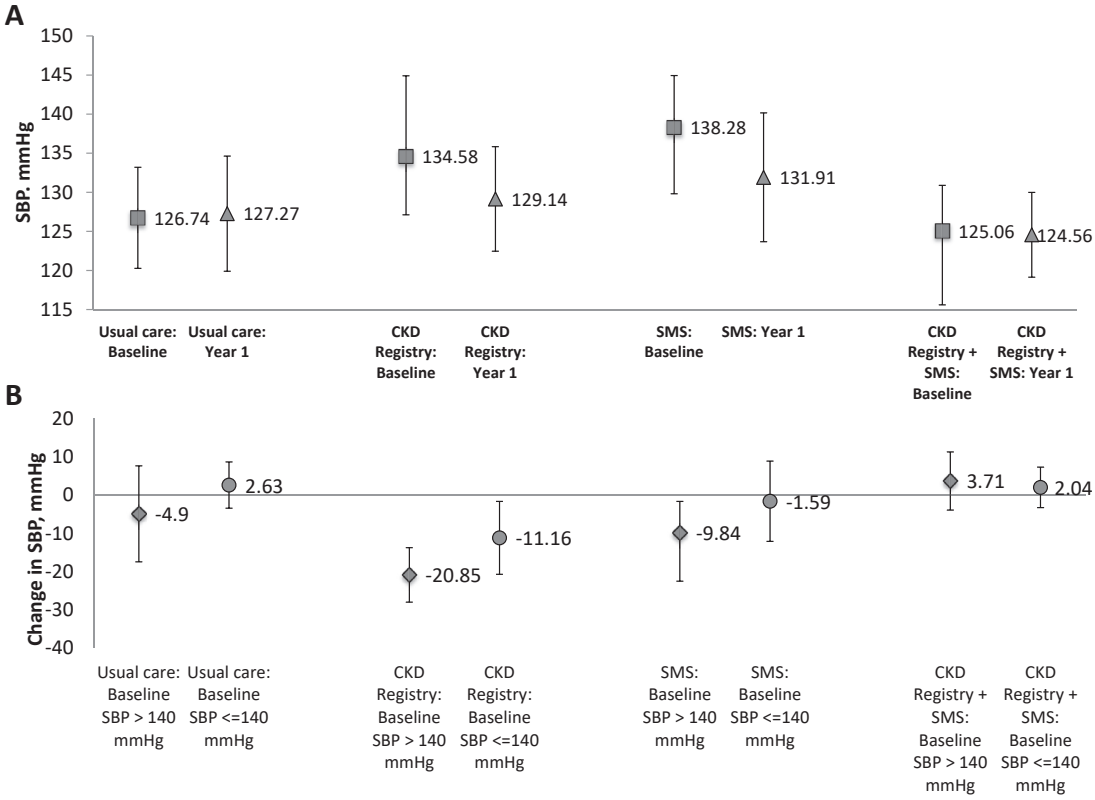

Figure 4. (A) Estimated mean systolic blood pressure (SBP) and 95% confidence interval (CI) at baseline and 1 year for each Kidney Awareness Registry and Education (KARE) group. (B) Estimated mean 1-year change and 95% CI in SBP by baseline SBP control for each KARE group. Abbreviations: CKD, chronic kidney disease; SMS, self-management support.

compared with those randomly assigned to usual care (odds ratio [OR], 2.5 [95% CI, 0.3-18.7] for the CKD registry only; OR, 1.6 [95% CI, 0.2-9.9] for CKD-SMS program only; and OR, 1.2 [95% CI, 0.2-7.0] for CKD registry plus CKD-SMS program). The percentage of patients with blood pressure control did not change substantially among the different groups (76.3% to 75.0% for usual care; 60.0% to 73.9% for CKD registry only; 51.4% to 58.6% for CKD-SMS program only; and 75.7% to 76.5% for CKD registry plus CKD-SMS program).

Randomization to any of the intervention groups was also associated with nonstatistically significant larger decreases in albuminuria compared with usual care: urinary albumin-creatinine ratio, −218.8 (95% CI, −622.1 to 184.5) mg/g larger for CKD registry only; −32.8 (95% CI, −440.8 to 375.1) mg/g larger for CKD-SMS program only; and −28.6 (95% CI, −303.9 to 246.6) mg/g larger for CKD registry plus CKD-SMS program (Fig S1A). There was no evidence of effect modification by baseline SBP ($P_{interaction}$ = 0.84), though decreases in albuminuria were greater in the subgroup with baseline SBP ≥ 140 mm Hg (Fig S1B).

Self-reported Patient Outcomes

Compared with usual care, randomization to any of the 3 intervention arms was not associated with changes in medication adherence, reported self-efficacy, communication with providers, quality of life, or CKD awareness (Table 2).

DISCUSSION

In this randomized controlled pilot trial of a range of single- and multilevel theory-informed interventions, we demonstrated: (1) the feasibility of implementing and testing a provider- and patient-level intervention, as well as their combination, in a public health care delivery system; (2) the challenges associated with trial recruitment among vulnerable low-income patients; and (3) nonstatistically significant improvement in SBP and albuminuria in the intervention groups compared with usual care among patients with blood pressures ≥ 140/90 mm Hg. However, we did not detect differences in changes in CKD awareness across trial arms or any signal of greater impact with the multilevel intervention compared with the single-level interventions.

Interventions integrated into health care delivery are complex and require buy-in from numerous stakeholders, including providers, nonphysician team members, clinic administrators, and executive leadership. Working with health care delivery partners, we were able to simultaneously embed a practice team–oriented CKD registry directly into primary care workflows and a telephone-based CKD-SMS system that was an adjunct to primary care. This was in part due to some of KARE's more pragmatic trial elements, including the integration of interventions into real-world settings, flexibility inherent to the health coaching intervention, and nonenforcement of adherence to the intervention. KARE demonstrates that public health care delivery systems can be sites in which novel interventions that reorganize health care delivery and leverage information technology can be studied.

One of the main challenges of KARE implementation was patient identification and recruitment. Among those identified as potentially having CKD from the electronic health record based on at least 2 low eGFRs or abnormal albuminuria values separated in time, only ∼50% had prevalent CKD at trial enrollment, defined as having sustained low eGFRs or elevated albuminuria. This is consistent with data from a recent methodological study that demonstrated that 68% of patients deemed to have CKD based on historic eGFRs had confirmed CKD determined by physician chart review.[44] Many potentially eligible patients in our study had experienced repeated episodes of acute kidney injury or had false-positive dipstick albuminuria results.

Identifying eligible patients for trial participation from the electronic health record is a core element of contemporary clinical trials, which will be important to ameliorate in future research. As an example, to improve efficiency and attain higher specificity of CKD diagnosis for our planned efficacy trial, we will eliminate dipstick albuminuria as a criterion for identifying patients with probable CKD, although studies have shown that persistent dipstick albuminuria identifies patients at higher risk for early mortality, CKD progression, and myocardial infarction.[45] However, it is important to note that high specificity of diagnosis may be less of an analytical concern in pragmatic trials embedded in health systems with cluster-randomized designs because inaccuracies are likely to be equally distributed among clusters of providers, health care teams, or clinics.

Because this was a pilot trial, we did not have the power to detect significant changes in clinical or behavioral outcomes. However, we were able to glean a few important insights. First, SBP improved among patients with higher baseline blood pressures randomly assigned to any intervention arm compared to usual care, suggesting that a larger trial among individuals with uncontrolled blood pressure at baseline may show statistically significant improvements.

Second, because there was no perceived benefit to the multilevel intervention compared to single intervention, the larger efficacy trial will focus on a refined more robust patient intervention. Data from this pilot study suggest that we will need to enroll 324 patients with uncontrolled blood pressure to detect a clinically meaningful 6–mm Hg difference in SBPs between groups, assuming 2-sided alpha of 0.05 and power of 0.8.

Third, there was no evidence for any behavior change among trial participants. The lack of change in medication adherence was particularly disappointing because this is one of the mainstays of hypertension self-management.

Table 2. Mean Predicted Values and Probabilities of Behavioral Outcomes at Baseline and at 1-Year Follow-up for Each Group and Mean Predicted Difference and Estimated Change in Intervention Groups Compared to Usual Care

Behavioral Outcome[a]	Mean (95% CI) Baseline (n = 137)	Mean (95% CI) y 1 (n = 122)	Mean Predicted Difference (95% CI)	β[b]	CI
Morisky Medication Adherence (scale: 0 [great adherence] to 4 [low adherence])					
Usual care	1.34 (0.98 to 1.71)	1.11 (0.75 to 1.47)	−0.2 (−0.5 to 0.1)	Ref	Ref
CKD registry only	1.46 (0.93 to 2.00)	1.2 (0.68 to 1.72)	−0.3 (−0.8 to 0.3)	−0.03	(−0.63 to 0.57)
SMS only	1.38 (0.92 to 1.83)	1.17 (0.72 to 1.62)	−0.2 (−0.6 to 0.2)	0.03	(−0.48 to 0.53)
CKD registry + CKD-SMS	1.22 (0.91 to 1.53)	1.07 (0.74 to 1.41)	−0.1 (−0.5 to 0.2)	0.09	(−0.36 to 0.53)
Stanford Chronic Disease Self-efficacy (scale of 1 [not confident] to 10 [very confident])					
Usual care	7.94 (7.39 to 8.48)	8.19 (7.63 to 8.74)	0.3 (−0.3 to 0.8)	Ref	Ref
CKD registry only	6.89 (6.14 to 7.64)	6.87 (6.07 to 7.68)	0.0 (−0.7 to 0.7)	−0.27	(−1.15 to 0.61)
SMS only	7.91 (7.23 to 8.59)	8.31 (7.78 to 8.85)	0.4 (−0.2 to 0.9)	0.15	(−0.60 to 0.91)
CKD registry + CKD-SMS	7.5 (6.95 to 8.05)	8.3 (7.81 to 8.80)	0.8 (0.3 to 2.4)	0.56	(−0.25 to 1.36)
Lorig Communication (Scale: 0 [poor communication] to 5 [excellent communication])					
Usual care	2.86 (2.46 to 3.26)	2.79 (2.41 to 3.18)	−0.1 (−0.4 to 0.3)	Ref	Ref
CKD registry only	2.75 (2.30 to 3.21)	2.33 (1.93 to 2.73)	−0.4 (−0.8 to 0.0)	−0.35	(−0.90 to 0.19)
SMS only	2.95 (2.56 to 3.35)	2.7 (2.28 to 3.12)	−0.2 (−0.7 to 0.2)	−0.18	(−0.74 to 0.38)
CKD registry + CKD-SMS	3.09 (2.78 to 3.40)	2.91 (2.62 to 3.21)	−0.2 (−0.5 to 0.2)	−0.11	(−0.61 to 0.39)
SF-12 (scale: 0 [lowest] to 100 [highest])					
Usual care	57.4 (50.47 to 64.33)	61.61 (54.30 to 68.92)	4.2 (−0.7 to 9.1)	Ref	Ref
CKD registry only	39.07 (30.05 to 48.09)	41.68 (32.91 to 50.45)	2.6 (−6.6 to 11.8)	−1.6	(−12.02 to 8.82)
SMS only	51.52 (41.69 to 61.34)	53.81 (43.99 to 63.63)	2.3 (−1.8 to 6.4)	−1.92	(−8.31 to 4.47)
CKD registry + CKD-SMS	46.58 (39.12 to 54.03)	47.96 (40.38 to 55.53)	1.4 (−4.0 to 6.8)	−2.83	(−10.16 to 4.49)
SF-12: Physical Health Component (scale: 0 [lowest] to 100 [highest])					
Usual care	54.33 (46.08 to 62.58)	58.16 (49.79 to 66.52)	3.8 (−2.6 to 10.3)	Ref	Ref
CKD registry only	33.03 (22.10 to 43.96)	36.79 (26.44 to 47.14)	3.8 (−7.5 to 15.0)	−0.07	(−13.06 to 12.92)
SMS only	46.99 (36.37 to 57.62)	49.88 (38.65 to 61.12)	2.9 (−2.3 to 8.1)	−0.94	(−9.23 to 7.36)
CKD registry + CKD-SMS	41.61 (32.54 to 50.68)	43.22 (34.13 to 52.30)	1.6 (−5.3 to 8.5)	−2.22	(−11.65 to 7.21)
SF-12: Mental Health Component (scale: 0 [lowest] to 100 [highest])					
Usual care	63.57 (56.78 to 70.36)	68.57 (61.88 to 75.27)	5.0 (−1.0 to 11.0)	Ref	Ref
CKD registry only	51.12 (42.67 to 59.57)	51.32 (43.14 to 59.50)	3.8 (−7.5 to 15.0)	−4.81	(−15.07 to 5.46)
SMS only	60.59 (51.02 to 70.16)	61.72 (53.52 to 69.92)	2.9 (−2.3 to 8.1)	−3.87	(−11.13 to 3.39)
CKD registry + CKD-SMS	56.5 (50.87 to 62.12)	57.29 (51.42 to 63.16)	1.6 (−5.3 to 8.5)	−4.21	(−11.71 to 3.28)

Behavioral Outcome[a]	Probability at Baseline	Probability at y 1	Mean Predicted Difference (95% CI)	OR[c]	CI
CKD Awareness: "Weak or Failing Kidneys": (scale: 0 [no one aware] to 1.00 [everyone aware])					
Usual care	0.4 (0.23 to 0.56)	0.43 (0.26 to 0.60)	0.03 (−0.11 to 0.17)	Ref	Ref
CKD registry only	0.3 (0.15 to 0.44)	0.29 (0.15 to 0.43)	−0.01 (−0.16 to 0.17)	0.68	(0.1 to 5.3)
SMS only	0.36 (0.22 to 0.50)	0.36 (0.21 to 0.51)	0.00 (−0.16 to 0.17)	0.77	(0.1 to 6.0)
CKD registry + CKD-SMS	0.35 (0.20 to 0.50)	0.44 (0.27 to 0.61)	0.09 (−0.06 to 0.24)	1.75	(0.3 to 11.4)
CKD Awareness: "Kidney Problem" (scale: 0 [no one aware] to 1.00 [everyone aware])					
Usual care	0.47 (0.28 to 0.66)	0.58 (0.40 to 0.76)	0.11 (−0.05 to 0.27)	Ref	Ref
CKD registry only	0.51 (0.29 to 0.72)	0.5 (0.29 to 0.71)	−0.01 (−0.08 to 0.07)	0.28	(0.0 to 2.3)
SMS only	0.36 (0.18 to 0.53)	0.46 (0.27 to 0.64)	0.10 (−0.06 to 0.26)	0.94	(0.1 to 11.5)
CKD registry + CKD-SMS	0.5 (0.35 to 0.64)	0.57 (0.41 to 0.72)	0.07 (−0.07 to 0.21)	0.65	(0.1 to 7.6)

Abbreviations: CI, confidence interval; CKD, chronic kidney disease; OR, odds ratio; Ref, reference; SF-12, 12-Item Short Form Health Survey; SMS, self-management support.
[a]Estimates from mixed model.
[b]Mean difference in 1-year change in outcome for each intervention arm compared to usual care (with 95% CI and *P* value).
[c]OR comparing time effect on outcome for each intervention compared with usual care (with 95% CI and *P* value)

Although the CKD-SMS program encouraged individual action planning and highlighted the importance of medication adherence for improved blood pressure control and kidney health, many participants opted to focus on other aspects of their health (ie, healthier diet and greater physical activity) rather than work on their medication adherence. While purely speculative, it is possible that engaging patients in shared decision making around

medication adherence during the clinic visit may be more valuable than during out-of-visit discussions.

Fourth, although education about kidney disease is key to self-management, CKD awareness did not change among patients randomly assigned to participate in the CKD-SMS program. To remain generalizable and relevant to provider concerns and priorities, the CKD-SMS program purposely discussed kidney disease within the context of cardiovascular health. This may have diluted the message related to kidney disease. The refined CKD-SMS intervention will include more information about kidney disease and its direct linkage to cardiovascular health and will focus more on diet and physical activity and potential mediators for improved blood pressure control.

Although we successfully conducted a pilot randomized controlled trial, this study is subject to limitations. The study took place in 2 primary care clinics within a single public health care delivery system with low-income participants who were able and willing to be contacted repeatedly by telephone. Results may not be generalizable to other health care systems or patient populations. Despite all efforts, ~10% of the study population dropped out. Also, provider teams' adherence to the registry and patient participation in the SMS intervention was variable, mimicking a real-world intervention but limiting the potency of the intervention. We did not collect robust data about providers within each practice team randomly assigned to the usual-care registry versus CKD registry and thus could not incorporate these variables in our analyses.

In summary, we successfully developed and tested 2 technology-enhanced interventions for safety-net primary care patients with mild to moderate CKD in a pilot randomized controlled trial. Because there was no perceived benefit to the multilevel intervention compared to single interventions on patient outcomes or CKD awareness, a larger efficacy trial with sufficient power to examine the effect of a refined self-management support intervention among patients with CKD and uncontrolled blood pressure is warranted.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Figure S1: (A) Estimated mean albuminuria value and 95% CI at baseline and 1 year for each KARE group. (B) Estimated mean 1-year change and 95% CI in albuminuria value, by baseline systolic blood pressure control, for each KARE group.

Table S1: Demographic characteristics of KARE participants and those who declined to participate.

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