Community Health Worker Support for Disadvantaged Patients With Multiple Chronic Diseases: A Randomized Clinical Trial

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Objectives. To determine whether a community health worker (CHW) intervention improved outcomes in a low-income population with multiple chronic conditions.

Methods. We conducted a single-blind, randomized clinical trial in Philadelphia, Pennsylvania (2013–2014). Participants (n = 302) were high-poverty neighborhood residents, uninsured or publicly insured, and diagnosed with 2 or more chronic diseases (diabetes, obesity, tobacco dependence, hypertension). All patients set a disease-management goal. Patients randomly assigned to CHWs also received 6 months of support tailored to their goals and preferences.

Results. Support from CHWs (vs goal-setting alone) led to improvements in several chronic diseases (changes in glycosylated hemoglobin: -0.4 vs 0.0; body mass index: -0.3 vs -0.1; cigarettes per day: -5.5 vs -1.3; systolic blood pressure: -1.8 vs -11.2; overall P = .08), self-rated mental health (12-item Short Form survey; 2.3 vs -0.2; P = .008), and quality of care (Consumer Assessment of Healthcare Providers and Systems; 62.9% vs 38%; P < .001), while reducing hospitalization at 1 year by 28% (P = .11). There were no differences in patient activation or self-rated physical health.

Conclusions. A standardized CHW intervention improved chronic disease control, mental health, quality of care, and hospitalizations and could be a useful population health management tool for health care systems.

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Policymakers, including the Department of Health and Human Services, have expressed a need to shift away from singledisease paradigms toward population health interventions. This shift is driven by a growing public health concern: nearly 1 in 3 Americans is diagnosed with multiple chronic conditions¹ and more than 65% of health care spending is associated with care for this population.² Low-income and minority individuals are more likely to have multiple chronic conditions and to suffer worse outcomes than their advantaged counterparts.^{3,4}

A large body of literature suggests that community health workers (CHWs), trained laypeople who share socioeconomic background with patients, can effectively improve chronic disease outcomes.^{5–10} However, with few exceptions,¹¹ many previous CHW interventions have been disease-specific,¹⁰ focusing, for instance, on asthma selfmanagement, diabetes education, or cervical cancer screening. This diseasespecific approach, likely a consequence of disease-based grant funding, can cause fragmentation for patients with multiple chronic conditions.¹²

The study team created IMPaCT (Individualized Management for Patient-Centered Targets),^{12–15} a CHW intervention that can be applied across diseases to address "upstream" socioeconomic and behavioral barriers. The intervention was designed by a community–academic–health system working group to use qualitative participatory action research with high-risk patients. In a previous randomized clinical trial of hospitalized patients with a variety of diseases,¹⁵ this intervention improved posthospital access to primary care, mental health, and quality of care while decreasing recurrent hospital readmission. IMPaCT has been adapted for various patient populations, including outpatients with multiple chronic conditions.¹⁴

In this study, we present findings from a clinical trial of 302 outpatients with multiple chronic conditions, randomized to chronic disease goal-setting with their primary care provider versus goal-setting plus support from a CHW. We hypothesized that a non-disease-specific CHW intervention could improve control of different chronic diseases, as measured by glycosylated hemoglobin (HbA1c), body mass index (BMI; defined as weight in kilograms divided by the square of height in meters), systolic blood pressure (SBP), and number of cigarettes per day. We also hypothesized that the CHW intervention would improve prespecified secondary outcomes: achievement of chronic disease management goals, self-rated health, patient activation, patient-reported quality of primary care, and all-cause hospitalizations assessed by statewide claims data.

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METHODS

Detailed methods have been previously described.^{16–18} In brief, this study was a 2-arm, single-blind, parallel-group randomized clinical trial. Study enrollment occurred between July 12, 2013, and October 15, 2014, at 2 academic Philadelphia, Pennsylvania, adult internal medicine clinics. Eligible patients had upcoming appointments at study clinics, lived in a high-poverty region of Philadelphia, and were diagnosed with 2 or more of the following chronic diseases: hypertension, diabetes, obesity, and tobacco dependence. During the study period, the University of Pennsylvania Health System adopted the IMPaCT CHW program as part of its system-wide population health management strategy for uninsured or publicly insured patients. To be consistent with inclusion criteria used across the health system, on March 6, 2014, the study team added the following inclusion criteria: uninsured or publicly insured.

To increase real-world applicability of the intervention, study enrollment was conducted during previously scheduled primary care appointments. When eligible patients arrived for their appointments, research assistants explained the study and obtained written informed consent. After providing written consent, patients used a low-literacy visual aid to select 1 of their multiple chronic conditions to focus on during the study period and, along with their primary care provider, set a disease management goal for that disease. This goal-setting process took approximately 5 minutes of providers' time and was folded into the workflow of a busy primary care appointment.

Research assistants then conducted a baseline assessment with validated survey instruments assessing sociodemographic characteristics including age, race, ethnicity, employment, severity of illness (adjusted clinical group score),¹⁹ unmet or delayed need for medical care, self-rated health (12-item Short Form [SF-12] survey),²⁰ the Patient Activation Measure,²¹ the Enhancing Recovery in Coronary Heart Disease (ENRICHD) Social Support Instrument,²² the Single-Item Literacy Screen,²³ and the Trauma History Questionnaire.²⁴ Research assistants also recorded height, weight, blood pressure, and HbA1c measured by clinic staff during the primary care visit. Research assistants then notified a study team member (not involved with outcomes assessment) who performed randomization by using a computer-generated algorithm. Randomization was stratified by the condition patients selected as their focus during goal-setting. This avoided imbalance between arms in case some conditions were easier to control than others. Patients assigned to goal-setting alone went on to receive usual care in accordance with guidelines at each site (including potential referrals to a social worker or diabetes nutritionist). Patients assigned to receive CHW support immediately began the IMPaCT intervention.

IMPaCT is an intervention in which CHWs provide tailored coaching, social support, advocacy, and navigation. 12,14,17,18 The intervention was developed and refined through a participatory action research framework. Patients were interviewed and their input was used to design the original IMPaCT intervention, which focused on supporting patients with the posthospital transition.²⁵ Further qualitative interviews were used to adapt IMPaCT for outpatients with multiple chronic conditions.14 Specifically, patient input guided the decision to have participants work on only 1 chronic disease goal, the development of the goalsetting aid, and the CHW training. The intervention consists of 3 stages: action planning, tailored support, and connection with long-term support. On the day of enrollment, CHWs used a semistructured interview guide to get to know patients holistically and understand social and behavioral determinants of health (e.g., food insecurity, housing instability, drug and alcohol use, social support). During this conversation, CHWs asked patients, "What do you think you will need in order to reach the health goal you sent with your doctor?" The CHWs and patients used this conversation to create patient-driven action plans. This process allowed patients to have control over action planning and to develop flexible, tailored strategies suited for their own needs and preferences.

In the second stage, CHWs helped patients to execute their action plans. For example, if patients wanted to find affordable, fresh produce, the CHW may have accompanied them to a food pantry. Community health workers provided a wide range of tailored support; however, they did not provide any

disease-specific education or clinical care (e.g., checking blood pressure). If patients wanted disease education or care, CHWs would navigate them to an appropriate clinician (e.g., a diabetes educator at the local YMCA). This allowed CHWs flexibility to focus on upstream sociobehavioral issues across diseases and minimized potential adverse outcomes and liability concerns that have been described when CHWs provide disease education and clinical care to a medically complex population.26 The CHWs communicated with their patients at least once per week for 6 months through telephone, text, or visits. As a third component of the intervention, CHWs led a weekly patient support group intended to create social networks among patients who could support each other even after the intensive 6-month CHW support ended. The goal of this support group was to establish long-term support leading to sustained change.

The CHWs sent electronic messages to primary care providers at 0, 3, and 6 months of the intervention, describing the patient action plans and progress. They also sent ad hoc messages or made telephone calls as needed for any clinical matters (e.g., patient running out of medications).

In addition to the workflow described here, the IMPaCT intervention includes detailed guidelines for the infrastructure of a CHW program including hiring, training, supervision, caseloads, safety protocols, documentation, reporting, and quality control. Detailed manuals describing these elements are available online (http://chw.upenn.edu) and are included as an appendix (available as a supplement to the online version of this article at http://www.ajph.org). Briefly, CHWs were recruited by circulating job descriptions to community-based organizations as a way to target potential "natural helpers" within the community. The CHWs were hired through the use of organizational psychology-based hiring tools (i.e., scenario-based interviews for job applicants) designed to assess interpersonal skills and traits. Those who were ultimately hired underwent a month-long collegeaccredited training covering topics such as action planning and motivational interviewing. After graduating from the classroom training, CHWs had on-the-job training through apprenticeship with a senior CHW. This continued until each new trainee demonstrated proficiency in core competencies.

The CHWs were supervised by a manager, typically a master's level social worker. The manager provided real-time support for safety, clinical, or psychosocial emergencies and caseload supervision. Managers assessed CHW performance through a recurring series of weekly assessments: detailed reviews of a CHW patient documentation, observation of CHWs, direct phone calls to patients to assess their experience with CHWs, and a performance dashboard of key metrics (e.g., chronic disease control, progress on patient action plans). Managers supervised between 4 and 6 CHWs who met biweekly for ongoing training and burnout prevention.

Outcome Measures

The prespecified primary outcome was mean change in control of patients' selected chronic disease. This was measured by change in HbA1c, BMI, SBP, and self-reported number of cigarettes per day between enrollment and 6-month follow-up. The primary treatment effect was the between-arm difference in these values. Prespecified secondary outcome measures were achievement (yes or no) of chronic disease management goals, mean change in self-rated health (SF-12) and patient activation measure²¹ between enrollment and 6-month followup,²⁰ proportion of patients reporting high quality of patient-centered care (as measured by the "comprehensiveness of care" and "support for patient self-management" domains of the Consumer Assessment of Healthcare Providers and Systems-Patient Centered Medical Home [CAHPS-PCMH] survey),²⁷ and all-cause hospitalizations (at 6 and 12 months).28

Research assistants blinded to study arms and hypotheses conducted an in-person follow-up assessment at 6 months postenrollment and extracted electronic medical record data within 4 weeks of the study completion date for patients who did not complete follow-up. Admission data were collected by linking patient identifiers with the Pennsylvania Health Care Cost Containment Council²⁸ statewide database for all hospital discharges across Pennsylvania.

Analysis

We tested all hypotheses with 2-sided *P* values by using an intention-to-treat analysis

based on random assignment. Multivariate models included baseline control of chronic disease as well as any imbalanced baseline variables.

We used a stratum-specific multivariate analysis of variance (MANOVA)¹⁶ based on generalized estimating equations to measure our primary treatment effect (between-arm difference in change in selected chronic disease). The MANOVA is an extension of analysis of variance that allowed all patients (regardless of their selected chronic disease) to be assessed in a single model for the primary outcome. We conducted hypothesis tests by using joint multivariate Wald test statistics. We used permutation-based P values for these tests as they preserve correct type I error without making any distributional assumptions. We then based difference-in-difference analyses on these multivariate models.

To analyze secondary outcomes, we tested the difference between treatment arms by using logistic regression for proportion of patients achieving their chronic disease management goal, linear regression for change in self-rated health (SF-12) and change in patient activation,²¹ logistic regression for the proportion of patients reporting each quality rating (CAHPS-PCMH), and logistic and binomial regression for the proportion and total count, respectively, of patients with all-cause hospitalizations.

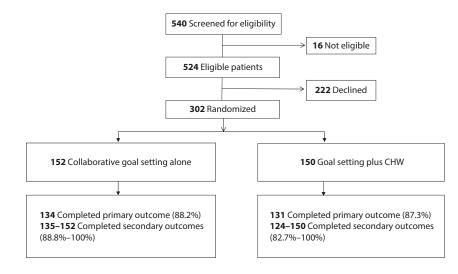
Determination of targeted sample size was based on detecting clinically meaningful differences observed in our pilot studies: 0.5% HbA1c, 0.5 BMI, 20.5 millimeters of mercury, and 3 cigarettes per day. To achieve at least 80% power with a type I error rate of 5%, we required 212 total participants. To account for 30% attrition, we aimed to accrue 302 participants.

We performed multiple imputation for missing data²⁹ simulating a multivariate normal distribution. The imputation model included all outcome variables, baseline variables that were imbalanced or stratified at randomization, and variables associated with missing outcome information. We combined 5 imputed data sets for inference. However, because we cannot prove that the missingness mechanism is missing at random, we performed an additional analysis including only patients with complete data. The results of this sensitivity analysis were nearly identical to those of the imputed model.

We analyzed open-ended feedback from patients receiving CHW support by using a grounded theory approach.³⁰ Two independent research assistants coded transcripts and resolved all discrepancies by consensus.

RESULTS

Of the 540 patients we screened, 16 were ineligible (Figure 1). Of the 524 that remained, 302 (57.6%) provided written



Note. CHW = community health worker.

FIGURE 1—CONSORT Diagram Showing the Flow of Participants Through the Trial: Philadelphia, PA, July 12, 2013–October 15, 2014 consent and were randomized. The most common reasons for declining were being too busy (n = 54; 24.3%) and not wanting to participate in any research (n = 26; 11.7%).

Complete primary outcome data were available in nearly equal numbers in both study arms (88.2% vs 87.3%; P = .83). The 37 noncompleters were more likely than completers to be younger (51.9 vs 56.9; P = .029), have a higher BMI (42.9 vs 39.3; P = .05), higher perceived stress (7.1 vs 5.7; P = .025), alcohol overuse (35.1% vs 19.5%; P = .030), a higher number of emergency visits in the previous year (3.1 vs 1.7; P = .039), and slightly higher baseline commitment to their chronic disease management goal (7.7 vs 7.3; P = .024). Admissions data were available for 100% of enrolled patients as these were obtained from statewide claims.

Baseline Measures

Baseline findings from this study have been published elsewhere¹⁷ and are summarized here. The mean age of the cohort was 56.3 years (SD = 13.1); 94.7% were Black and 96.3% had a history of a traumatic event (Table 1). Participants were diagnosed with an average of 2.5 chronic conditions. Patients who chose to work on their obesity, diabetes, or smoking had relatively poor control at baseline (BMI of 39.7 [SD = 7.9]; HbA1C of 8.9% [SD = 2.6]; and average 9.3 cigarettes per day [SD = 7.5]; respectively) compared with those who chose to work on their hypertension (mean baseline SBP = 143.8 mm Hg [SD = 20.5]). Patients and their providers collaboratively set ambitious goals: the mean weight loss goal for patients focusing on obesity was 16.8 pounds (SD = 19.5), mean goal HbA1C reduction was 1.3% (SD = 1.7%), and mean goal blood pressure reduction was 9.8 millimeters of mercury (SD = 19.2). The 2 study arms were similar in all baseline characteristics with the exception of employment (P = .002).

Outcome Measures

There were differences in the 6-month change in chronic disease control between CHW support versus goal setting–alone arms (changes in HbA1c: -0.4 vs 0.0; BMI: -0.3 vs -0.1; cigarettes per day: -5.5 vs -1.3; SBP: -1.8 vs -11.2; respectively; P = .08; Table 2). To determine whether the overall effect was

TABLE 1—Baseline Characteristics of Trial Participants: Philadelphia, PA, July 12, 2013– October 15, 2014

Characteristic	Goal-Setting Alone (n = 152), No. (%) or Mean ±SD	Goal-Setting Plus CHW (n = 150), No. (%) or Mean ±SD		
Female	113 (74.3)	115 (76.7)		
African American	144 (94.7)	142 (94.7)		
Hispanic	4 (2.7)	4 (2.8)		
Employed ^a	12(8.0)	30 (20.1)		
	12(0.0)	50 (20.1)		
Household income, \$ <15 000	72 (47 4)	(2) (12 0)		
< 15 000 ≥ 15 000	72 (47.4) 51 (33.6)	63 (42.0) 57 (38.0)		
≥ 15 000 Unknown	29 (19.1)	30 (20.0)		
Trauma history ^b		· ·		
	144 (94.7)	146 (98.0)		
Low social support	30 (19.7)	29 (19.5)		
Public insurance	128 (84.2)	120 (80.0)		
Delayed health need	56 (37.1)	59 (39.9)		
Unmet health need	22 (14.6)	24 (16.2)		
Lack of basic needs ^c	48 (31.6)	42 (28.0)		
Alcohol overuse	33 (22.0)	31 (20.8)		
Drug use	14 (9.3)	20 (13.4)		
Age, y	56.1 ±12.6	56.6 ±13.6		
Self-rated health				
Mental component	45.1 ±13.3	44.5 ±14.8		
Physical component	34.8 ±11.1	36.5 ± 11.8		
Patient activation measure	61.8 ±13.7	60.0 ±13.1		
Perceived stress ^d	5.8 ±3.9	5.9 ±3.7		
Health literacy ^e	2.2 ±1.3	2.1 ±1.3		
	2.1 ±4.2	<u> </u>		
Emergency department visits in previous 12 mo	2.1 - 4.2	1.7 - 4.5		
Admissions in previous 12 mo	1.0 ±2.7	0.8 ±2.4		
Severity of illness ^f	3.6 ±0.8	3.5 ±0.8		
Chronic disease prevalence ⁹				
Hypertension	139 (91.5)	140 (93.3)		
Obesity	123 (80.9)	112 (74.7)		
Diabetes	83 (54.6)	92 (61.3)		
Tobacco dependence	31 (20.4)	24 (16.0)		
Selected condition ^h				
Hypertension	26 (18.7)	25 (17.9)		
Obesity	72 (58.5)	74 (66.1)		
Diabetes	38 (45.8)	36 (39.1)		
Tobacco dependence	16 (51.6)	15 (62.5)		
Baseline control				
Systolic blood pressure, mm Hg	146.2 ±23.8	141.4 ±16.4		
Obesity (BMI), kg/m²	39.0 ±7.7	40.5 ±8.0		
Diabetes, HbA1c%	9.0 ±2.2	8.7 ±2.9		
Tobacco dependence (cigarettes per day)	8.2 ±5.8	10.4 ±9.0		

TABLE 1—Continued						
Goal-Setting Alone (n = 152), No. (%) or Mean ±SD	Goal-Setting Plus CHW (n = 150), No. (%) or Mean ±SD					
-12.4 ±22.6	-7.0 ±14.8					
-18.4 ±26.8	-15.1 ±7.0					
-1.3 ±1.4	-1.2 ±2.0					
	No. (%) or Mean ±SD					

Note. BMI = body mass index; CHW = community health worker; HbA1c = glycosylated hemoglobin; mm Hg = millimeters of mercury. Scales from 1 to 100 unless otherwise indicated. For all variables, there is < 5% missing data.

 $^{a}P = .002.$

^bAny item endorsed on the 24-item Trauma History Questionnaire,²⁴ which assesses a range of trauma events in 3 areas: (1) crime-related events (e.g., robbery, mugging), (2) general disaster and trauma (e.g., injury, disaster, witnessing death), and (3) unwanted physical and sexual experiences.

 $^{\rm c}$ Shelter, food, wash, bathroom, transportation, telephone. Scores ranged from 4 to 16, score \geq 5 threshold for some difficulty.

^dMeasured on scale of 0 (low) to 16 (high).

^eMeasured on a scale of 5 (low) to 1 (high).

^fSeverity of illness: measured by adjusted clinical group score of 0 (low) to 5 (high).

^gAmong those with condition.

^hAmong those who selected condition as their focus.

ⁱPatients who chose to work on tobacco dependence were assigned a cessation goal.

being driven by the blood pressure results (where the effect was in the opposite direction as our hypothesis), we performed an additional analysis excluding participants who chose to work on a hypertension goal. The results of this sensitivity analysis were similar (P=.09) to those of the original model.

Although most patients had incremental improvement in their selected condition, few patients in either arm achieved the goal that they had set with their provider at the time of study enrollment: 24 (18.3%) versus 23 (17.2%; P = .81). However, patients receiving

CHW support showed greater improvements in mental health (2.3 vs -0.2; P = .008) and reported higher quality primary care that was comprehensive (49.2% vs 39.7%; P = .010) and supportive of disease self-management (62.9% vs 38%; P < .001). Sixteen percent of patients in the CHW arm were hospitalized at 6 months versus 17.8% in the goal-setting arm (P = .68). By 1 year, 23.3% of patients in the CHW arm were hospitalized versus 31.6% in the goal-setting arm (P = .11). At 1 year, there were 68 total hospitalizations (278 hospital days) in the CHW arm versus 98

TABLE 2—Change in Control of Selected Chronic Condition: Philadelphia, PA, July 12, 2013– October 15, 2014

	Goal-Setting		Goal-Setting Plus CHW				
Condition	Baseline Score	Follow-Up Score	Change	Baseline Score	Follow-Up Score	Change	Difference in Differences (95% Cl)
HbA1c (n = 73)	9.0	8.9	0.0	8.7	8.3	-0.4	-0.4 (-1.3, 0.4)
BMI, kg/m ² (n = 146)	39.0	38.9	-0.1	40.5	40.2	-0.3	-0.2 (-0.8, 0.5)
Cigarettes per day (n = 31)	8.2	6.9	-1.3	10.4	4.9	-5.6	-4.3 (-9.3, 0.7)
SBP, mm Hg (n = 51)	146.2	135.0	-11.2	141.3	139.6	-1.8	9.4 (-1.6, 20.4)

Note. BMI = body mass index; CHW = community health worker; CI = confidence interval; HbA1c = glycosylated hemoglobin; SBP = systolic blood pressure. The overall P value for difference in differences is P = .08. The sample size was n = 302. (414 hospital days) in the goal-setting arm (P=.17). There were no differences in change in patient activation (2.2 vs 1.5; P=.66) or change in self-rated physical health (0.9 vs 0.5; P=.67).

Process Measures

Eighty-two percent of patients assigned to a CHW engaged with the program for the full 6 months. The remaining 27 patients (18%) were either lost to the CHW despite 10 attempts to contact the patient (including 1 home visit) or said they no longer wanted to work with a CHW. The CHWs spent an average of 38.4 hours with each patient over the 6-month intervention period. Thirty-five percent of participants participated in 3 or more sessions of the peer-support group. Patients and CHWs created an average of 4.6 action plans over the course of their 6-month relationship. These action plans most commonly related to health behavior changes (58.9%) and psychosocial issues (23.5%; Table 3). Patients completed 60.7% of their action plans. There were no differences in process or outcome measures across the 3 CHWs delivering the intervention. There was no difference in the number of primary care appointments completed over the 6-month intervention period between goal settingalone and CHW arms (11.4 vs 12.2; P = .57). Most patients who received CHW support (86.0%) had positive open-ended feedback about their experience.

DISCUSSION

In a high-risk population of disadvantaged patients with multiple chronic diseases, a CHW intervention combined with collaborative goal-setting led to modest improvements in diabetes, obesity, and smoking, but not in hypertension, compared with collaborative goal-setting alone. The CHW support also improved mental health and quality of primary care and appeared to reduce hospital admissions. These findings are consistent with a previous randomized controlled trial of the IMPaCT intervention among hospitalized patients that showed improvements in mental health and quality of care and reductions in hospitalization.¹⁵

Hospitalizations were somewhat lower in the CHW arm at the end of the 6-month

Category, No. (%)	Patient Overview	Action Plan Patient and CHW asked patients' friends, cousin, and daughters if they would like to start a weight-loss contest.		
Health behavior change, 304 (58.9)	Woman aged 37 years with hypertension, prediabetes, obesity, and depression, whose chronic disease goal is to lose 18 lbs (from 274 lbs to 256 lbs). Patient told CHW that she would like to have her daughters exercise with her because they are also overweight.			
Psychosocial, 121 (23.5)	Woman aged 65 years with obesity, asthma, and hypertension, whose chronic disease goal is to lose 11 lbs (from 201 lbs to 190 lbs). She has been blamed for the death of her brother ever since a childhood incident, which creates a lot of stress. She likes to use her hands and feels calmer after doing arts and crafts.	CHW introduced patient to local senior center and helped her enroll in pottery classes. Patient attended CHW-led peer-support group and presented her art and other activities of the senior center.		
Health system navigation, 44 (8.5)	Woman aged 44 years with hypertension and diabetes, whose chronic disease goal is to lower her systolic blood pressure from 160 to 140. She often forgets to take her medications because they have been changed frequently.	CHW connected patient to pharmacy and chronic care nurse appointments and gave patient a pillbox to help keep medications organized.		
Resources for daily life (e.g., housing, food, transportation), 41 (8.0)	Woman aged 47 years with hypertension, asthma, obesity, and sciatica, whose goal is to lose 15 lbs (from 233 lbs to 218 lbs). The building where she has lived for 20 years has been sold and she is worried about finding low-income housing that she can navigate with her limited mobility.	CHW helped patient apply for Section 8 housing through the Office of Supportive Housing.		
Medical issues, 6 (1.2)	Man aged 48 years with a history of spinal cord injury after a gunshot wound a few years ago, hypertension, and obesity. He gained a lot of weight since his injury. His goal is to lose 31 lbs (from 256 to 225 lbs). He is able to walk but has foot pain that makes it hard for him to be mobile.	appointment with his provider to talk about his pain. The provider titrated his nerve pain medication, which helped		

TABLE 3—Community Health Worker-Patient Action Plans: Philadelphia, PA, July 12, 2013–October 15, 2014

Note. CHW = community health worker. The sample size was n = 516.

intervention but not significantly so; the effect widened after the intervention ended through 1 year after enrollment. The CHWs work with their patients to address the root causes of their chronic disease, including trauma and housing instability. Many of these changes take time to yield results. This is one possible explanation for the delayed effect of the intervention on hospitalization. We are currently conducting another randomized clinical trial with longer follow-up for all outcomes.

In the study intervention, CHWs did not provide disease education or clinical care, yet the patients in the CHW group had improved clinical outcomes. This adds to the body of literature underscoring the importance of addressing social and behavioral determinants of health. Flexible interventions focused on patient-identified social and behavioral factors (Table 3) appear to have removed barriers to chronic disease control. This has practical implications for health system leaders who are interested in moving from disease-specific interventions to population health interventions that can influence outcomes across multiple conditions.³¹ Currently, health systems and primary care practices with limited resources are often forced to choose between disease-specific interventions.³² These fragmented interventions can be confusing for patients and paradoxically make navigating the health system even more challenging.33,34 Furthermore, disease-specific initiatives often miss the opportunity to intervene on powerful social and behavioral determinants, such as trauma or food insecurity, which are common across diseases.35

It is interesting that this intervention led to positive results across multiple domains; one factor contributing to this may have been the flexibility of CHWs' approach. Many interventions for high-risk patients rely on a "screen and refer" case management approach to addressing unmet social needs. In this intervention, patients and CHWs developed tailored and creative action plans, most commonly focusing on health behavior change (e.g., starting a weight-loss contest with friends and family) and taking a personalized approach to addressing psychosocial needs (e.g., going to a pottery class at a local recreation center as a way to cope with past trauma).

Cumulative reductions in hospitalization from this and a previous randomized controlled trial have been used by the University of Pennsylvania Health System analytics department to estimate a return on investment of \$2.00 for every dollar invested in the IMPaCT intervention.¹³ These findings led the University of Pennsylvania Health System to adopt the intervention as part of its system-wide population health management strategy for high-risk, socially disadvantaged patients. The intervention has been delivered to 6000 individuals at the University of Pennsylvania Health System and adapted for use across different care settings including a Veterans Affairs Medical Center, a federally qualified health center, a large academic medical center in New England, and an integrated payer-provider network in Western Pennsylvania. An open-source toolkit including intervention manuals has been accessed by more than 1000 organizations across the country.

Dissemination of the study intervention is likely facilitated by the fact that it was designed and tested under "real-world" conditions. Inclusion and exclusion criteria were simple and readily extractable from the electronic medical record of most clinics. Enrollment, collaborative goal-setting, and the initial meeting with a CHW fit into the busy workflow of a primary care appointment. The CHW intervention is standardized and described in detailed manuals to promote scalability.

Limitations

This study had several limitations. First, patients with hypertension were relatively well-controlled at baseline. We did not require participants to have poor control of their chronic disease, reasoning that it can be difficult for patients to even maintain control of multiple chronic conditions in the face of psychosocial barriers. In a separate ongoing study, we are restricting inclusion to poor control and will determine whether this affects outcomes.

Second, this was a single-center study among patients in severely resource-limited settings. In addition, as with all trials that randomize at the individual level, external validity can be limited because of differences between individuals who enroll and those who do not. However, enrollment rates for this study are above reported rates for many sociobehavioral interventions. For instance, Berkowitz et al.³⁶ found an uptake rate of 19.9% for the Health Leads program among individuals with unmet social needs.

Third, there were differences between completers and noncompleters and we cannot prove that the missingness mechanism is missing at random, which can make multiple imputation problematic. However, we had a relatively small number of noncompleters and the results of imputation were similar to the completers-only analysis. Finally, both study arms were active comparators so we cannot assess effectiveness compared with usual care.

Public Health Implications

A standardized CHW intervention improved chronic disease control, mental health, quality of care, and hospitalizations in a population of disadvantaged outpatients with multiple chronic conditions. This study bridges clinical care and public health, and adds to the body of work that suggests that addressing socioeconomic and behavioral issues can improve clinical outcomes in high-risk populations. This intervention is a potentially cost-effective population health management strategy that can be integrated into routine clinical care. *A***IPH**

CONTRIBUTORS

S. Kangovi contributed to the conceptualization of the work, data analysis and interpretation, and drafting the article. N. Mitra and H. Huo contributed to data analysis and interpretation and critical revision of the article. D. Grande and J. A. Long contributed to design of the work and critical revision of the article. All to data collection and critical revision of the article. All of the authors contributed to final approval of the version to be published.

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HUMAN PARTICIPANT PROTECTION

This study was approved by the institutional review board of the University of Pennsylvania.

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