Does the Doctor–Patient Relationship Affect Enrollment in Clinical Research?

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Abstract

Purpose

Recruiting patients for clinical research is challenging, especially for underrepresented populations, and may be influenced by patients' relationships with their physicians, care experiences, and engagement with care. This study sought to understand predictors of enrollment in a research study among socioeconomically diverse participants in studies of care models that promote continuity in the doctor–patient relationship.

Method

A study of the effects of vitamin D levels and supplementation on COVID-19 risk and outcomes was implemented from 2020 to 2022 within 2 studies of care models at the University of Chicago that promoted continuity of inpatient and outpatient care from the same physician. Hypothesized predictors of vitamin D study enrollment included patient-reported measures of the care experience (quality of relationship with the doctor and their staff, timely receipt of care), engagement in care (scheduling and completing outpatient visits), and engagement with these "parent" studies (follow-up survey completion). The authors used univariate tests and multivariable logistic regression to examine the association of these predictors with enrollment in the vitamin D study among participants in the parent study intervention arms.

Results

Among 773 eligible participants, 351/561 (63%) in the parent study intervention arms enrolled in the vitamin D study, versus 35/212 (17%) in the control arms. Among intervention arm participants, vitamin D study enrollment was not associated with reported quality of communication with or trust in the doctor, or helpful/respectful office staff, but was associated with report of receiving timely care, more completed clinic visits, and higher parent study follow-up survey completion.

Conclusions

Study enrollment may be high in care models with high levels of continuity in the doctor–patient relationship. Rates of clinic involvement, parent study engagement, and experience of receiving timely access to care may better predict enrollment than quality of the doctor–patient relationship.

Recruiting participants for clinical research is challenging, and insufficient or delayed recruitment has significant scientific, financial, and ethical consequences.[1] Racial and ethnic minorities remain underrepresented in clinical research,[2] despite requirements for their representation in federally funded studies.[3] One common theme among strategies to increase research recruitment, especially for minority populations, is the importance of physicians and the quality of the doctor–patient relationship, a central mission of the Bucksbaum Institute for Clinical Excellence at the University of Chicago.[4–6] Treating physicians are among patients' most trusted sources of information,[7] and patients whose physicians advised them to participate in a clinical trial are more likely to enroll.[8,9] Given the historical failures of biomedical research to protect minority patients, trust in one's physician may be a particularly important driver of willingness to engage in research for such individuals.

Understanding how elements of the doctor–patient relationship and care experience predict patient willingness to participate in research may provide insights into how to increase patient engagement. One study found that when patients learn about clinical research from their physician, those reporting greater trust in the physician, more open communication, and a personal, respectful relationship were more likely to participate.[10] Individuals already engaged in research may be more likely to engage in further studies. Alternatively, such patients may lack the time, resources, or inclination to enroll in additional research. Experiences in receipt of care, such as timely access to care when needed, may also predict willingness to engage in research.

We had an opportunity to examine whether such relational variables predict engagement in clinical research when we initiated a study of the association of vitamin D levels and supplementation with COVID-19 risk and outcomes within the context of 2 existing randomized controlled trials at the University of Chicago Medicine (UCM). The "parent" studies we recruited subjects from are the Comprehensive Care Program (CCP) and the Comprehensive Care, Community, and Culture Program (C4P). Both examine how increased continuity in doctor–patient relationships by consolidating inpatient and outpatient care under a physician whose practice focuses on patients at increased risk

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of hospitalization affects outcomes for patients with complex medical and social needs.[11]

Here, we describe implementation of the vitamin D study within the intervention arms of the CCP/C4P studies and examine the association of several doctor–patient relationship measures with patient enrollment into the vitamin D study. We examined 3 domains of variables we hypothesized might influence enrollment: patients' assessments of the quality of their relationship with their physician and overall care experience (overall physician ranking, communication, trust in, and degree of caring and timeliness of care from their physician), clinic engagement (e.g., outpatient clinic visits completed versus scheduled), and engagement with the parent research study. We explored each domain separately, then together in a combined model assessing which variables were most strongly associated with enrollment in the vitamin D study.

Method

Sample

Participants in the vitamin D study were recruited from among CCP/C4P study patients. This research was approved by the UCM Institutional Review Board.

CCP/C4P parent studies. The CCP/C4P studies enrolled patients with Medicare Parts A and B at increased risk of hospitalization based on having ≥ 1 hospitalization in the past 1–2 years or receiving care in the UCM emergency department at the time of enrollment. From 2012 to 2016, the CCP study randomized 2,000 patients equally between 2 arms. In the CCP arm, patients received access to a CCP physician for inpatient and outpatient care. In the standard care arm, different physicians provided inpatient and outpatient care. The C4P study started in 2016 and added randomization to a third arm that enhanced CCP care with systematic screening for unmet social needs and access to community health workers, and community-based arts and social programming. The C4P study aimed to better address unmet social needs to increase program engagement and improve outcomes. In both studies, patient self-reported data on quality of life, satisfaction with health care providers and care experience, general and mental health, and demographics were collected at baseline and in quarterly phone follow-up surveys. Preliminary results demonstrate improved patient ratings of their care providers and mental health, and decreased hospitalization.[12]

Embedded CCP/C4P vitamin D COVID-19 study. The CCP/C4P vitamin D study examined whether vitamin D levels and supplementation were associated with risk and/or severity of COVID-19 infection and practical issues in vitamin D supplementation for the medically complex CCP/C4P population. Vitamin D deficiency is common, especially in older[13] and African American populations,[14] which comprise most patients served by the CCP/C4P programs. Evidence shows that vitamin D deficiency reduces immune function and is associated with increased COVID-19 risk,[15,16] and that vitamin D supplementation may reduce the risk of viral respiratory tract infections.[17]

We recruited participants for the vitamin D study from CCP/C4P patient rosters. Patients in the CCP/C4P intervention arms were offered vitamin D level testing and no-cost vitamin D supplements based on test results, with dosing determined through discussion with their CCP. Patients in the 2 control arms were offered free Vitamin D level testing but not test results or supplements. Intervention and control participants consenting to vitamin D study participation were asked questions in their enrollment and parent study follow-up surveys regarding pandemic-related behavior modifications, supplement use, COVID-19, and other respiratory infections.

Patients in the CCP/C4P arms were eligible if they had been seen in the CCP/C4P clinic within 1 year and chart review of recent lab values and medications did not identify exclusion criteria. To minimize complications resulting from increased calcium absorption due to vitamin D supplements, individuals with calcium levels ≥ 10.5 mg/d were excluded. Recruitment of control arm participants took place among patients active in research in the CCP/C4P study control arms receiving ongoing care at UCM. We considered patients active in research if they had not withdrawn from the study or declined all future follow-up surveys. Control arm patients did not undergo chart review since they were not provided supplements. A total of 1,002 participants (790 intervention, 212 control) were active in clinic or research. The lower number of eligible control arm patients reflects the presence of 2 intervention arms versus 1 control arm in the C4P study, the higher rate of continued activity in intervention than control arms, and the requirement that control arm patients receive ongoing care from UCM. After exclusions based on chart review and by CCP physicians who deemed some patients inappropriate for participation, 773 participants were eligible for study recruitment (561 intervention, 212 control). The CCP/C4P research and clinical teams recruited participants for the vitamin D study from September 2020 to June 2021. Of 561 eligible intervention patients, 351 (63%) consented to the vitamin D study, 111 (20%) declined, and 99 (18%) were not reached after ≥ 3 attempts. Of 212 eligible control patients, 35 (17%) consented to the vitamin D study, 83 (39%) declined, and 94 (44%) could not be contacted.

All participants had choice of vitamin D level testing using a finger stick home test kit (Everlywell) or in-clinic blood draw. After intervention participants completed vitamin D tests, their CCPs reviewed results and recommended a vitamin D dose, ranging from 400 to 10,000 IU/day, and typically from 1,000 to 5,000 IU/day. Intervention participants also could choose to receive vitamin D supplements without a vitamin D test, and were typically recommended 5,000 IU/day. All study patients were asked if they wished to continue in the study at 3, 6, 9, and 12 months. We analyzed factors associated with successful initial study enrollment among the 462 intervention participants who enrolled or declined participation.

Patient assessment of the doctor–patient relationship and care experience

The quality of the doctor–patient relationship and care experience were evaluated by self-reported responses to questions in the parent CCP/C4P follow-up surveys drawn from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician & Group Survey (Version 2.0) and the Ambulatory Care Experiences Survey (ACES). CAHPS queries 3 areas of patient experiences with physicians and staff: getting timely appointments, care, and information

(timeliness subscale, 5 questions); how well doctors communicate with patients (communication subscale, 6 questions); and helpful, courteous, respectful office staff (office staff subscale, 2 questions).[18] We modified the questions to ask about the past 3 months to align with follow-up survey frequency. All questions were answered on a 4-point Likert scale. We calculated composite scores for each subscale by assigning a numerical value to each answer response (1 = never to 4 = always) and averaging all questions in that subscale with non-missing values. Higher scores indicated more favorable ratings. A question asked patients to rate the physician from 0 (worst possible) to 10 (best possible). Answers were dichotomized into 10 versus ≤ 10, plus an indicator for missing values.

ACES is a validated measure of the quality of the patient's experience with their primary care physician, using the Institute of Medicine definition of primary care as the conceptual model.[19,20] ACES produces 11 summary measures of patients' experiences across 2 dimensions: quality of physician–patient interactions and organizational features of care (see Supplemental Digital Appendix 1, at http://links.lww.com/ACADMED/B392). Given overlap in the CAHPS and ACES domains, only the 3-question patient trust measure and 1 question from the interpersonal treatment measure ("How often was your personal doctor caring and kind?") from ACES were included in the parent CCP/C4P surveys. All questions were answered on a 4-point Likert scale. Answers to the patient trust questions were averaged as for the CAHPS survey. Answers to the interpersonal treatment question were dichotomized into "always" versus "usually," "sometimes," or "never," with an indicator for missing values.

As CAHPS and ACES questions pertain to doctor–patient interactions, only patients who reported seeing their doctor in the past 3 months were asked these questions in that round of the survey. To measure these variables for as many study participants as possible, we used the patient's most recent survey response in which they reported seeing their doctor before their attempted recruitment into the vitamin D study.

Clinic engagement

Clinic engagement was measured primarily by number of completed clinic visits in the year before vitamin D study recruitment. The number of cancelled clinic appointments and number of times a patient did not show up to a scheduled appointment were included as measures.

Parent study engagement

We assessed engagement in the parent CCP/C4P studies by the number of years in the parent study before a patient was approached for the vitamin D study, the total follow-up survey completion rate (percent of eligible surveys completed categorized as 0%–< 25%, 25%–< 50%, 50%–< 75%, and 75%–100%), and number of surveys a patient completed in the year before vitamin D study recruitment.

Statistical analysis

Analysis focused on predictors of enrollment into the vitamin D study among participants in the CCP/C4P parent study intervention arms. We determined descriptive statistics for all explanatory variables. Univariate analyses assessed the relationship between each individual engagement and doctor–patient relationship variable with enrollment into the vitamin D study. Differences between patients who enrolled and those who declined were assessed by t-tests for continuous variables and chi-squared tests for categorical variables. We used logistic regression to perform domain-specific multivariable analyses for the 3 domains of doctor–patient relationship and care experience, engagement in care, and engagement in parent study. Each domain-specific model was created by including all variables relevant to that domain. For the doctor–patient relationship model, indicator variables were created denoting missing responses to average composite scores, to preserve all individuals in the model. For the clinic engagement model, due to collinearity between the follow-up survey completion rate and the total number of surveys completed in the prior year, only survey completion rate was included. The final combined model included all variables from all 3 domains in one multivariable logistic model examining vitamin D study enrollment. Data were analyzed using Stata-MP, v17.0 for Windows (Stata Corp, College Station, Texas).

Results

Table 1 reports descriptive statistics for demographic variables, parent study engagement, and clinic participation for the full sample, those participating in the vitamin D study, and those declining to participate. There were no significant differences in demographic characteristics, or study arm (CCP vs C4P). However, greater clinic engagement, as measured by the number of scheduled visits and completed visits, was significantly associated with enrollment. Increased engagement in the parent studies, measured by follow-up survey completion rate and number of follow-up surveys completed in the year before recruitment, was also significantly associated with vitamin D study enrollment.

Table 2 reports descriptive statistics for self-reported measures of the doctor–patient relationship and other aspects of the care experience (3 CAHPS subscales, CAHPS provider rating, ACES trust measure, and ACES degree of caring question) for the full sample, those enrolling in the vitamin D study, and those not enrolling. Information is only provided for 440 of 462 intervention participants because 22 participants had not seen their physician before vitamin D study recruitment and therefore lacked care experience measures. Of these measures, only the CAHPS timeliness subscale was associated with enrollment, with those who enrolled reporting more favorable scores than those who did not (mean = 3.70 [0.60] vs mean = 3.46 [0.82], respectively, $P = .02$). Neither the communication nor office staff CAHPS subscales, nor either ACES measure, were significantly associated with enrollment.

Further examination of these subscales by analyses of individual survey items (see Supplemental Digital Appendix 1, at http://links.lww.com/ACADMED/B392) demonstrated substantial rates of missingness for single items due to skip patterns related to appropriateness of the item (e.g., items applying only to patients who used urgent care). Also, there was little variation in the answers due to high rates of selecting the most favorable response. Only the item in the timeliness subscale asking whether the patient was seen within 15 minutes of appointment time was significantly different between participants enrolling in and those declining the vitamin D study ($P = .004$), with the enrolled group more likely to answer favorably.

Table 1

Univariate Analyses Between Enrollment in the Vitamin D Study and Demographic Characteristics, Parent Study Engagement Measures, and Clinic Engagement Measures, With Recruitment From CCP and C4P Patient Rosters, University of Chicago Medicine, September 2020–June 2021

Demographic and other characteristics	Overall (N = 462)	Enrolled in study (n = 351)	Declined study (n = 111)	*P* value
Study arm, no. (%)				.91
CCP	133 (29)	102 (29)	31 (28)	
C4P	329 (71)	249 (71)	80 (72)	
Sex, no. (%)				.71
Male	167 (36)	129 (37)	38 (34)	
Female	295 (64)	222 (63)	73 (66)	
Age, mean (SD)	64 (15)	65 (15)	63 (16)	.44
Race, no. (%)				.89
White	41 (9)	31 (9)	10 (9)	
Black	394 (85)	298 (85)	96 (86)	
Multiple races	9 (2)	8 (2.3)	1 (1)	
American Indian	3 (1)	2 (1)	1 (1)	
Missing race	15 (3)	12 (3)	3 (3)	
Engagement in parent study follow-up surveys, mean (SD)				
Years in study	3.51 (2.22)	3.57 (2.23)	3.31 (2.20)	.28
No. surveys completed ever	13 (9)	13 (9)	11 (8)	.01
No. surveys completed in prior year	3.12 (1.47)	3.33 (1.33)	2.48 (1.71)	<.01
Survey completion rate	0.55 (0.21)	0.58 (0.19)	0.47 (0.23)	<.01
Clinic engagement in the one year before vitamin D study recruitment				
Had at least 1 scheduled visit, no. (%)				.02
Yes	419 (91)	325 (93)	94 (85)	
No	43 (9)	26 (7)	17 (15)	
No. scheduled clinic visits, mean (SD)	5.7 (4.4)	6.0 (4.5)	4.6 (4.0)	<.01
No. completed clinic visits, mean (SD)	4.2 (3.4)	4.5 (3.6)	3.2 (2.6)	<.01
% Completed (out of scheduled), mean (SD)[a]	0.74 (0.25)	0.75 (0.24)	0.70 (0.27)	.15
No. no-show clinic visits, mean (SD)	0.69 (1.18)	0.68 (1.20)	0.70 (1.10)	.87
% No-Show (out of scheduled), mean (SD)[a]	0.13 (0.21)	0.12 (0.19)	0.16 (0.24)	.11
No. cancelled clinic visits, mean (SD)	0.84 (1.33)	0.87 (1.28)	0.73 (1.49)	.34
% Cancelled (out of scheduled), mean (SD)[a]	0.13 (0.18)	0.13 (0.17)	0.14 (0.19)	.92

Abbreviations: CCP, Comprehensive Care Program; C4P, Comprehensive Care, Community, and Culture Program.
[a]Values are missing for those individuals who did not have any scheduled visits: N = 419 (overall); 325 (consented); 94 (declined).

The 3 domain-specific multivariable logistic regression models (including the effects of only demographic variables and variables from 1 of the 3 domains) confirmed the significant associations found in univariate analyses (Table 3). In the combined model including all predictors of enrollment across 3 domains, these significant relationships persisted and were only slightly attenuated, despite controlling for all patient engagement variables. For clinic engagement, number of completed visits was still significantly associated with enrollment (odds ratio [OR] = 1.17; 95% confidence interval [CI] 1.06, 1.28). Follow-up survey completion rates remained significantly positively associated with enrollment: individuals with a completion rate > 75% were over twice as likely to enroll (OR = 5.50; 95% CI 2.04, 14.8) as patients with a completion rate of 25%–50% (OR = 2.59; 95% CI 1.16, 5.76). Finally, there was a significant association between enrollment and the CAHPS timeliness subscale, with each point increase in the composite score increasing enrollment odds by 1.94 (95% CI 1.21, 3.12). No other doctor–patient variable (quality of communication, helpful and respectful office staff, patient trust in the physician) was significantly associated with vitamin D study enrollment in the combined or the domain-specific doctor–patient relationship model.

Discussion

Intervention group participants in the parent CCP/C4P studies had a high probability (63%) of enrolling in the vitamin D study versus 17% among those randomized to standard care. This suggests that continuity in doctor–patient relationships can increase participation in research. Nevertheless, these enrollment differences may be explained by the disparity in offering complementary vitamin D testing results and supplements to

Table 2

Univariate Analyses Between Enrollment in Vitamin D Study and Average Scores in the Self-Reported Subscale Measures of Doctor–Patient Relationship, With Recruitment in the Vitamin D Study From CCP and C4P Patient Rosters, University of Chicago Medicine, September 2020–June 2021[a]

	Overall (N = 440)		Enrolled in study (n = 340)		Declined study (n = 100)		
Measure	No. (%)	Mean (SD)	No. (%)	Mean (SD)	No. (%)	Mean (SD)	*P* value
CAHPS: Getting timely appointments, care, information	266 (60)	3.64 (0.66)	206 (61)	3.70 (0.60)	60 (60)	3.46 (0.82)	.02
CAHPS: How well physicians communicated with patients	437 (99)	3.91 (0.26)	339 (100)	3.90 (0.28)	98 (98)	3.92 (0.21)	.54
CAHPS: Helpful, courteous, respectful office staff	370 (84)	3.82 (0.52)	286 (84)	3.82 (0.53)	84 (84)	3.88 (0.47)	.29
ACES: Patient trust	425 (96)	3.82 (0.41)	332 (95)	3.81 (0.42)	98 (98)	3.86 (0.35)	.33
ACES: Physician was caring toward patient (always vs less than always)	425 (96)	n/a	332 (95)	n/a	98 (98)	n/a	.26

Abbreviations: CCP, Comprehensive Care Program; C4P, Comprehensive Care, Community, and Culture Program; CAHPS, Consumer Assessment of Healthcare Providers and Systems Clinician & Group Survey; ACES, Ambulatory Care Experiences Survey.

[a]Counts represent those who had completed a survey in which they responded seeing their doctor, and therefore answered the doctor–patient relationship questions.

intervention patients, but not standard care patients. Accordingly, we focused analysis on whether measures of the care experience and doctor–patient relationship, engagement in clinical care, and study engagement within the CCP/C4P arms predicted continued research engagement. Measures in all 3 domains predicted greater participation, supporting prior work suggesting the importance of the relationship with clinicians, including engagement in clinical care and prior research, in recruiting for clinical research.[21]

Within the domain of doctor–patient relationships and care experience, we found no association of enrollment in the vitamin D study with measures of relational quality other than reported receipt of timely care. The importance of timeliness of care is understandable since participation is voluntary, and economic constraints related to time off from work or access to transportation may be greater among minority populations. The lack of significance of other direct measures of the doctor–patient relationship is more surprising. The high rate of top-coded answers CCP/C4P participants reported concerning their care experiences may have contributed to the lack of statistical significance; the one care experience question that was significantly associated with vitamin D study participation, the frequency of seeing the physician within 15 minutes of appointment time, showed higher variability in answer response, with less-than-ideal ratings comprising ~25% of responses, versus low single digits for other questions. Given the association of vitamin D study enrollment with overall clinic participation rates, clinic participation may be a more sensitive indicator of the doctor–patient relationship than direct patient reports, though clinic participation could reflect other factors associated with patient willingness to participate in care. The same applies to the observed associations with parent study participation rates in the parent studies.

Regardless of whether the observed associations operate through the doctor–patient relationship, the finding that greater participation in care and in the parent study predicted greater likelihood of participation in the vitamin D study suggests that patient engagement in care and in clinical research may increase patient likelihood of enrollment in clinical studies. Recruiting research subjects through clinicians with whom they have a relationship is common, but targeting patients with greater involvement in care may help better target and increase the effectiveness of recruitment efforts. Support for co-enrollment of patients into multiple clinical trials has been increasing, and ethical, scientific and safety considerations of co-enrollment can generally be managed.[22] Evidence suggests patients are willing and able to enroll in multiple studies, although research has mostly been done with critically ill patients.[23] Co-enrollment is more common in younger patients, with more experienced investigators, more experienced research coordinators, and larger center size.[24,25]

Our study builds upon this past research and extends the question of co-enrollment to non-critically ill patients. The strong statistical significance and large magnitude of associations with objective measures of clinic and study engagement compared with the weaker association with self-reported measures of the doctor–patient relationship suggests the value of objective measures of engagement as indicators of commitment to clinical care and research, and the limitations of self-reported measures of relational quality. Patients who visit clinic frequently have more opportunities to hear about studies and enroll. Such patients may also become more aware of research processes and procedures, which may increase their comfort with study participation.[26] Our findings also confirm prior research demonstrating the efficacy of recruiting older and racial and ethnic minority populations into clinical research through the health system and physician referral.[27–29] Active parent study survey completion also strongly predicted vitamin D study enrollment. Individuals demonstrating willingness to respond to parent study follow-up, instead of being deterred by additional study protocols and follow-up questions, were more willing to engage in additional research. This may also reflect the expertise and experience of the CCP/C4P study staff, who are trained in culturally appropriate, personalized approaches and tailored retention strategies,[30] with greater contact

Table 3

Multivariable Logistic Regressions Predicting Enrollment in the Vitamin D Study, With Recruitment in Vitamin D Study From CCP and C4P Patient Rosters, University of Chicago Medicine, September 2020–June 2021[a]

		Odds ratio (95% confidence interval)			
Variable domain	Variable	Study engagement predictors only	Clinic engagement predictors only	Doctor–patient relationship predictors only	Combined model
Study engagement	Length of time in study (years)	1.04 (0.92, 1.18)			0.98 (0.83, 1.15)
	Follow-up survey completion rate				
	0–0.25	Ref			Ref
	0.25–0.50	2.72 (1.34, 5.49)			2.59 (1.16, 5.76)
	0.50–0.75	4.31 (2.20, 8.45)			3.85 (1.79, 8.28)
	0.75+	6.94 (2.78, 17.3)			5.50 (2.04, 14.8)
Clinic engagement	No. completed visits		1.17 (1.07, 1.27)		1.17 (1.06, 1.28)
	No. no-show		0.94 (0.77, 1.14)		0.96 (0.77, 1.18)
	No. cancelled		1.00 (0.83, 1.20)		0.95 (0.78, 1.15)
Doctor–patient relationship	CAHPS timeliness				
	Timeliness subscale			1.76 (1.13, 2.72)	1.94 (1.21, 3.12)
	Timeliness missing[b]			6.81 (1.31, 35.5)	8.52 (1.39, 52.4)
	CAHPS communication				
	Communication subscale			1.30 (0.35, 4.77)	1.45 (0.37, 5.74)
	Communication missing[b]			0.72 (0.00, 158.2)	1.00 (0.00, 320.5)
	CAHPS office staff				
	Office staff subscale			0.64 (0.34, 1.21)	0.59 (0.31, 1.13)
	Office staff missing[b]			0.20 (0.02, 2.48)	0.13 (0.01, 1.75)
	CAHPS patient's rating of physician				
	Less than perfect 10			Ref	Ref
	Perfect 10			1.19 (0.71, 1.99)	0.94 (0.54, 1.63)
	Missing			3.67 (0.31, 43.6)	3.21 (0.21, 48.3)
	ACES patient trust				
	Patient trust subscale			0.66 (0.30, 1.47)	0.60 (0.26, 1.37)
	Patient trust missing			0.10 (0.00, 4.11)	0.07 (0.00, 3.23)
	ACES patient caring				
	Never/sometimes/usually			Ref	Ref
	Always			0.56 (0.11, 2.86)	0.69 (0.13, 3.74)
	Missing			0.35 (0.02, 5.22)	0.88 (0.05, 14.9)

Abbreviations: CCP, Comprehensive Care Program; C4P, Comprehensive Care, Community, and Culture Program; CAHPS, Consumer Assessment of Healthcare Providers and Systems Clinician & Group Survey; ACES, Ambulatory Care Experiences Survey; Ref, reference.

[a]The first 3 models include only those variables belonging to each domain of patient engagement. The last model combines all variables from all domains. For all models, N = 462.

[b]Indicator variables representing patients who had missing values on all questions in that subscale.

with study staff increasing willingness to enroll in additional research.

Limitations include that we could only analyze predictors of enrollment among intervention arm participants. These patients, receiving integrated inpatient and outpatient care through the parent study intervention, were more willing to participate in additional research than control arm participants. Access to vitamin D at no cost in CCP/C4P arms, but not the control arm, might have contributed to higher participation in CCP/C4P arms. Also, as questions relating to doctor–patient relationship were only included in quarterly interviews if patients had visited their physician within 3 months, some older survey responses may not accurately reflect the patient's attitudes toward their physician at the time of vitamin D study recruitment. In general, however, physicians in the parent study scored very highly on doctor–patient relationship measures. While this reflects favorably on the parent studies, the lack of variation in these variables may have attenuated the association between the doctor–patient relationship and vitamin D study enrollment. Also, we did not analyze predictors of engagement in clinical care or participation in follow-up surveys in the parent studies, which were likely affected by patterns of unmet social

need among study participants. Finally, we did not examine retention of patients in the vitamin D study in successive follow-ups. Future studies should assess rates of drop-out for patients enrolled in multiple studies.

We found we were able to enroll a large portion of an older, physically vulnerable Medicare population enrolled in interventions to increase continuity in inpatient–outpatient care into a sub-study within their parent studies. Somewhat surprisingly, many measures of self-reported quality of doctor–patient relationships were not strongly associated with vitamin D study enrollment, though this may reflect limitations in the sensitivity of the available measures. In contrast, measures of clinic and parent study engagement were associated with continued research participation. Those measures are also readily available for use in identifying persons who may be more likely to engage in future studies, and may suggest actionable strategies to increase engagement in research by underrepresented minorities by increasing clinical care availability that provides timely access to care with physician with whom patients have continuing relationships. Our findings suggest that such care is may provide experiences with research opportunities in which patients participate at high levels, increasing their engagement in future studies.

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