Comparative Effectiveness of a Complex Care Program for High-Cost/High-Need Patients: a Retrospective Cohort Study



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BACKGROUND: High-cost/high-need (HCHN) adults and the healthcare systems that provide their care may benefit from a new patient-centered model of care involving a dedicated physician and nurse team who coordinate both clinical and social services for a small patient panel.

OBJECTIVE: Evaluate the impact of a Complex Care Program (CCP) on likelihood of patient survival and hospital admission in 180 days following empanelment to the CCP.

DESIGN: Retrospective cohort study using a quasiexperimental design with CCP patients propensity score matched to a concurrent control group of eligible but unempaneled patients.

SETTING: Kaiser Permanente Mid-Atlantic States (KPMAS) during 2017–2018.

PARTICIPANTS: Nine hundred twenty-nine CCP patients empaneled January 2017–June 2018, 929 matched control patients for the same period.

INTERVENTIONS: The KPMAS CCP is a new program consisting of 8 teams each staffed by a physician and nurse who coordinate care across a continuum of special-ty care, tertiary care, and community services for a panel of 200 patients with advanced clinical disease and recent hospitalizations.

MAIN OUTCOMES: Time to death and time to first hospital admission in the 180 days following empanelment or eligibility.

RESULTS: Compared to matched control patients, CCP patients had prolonged time to death (hazard ratio [HR]: 0.577, 95% CI: 0.474, 0.704), and CCP decedents had longer survival (median days 69.5 vs. 53.0, p=0.03). CCP patients had similar time to hospital admission (HR: 1.081, 95% CI: 0.930, 1.258), with similar results when

Key Points Question: Does an intervention focused on the secondary and tertiary care coordination and palliative care needs of high-cost/high-need adults modify their short-term risk of repeat hospitalization and mortality?

Findings: The intervention implemented at Kaiser Permanente Mid-Atlantic States significantly reduced the 180-day mortality hazard ratio [HR] by 42.3% but did not significantly change the 180-day medical/ surgical admission HR—compared to a matched patient cohort.

Meaning: An intervention designed to address the specific care requirements of high-cost/high-need adults achieved significantly reduced shortterm mortality HR.

Received June 24, 2020 Accepted February 17, 2021 Published online March 19, 2021 adjusting for competing risk of death (HR: 1.062, 95% CI: 0.914, 1.084).

LIMITATIONS: Non-randomized intervention; single healthcare system; patient eligibility limited to specific conditions.

CONCLUSION: The KPMAS CCP was associated with significantly reduced short-term mortality risk for eligible patients who volunteered to participate in this intervention.

J Gen Intern Med 36(7):2021–9 DOI: 10.1007/s11606-021-06676-x © Society of General Internal Medicine 2021

INTRODUCTION

A relatively small number of multi-morbidity patients use a disproportionate share of healthcare resources.¹⁻⁴ High-cost high-need (HCHN) patients require complex coordination of care to address advanced clinical disease with interacting morbidities and social needs that, if unrecognized or unaddressed, can compromise safe and effective healthcare delivery.^{2, 3, 5} HCHN patients may benefit from models of care that differ from the traditional primary care physician (PCP) model, ^{5–17} such as patient panels limited exclusively to HCHN patients whose advanced care needs require a focus on coordinating and integrating care across a broad continuum of institutions (including community services) and medical subspecialties.^{5, 18–23}

Kaiser Permanente Mid-Atlantic States (KPMAS) initiated a Complex Care Program (CCP) that empanels HCHN patients with a dedicated CCP physician who, along with a support team, assumes full responsibility for providing and coordinating patient care. The CCP is a "clinic-based replacement model" for traditional primary care.²⁰ CCP goals included reducing the risk of acute exacerbations of disease while improving survival, quality of care, and quality-of-life for empaneled patients.

The objective of this study was to evaluate whether the CCP achieved reduced risks of 180-day medical/surgical hospital admission and/or mortality. The CCP is not a randomized trial. Eligible patients voluntarily consent, but are not prospectively assigned, to the CCP. Thus, we used a quasi-experimental design to match CCP intervention patients with eligible but unempaneled patients.

METHODS

Study Setting

KPMAS is an integrated delivery system for approximately 750,000 residents of Washington DC, Baltimore, and the Maryland and northern Virginia suburban areas of Washington DC. Most medical services (primary, specialty) are provided by a pre-paid group practice at 34 medical offices—6 of which provide 24/7 urgent care and hospital triage. Hospital care is primarily provided at 8 contract hospitals. Beneficiaries are insured through employer-sponsored plans (62%), individual plans (15%, including ACA Marketplace plans), Medicaid (12%), or Medicare (11%). The KPMAS IRB reviewed and approved the CCP intervention and evaluation protocols.

Intervention (See Also Supplemental Material)

KPMAS initiated its current CCP model in January 2017 following a year of pilot testing.

Empanelment occurs through pro-active CCP outreach and PCP referrals. Pro-active outreach involves a monthly query of KPMAS electronic health records (EHRs) to identify adults who have (1) four or more hospital admissions (excluding surgical, obstetrics/gynecology, psychiatric, and rehabilitation) within the prior 12 months; (2) an admission in the prior 30 days and history of chronic obstructive pulmonary disease, cancer, end-stage renal disease, congestive heart failure with ejection fraction < 20%, dementia, or respiratory failure; or (3) hospital triage care in the prior 30 days with principal diagnosis of gastroparesis. Patients referred by their PCPs must meet these same eligibility criteria. To become empaneled to the CCP, a patient consents to have responsibility for care transferred from the PCP to a CCP physician. CCP physician panels are limited to 200 HCHN patients, versus a typical internal medicine PCP panel of 1,800 adults. The small panel sizes allow CCP physicians time for extended, dedicated in-person (45 min) and "non-traditional" (e.g., home, nursing home, video, and phone) visits. CCP physicians and their nurses spend significant non-visit time contacting patients and reviewing patients' medical records for updating of care management plans (e.g., reconciling medication orders from multiple specialists) and addressing social needs that can compromise medical care effectiveness (e.g., lack of transportation to clinics, inability to pay medication copayments).

Study Population and Period

Any KPMAS patient 18 years of age or older who met the CCP eligibility criteria for CCP participation between January

2017 and June 2018 (inclusive) was included in the study population. No other inclusion or exclusion criteria applied. The study population was divided into two cohorts: patients who volunteered to switch their care from a PCP to a CCP physician ("CCP patients"), and patients who declined the invitation to switch ("control patients"). Outcomes were observed for up to 180 days following an "index date" (below).

Analytic Data Model

The CCP is a non-randomized intervention. To create a common point of reference, we created the "index date" to measure time to mortality and time to next medical/surgical admission. For CCP patients, the index date was the date the patient was empaneled to their CCP physician. For control patients, the index date was defined within their CCP eligibility month. If control patients had more than one CCP eligibility month from January 2017 through June 2018, we selected the most recent month. Within that month, we identified the last date of service initiation (e.g., hospital admission date, visit date) as the index date. For the small percentage of patients with no service date in the month, we defined the index date as a randomly selected day within the month.

Data Sources

CCP Administrative Datasets. Each month, the CCP Administrative Team identifies eligible patients from the KPMAS EHR system for invitation to enroll in the CCP. The eligibility dataset contains information on patient contact and clinical criteria for eligibility. An empanelment dataset is maintained for those who enroll (through outreach or physician referral), with empanelment date and assigned CCP physician.

Medical Services Datasets. EHR medical services records include service date, service type and location, procedure and diagnoses code(s), and patient disposition. Services provided by non-KP providers are incorporated into EHR datasets.

Health Plan Coverage Dataset. For each KPMAS beneficiary, dates of enrollment and disenrollment are available for each period of health benefits coverage.

Demographic Dataset. This dataset contains a beneficiary's date of birth, gender, race, and ethnicity.

US Census Dataset. Each KPMAS beneficiary is geocoded to the latitude and longitude of the residential address as of the end of each year. The latitude and longitude are assigned the Census block group as of the 2010 Census and linked to the Summary Files to obtain area-level demographic and socio-economic data.²⁴

Mortality Dataset. KPMAS maintains a dataset with date of death. These variables are obtained from the health plan coverage dataset supplemented with the Social Security Administration.²⁵

Measures

Mortality. Time to death is the difference between the death date and the index date.

First Hospital Admission. Time to admission is the difference between first medical/surgical hospital admission date (if any) and the index date. Medical/surgical admissions were identified by hospital type (e.g., general acute vs. rehabilitation) and principal diagnosis.

Disenrollment. Time to disenrollment is time from the index date to the date of termination of health plan benefits. A break in enrollment of \geq 30 days following the index date and before December 31, 2018, was considered disenrollment.

Patient Demographics. Age was calculated as of the index date, and classified into 4 groups: ≤60 years, 61–70 years, 71–80 years, and >80 years. Gender is female or male. Race is White/Caucasian, Black/African American, Asian, or other/unknown.

Comorbidity Index. Comorbidities were measured using ICD-10 codes from urgent/emergent and hospital care for a 365-day period ending at 30 days before the index date. We used the Charlson comorbidity index.^{26–32} For each patient, comorbidity classes were counted and classified as 0–2, 3–4, 5–6, and \geq 7.

Acuity Index. To account for differences in illness acuity not captured by the Charlson comorbidity index, we adapted an Intermountain laboratory-based index based on results of 4 laboratory tests associated with outpatient visits for a 180-day period before the index date.³³ Patients were assigned to one of four classes from "0" (minimum risk, or no relevant laboratory test) to "4" (maximum risk) based on the count of abnormal results.

Socioeconomic Status. Individual-level socioeconomic status (SES) measures are not available; therefore, we used areabased median household income (classified into 4 groups) and percent of households on public assistance (dichotomized as $\geq 3\%$ and <3%) for the beneficiary's residential Census block group according to the 2010 Census. Area-level measures, on average, represent KP adults' sociodemographic characteristics.³⁴

Utilization in the 180 Days Prior to the Index Month. For each patient, we calculated the number of hospital days, ED visits, office visits, hospital observation stays, and ambulatory surgeries in the 180 days prior to the index date. In addition, we determined whether or not the patient was admitted to an intermediate care facility during this period.

Statistical Analysis

All analyses were conducted, using SAS version 9.4 (SAS Institute, Cary, NC), at the patient level, following an intention-to-treat framework.

Comparisons of CCP and Control Patients on Baseline Characteristics. As of the index date, we compared CCP patients and control patients on age group, gender, race, comorbidity index, acuity index, prior 180-day utilization, and SES. Comparisons were made using a chi-square statistic for categorical measures, and a *t*-test for continuous measures. Significance was declared for *p* values ≤ 0.05 .

Propensity Score Matching. We used propensity score matching^{35–39} to address the non-randomized nature of the CCP intervention. Propensity score matching is a means to establish equivalence on observable patient characteristics between CCP and non-CCP patients as of the index date. One CCP patient was matched with one control patient using a sensitivity of 0.25 standard deviation of the dependent variable (i.e., CCP empaneled vs. unempaneled).

Regression Analysis of Survival Time and Time to First Hospital Admission. We compared median times to death or first medical/surgical admission, and censoring times, between CCP patients and matched control patients using Wilcoxon tests of differences. Censoring is defined as 180 days following the index date, disenrollment following the index date, or December 31, 2018—whichever occurred first. The 180 days criterion ensured all eligible patients (especially newly eligible as of June 2018) would be observed for outcomes over an equal period of time.

We estimated hazard ratios (HRs) for times to death and first hospital admission using Cox proportional hazards (CPH) models.⁴⁰ We also estimated a competing risk model^{41–44} of hospital admission, since death precludes hospital admission if it occurs first. In the competing risk model, censoring included time from the index date to death among decedents for whom a hospital admission was not observed.

Heterogeneity of CCP Effects. We examined whether CCP effects significantly differed by selected patient groups: age (\leq 70 vs. >70 years), gender, race (Black, Asian/other/un-known, White), or pre-existing comorbidity (\geq 3 vs. 0–2 Charlson comorbidity groups). We re-estimated the CPH models with the CCP effect, the group effect, and an interaction between the CCP effect and the group effect (i.e., the heterogeneity effect).

Sensitivity Analysis. To test the sensitivity of outcomes to matching methods, we also used an inverse probability weighting⁴⁵ approach where the weights were based on a prediction model of CCP participation versus not on the entire sample (5,404 eligible but unempaneled, 933 CCP patients; Fig. 1). We estimated the CPH models without and then with the same patient covariates used in matching, since patient factors may affect outcomes in addition to selection into the CCP.

RESULTS

Comparisons of CCP and Non-CCP Patients on Baseline Characteristics

Between January 2017 and June 2018, 6,337 patients met CCP eligibility criteria (Fig. 1). Of these, 933 (14.7%) volunteered for CCP empanelment. Of those, the majority (71.8%; 670 of 933) enrolled through proactive outreach; 28.2% (263 of 933) enrolled through PCP referral. Of the 933 CCP patients, 929 (99.6%) had complete covariate measures.

Before propensity score matching, CCP patients differed from potential control patients on comorbidity index (higher for CCP patients), acuity index (higher for CCP patients), several of the pre-index month utilization measures (higher for CCP patients), and percentage of households on public assistance in a neighborhood (less likely for CCP patients; Table 1). After propensity score matching, we no longer observed any significant differences between CCP patients and matched controls (Table 1).

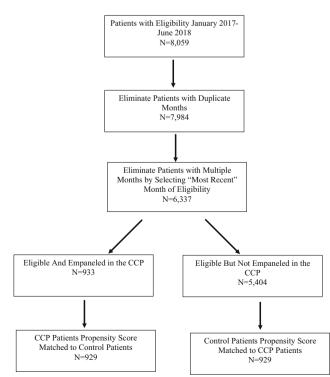


Figure 1 CCP evaluation study cohort: allocation of patients.

Comparison of CCP Patients and Matched Control Patients on Mortality

Following the index date, 17.2% (160 of 929) of CCP patients versus 26.4% (255 of 929) of matched control patients died within 180 days (Table 2). Among decedents, the median time to death was 69.5 days among CCP patients versus 53 days among matched control patients (p=0.03).

The 180-day mortality HR was 0.577 (95% CI: 0.474, 0.704) for CCP patients versus matched control patients. Figure 2 illustrates the lower accrual of deaths among CCP patients compared to matched control patients.

Comparison of CCP Patients and Matched Control Patients on Hospital Admission

Following the index date, 39.3% (365 of 929) of CCP patients versus 34.3% (319 of 929) of matched control patients had a hospital admission within 180 days (Table 2). Among those who had a hospital admission, the median time to first admission was 73 days among CCP patients versus 58 days among control patients (*p*=0.03). Principal diagnoses on first admission were comparable in both groups, the most frequent being atrial fibrillation, heart failure, cerebral infarct, pneumonia, obstructive pulmonary disease, respiratory failure, acute kidney disease, chronic kidney disease, and urinary tract infection.

The 180-day admission HR was 1.081 (95% CI: 0.930, 1.258) for CCP patients versus matched control patients. Figure 3 illustrates the similar rate of accrual of first hospital admission in the first 180 days following the index date. The CPH regression with a competing risk specification reduced the hazard ratio slightly to 1.062 (95% CI: 0.914, 1.062).

Heterogeneity of the CCP Intervention Effect

All of the subgroups who were empaneled to the CCP were associated with significant reductions in 180-day mortality HRs (all \leq 1.000; eTable 1). By comparison, there were few significant differences between subgroups in 180-day admission HRs. One exception was the higher 180-day admission HR among Black versus White patients in the CCP (HR: 1.263, 95% CI: 1.029, 1.550).

Sensitivity Analyses

Results from inverse probability weighting were consistent with the propensity score matching (eTables 2a and 2b). CCP patients had decreased 180-day mortality HR, but increased 180-day admission HR. Compared to the propensity score matched results, however, the inverse probability weighting estimates suggested smaller differences between CCP and control patients in decreased 180-day mortality HR and larger differences in increased 180-day admission HR. Inclusion of patient covariates made little difference on CPH effect estimates.

		unmatched dataset			Propensity score matched dataset		Propensity score model		
		ССР	Non- CCP	<i>p</i> value	Matched controls	<i>p</i> value	OR	95% CI	<i>p</i> value
N of Patients		933	5,404	_	929	_	_	_	_
Age group (years)	≤60 61–70	23.0% 22.8	23.9% 25.0	0.31	21.5% 23.4	0.84	-0.847		0.15
	71-80	26.3	25.6		27.7		0.914	0.731, 1.104	0.43
	≥81	27.9	25.5		27.5		0.993	0.792, 1.246	0.95
Gender	Female	53.2%	52.0%	0.51	52.2%	0.68	1.105	0.951, 1.284	0.19
Dage	Male	46.8	48.0	0.46	47.8	0.04	-	-	—
Race	White Black	37.2% 51.6	38.0% 49.2	0.46	37.2% 51.3	0.94	0.907		0.25
	Asian	5.6	6.3		5.3		0.832	0.594, 1.164	0.28
	Other/unk.	5.6	6.5		6.5		0.970	0.695, 1.352	0.86
Comorbidity index in the 12 months prior to index date (count of Charlson comorbidity groups)	0–2 3–4	27.0% 27.6	61.9% 18.1	<0.01	22.7% 31.0	0.10	2.540	2.078, 3.108	_ <0.01
	5–6	26.9	12.8		28.8		3.206	2.581, 3.982	< 0.01
	≥7	18.5	7.2		17.8		3.326	2.579, 4.289	< 0.01
Clinical acuity index in the 180 days prior to index date (count of IHC risk score groups with abnormal lab values)	0 1	31.6% 18.8	46.6% 19.4	<0.01	28.1% 21.0	0.46	_ 1.100		_ 0.39
	2	22.3	16.4		23.4		1.270	1.365 1.019,	0.03
	3	18.7	12.0		18.3		1.294	1.583 1.013,	0.04
	4	8.7	5.6		9.3		1.093	1.653 0.795, 1.503	0.58
Utilization in 180 days prior to index date	Hospital days (mean)	3.32	1.17	< 0.01	2.89	0.17	1.028	1.013, 1.044	< 0.01
	ED visits (mean)	3.73	1.76	< 0.01	3.44	0.26	1.142	1.112, 1.172	< 0.01
	Office visits (mean)	13.11	10.67	< 0.01	13.42	0.41	0.993	0.984, 1.002	0.13
	HOBS (mean)	0.04	0.02	< 0.01	0.04	0.92	0.882	0.618, 1.260	0.49
	Ambulatory surgery (mean)	0.13	0.14	0.29	0.13	0.73	0.818	0.680, 0.984	0.03
	Intermediate facility care	32.6%	12.3%	< 0.01	31.5%	0.58	1.857	1.371, 2.003	< 0.01
Median household income	<\$65,000	27.8%	26.4%	0.50	28.6%	0.59	1.040	0.830, 1.304	0.73
	\$66-89,000	24.2	24.0		26.2		0.972	0.782, 1.208	0.80
	\$90-119,000	23.0	25.2		22.4		0.859	0.692, 1.068	0.17
Households on public assistance	≥\$120,000 ≥3 %	25.0 22.3%	24.4 25.3%	0.05	22.8 22.4%	0.96	-0.807	0.669,	0.02
	<3%	77.7	74.7		77.6		_	0.973	_

Table 1 Study Population and Propensity Score Matching of CCP patients with Non-CCP Patie	Table 1 Study Population and F	Propensity Score Matching of CCP p	patients with Non-CCP Patients
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Percentages may not add to 100.0% due to rounding

For the propensity score model, the following are the omitted category for each variable: $age \leq 60$ (for age group); male (for gender); White race (for race); "0–2" comorbidity index score (for Charlson comorbidity index score); "0" lab risk score (for Clinical Acuity Index), no intermediate facility care use (for prior utilization); \geq \$120,000 median household income in the residence's census block group (for median household income); and < 3% households on public assistance in the residence's census block group (for households on public assistance) OR odds ratio (adjusted), IHC Intermountain Health Care, HOBS hospital observation stay

DISCUSSION

We evaluated the mortality and hospital admission outcomes of a non-randomized intervention designed to improve the care of HCHN adults with advanced disease and recent high acute care use. We have three principal findings from our evaluation.

One, the CCP intervention resulted in empanelment of "the sickest of the sick." Compared to eligible patients who chose not to switch to the CCP model of care, CCP patients had more

Outcome	Endpoint	Matched control patients		CCP patients		Median time: CCP patients vs. matched controls (p value)	Hazard ratio (95% confidence interval)	
		N	Median time (days)	N	Median time (days)	φ value)	intervar)	
Death	Event	255	53	160	69.5	0.03	0.577	
	Censored	674	180	767	180	0.18	(0.474, 0.704)	
Medical/surgical admission	Event	319	58	365	73	0.03	1.081	
8	Censored	610	180	564	180	< 0.01	(0.930, 1.258)	
Medical/surgical	Event	319	58	365	73	0.03	1.062	
admission: competing risks	Censored: disenrollment	432	180	466	180	0.87	(0.914, 1.084)	
	Censored: death	178	48.5	98	67.5	0.25		

Table 2 Cox Proportional Hazards Regression for Death or First Hospital Admission in the 180 Days Following the Index Date

Difference in median times assessed with a Wilcoxon test, 2-tailed p values using a t-approximation

"Censored: disenrollment" includes observations for a maximum of 180 days and also observations until December 31, 2018

comorbidities, higher clinical acuity, and greater utilization (hospital days, ED visits, office visits, intermediate facility care stay) prior to empanelment.

Two, CCP patients—those HCHN patients whose care was provided and coordinated through the CCP model of care had a significant reduction in 180-day mortality HR compared to matched control patients whose care remained within a PCP model of care. The reduction was substantial—42.3% lower than the 180-day mortality HR of matched control patients. Among decedents, CCP patients lived a median time of approximately 2 weeks longer than matched control patients.

Three, CCP patients had slightly increased 180-day medical/surgical admission risk. The 180-day admission HR for CCP patients was 8.1% higher than matched controls. Inverse probability weighting and accounting for the competing risk of death, which was higher among matched control

patients, modified this finding (increased risk with inverse probability weighting, decreased risk with competing risks).

The magnitude of the reduced 180-day mortality HR for CCP patients is unexpected. A recent meta-analysis found a small but insignificant mortality reduction across multiple interventions for "at risk patients."⁴⁶ One study found mortality reduction at 1 year of a relative 42% (6.2% vs. 10.6% for controls).^{47, 48} A Swedish intervention study found reduced mortality risk (HR-0.66) over 24 months,⁴⁹ and another found reduced relative mortality of 45% (16% vs 29%) at 6-months,⁵⁰ among older frail patients. Thus, our findings are not unprecedented. The recent Camden Study reports reduced 180-day mortality, but the difference (-1.2%) was not significant.⁵¹ However, our study differs from the Camden Study in important ways. First, the Camden Study was a randomized controlled trial, whereas the CCP is a practice-based

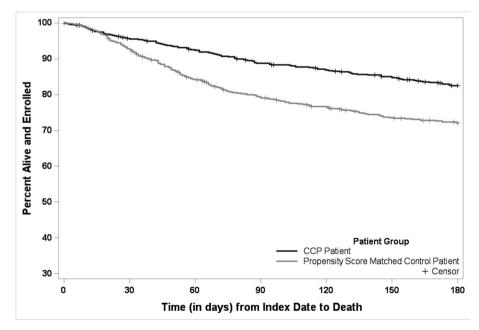


Figure 2 Time to death following the index date in the propensity score matched dataset. The graph shows the cumulative hazard of death from the index date to 180 days out within the propensity score matched data set.

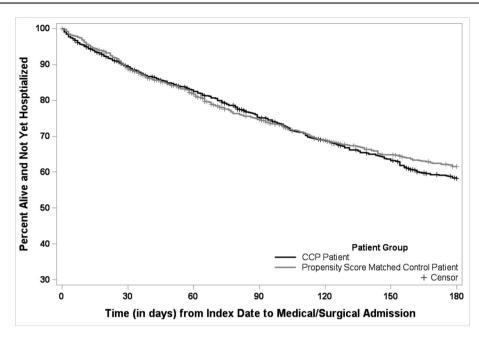


Figure 3 Time to first medical/surgical hospital admission following the index date in the propensity score matched dataset. The graph shows the cumulative hazard of next medical/surgical hospital admission from the index date to 180-days out within the propensity score matched dataset.

intervention. Second, the CCP mortality rates (17.2% in the CCP group and 27.4% in the control group) were more than double the Camden Study mortality rates (7.4% in the treatment group and 8.6% in the control group),⁵¹ and are similar to mortality rates in other HCHN populations.⁵² Thus, the CCP enrolled more acutely ill patients who, with greater mortality risk, presented an opportunity for greater reduction in mortality.

The increase in short-term readmission risk of CCP patients is also unexpected, although not always statistically significant. The Camden Study and VA randomized trials of HCHN patients have not demonstrated significant reductions in hospital utilization.^{51, 53} Many utilization and disease management programs that are clinically effective are not necessarily cost saving.^{54–61}

Limitations

CCP participation was not randomized. We used propensity score matching to control for observable differences between CCP and control patients. Other factors, unobserved and unmeasured in our study, could account for differences in CCP selection and 180-day mortality and admission HRs. For example, sicker patients may have stronger attachments to their PCP and choose not to enroll in the CCP. CCP patients and control patients may also differ in activation, self-efficacy, and lifestyle and adherence behaviors. While we matched on many observable measures (demographic, clinical, utilization prior to the index date), such unobserved differences could introduce bias into the HR estimates. We addressed the possibility that our specification of control group index date could introduce bias in time to death and hospital admission by examining alternative specifications for the index date. We found no significant differences in HRs. Our evaluation's findings are for a patient population with specific clinical conditions and may not be generalizable to other clinical conditions. The small CCP patient panels may be more feasible in capitated or salary-based settings (e.g., KPMAS) than in service-based reimbursement systems. Our analyses and findings are limited to a 180-day period of observation of mortality and next medical/surgical admission and may differ with longer periods of follow-up.

CONCLUSIONS

The KPMAS CCP organized care for HCHN patients so that they would receive care from a provider team with small panels, intimate and personalized attention to clinical and social needs, and a focus on secondary prevention, care transitions, and palliative care. Compared to matched control patients who continued to receive care in the PCP model, CCP patients experienced reduced 180-day mortality HR with minimal increase in hospital admission HR.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11606-021-06676-x.

Acknowledgements: The authors would like to acknowledge the 2017–2018 KPMAS Complex Care Program physicians (Drs. F. Abdulsalam, S. Flagg, C. Freeman, F. Freisinger, L. Luo, K. Nagi, S. Nokuri, J. Swett, R. Yelamanchi), nurses (Ms. J. Garza, R. Leonard, E. McKinney), and administrative team (Ms. C. Campbell, Mr. C. Ma) who provided helpful suggestions during presentations of interim results at steering committee meetings.

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Funding The KPMAS Community Benefit Fund provided funds for the evaluation. It had no role in the design of the study; the collection, analysis, and interpretation of the data; and the decision to approve publication of the finished manuscript.

Declarations:

Conflict of Interest: The authors have no financial conflicts of interest to disclose. Drs. McCarthy, Mendiratta, and Roblin are affiliated with the medical group which designed and implemented the intervention.

Human Subjects: The evaluation protocol has been reviewed, approved, and monitored by the Institutional Review Board of Kaiser Permanente Mid-Atlantic States (IRB Protocol number MA-16-138).

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