Title

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Journal

American Journal of Kidney Diseases, 76(5)

ISSN

0272-6386

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Publication Date

2020-11-01

DOI

10.1053/j.ajkd.2020.05.013

Peer reviewed

HHS Public Access

Author manuscript

Am J Kidney Dis. Author manuscript; available in PMC 2021 November 01.

Published in final edited form as:

Am J Kidney Dis. 2020 November ; 76(5): 636–644. doi:10.1053/j.ajkd.2020.05.013.

Electronic Decision Support for Management of CKD in Primary Care: A Pragmatic Randomized Trial

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Abstract

Rationale & Objective—Most adults with chronic kidney disease (CKD) in the U.S. are cared for by primary care providers (PCP). We evaluated the feasibility and preliminary effectiveness of an electronic clinical decision support system (eCDSS) within the electronic health record (EHR) with or without pharmacist follow-up to improve management of CKD in primary care.

Study Design—Pragmatic, cluster randomized trial

Setting & Participants—524 adults with confirmed eGFRCr 30–59 mL/min/1.73m^2 cared for by 80 PCPs at the University of California San Francisco. EHR data were used for patient identification, intervention deployment, and outcomes ascertainment.

Interventions—Each PCP's eligible patients were randomized as a group into one of three treatment arms: 1) usual care, 2) eCDSS: testing of creatinine, cystatin C and urinary albumin-to-creatinine ratio with individually tailored guidance for PCPs on blood pressure, potassium and

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Authors' Contributions: Research idea and study design: CAP, LSK; data analysis and interpretation: CAP, LSK; clinical oversight, protocol design: LL; data analysis: JL-T; conducted study and/or recruited and interacted with participants: MS, AR, SP, RS. Each author contributed important intellectual content during manuscript drafting or revision and agrees to be personally accountable for the individual's own contributions and to ensure that questions pertaining to the accuracy or integrity of any portion of the work, even one in which the author was not directly involved, are appropriately investigated and resolved, including with documentation in the literature if appropriate.

Financial Disclosure: Dr. Peralta is the Chief Medical Officer of Cricket Health. The remaining authors declare that they have no relevant financial interests.

Data Sharing Statement: Per NIH's policy no identifiable data is available to the public. However, the study protocol and statistical analysis plan is available at ClinicalTrials.gov.

proteinuria management, cardiovascular risk-reduction, and patient education, or 3) eCDSS plus pharmacist counseling (eCDSS-PLUS).

Outcomes—Primary clinical outcome was change in blood pressure over 12 months. Secondary outcomes were PCP awareness of CKD as well as use of ACEi/ARB and statin.

Results—All 80 eligible PCPs participated. Mean patient age was 70, 47% were non-white, mean eGFRcr was 56 +/−0.6 mL/min/1.73m^2. Among patients receiving eCDSS with or without pharmacist counseling (n=336), 178 (53%) completed labs and 138 (41%) had labs followed by a PCP visit with eCDSS deployment. eCDSS was opened by the PCP for 102 (74%) patients, with at least one suggested order signed for 83 of these 102 (81%). Changes in systolic blood pressure were − 2.1 ± 1.5 mmHg with usual care, −2.8 ± 1.8 with eCDSS and −1.1 ± 1.1 with eCDSS-PLUS (p=0.69). PCP awareness of CKD was 16% with usual care, 26% with eCDSS, and 32% for eCDSS -PLUS (p=0.09). In as-treated analyses, PCP awareness of CKD was significantly greater with eCDSS and eCDSS-PLUS (73% and 69%) vs. usual care (47%), p<0.01.

Limitations—Recruitment of smaller than intended sample size, and limited uptake of the testing component of the intervention.

Conclusions—While we were unable to demonstrate the effectiveness of eCDSS to lower blood pressure, and uptake of the eCDSS was limited by low testing rates, eCDSS utilization was high once labs were available and was associated with higher PCP awareness of CKD.

Trial Registration—ClinicalTrials.gov Registration #: NCT02925962

Plain Language Summary

Most adults with chronic kidney disease (CKD) in the U.S. are cared for by primary care providers (PCP). We conducted a clinical trial to evaluate the feasibility and effectiveness of an electronic clinical decision support system (eCDSS) within the electronic health record (EHR) designed to help primary care doctors improve CKD care. We studied 524 adults with CKD, cared for by 80 PCPs in San Francisco. While this study had limited power and did not show significant differences in blood pressure, electronic clinical decision support did increase primary care doctors' awareness of CKD.

Introduction

The enormous burden that is due to chronic kidney disease (CKD) and end stage renal disease (ESRD) in the U.S. is in the national spotlight after signature of the "Advancing Kidney Health" executive order.[1] Part of this initiative aims to improve identification and management of people with earlier stages of kidney disease. Since the majority of adults with CKD in the U.S. receive medical care from primary care providers (PCP), improved CKD management in primary care is imperative.

Many persons with earlier stages of CKD can be safely managed in primary care without the need for nephrology co-management,[2,3] but the majority of adults with CKD remain undiagnosed, improperly risk stratified and undertreated.[4–7] These gaps persist despite international guidelines which recommend risk stratification with both a measure of filtration (eGFR) and one of damage (albumin to creatinine ratio, ACR), followed by

evidence-based treatments that can reduce complications.[8] Barriers that hinder effective CKD care in primary care settings include lack of awareness and understanding of guidelines for risk stratification and management of CKD, confusion regarding appropriate referral criteria and timing, and lack of confidence in managing CKD.[9] Additionally, PCPs have limited time to manage complex visit agendas.[10,11]

The advent of electronic health records (EHR) has propelled an interest in utilizing electronic decision supports to improve care.[12] However, whether EHR embedded automated decision support can improve outcomes for those with CKD managed in primary care is not well understood. Prior interventions have been hindered by alert fatigue, lack of individualization of care recommendations that are actionable by the PCP, limited focus on PCP education, the need for additional clinical personnel, and limited pre-trial design phases to allow close integration into the primary care clinical workflow.[13–15] Moreover, the paucity of experience in conducting pragmatic, randomized trials in the field of kidney care adds to our inability to understand the impact of electronic decision support tools on CKD care in the "real world".[16]

Therefore, we designed an electronic, automated CKD decision support tool (eCDSS) embedded into the EHR to provide guidance on risk stratification and individualized CKD management optimization in primary care. We then conducted a 3-arm, pragmatic randomized trial to evaluate the feasibility of implementation, usability, and preliminary effectiveness of the eCDSS to improve CKD management.

Methods

Design

We previously published the rationale, design, pre-trial pilot activities and preliminary implementation metrics for this study. In brief, we used the EHR to identify participants, deliver the eCDSS, and ascertain study outcomes. The three arms were: (1) eCDSS; (2) eCDSS PLUS, which added a pharmacist phone call to reinforce CKD-related education after a PCP visit in which the eCDSS was utilized; and (3) usual care.

Study intervention dates were October 4, 2017 to October 4, 2018, with an additional 9 months of follow up for a total 21-month duration. This trial was registered on ClinicalTrials.gov (NCT02925962) and the University of California San Francisco Human Research Protection Program approved the protocol.

Eligibility and Consent

All providers practicing in the general internal medicine practice with a primary care panel were eligible. Providers received an email explaining the study and had two weeks to opt out.

We identified eligible patients via the EHR who were age 18–80, preferred language of English, Spanish, or Chinese (Cantonese or Mandarin), had at least two outpatient $eGFR_{Cr}$ 30–59 (mL/min/1.73m^2) by CKD Epi equation at least 90 days apart, and had a primary care visit with their assigned PCP in the prior 18 months. We excluded persons with ongoing

nephrology follow up, and additional exclusions are in supplementary materials (Item S1). For patients, we mailed letters to eligible persons randomized to the intervention arms with a subsequent two-week opt out period.

Randomization and Blinding

We block-randomized at the PCP level based on panel size (Item S2). The study statistician was blinded to the identification of the PCPs and to allocation of patients to each arm during the study period.

Interventions

eCDSS—The first step of the intervention consisted of obtaining appropriate laboratory testing for risk stratification. Study staff ordered triple-marker testing (serum creatinine and cystatin C and urinary albumin-to-creatinine ratio) for all participants randomized to either intervention arm, to be done the next time they visited the laboratory for usual clinical care. We programmed the eCDSS to deploy at a subsequent visit with their assigned PCP only if all three test were resulted. Details have been previously published.[17] In brief, the eCDSS was designed to follow PCP workflow during a patient encounter and was built into the current EHR (EpicCare®, Epic Systems, Verona, WI). The eCDSS appeared as an alert at the time the encounter was opened. The eCDSS first risk stratified participants into low risk unconfirmed CKD (eGFRcreat <60 with eGFRcys >60 ml/min/1.73m^2 and ACR < 30 mg/g) vs. higher risk, confirmed CKD (all others with confirmed CKD stage <=3) as per guidelines.[8,18] If the patient was categorized as low risk, the alert notified the PCP along with recommendation for re-testing in 6 months. For patients for whom CKD was confirmed, the alert allowed navigation to a SmartSet, which contained tailored recommendations individualized to each patient and with pre-populated orders.

The eCDSS SmartSet delivered individualized guideline-concordant recommendations to the PCP: statin use for those with CKD age >50 years,[19] dietary and diuretic recommendations for those with mild hyperkalemia (K=5.2–5.5 mg/dL), initiation or up- titration of ACEi/ARB, and nephrology referral for highest risk participants. Highest risk was defined as any of the following: $eGFR_{Cys}$ <30 mL/min/1.73m^2, potassium >5.5 mEq/L, ACR >300 mcg/mg, systolic blood pressure (SBP) > 150 mmHg on >=3 agents including a diuretic; >3% probability of five-year progression to ESRD based on Kidney Failure Risk Equation).[8,20] The eCDSS also included education materials, based on National Kidney Disease Education Program (NKDEP) materials[21] and translated into Spanish and Chinese, on CKD general information, avoidance of nonsteroidal anti-inflammatory drugs (NSAIDs), and dietary recommendations to be printed in the patient's after visit summary. If the eCDSS was ignored, we allowed redeployment at up to two subsequent PCP visits during the study period.

eCDSS PLUS

In the second intervention arm, a pharmacist scheduled a follow-up visit by telephone within two weeks of the PCP visit when eCDSS deployed. The call was scripted to reinforce medication changes ordered at the PCP visit, CKD-related teaching and a comprehensive

medication review. Information on the telephone encounter was documented in the EHR and sent to the PCP.

A study nephrologist (L.L.) reviewed weekly laboratory results to identify: $eGFRc_r$ decline >30% from baseline, ACR ≥1,000 mcg/mg, adherence to nephrology referrals, and any discordance >30% between $eGFR_{Cr}$ and $eGFR_{Cys}$. to ensure appropriate follow up.

Data collection

We used the EHR and Epic© systems data warehouse to identify participants and ascertain participant characteristics and study outcomes. (see Item S3). Details on variable definitions have been previously published. [17]

In addition to EHR derived outcomes, we surveyed participating PCPs who were randomized to intervention to ascertain their perception of study burden using the question: “What level of burden did the eCDSS place on your practice?” Response options were high, medium, low or none.

Outcomes

The primary clinical outcomes were changes from baseline in systolic and diastolic blood pressure. As this study was initiated prior to the most recent AHA/ACC guidelines, we defined adequate control as <140/90 mmHg as a secondary clinical outcome. We assessed blood pressure at the end of the intervention period (12 month) and then 9 months after study completion using blood pressure measures only from encounters at the general internal medicine practice.

Process outcome of primary interest was PCP awareness of the patient participant’s CKD defined as inclusion of CKD-related ICD-10 codes on the problem list or visit diagnosis. We measured CKD awareness overall at study end and also newly recorded among patients without a CKD diagnosis at baseline. Additional secondary outcomes included pre-specified clinical process outcomes: use of ACEi/ARB, and use of statin (for persons age >50), defined as having active prescription for ACEi/ARB or statin, respectively. We estimated overall use at study end, and new use, defined as having a new prescription among those who were not on these agents at baseline. We also estimated total and new use of diuretic. Finally, we report on implementation metrics based on the RE-AIM framework (reach, effectiveness, adoption, implementation, and maintenance) for pragmatic interventions.

Analyses

We compared baseline demographics, clinical characteristics and study outcomes by study arm. For bivariate unadjusted comparisons across study groups, we specified PCPs as the cluster level variable. (Item S4) In adjusted analyses, we compared outcomes across study arms using multilevel mixed effects models accounting for clustering within PCPs and specifying robust standard errors. Primary analyses followed intention to treat principles.

We also performed pre-specified “as treated” analyses restricted to participants who completed testing. In order to understand sources of potential bias, we compared characteristics by study arm (intervention vs. usual care) including only those who received

the intervention. Since we found some differences in age, gender and diabetes status, we adjusted for these to understand the association of the intervention with outcomes in as-treated analyses. Finally, we estimated use of ACEi/ARB in those with albuminuria among patients tested within each intervention arm.

As previously reported,[17] we powered this study for the clinical outcome of BP change. We anticipated that if we recruited 1400 participants, we would have 80% power to detect a difference of 1.27mm Hg mean blood pressure between arms. See Item S4 for original sample size calculations. All analyses were performed using Stata version 14.2.

Results

Setting and Participants

All 80 eligible PCPs (49 attendings, 28 residents and 3 nurse practitioners) agreed to participate (100%). We excluded providers with no eligible patients.

We identified 995 patients who met initial criteria for participation. Among these, 326 were excluded based on protocol, with an additional 87 patients excluded by PCPs. Details on reasons for exclusions have been previously published and are documented in the footnote of Figure 1.[17] Only 55 intervention patients (9%) opted out or withdrew after receiving study information by mail. The total final sample was 524 patient participants randomized across the three arms.

Patient participant characteristics were well balanced at baseline, as shown in Table 1. Characteristics of those who opted out vs. those who participated were similar, as previously reported.[17] Overall, participants were fairly old, had relatively early CKD, and had high rates of CKD guideline concordant care with the exception of baseline albuminuria testing. Baseline CKD awareness by PCP was limited, with only 47% of patients having a CKD diagnosis on the problem list or at a prior visit. (Table 1)

Adoption and Implementation

At study end, 178 intervention patient participants completed a triple marker screen. Among these, 138 (78%) had a subsequent visit with their PCP during the intervention period. The eCDSS was highly utilized by the PCPs. Among the 138 encounters with an eligible PCP visit, the eCDSS was opened by the PCP for 102 participants (74%), and during these 102 encounters, orders were signed or patient education was given from the SmartSet for 83 participants (81%). (Figure) Among those with orders signed, 67 had confirmed high risk CKD and 16 had low risk unconfirmed CKD. (Item S6 details orders signed)

The eCDSS identified 33 patients (10% of intervention) that met criteria for nephrology referral. During the entire study period, a total of 425 (81%) patients had a PCP visit (69% usual care, 89% eCDSS and 87% eCDSS PLUS). Out of 524 patients, 22 (4%) changed PCP’s from one in an intervention group to one in the usual care group before they had an eligible intervention visit.

CKD Risk Stratification and Utility of the Triple Marker

Among the 178 patients who completed the triple marker screening, we found that 40 (22%) had CKD that was not confirmed by either eGFRcys <60 ml/min/1.73m^2 or ACR >=30 mg/g (considered low-risk CKD). Out of the remaining 138 patients who had CKD confirmed, 69 (50%) were confirmed by eGFRcys <60 ml/min/1.73m^2 only (ACR <30 mg/g). The remaining 69 (50%) patients had all three triple marker tests positive for CKD (eGFRcreat <60, eGFRcys <60 ml/min/1.73m and ACR >=30 mg/g), the highest risk category.

Intention-to-treat Analyses

We found no significant differences in BP change or BP control between arms. (Table 2) When analyzing only those with uncontrolled BP at baseline, there were no differences in BP control achieved (12, 14 and 12% for usual care, eCDSS and eCDSS PLUS respectively).

The overall proportion of patients with a CKD diagnosis documented at study end was somewhat higher among intervention groups compared with usual care, while the proportion of patients with new documentation of a CKD diagnosis was almost double than in the intervention arms compared with usual care after 12 months, although these differences did not reach statistical significance. (Table 2) Utilization of ACEi/ARB and statins remained high during the study period. There were no differences in total use or new use of ACEi/ARB by study arm. While the use of statins remained higher in usual care as seen at baseline, there were no differences in new use of statins by study arm. (Table 2) Results were not materially different with an additional 9 months of follow-up after study completion (Table S1). In exploratory analyses, we found that patients in the intervention arms had lower rates of nephrology consult (9%) compared with usual care (14%), although not statistically significant, p-value 0.2.

As-treated analyses

We first compared baseline characteristics of participants who completed testing by study arm and with usual care. Overall, characteristics remained balanced, except for higher rates of diabetes in the intervention arms compared with usual care. (Table S2). Among intervention arms, compared to patients who did not have the eCDSS deploy during a visit, those who completed triple marker tests and had an eligible PCP visit (i.e., received the intervention) were more likely to be non-white, report a non-English speaking preference, more likely to have heart disease or diabetes, and they were more likely to be on ACEi/ARB and statin treatment at baseline (Table S3).

PCP total and new awareness were significantly higher among intervention arms vs. usual care. (Table 3). Compared to usual care, the odds of PCP CKD awareness was higher in the eCDSS (OR 3.18, 95%CI 1.29 to 7.82) and eCDSS PLUS (OR 2.49, 95%CI 1.21 to 5.10) groups after adjustment. Similarly, the adjusted odds of PCP “new” CKD awareness was higher in the eCDSS (OR 10.3 95%CI 1.48 to 71.37) and eCDSS PLUS (OR 8.34, 95% 1.90 to 36.62) (Table S4). There were no significant differences in blood pressure change or blood pressure control. In extended follow up analyses, we found higher use of ACEi/ARB in the intervention arms (Table S5).

Among 138 persons in the intervention arms who were tested and had eCDSS deploy, 53 (38%) had ACR >=30 mg/g. Among these 53 participants, use of ACEi/ARB was 64% and 61% in eCDSS and eCDSS Plus arms respectively (p=0.86).

Burden

A total of 35 (66%) providers randomized to an intervention arm responded to the physician survey and 27/35 (77%) recalled seeing the eCDSS. Among those, 20 (74%) reported low or no burden from the eCDSS on their practice.

Discussion

In this study, we efficiently utilized the EHR to identify patient participants, deploy the intervention, and ascertain outcomes. We also demonstrated that, when deployed during an eligible encounter, more than 70% of the PCPs engaged with the electronic clinical decision support tool. Moreover, use of the eCDSS improved documented recognition of CKD. However, due to the limited uptake of the patient laboratory testing part of the intervention, we were unable to determine whether the eCDSS can improve CKD-related management and clinical outcomes in primary care.

This study is important given recent payment reforms announced by the U.S. Department of Health and Human Services to incentivize earlier detection, risk stratification and evidence-based management of CKD. To do so, we must begin by improving our ability to identify individuals with CKD at earlier stages, distinguish those at highest risk for complications, and empower primary care providers to manage patients with CKD that may not require nephrology co-management. With the use of an automated tool integrated into the EHR and utilizing a triple marker approach to testing and risk stratification, we found that one-fifth of patients with previous two eGFRcreat <60 ml/min/1.73m^2 had CKD that was not confirmed by cystatin C or albuminuria. These individuals have lower risk for complications, and international guidelines consider them as not having CKD.[8] Our tool, which recommended guideline-concordant care interventions and identified those patients in need of nephrology referral, was opened at 74% of the eligible encounters. This very high rate suggests that when designed with physician input to follow workflow and incorporate individualized action items for each patient, electronic decision tools can be highly utilized. While we were unable to conclusively determine whether the use of the automated tool improved clinical outcomes, a pre-specified as-treated analysis showed that the eCDSS did increase CKD documentation by PCPs. Given prior reports on the low levels of awareness of CKD by PCPs,[5] we believe our tool could lead to improved outcomes by raising clinician awareness of the diagnosis.

For clinical decision support to be useful, it must be integrated into the EHR workflow, which is challenging due to the need to program complex clinical information in the background, use current evidence, and provide clinically meaningful recommendations.[22,23] Prior CKD studies using enhanced EHR or registries had been limited in their ability to integrate into primary care provider workflows and provide individualized recommendations,[13,15] and required additional clinical staff on site, which can be costly.[14] This study extends these prior studies to inform the field on how to design and conduct

pragmatic, “real-world” interventions leveraging the EHR. With this study design, the costs were low and our success in using the EHR for patient identification, deployment of the intervention and ascertainment of outcomes constitutes an important example for future interventions. The low opt-out rate by physicians and patients demonstrated willingness to participate in research and allowed us to include a diverse cohort of participants with early stages of CKD, including non-English speakers.

Despite these successes, we also had some difficulties in the implementation of the protocol. These challenges provide important insights that can inform future research and clinical implementation. Our sample size was smaller than planned due both to fewer patients meeting inclusion criteria and to exclusion criteria applying to more patients than we had expected, thus limiting our power to detect differences between arms. Due to the limited intervention time-frame of this study, one of the investigators ordered all of the triple marker tests with the expectation that intervention group patients would get the tests done the next time they visited the lab for clinical care. However, only 41% of participants randomized to an intervention arm obtained the required testing and had a subsequent follow up appointment where the eCDSS launched. In a larger trial, incorporating triple marker test ordering into the PCP facing intervention may improve uptake. Patient reminders about lab tests would also likely increase intervention uptake, but may reduce pragmatism. We also found that pharmacists were frequently unable to reach patients for follow up. Future studies could consider other forms of communication such as texting or patient facing tools instead of phone calls to provide guidance. Use of blood pressure measures from the EHR may be limited by missing data and lack of standardization, although the medical assistants in the studied general medicine practice undergo certification of appropriate technique. While deployment in a single academic practice may also limit generalizability, the patients included are representative of the San Francisco area. An additional consideration for pragmatic trial implementation relates to consent procedures. The requirement to send a letter and then wait two weeks for patients to have the opportunity to opt out of a clinician-facing intervention limited our ability to test patients as they became eligible for the study. In the future, a rolling enrollment procedure could increase intervention uptake, but this would require modified consent procedures or waived consent.

In summary, while we are unable to determine whether a CKD eCDSS can improve clinical outcomes for patients with CKD in primary care, this study represents a foundation for pragmatic trials in nephrology that use the EHR to embed kidney-related interventions in primary care. The findings that one-in-five patients with CKD by creatinine had low risk CKD by other markers, coupled with the high engagement with the tool and increased documented recognition of confirmed CKD diagnoses, argue for a larger study of primary-care embedded electronic decision support.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Funding: National Institute of Diabetes and Digestive and Kidney Diseases, grant number R18DK110959 (PI: Peralta, Karliner). Dr. Peralta receives additional support for this work from an American Heart Association Established Investigator Award (17EIA33410161) (PI: Peralta). Dr. Karliner receives additional support for this work from National Institute on Aging, grant number P30AG015272 (PI: Karliner).

Support: This was work was supported by the National Institute of Diabetes and Digestive and Kidney Diseases, grant number R18DK110959 (PI: Peralta, Karliner). C.P was also supported by an American Heart Association Established Investigator Aware (PI: Peralta; 17IEA33410161). Dr. Karliner receives additional support for this work from National Institute on Aging, grant number P30AG015272 (PI: Karliner). The funders had no role in study design, data collection, analysis, reporting, or the decision to submit for publication.

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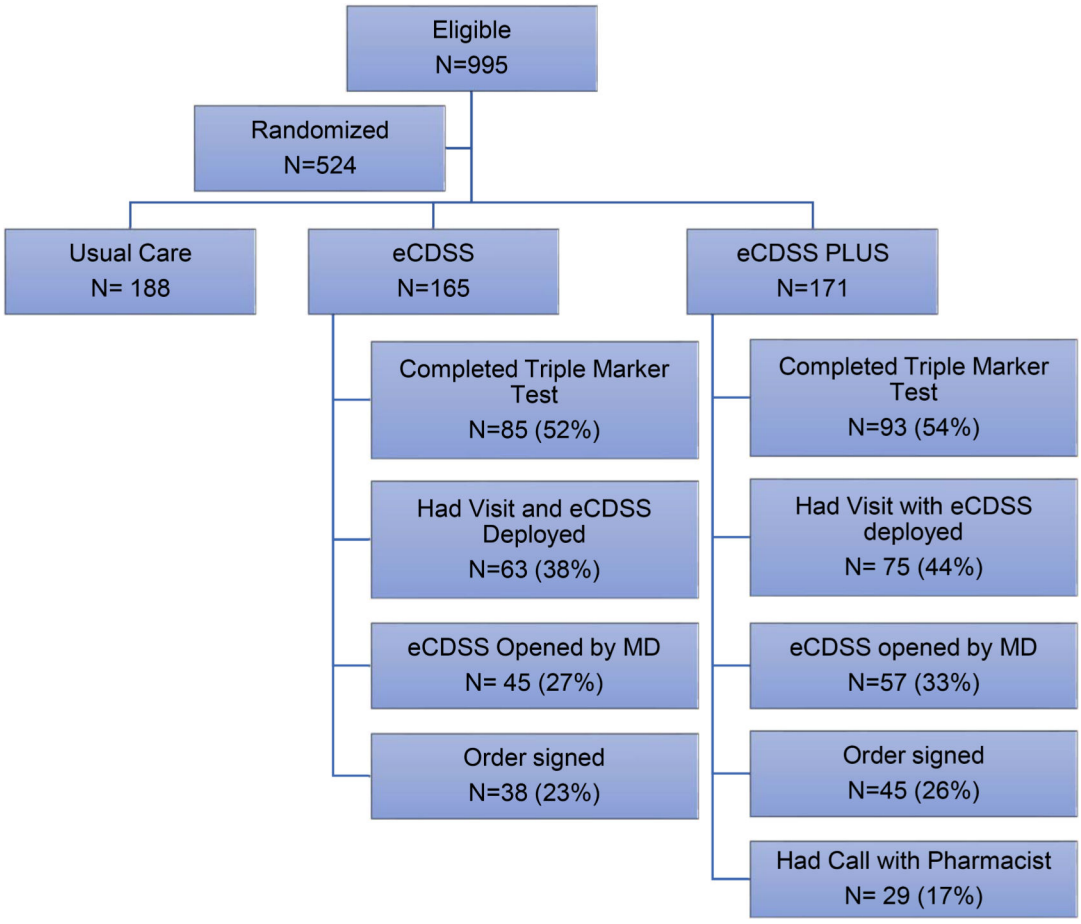

Figure 1:

Study Flow. Among 995 initially eligible persons, 326 were excluded due to: ESRD=53; 2+nephrology visits=136; excluded language=57; kidney transplant=42; dementia=38. Physicians directed additional exclusions=87 (18 death). An additional 55 opted out or withdrew, and an additional 3 were ultimately found to be ineligible.[17]

Table 1.

Baseline Patient Participant Characteristics by Study Arm (N=524)

	Usual Care (N=188 patients, 27 PCPs) N (%)	CDSS (N=165 patients, 25 PCPs) N (%)	CDSS Plus (N=171 patients, 28 PCPs) N (%)	Total (N=524 patients, 80 PCPs) N (%)	p-value*
Age (years): mean ± SD	71.1 ± 8.4	70.2 ± 8.6	69.4 ± 9.6	70.3 ± 8.9	0.4
Gender					
Female	75 (39.9)	75 (45.5)	86 (50.3)	236 (45.0)	0.4
Male	113 (60.1)	90 (54.5)	85 (49.7)	288 (55.0)	
Race/ethnicity					
White	99 (52.7)	98 (59.8)	80 (46.8)	277 (53.0)	0.2
Black/African American	17 (9.0)	21 (12.8)	31 (18.1)	69 (13.2)	
Asian	53 (28.2)	29 (17.7)	35 (20.5)	117 (22.4)	
Hispanic	15 (8.0)	9 (5.5)	14 (8.2)	38 (7.3)	
Other	4 (2.1)	7 (4.3)	11 (6.4)	22 (4.2)	
Preferred language					
English	159 (84.6)	153 (92.7)	157 (91.8)	469 (89.5)	0.4
Chinese	22 (11.7)	9 (5.5)	8 (4.7)	39 (7.4)	
Spanish	7 (3.7)	3 (1.8)	6 (3.5)	16 (3.1)	
Co-morbidities					
Cerebrovascular disease	17 (9.0)	9 (5.5)	10 (5.8)	36 (6.9)	0.3
Congestive heart failure	17 (9.0)	14 (8.5)	9 (5.3)	40 (7.6)	0.4
Coronary artery disease	39 (20.7)	29 (17.6)	27 (15.8)	95 (18.1)	0.5
Diabetes mellitus	75 (39.9)	55 (33.3)	69 (40.4)	199 (38.0)	0.3
Hyperlipidemia	115 (61.2)	97 (58.8)	90 (52.6)	302 (57.6)	0.4
Hypertension	137 (72.9)	122 (73.9)	118 (69.0)	377 (72.0)	0.6
Medication use					
ACEi/ARB	115 (61.2)	102 (61.8)	102 (59.7)	319 (60.9)	0.9
Diuretic	73 (38.8)	66 (40.0)	60 (35.1)	199 (38.0)	0.5
Statin	136 (72.3)	107 (64.9)	110 (64.3)	353 (67.4)	0.3
CKD related variables					
Had albuminuria test	90 (47.9)	59 (35.8)	71 (41.5)	220 (42.0)	0.3
CKD diagnosis	98 (52.1)	78 (47.3)	71 (41.5)	247 (47.1)	0.3

	Usual Care (N=188 patients, 27 PCPs) N (%)	CDSS (N=165 patients, 25 PCPs) N (%)	CDSS Plus (N=171 patients, 28 PCPs) N (%)	Total (N=524 patients, 80 PCPs) N (%)	p-value*
Systolic BP (mm Hg) [median, IQR]	130 [118–142]	126 [116–137]	131 [118–143]	128 [117–140]	0.2
Diastolic BP (mm Hg) [median, IQR]	68 [63–75]	68 [62–76]	68 [63–73]	68 [63–75]	0.8
BP controlled (<140/90)	130 (69.2)	128 (77.6)	115 (67.3)	373 (71.2)	0.09
eGFRcr (mL/min) mean ± SD	56 ± 12.2	55 ± 11.5	58 ± 11.4	56 ± 11.8	0.1

* p-values account for clustering of patients within physicians.

Table 2.

eCDSS and Outcomes: Intention-to-Treat Analyses at 12 months(N=524)

	Usual Care (N=188 patients, 27 PCPs) N (%)	CDSS (N=165 patients, 25 PCPs) N (%)	CDSS Plus (N=171 patients, 28 PCPs) N (%)	Total (N=524 patients, 80 PCPs) N (%)	p-value
Clinical Primary and Secondary Outcomes					
Change in systolic BP (mmHg) **, mean ± SD	−2.1 ± 18.2	−2.8 ± 20.9	−1.1 ± 20.2	−2.0 ± 19.7	0.7
Change in diastolic BP (mmHg) **, mean ± SD	−0.2 ± 10.4	0.1 ± 12.0	−0.4 ± 10.8	−0.2 ± 11.0	0.9
Controlled BP ** **(<140/90 mmHg)**	109 (65)	114 (74)	100 (63)	323 (67)	0.1
CKD Awareness- Process Outcome					
PCP awareness of CKD diagnosis at study end (inclusion on problem list or visit diagnosis)	88 (47)	86(52)	86(50.3)	260 (50)	0.7
New PCP awareness – new diagnosis from study baseline	14 (16)	23 (26)	32 (32)	69 (25)	0.09
Secondary Clinical Process outcomes					
ACEi/ARB use ***	95 (51)	86 (52)	75 (44)	256 (49)	0.3
ACEi/ARB initiation (new use)	5 (7)	6 (9)	3 (4)	14 (7)	0.5
Statin therapy use ***	112 (61)	79 (49)	94 (58)	285 (56)	0.03
Statin therapy initiation (new use) ***	3 (6)	3 (5)	4 (7)	10 (6)	0.9
Diuretic use at end of study ***	47 (25)	35 (21)	32 (19)	114 (22)	0.3
Diuretic initiation (new use)	5 (4)	3 (3)	1 (1)	9 (3)	0.4

* p-values account for clustering of patients within physicians.

** Only out of those 480 patients with valid BP measure during study period (number missing BP: 20 Usual Care, 11 CDSS, 13 CDSS PLUS)

*** ACEi/ARB, Statin therapy and Diuretic medication “use” includes only patients who are still on the medication at the end of the study period.

Table 3.

Outcome measures by study arm at 12 months – AS TREATED Analyses (N=326)

	Usual Care (N=188 patients, 27 PCPs) N (%)	CDSS (N=63 patients, 17 PCPs) N (%)	CDSS Plus (N=75 patients, 21 PCPs) N (%)	Total (N=326 patients, 65 PCPs) N (%)	p-value
Clinical Primary and Secondary Outcome					
Change in systolic blood pressure ** **(mm Hg),** mean ± SD	−2.1 ± 18.2	−3.9 ± 20.7	−0.9 ± 18.1	−2.2 ± 18.7	0.6
Change in diastolic blood pressure ** **(mm Hg),** mean ± SD	−0.2 ± 10.4	−1.3 ± 12.0	0.5 ± 9.0	−0.3 ± 10.4	0.7
Controlled blood pressure ** **(<140/90 mmHg)**	109 (65)	43 (68)	50 (67)	202(66)	0.9
CKD Awareness - Process Outcome					
PCP awareness of CKD at study end	88 (47)	46 (73)	52 (69)	186 (57)	0.002
PCP New Awareness	14 (16)	18 (55)	22 (52)	54 (33)	<0.001
Secondary Clinical Process outcomes					
ACEi/ARB use ***	95 (51)	35 (56)	40 (53)	170 (52)	0.7
ACEi/ARB initiation (new use) ***	5 (7)	5 (24)	1 (5)	11(10)	0.04
Statin therapy use ***	112 (61)	36 (59)	44 (61)	192 (61)	0.9
Statin therapy initiation (new use) ***	3 (2)	2 (3)	2 (3)	7 (2)	0.7
Diuretic use ***	47 (25)	16 (25)	16 (21)	79 (24)	0.8
Diuretic initiation (new use)	5 (4)	2 (7)	0	7 (4)	0.5

* p-values account for clustering of patients within physicians.

** Only out of those 306 patients with valid BP measure during study period (number missing BP: 20 Usual Care, 0 CDSS, 0 CDSS PLUS).

*** ACE/ARB, Statin therapy and Diuretic medication “use” includes only patients who are still on the medication by the end of the study period.