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Addressing Unmet Basic Resource Needs as Part of Chronic Cardiometabolic Disease Management

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IMPORTANCE It is unclear if helping patients meet resource needs, such as difficulty affording food, housing, or medications, improves clinical outcomes.

OBJECTIVE To determine the effectiveness of the Health Leads program on improvement in systolic and diastolic blood pressure (SBP and DBP, respectively), low-density lipoprotein cholesterol (LDL-C) level, and hemoglobin A_{1c} (HbA_{1c}) level.

DESIGN, SETTING, AND PARTICIPANTS A difference-in-difference evaluation of the Health Leads program was conducted from October 1, 2012, through September 30, 2015, at 3 academic primary care practices. Health Leads consists of screening for unmet needs at clinic visits, and offering those who screen positive to meet with an advocate to help obtain resources, or receive brief information provision.

MAIN OUTCOMES AND MEASURES Changes in SBP, DBP, LDL-C level, and HbA_{1c} level. We compared those who screened positive for unmet basic needs (Health Leads group) with those who screened negative, using intention-to-treat, and, secondarily, between those who did and did not enroll in Health Leads, using linear mixed modeling, examining the period before and after screening.

RESULTS A total of 5125 people were screened, using a standardized form, for unmet basic resource needs; 3351 screened negative and 1774 screened positive. For those who screened positive, the mean age was 57.6 years and 1811 (56%) were women. For those who screened negative, the mean age was 56.7 years and 909 (57%) were women. Of 5125 people screened, 1774 (35%) reported at least 1 unmet need, and 1021 (58%) of those enrolled in Health Leads. Median follow-up for those who screened positive and negative was 34 and 32 months, respectively. In unadjusted intention-to-treat analyses of 1998 participants with hypertension, the Health Leads group experienced greater reduction in SBP (differential change, −1.2; 95% CI, −2.1 to −0.4) and DBP (differential change, −1.0; 95% CI, −1.5 to −0.5). For 2281 individuals with an indication for LDL-C level lowering, results also favored the Health Leads group (differential change, −3.7; 95% CI −6.7 to −0.6). For 774 individuals with diabetes, the Health Leads group did not show HbA_{1c} level improvement (differential change, −0.04%; 95% CI, −0.17% to 0.10%). Results adjusted for baseline demographic and clinical differences were not qualitatively different. Among those who enrolled in Health Leads program, there were greater BP and LDL-C level improvements than for those who declined (SBP differential change −2.6; 95% CI,−3.5 to −1.7; SBP differential change, −1.4; 95% CI, −1.9 to −0.9; LDL-C level differential change, −6.3; 95% CI, −9.7 to −2.8).

CONCLUSIONS AND RELEVANCE Screening for and attempting to address unmet basic resource needs in primary care was associated with modest improvements in blood pressure and lipid, but not blood glucose, levels.

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Chronic cardiometabolic diseases, such as hypertension, diabetes, and lipid disorders, are leading causes of morbidity and mortality in the United States.[1,2] The connection between poor outcomes in these conditions and unmet resource needs, such as difficulty affording food, housing, and medications, has become increasingly clear.[3-17] This has led to interest in programs that seek to "link" patients identified in clinical care sites as having unmet basic resource needs to community-based resources.[18] This interest is exemplified by the recent Accountable Health Communities (AHC) model proposed by the Centers for Medicare & Medicaid Services (CMS).[3] Specifically, interventions to screen for unmet needs and link patients to community resources in order to address them are at the heart of track 2 and track 3 of the AHC model.[3]

Despite growing interest and intuitive appeal, there is as yet scant evidence to support the effectiveness of linkage interventions for improving cardiometabolic disease control. To help understand the potential of linkage interventions in chronic cardiometabolic disease management, we conducted a pragmatic evaluation of the Health Leads program in 3 primary care practices.[19] The Health Leads program includes screening for unmet resource needs, an assessment of those who report these needs, and assignment to an advocate, who then works with a patient to receive resources and benefits to meet those needs.[19] For example, a patient who reports difficulty affording food could be assisted with enrollment in the Supplemental Nutrition Assistance Program (SNAP). Conceptually, such assistance could enhance and make more effective the routine care being delivered to patients. For example, addressing transportation issues could enable patients to attend a greater proportion of clinic appointments, and assisting with medication affordability could enable patients to adhere to their treatment plan more closely. Therefore, we hypothesized that participation in the Health Leads program would be associated with improvements in key indicators of cardiometabolic disease management: blood pressure, low density lipoprotein cholesterol (LDL-C) and hemoglobin A_{1c} (HbA_{1c}) control.

Key Points

Question Does screening for and addressing unmet basic resource needs in primary care help improve blood pressure and cholesterol and blood glucose levels?

Findings The Health Leads program screens primary care patients for unmet basic needs, such as food, medication, housing, and transportation, and helps link those who report needs to community resources to address them. In a pragmatic evaluation, for 5125 patients screened, those who screened positive, and were encouraged to enter the program, saw statistically significant improvements in blood pressure and cholesterol levels, but not blood glucose level, compared with those who screened negative.

Meaning Screening for and attempting to address unmet basic needs may help primary care be more effective.

Methods

Setting and Study Participants

We conducted a pragmatic evaluation of the Health Leads program in 3 academic adult (age >18 years) internal medicine practices within a primary care network in the Boston metropolitan area. Patients who presented for routine care completed screening for unmet basic resource needs at visit check-in. All who completed screening between October 1, 2013 (when the program began in the clinics), and April 30, 2015, were included in the study. Electronic health record data for participants were obtained from October 1, 2012 (ie, ≥1 year prior to screening), through September 30, 2015 (ie, ≥5 months after screening).

The Health Leads program was implemented as the standard of care during the study period; therefore, the human research committee at Partners Health Care approved this analysis of usual care data with a waiver of the informed consent requirement. Patients were not compensated for their participation.

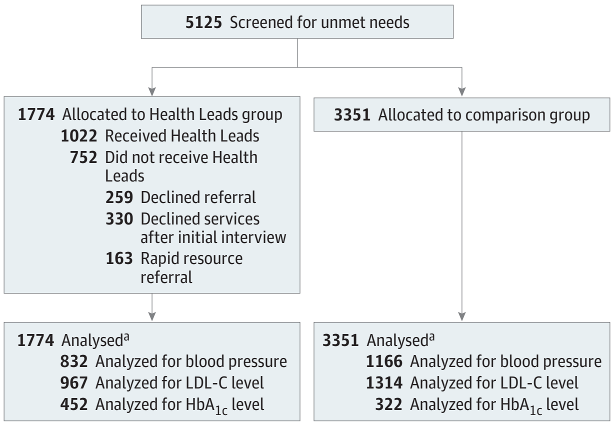
Screening and Intervention

The Health Leads program has been described in detail elsewhere.[19] In brief, patients complete a standardized screening form that allowed the patient to self-identify unmet resource needs related to food, medications, transportation, utilities, employment, elder care services, and housing. Patients who report unmet needs are referred to program staff to complete an assessment and determine if the patient should be enrolled in the program or receive a rapid resource referral, which consisted of 1-time provision of information. Patients who choose to enroll in the program are assigned to an advocate, usually an undergraduate student volunteer, operating under the supervision of professional program staff, who works with the patient to prioritize unmet basic resource needs, identify community resources and/or public benefits to meet them, and facilitate receipt of those resources and/or benefits. Each situation had standardized guidelines to indicate when a case could be closed with 1 of 3 resolution types: (1) benefits had been received (successful), (2) the need was met elsewhere, could not be met or the advocate lost contact with the patient (unsuccessful), or (3) the patient indicated they were able to move forward without continued assistance (equipped).[19] As an example, if a patient reported a food need and was eligible for but not enrolled in SNAP, the advocate would work with the participant until they were enrolled and benefits were available on an electronic benefit transfer card.[19]

Outcomes

Our primary outcome was systolic blood pressure (SBP) trend because it is the most common cardiometabolic risk factor and is strongly associated with morbidity and mortality.[20] Our secondary outcomes were diastolic blood pressure (DBP) and LDL-C and HbA_{1c} levels. These outcomes are targeted for clinical management in adults with preexisting cardiometabolic diseases. Therefore, for blood pressure outcomes we included those individuals with a history of hypertension. Similarly, for analyses of LDL-C levels, participants had a diagnosis of hypertension, coronary heart disease, chronic kidney disease, or

Figure 1. Study Flow Diagram



[a] All screened participants were analyzed in main analyses by intention-to-treat principle. Participants could be analyzed for more than 1 outcome if applicable.

diabetes mellitus. For analyses of HbA_{1c} levels, we included participants with diabetes mellitus. These diagnoses were assessed at time of screening and were determined using previously validated electronic health record algorithms, which have been used in prior studies (validation documents are available on request).[19,21,22] Outcome data were collected as part of routine clinical care. Just as patients often qualify for more than 1 clinical performance metric, participants could be included in the analysis of more than 1 outcome (eg, a participant with diabetes and hypertension would be included in the analyses of SBP, DBP, and LDL-C and HbA_{1c} levels).

We also considered several covariates that may influence the trend in study outcomes. Age, self-reported gender (male or female), race/ethnicity, educational attainment, health insurance, primary language, clinical conditions, and comorbidity as indicated by the Charlson comorbidity score were abstracted from the electronic health record and adjusted for in our analyses.[19]

Statistical Analysis

We first performed descriptive statistics. Given that the Health Leads program had adequate capacity to serve all patients identified through screening in the 3 practices, there was no group of participants who completed screening but were not offered interventional services. Therefore, to test whether program referral was associated with improved health outcomes, we used a difference-in-difference approach. In this design, participants serve as their own controls by comparing trends in outcome before and after the intervention. Simultaneously, those who received care in the same practices during the same time but screened negative for unmet resource needs were used to account for secular trends: other occurrences, aside from the Health Leads program, that may have influenced the outcomes, such as on-going chronic disease management programs in the clinics. Our primary analyses compared those with 1 of the defined conditions who screened positive (regardless of whether they enrolled in the Health Leads program) to those with one of the defined conditions who screened negative for unmet resource needs. Analogous to an intention-to-treat analysis of a randomized clinical trial (RCT), this approach provides the best estimate of the real-world effectiveness of the program. As secondary analyses, we also examined change in outcome trend by Health Leads participation category—comparing those who screened negative to those who screened positive but declined a referral to Health Leads, those who declined services after an initial interview with Health Leads, those who received only a rapid resource referral, and those who fully enrolled in the Health Leads program. The date of screening demarcated the preintervention and postintervention periods for both groups. Participants needed to have at least 1 outcome measurement in the preperiod and postperiod to be included in the main analyses, but we conducted sensitivity analyses that did not include this requirement. We analyzed the outcomes as continuous variables because blood pressure, LDL-C level, and HbA_{1c} level have a linear association with poor health outcomes over most of their clinically relevant range.[23-25] Because outcomes could be measured multiple times per participant and were not measured on a fixed schedule (unbalanced design), we used longitudinal mixed-effects linear regression models for hypothesis testing, with patient-level random effects to account for repeated measurements within patients. All observations of a particular parameter (eg, blood pressure) were used for analysis. $P < .05$ indicated statistical significance.

Analyses were conducted using SAS statistical software (version 9.4; SAS Institute).

Results

Overall, 5125 people were screened for unmet basic resource needs at the participating practices from October 1, 2013, to April 30, 2015 (**Figure 1**). Of these, 1774 (34.6%) screened positive for at least 1 unmet resource need. Of those who screened positive, they reported a median of 2 (25th percentile: 1; 75th percentile: 3) unmet needs. Overall, those reporting unmet resource needs were more likely to self-identify as a racial/ethnic minority, have less than a high school diploma–level education, speak a primary language other than English, and have Medicaid insurance (**Table 1**).

Of those who screened positive, 1021 (57.6%) enrolled in the Health Leads program, 259 (14.6%) declined referral, and 329 (18.6%) declined services after an initial interview. The most commonly reported needs were in the areas of health care, including medication affordability, utilities, and food. For those enrolled in Health Leads, cases were open for a median of 42 days (25th percentile: 24; 75th percentile: 71), and participants received a median 5 contacts (25th percentile: 3 contacts; 75th percentile: 9 contacts) from their advocate. Of those who discussed their needs with Health Leads, 29.7% of reported needs were closed as successful, 27.9% as equipped, 34.9% as unsuccessful, and 7.1% handled with a rapid resource referral. Almost all (93.2%) of the unsuccessful category involved participants who stopped responding to attempts to contact them from Health Leads advocates.

For blood pressure analyses, 832 participants who screened positive and 1166 participants who screened negative met inclusion criteria (eTable 1 in the Supplement). For LDL-C analyses, 967 participants who screened positive and 1314 participants who screened negative were included. For HbA_{1c} analyses, 452 participants who screened positive and 322 who screened negative were included. Those who screened positive represent the Health Leads group for the following analyses. Median time studied was 34 months (25th percentile: 25 months; 75th percentile: 36 months) for those who screened positive and 32 months (25th percentile: 26 months; 75th percentile: 36 months) for those who screened negative. Those who screened positive had a median time studied prior to screening of 17 months (25th percentile: 11 months; 75th percentile: 26 months), and median time followed after screening of 12 months (25th percentile: 7 months; 75th percentile: 19 months). Those who screened negative had a median time studied prior to screening of 25 months (25th percentile: 18 months; 75th percentile: 28 months), and median time followed after screening of 6 months (25th percentile: 6 months; 75th percentile: 8 months) (eTable 2 in the Supplement).

Of those with hypertension, baseline SBP was slightly higher (133.1 mm Hg vs 131.8 mm Hg; *P* = .04) in the Health Leads group, but DBP was similar (76.6 mm Hg vs 76.3 mm Hg; *P* = .35) (**Table 2** and **Figure 2**A and B). In unadjusted difference-in-difference analyses, the differential change after screening favored the Health Leads group, with greater reduction in SBP (differential change, −1.2 mm Hg; 95% CI, −2.1 to −0.4 mm Hg) and DBP (differential change, −1.0 mm Hg; 95% CI, −1.5 to −0.5 mm Hg) (Figure 2). In models adjusted for age, self-reported gender, race/ethnicity, educational attainment, primary language, health insurance, clinical conditions (diabetes, chronic kidney disease, coronary heart disease, cerebrovascular disease, and depression), and comorbidity score, the differential change again favored the Health Leads group (differential change in SBP, −1.6 mm Hg; 95% CI, −2.5 to −0.6 mm Hg; differential change in DBP −1.1 mm Hg; 95% CI −1.6 to −0.6 mm Hg).

For those with an indication for LDL-C level lowering, baseline LDL-C level was similar comparing the Health Leads group (103.0 mg/dL) to those who screened negative (100.2 mg/dL) (*P* = .14). Unadjusted difference-in-difference results again favored the Health Leads group (differential change, −3.7 mg/dL; 95% CI, −6.7 to −0.6 mg/dL) (Figure 2C). Adjusted results were similar (differential change, −3.9 mg/dL; 95% CI, −7.2 to −0.6 mg/dL). (To convert LDL-C to millimoles per liter, multiply by 0.0259).

For those with diabetes, baseline HbA_{1c} level was greater in the Health Leads group compared with those who screened negative (7.53% vs 7.19%; *P* = .002). However, the Health Leads group did not see improvement in HbA_{1c} level (differential change, −0.04%; 95% CI, −0.17% to 0.10%) (Figure 2D). Adjusted results also revealed no differential improvement (0.03%; 95% CI, −0.12 to 0.17). (To convert HbA_{1c} to a proportion of total hemoglobin, multiply by 0.01.)

In secondary analyses based on program enrollment, rather than just screening positive for unmet needs, enrollment in Health Leads was associated with statistically significant benefit in SBP, DBP, and LDL-C level reduction (**Table 3**). There remained no benefit for HbA_{1c} level reduction. The magnitude of these benefits was greater than the magnitude seen in the intention-to-treat analyses. Declining services, being lost to contact, or receiving a 1-time referral to a resource were generally not associated with benefit.

Sensitivity analyses that did not require participants to have an outcome measurement in both the prescreening and postscreening period were not substantially different from the main analyses (eTable 3 in the Supplement). Information on health-related quality of life in a subset of randomly selected participants (eTable 4 in the Supplement), a responder analysis of those with out-of-control parameters that came under control in the postintervention period (eTable 5 in the Supplement), and a more detailed breakdown of presenting needs (eTable 6 in the Supplement) is available in the supplemental material.

Table 1. Patient Characteristics

Characteristic	Unmet Needs, No. (%)[a] Screened Negative (n = 3351)	Screened Positive (n = 1774)[b]
Age, mean (SD), y	56.7 (16.2)	57.6 (15.5)
Female	1811 (56.5)	909 (55.7)
Race/ethnicity		
Non-Hispanic white	2755 (85.9)	867 (53.2)
Non-Hispanic black	160 (5.0)	383 (23.5)
Hispanic	103 (3.2)	224 (13.7)
Asian/multiethnic/other	188 (5.9)	157 (9.6)
Insurance		
Commercial	2147 (64.1)	677 (38.2)
Medicare	917 (27.4)	673 (38.0)
Medicaid	143 (4.3)	275 (15.5)
Self-pay	144 (4.3)	148 (8.4)
≤High school diploma education	616 (22.1)	776 (58.3)
Non-English primary language	279 (8.3)	24 (23.8)
Charlson score, mean (SD)	3.1 (2.4)	4.0 (2.9)
Cardiometabolic disease groups		
Hypertension	1166 (34.8)	832 (46.9)
Indication for LDL-C level lowering	1314 (39.2)	967 (54.5)
Diabetes	322 (9.6)	452 (25.5)
Program enrollment status		
Enrolled	NA	1021 (57.6)
Declined referral	NA	259 (14.6)
Declined services after initial interview	NA	329 (18.6)
Rapid resource referral	NA	164 (9.2)

Abbreviations: LDL-C, low-density lipoprotein cholesterol; NA, not applicable.

[a] Data do not add up owing to missing data for some variables.

[b] Considered the intervention group for main, intention-to-treat analyses.

Discussion

In this study, we found that screening for unmet basic needs coupled with referral to a program that helped link patients to community resources and public benefits to meet those

Table 2. Unadjusted and Adjusted Difference-in-Difference Results for Blood Pressure and LDL-C and Hemoglobin A_{1c} Levels by Screening Status

Screening Result	Baseline (95% CI)	*P* Value	Differential Change, Unadjusted (95% CI)	*P* Value	Differential Change, Adjusted (95% CI)[a]	*P* Value
SBP, mm Hg						
Positive	133.1 (132.2 to 134.0)	.04	−1.2 (−2.1 to −0.4)	.006	−1.6 (−2.5 1 to −0.6)	.001
Negative[b]	131.8 (130.9 to 132.7)	NA	1 [Reference]	NA	1 [Reference]	NA
DBP, mm Hg						
Positive	76.6 (76.1 to 77.1)	.35	−1.0 (−1.5 to −0.5)	<.001	−1.1 (−1.61 to −0.6)	<.001
Negative[b]	76.3 (75.8 to 76.8)	NA	1 [Reference]	NA	1 [Reference]	NA
LDL-C level, mg/dL						
Positive	103.0 (100.1 to 105.9)	.14	−3.7 (−6.7 to −0.6)	.02	−3.9 (−7.2 to −0.6)	.02
Negative[b]	100.2 (97.7 to 102.6)	NA	1 [Reference]	NA	1 [Reference]	NA
HbA_{1c} level, %						
Positive	7.53 (7.39 to 7.66)	.002	−0.04 (−0.17 to 0.10)	.59	0.03 (−0.12 to 0.17)	.72
Negative[b]	7.19 (7.03 to 7.35)	NA	1 [Reference]	NA	1 [Reference]	NA

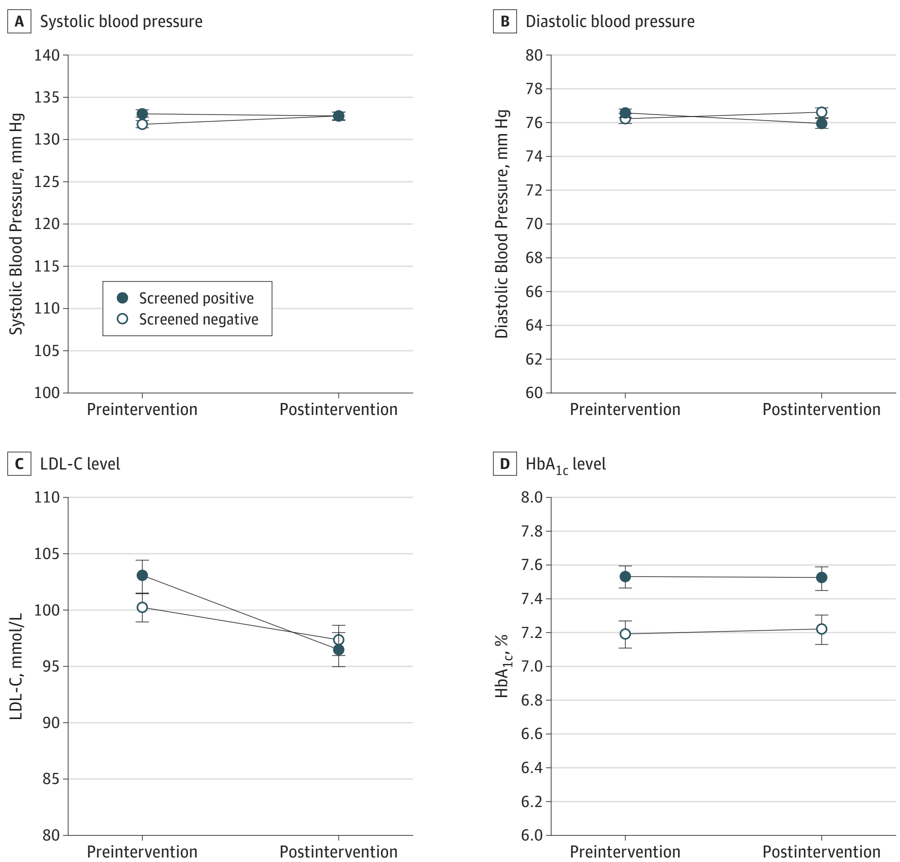
Abbreviations: DBP, diastolic blood pressure; HbA_{1c}, hemoglobin A_{1c}; LDL-C, low-density lipoprotein cholesterol; NA, not applicable; SBP, systolic blood pressure.

SI conversion factors: To convert HbA_{1c} to a proportion of total hemoglobin, multiply by 0.01; to convert low-density lipoprotein cholesterol to millimoles per liter, multiply by 0.0259.

[a] Adjusted for age, self-reported gender, race/ethnicity, educational attainment, primary language, health insurance, comorbidity score, and presence of diabetes, chronic kidney disease, coronary heart disease, cerebrovascular disease, and depression.

[b] A negative value for differential change represents a greater decrease, compared with the referent category (a negative result).

Figure 2. Change From Preintervention to Postintervention



Change from preintervention to postintervention, with error bars indicating 95% CIs, comparing those who screened positive with those who screened negative for unmet needs. HbA_{1c} indicates hemoglobin A_{1c}; LDL-C, low-density lipoprotein cholesterol. To convert HbA_{1c} to a proportion of total hemoglobin, multiply by 0.01; to convert low-density lipoprotein cholesterol to milligrams per deciliter, divide by 0.0259.

needs resulted in modest improvements in blood pressure and LDL-C level but not HbA_{1c} level. These findings persisted even after adjustment for potential confounders. The association between intervention and blood pressure and cholesterol level improvement was stronger for those who enrolled in the program, although this study cannot demonstrate causality.

Table 3. Unadjusted and Adjusted Difference-in-Difference Results for Blood Pressure, LDL-C, and HbA_{1c}, by Health Leads Enrollment Status

Category	Baseline (95% CI)	*P* Value	Differential Change, Unadjusted (95% CI)	*P* Value	Differential Change, Adjusted (95% CI)[a]	*P* Value
SBP, mm Hg						
Enrolled	132.4 (131.6 to 133.1)	.50	−2.6 (−3.5 to −1.7)	<.001	−2.7 (−3.7 to −1.7)	<.001
Declined referral	131.8 (130.4 to 133.2)	.26	−0.2 (−2.1 to 1.7)	.82	−0.4 (−2.4 to 1.6)	.69
Declined services after initial interview	132.8 (131.4 to 134.1)	.72	−0.7 (−2.6 to 1.1)	.44	−0.7 (−2.7 to 1.4)	.51
RRR	133.2 (131.2 to 135.2)	.50	−2.2 (−5.3 to 1.0)	.18	−4.0 (−8.1 to 0.1)	.06
Screened negative	132.6 (131.9 to 133.2)	NA	1 [Reference]	NA	1 [Reference]	NA
DBP, mm Hg						
Enrolled	76.4 (75.9 to 76.8)	.18	−1.4 (−1.9 to −0.9)	<.001	−1.5 (−2.1 to −0.98)	<.001
Declined referral	75.9 (75.1 to 76.7)	.07	−0.2 (−1.2 to 0.9)	.75	0.0 (−1.1 to 1.2)	.96
Declined services after initial interview	76.6 (75.8 to 77.4)	.99	−1.1 (−2.2 to −0.1)	.03	−1.1 (−2.3 to 0.0)	.06
RRR	75.7 (74.6 to 76.8)	.11	0.4 (−1.4 to 2.2)	.65	0.0 (−2.4 to 2.3)	.97
Screened negative	76.6 (76.2 to 77.0)	NA	1 [Reference]	NA	1 [Reference]	NA
LDL-C level, mg/dL						
Enrolled	105.0 (101.5 to 108.6)	.02	−6.3 (−9.7 to −2.8)	<.001	−7.0 (−10.7 to −3.3)	<.001
Declined referral	96.5 (88.8 to 104.2)	.40	1.9 (−4.8 to 8.6)	.58	1.7 (−5.4 to 8.8)	.63
Declined services after initial interview	104.2 (96.5 to 111.8)	.31	−0.6 (−7.0 to 5.8)	.85	2.5 (−4.6 to 9.6)	.49
RRR	92.1 (81.0 to 103.1)	.17	4.5 (−4.6 to 13.6)	.33	3.9 (−7.6 to 15.4)	.50
Screened negative	100.0 (97.6 to 102.5)	NA	1 [Reference]	NA	1 [Reference]	NA
HbA_{1c} level, %						
Enrolled	7.55 (7.39 to 7.72)	.002	−0.07 (−0.21 to 0.07)	.34	−0.02 (−0.17 to 0.13)	.81
Declined referral	7.15 (6.79 to 7.50)	.85	0.04 (−0.22 to 0.29)	.77	0.16 (−0.12 to 0.44)	.26
Declined services after initial interview	7.73 (7.35 to 8.12)	.01	−0.07 (−0.31 to 0.18)	.61	−0.02 (−0.27 to 0.24)	.90
RRR	7.49 (6.95 to 8.03)	.29	0.08 (−0.25 to 0.41)	.64	0.06 (−0.31 to 0.43)	.76
Screened negative	7.19 (7.02 to 7.35)	NA	1 [Reference]	NA	1 [Reference]	NA

Abbreviations: DBP, diastolic blood pressure; HbA_{1c}, hemoglobin A1c; LDL-C, low-density lipoprotein cholesterol; NA, not applicable; RRR, rapid resource referral; SBP, systolic blood pressure.

SI conversion factors: To convert HbA_{1c} to a proportion of total hemoglobin, multiply by 0.01; to convert low-density lipoprotein cholesterol to millimoles per liter, multiply by 0.0259.

[a] Adjusted for age, self-reported gender, race/ethnicity, educational attainment, primary language, health insurance, comorbidity score, and presence of diabetes, chronic kidney disease, coronary heart disease, cerebrovascular disease, and depression. Enrollment Categories: enrolled indicates enrolled in Health Leads program; declined services, screened positive for unmet needs, but did not contact Health Leads program; lost from triage, screened positive for unmet needs, made contact with Health Leads but did not complete enrollment; rapid referral, screened positive for unmet needs, received 1-time information or advice, did not enroll in Health Leads program; screened negative, screened negative for unmet needs. A negative value for "differential change" represents a greater decrease compared with the referent category.

This study is consistent with, and extends our knowledge of, health care interventions to address basic resource needs. While few other programs have focused specifically on unmet needs, several other strategies to address social determinants of health in clinic care have been tried, with variations in workforce (lay vs professional), setting (clinic vs community-based), and on-going interaction (longitudinal empanelment vs episodic engagement).[26-36] For example, community health worker programs often use a lay workforce, based outside of the clinic, who work with specific patients over a long period of time.[29] Alternatively, care coordination and case management programs are often based in clinics or health care systems and use professional staff, such as registered nurses or licensed clinical social workers.[32,35] Case management programs often feature longitudinal panels, while some social work referrals are more episodic in nature. Several of these approaches have achieved success for chronic disease management, although none focus specifically on unmet basic needs. This study presents an alternative model—lay clinic-based undergraduate volunteers, trained and equipped with tools to address episodic issues with basic resource needs—and finds that this approach can be successful.

The magnitude of the benefits in blood pressure and LDL-C level improvement seen in this study may not be important clinically to an individual but are likely important at the population level, particularly considering (1) that the results occurred in patient populations that typically benefit less from usual medical care, and (2) that there is unlikely to be substantial harm from participation in the program. The reductions in blood pressure and LDL-C level seen in patients who enrolled in Health Leads are similar to those seen in a recent successful RCT of a multifaceted quality improvement intervention that did not focus on unmet basic resource needs.[26] Furthermore, a 2-mm Hg reduction in SBP or a 1-mm Hg reduction in DBP is associated with an approximately 5% reduction in relative risk for coronary heart disease events.[24] Similarly, a 4 mg/dL reduction in LDL-C level is associated with a 4% reduction in relative risk for coronary heart disease events.[23]

An unanswered question resulting from this study is why BP and LDL-C level improved while HbA_{1c} level did not. At this time, we are not sure why we observed this. Prior studies have established the importance of improving dietary quality, in addition to medication, in controlling hyperglycemia.[37] The data in this study suggest that connections to resources to meet various needs (eg, medication affordability and food) occur with equal success. However, the result of that connection may vary depending on the adequacy and efficacy of the resource landscape available. For example, reducing financial barriers to medications (such as may occur if patients enroll in a pharmacy assistance program) is closely linked to improved adherence and improved health.[12] However, connection to food resources, such as enrollment in SNAP or receipt of food from a food pantry, while effective for improving food insecurity, may not support the changes in dietary quality necessary to improve HbA_{1c} level. The CMS's AHC model, which seeks to test linkage interventions to improve health, acknowledges the important role of the resource landscape.[3] In the AHC's track 3—Engagement—the CMS calls on health care delivery organizations to partner with social service providers in the same community to help tailor the resources available both to meet basic resource needs and to improve health.[3]

An important strength of this study is its pragmatic design. Compared with a highly selected population in an RCT, this study evaluated program operation in real-world conditions, and with the intention-to-treat analytic approach, the estimates of effects are likely generalizable to other primary care settings serving populations that are underrepresented in RCTs. We should note, however, that clinic-based interventions such as this one do not reach those who are out of care. Although participants chose whether to enroll in the program after screening, we do not believe that differences in engagement with care or self-efficacy among those who enrolled are likely to have influenced improvement in the study outcomes. The difference-in-difference design helps account for these unmeasured differences in participant characteristics by comparing participants with their own preintervention results. Furthermore, the lack of benefit observed with regard to HbA_{1c} level suggests enrollment is not synonymous with improvement. However, without randomization it is impossible to exclude these differences as possible contributors to the findings observed. Finally, because program entry was predicated not on having elevated values of the study outcomes but rather on unmet needs, regression to the mean is unlikely to explain the observed differences between the groups.

Limitations

Despite these strengths, the results of this study should be interpreted in the light of several limitations. First, the 3 practices in this study already had advanced population health management programs that focused on blood pressure and on cholesterol and HbA_{1c} levels. How these results would generalize to practices without such programs is unclear; it is possible that other settings could see larger reductions. Nevertheless, the results help understand what can be gained by adding programs that address unmet basic needs to current chronic disease management efforts. Second, the study was set in Massachusetts, where health insurance coverage is high.[38] However, because national health insurance rates are, after the implementation of the Affordable Care Act, rising to the level of Massachusetts, the results are likely relevant in many settings.[38] Other limitations include lack of information on those who did not complete screening, lack of information on duration of diabetes and tobacco use, and that the study analyst was not blinded to the exposure groups.

This study has several implications for the future study and use of linkage interventions. First, the rapid resource referral used in this study is similar to what is proposed in Track 1 of the AHC model and did not show benefit.[3] Second, because 40% of our participants reporting unmet needs had commercial insurance, linkage programs may be worthwhile in a broad array of clinical settings. It will be important to determine whether linkage programs can be combined with ongoing population management efforts, such as identifying patients overdue for visits or not meeting clinical goals. In addition, future work should focus on improvements to the program that may increase the benefits seen, and increase the conversion rate between those reporting needs and ultimate linkage to resources. Also, studies of linkage interventions incorporating randomized designs, particularly with cluster randomization above the level of the participant (to include a more real-world selection of participants compared with participant-level randomization), would provide important complementary information. Finally, while this study focused on indicators of cardiometabolic control, there are several other potentially important outcomes for a linkage intervention that should be considered when evaluating its impact. Health-related quality of life, reduction in stress and depressive symptoms, along with other indicators of mental well-being, engagement with care, and the cost-effectiveness of the intervention are all important areas for future studies to investigate.

Conclusions

An intervention program that screens for unmet basic needs and attempts to link patients with these needs to community resources improved blood pressure and LDL-C level but not HbA_{1c} level. Further refinement of these types of interventions, and their dissemination, holds promise for improving the health of vulnerable populations.

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Acquisition, analysis, or interpretation of data: Standish, Reznor, Atlas.
Drafting of the manuscript: Berkowitz, Reznor.
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Invited Commentary

Targeting Unmet Social Needs—Next Steps Toward Improving Chronic Disease Management

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Addressing unmet social needs has become increasingly recognized as a critical component of effective health care delivery. We know that the everyday conditions in which our patients live and work affects their health.[1] A lack of basic resources, such as food and stable housing, increases both the risk of developing chronic medical conditions and presents a substantial barrier to adequate treatment. Thus, in this era of value-based care and shared-savings initiatives, physicians are further incentivized to routinely identify these "upstream" determinants of health as targets for therapeutic intervention. The new Accountable Health Communities (AHC) model proposed by the Centers for Medicare & Medicaid Services (CMS) illustrates this concept by promoting collaboration between clinical practices and community-based services.[2] Interventions designed to link patients having unmet social needs with necessary resources in the community represent 1 potential strategy for improving health outcomes and reducing downstream health expenditures among vulnerable populations. However, there are minimal data to support the efficacy of such interventions in real-world practice.[3]

In this issue of *JAMA Internal Medicine*, Berkowitz et al[4] evaluate an established community linkage program, Health Leads, and its impact on cardiometabolic outcomes among patients at 3 Boston primary care practices. Patients self-identified as having unmet needs were optionally enrolled in the program, which provides an undergraduate advocate to help determine and facilitate the receipt of appropriate community resources and/or benefits to meet those needs. The authors then applied intention-to-treat, difference-in-differences analyses to compare trends in cardiometabolic parameters before and after intervention. Among those who screened positive for having unmet needs, 58% were enrolled in Health Leads. Individuals in this intent-to-treat group were found to have modest but significant improvements in blood pressure and low-density lipoprotein cholesterol levels following intervention compared with those who screened negative. Effects were sustained even after adjusting for several key confounders and baseline trends in disease control at each practice site. Effects were stronger when limited to those persons who actually enrolled in the program. The findings in their study[4] demonstrate that we can achieve measurable improvements in cardiometabolic outcomes by addressing unmet needs in the clinical setting. Unfortunately, the authors were unable to address how meeting these social needs may have also improved quality of life or other useful nonclinical outcomes.

In considering how to translate the findings into clinical practice, there are several critical questions, namely, who should we be screening for unmet needs and how? Screening represents a unique challenge for providers given the sensitive nature of socioeconomic hardship and its potential impact on the patient-clinician relationship. As Garg et al[5] recently pointed out, there is a very real possibility for unintended harm, especially if such inquiries are perceived as being invasive or judgmental, or if screening generates patient expectations that are subsequently left unfulfilled. They offer several key strategies for minimizing inadvertent damage. To begin, screening should never occur without the appropriate systems in place to help connect patients with resources. The strength of these connections will vary depending on the organizational structure of the clinic and the resource landscape of the community. Clinicians must certainly be aware of these limitations and take them into account when addressing difficult social circumstances. Likewise, if screening is to occur within a practice, all patients should be considered and not just certain subgroups or individuals. Regardless of intent, targeting the process of identifying unmet social needs to certain groups only serves to further stigmatize and reinforce stereotypes. Finally, as with most if not all clinical interventions, addressing social needs should be a patient-centered, shared-decision process. As such, medical education must also evolve to not only raise awareness of social determinants of health but teach trainees how to openly discuss these issues with patients in ways that are empathic and not demeaning.

Approaching social needs with the same intention as chronic disease represents an important step toward making optimal health a tangible reality for all members of society. Advocates from Health Leads help offload the work faced by many social workers and case managers working in safety net settings so that they can focus on those patients who need clinical help. However, additional efforts must be made to close the gap between identifying unmet needs and successfully connecting patients to indicated resources. Notably only slightly