Improving Chronic Disease Care by Adding Laypersons to the Primary Care Team
A Parallel Randomized Trial

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Background: Improving the quality and efficiency of chronic disease care is an important goal.

Objective: To test whether patients with chronic disease working with lay "care guides" would achieve more evidence-based goals than those receiving usual care.

Design: Parallel-group randomized trial, stratified by clinic and conducted from July 2010 to April 2012. Patients were assigned in a 2:1 ratio to a care guide or usual care. Patients, providers, and persons assessing outcomes were not blinded to treatment assignment. (ClinicalTrials.gov: NCT01156974)

Setting: 6 primary care clinics in Minnesota.

Patients: Adults with hypertension, diabetes, or heart failure.

Intervention: 2135 patients were given disease-specific information about standard care goals and asked to work toward goals for 1 year, with or without the help of a care guide. Care guides were 12 laypersons who received brief training about these diseases and behavior change.

Measurements: The primary end point for each patient was change in percentage of goals met 1 year after enrollment.

Results: The percentage of goals met increased in both the care guide and usual care groups (changes from baseline, 10.0% and 3.9%, respectively). Patients with care guides achieved more goals than usual care patients (82.6% vs. 79.1%; odds ratio, 1.31 [95% CI, 1.16 to 1.47]; $P < 0.001$); reduced unmet goals by 30.1% compared with 12.6% for usual care patients; and improved more than usual care patients in meeting several individual goals, including not using tobacco. Estimated cost was $286 per patient per year.

Limitations: Providers' usual care may have been influenced by contact with care guides. Last available data in the electronic health record were used to assess end points.

Conclusion: Adding care guides to the primary care team can improve care for some patients with chronic disease at low cost.

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Almost half of Americans with chronic disease do not receive evidence-based care (1–3). Reasons for this include limited access (4, 5) and payment systems that undervalue primary care and provide incentives for more care but not better results (6). A consensus is emerging that chronic disease care can best be provided by a team that is centered in the primary care office and works directly to engage patients and give providers feedback about care quality (4, 7). These principles are integral to the chronic care model (8–10) and the patient-centered medical home (11). Questions remain about how these teams will be structured, how they will be paid for, and which patients will benefit (12, 13).

Despite potential global savings, active care management does not fit within the budgets of most primary care practices (12–14). This service is usually provided by nurses (15–18) rather than lower-salaried nonclinical personnel (19–27). Telephone coaching from a central location is less expensive but often ineffective (28–30).

Seeking a pragmatic way to help patients with chronic disease, investigators at the University of Minnesota and Allina Health, a large not-for-profit network of hospitals and clinics in Minnesota and western Wisconsin, blended ideas from several sources and introduced a new type of clinic employee: a lay "care guide," whose only job was to help patients and providers achieve care goals recommended by national authorities (31). This trial tests the hypothesis that care guides can improve care at a reasonable cost.

METHODS
Design Overview

This trial was a 1-year, multicenter, randomized, parallel-group study conducted in 6 primary care clinics in Minnesota. Patients were stratified by clinic and were assigned in a 2:1 ratio to a care guide or usual care. Patients, providers, and persons performing outcome assessments were not blinded to treatment assignment. A 6-month recruitment period began in 3 clinics in July 2010 and in 3 clinics in October 2010. Follow-up was completed in April 2012. No changes in methods, outcomes, or data collec-

Context

Chronic diseases can be expensive and difficult to treat.

Contribution

Researchers recruited 2135 patients with diabetes, hypertension, or heart failure from 6 clinics. Patients received care goals for their diseases and were randomly assigned to work with or without a lay care guide to achieve these goals. After 1 year, care guide patients had achieved more goals and had fewer unmet goals than usual care patients. The estimated cost of the guide was $286 per patient.

Caution

Providers' usual care may have been influenced by contact with care guides.

Implication

Lay care guides might help improve care for some patients with chronic diseases.

—*The Editors*

tion methods were made after the study began. The Institutional Review Boards of Allina Health and the University of Minnesota approved the study. All patients gave written informed consent.

Setting and Participants

From 50 Allina Health primary care clinics, we chose 6 that differed in size, location (urban, suburban, or rural), provider specialty (family practice or internal medicine), and duration of exposure to Allina Health quality improvement initiatives. Patients with hypertension, diabetes, or congestive heart failure (common chronic diseases with objective standards for care [32–34]) were eligible if they were aged 18 to 79 years, were not pregnant, and had a primary care office visit during the 6-month enrollment period. There were no other exclusion criteria. We gave providers lists of eligible patients on each day's schedule and asked them to refer patients who "needed help." Analysis confirmed that providers preferentially referred patients with higher blood pressures and glycated hemoglobin values from these lists.

Randomization and Interventions

Twelve care guides were hired and assigned by clinic size: 1 clinic had 1 care guide, 4 clinics had 2, and 1 clinic had 3. Research supervisors prepared sealed opaque envelopes containing either a purple card (assignment to a care guide) or gold card (assignment to usual care). One hundred eighty envelopes (120 with purple cards and 60 with gold cards) were given to the small clinic, 360 (240 purple and 120 gold cards) were given to the medium-sized clinics, and 540 (360 purple and 180 gold cards) were given to the large clinic. Each clinic's envelopes were shuffled before delivery and daily thereafter.

When a patient was referred for enrollment, a care guide explained the study and the randomization process.

Consent forms included an agreement to work with a patient's primary provider to achieve care goals recommended by the American Diabetes Association; the American Heart Association; and the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (**Table 1**) (32–34). Patients who consented to enroll received identical written information about the benefits of meeting disease-specific goals. They then selected and opened an envelope to determine treatment assignment. Care guides and patients were not blinded to treatment assignment. Each care guide worked primarily with a small group of providers who cared for both care guide and usual care patients.

For the care guide position, we hired laypersons with at least 2 years of college education and strong interpersonal skills. We provided them with 2 weeks of training that included basic information about hypertension, diabetes, and heart failure; barriers to care and resources for overcoming them; professional behavior; how to use the electronic health record (EHR); and behavior change techniques, including motivational interviewing, goal setting, contracting, and feedback (35). The nonclinical nature of the position was stressed, and a "scope of practice" document was created. Care guide workstations were located in clinic waiting rooms to facilitate face-to-face interactions with patients, providers, and nurses. Details are described

Table 1. Care Goals, by Diagnosis

Care Goal	Patient Diagnosis		
	Hypertension	Diabetes Mellitus	Congestive Heart Failure
No tobacco use	√	√	√
Systolic blood pressure <140 mm Hg	√		
Diastolic blood pressure <90 mm Hg	√		
HbA$_{1c}$ level <8.0%		√	
LDL cholesterol level <2.6 mmol/L (<100 mg/dL)		√	
Systolic blood pressure <130 mm Hg		√	
Diastolic blood pressure <80 mm Hg		√	
Retinal examination within 2 y		√	
Measurement of urinary albumin within 2 y		√	
ACEI or ARB prescription if urinary albumin level >30 mg/g of creatinine		√	
Pneumonia vaccination		√	√
Echocardiography			√
β-Blocker prescription if LVEF <0.40			√
ACEI or ARB prescription if LVEF <0.40			√

ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin-receptor blocker; HbA$_{1c}$ = glycated hemoglobin; LDL = low-density lipoprotein; LVEF = left ventricular ejection fraction.

Figure. **Study flow diagram.**
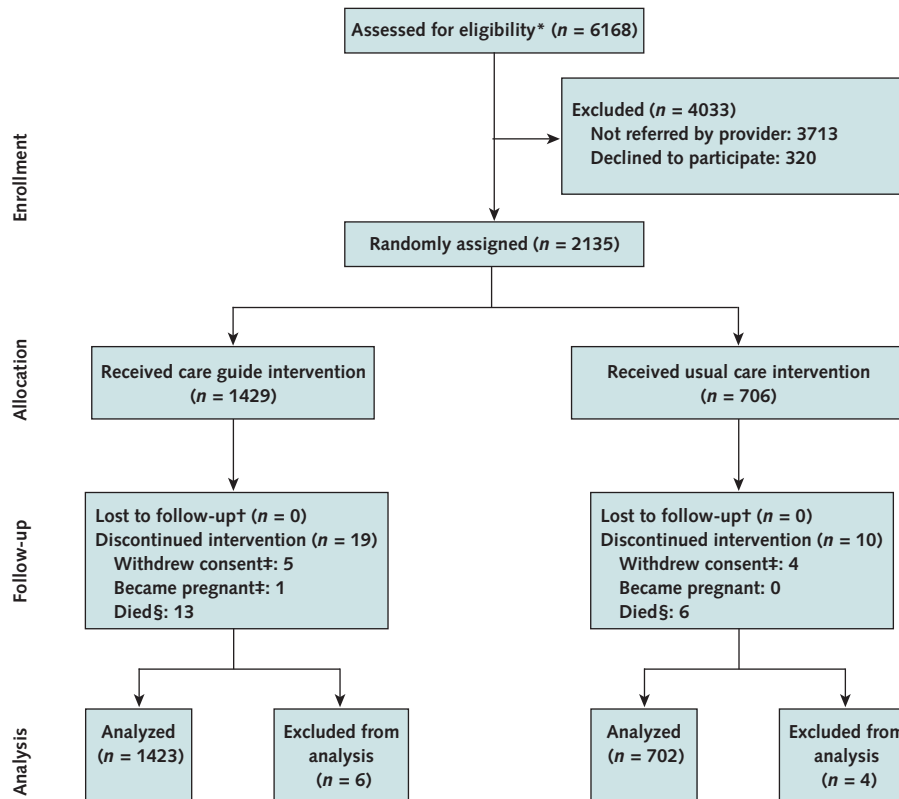
* Includes all nonpregnant patients aged 18 to 79 y with diabetes, hypertension, or heart failure seen during the enrollment period.
† The last available data for patients who moved or changed clinics were included in the analysis because these patients could (and sometimes did) return.
‡ Data were removed at the request of the 9 patients who withdrew and for the pregnant patient because she discovered that she was pregnant soon after enrollment.
§ Used last available data in the electronic health record.

in a pilot study (31). Two experienced registered nurses were hired as supervisors.

The main objective for the care guides was to help assigned patients and their primary care providers achieve recommended care goals. Care guides asked patients to sign a contract (which was scanned into the EHR) agreeing to work toward their disease-specific goals. Care guides met with providers and sent them electronic messages as needed. Care guides and patients mutually decided how often and how (face-to-face or by telephone) they would contact each other. Quarterly reports about care goals achieved and not achieved were printed for patients and delivered electronically to primary care providers. Otherwise, we did not specify how care guides would go about the work of improving goal achievement.

Care guides and the research team did not interact with the usual care patients after enrollment and randomization. Usual care patients and providers knew that a study was in progress. Providers were exposed to many other Allina Health care improvement activities during the study, including EHR prompts to repeat blood pressure measurement after abnormal readings, alerts when glycated

hemoglobin and cholesterol measurements were overdue, and efforts to reduce rehospitalizations. These activities applied equally to care guide and usual care patients.

Outcomes and Follow-up

The primary end point for each patient was the change in percentage of disease-specific care goals (**Table 1**) met 1 year after enrollment. At enrollment and exactly 1 year later, the last available data from the EHR were used to determine the number of goals assigned (that is, the number at risk for not meeting) and the number met.

Secondary end points were the percentage of goals met by patients with each diagnosis and the achievement of each individual goal. Other objectives were to determine whether the benefit of working with a care guide could be predicted by patient demographic data, including age, sex, self-identified race, language spoken at home, insurance type, and educational attainment; to evaluate the influence of working with a care guide on patients' perceptions of care; and to measure costs. No changes were made in these end points or how they were collected after the study began.

Patients were asked to answer 14 survey questions about perceptions of care before randomization and 1 year later (see the **Supplement**, available at www.annals.org). We recorded compensation for care guides and supervisors, the cost of training, and the cost of creating 12 workstations. Because care guides and supervisors helped to enroll patients and collect and audit research data, we asked them to estimate the percentage of their time spent on patient care rather than research. To investigate the influence of working with a care guide on resource use, we obtained global Allina Health billing data and counted Allina Health emergency department visits and hospitalizations for 1 year before and after each patient's enrollment.

We did not anticipate potential harms from this intervention; adverse event collection was restricted to deaths. The accuracy of the clinical data collection process was monitored monthly for 3 months and then quarterly by care guides, nurse supervisors, and the research team using self-audits and second-party audits.

Statistical Analysis

A power calculation suggested that if two thirds of goals were met at baseline, 729 patients would provide an 80% chance of detecting a 10% change (relative to baseline, within the active treatment group) and 3079 patients would provide the same chance of detecting a 5% change. We aimed to enroll 2000 patients. For all analyses, we used Stata, release 12 (StataCorp, College Station, Texas).

Each patient had 3 to 12 goals, depending on diagnoses. Because we accepted all goals recommended by national authorities, we treated all goals equally even though some could be considered more important or more difficult to achieve. Some were conditional (for example, a recommendation that diabetic patients receive a drug affecting the renin–angiotensin system to preserve renal function if they were found to have albuminuria). This resulted in a slightly increased denominator (goals at risk

for not being met) at 1 year as data on albuminuria and left ventricular ejection fraction became available.

We compared the average probability of meeting goals by using a binomial (events/trials) logistic regression model in which, for each patient, the numerator (events) was the number of goals met and the denominator (trials) was the number of possible goals, controlling for goals met at baseline and clustering SEs by clinic. We used Stata's blogit command, which uses maximum likelihood estimation for grouped data for all patients (the primary end point) and for patients in each diagnosis group and at each site. We used Stata's logit command to evaluate achievement of each individual clinical goal. For the primary end point, we performed a post hoc sensitivity analysis by repeating the

Table 2. Baseline Characteristics of Care Guide and Usual Care Patients

Characteristic	Care Guide (n = 1423)	Usual Care (n = 702)
Diabetes, %	65	62
Hypertension, %	82	80
Heart failure, %	6	5
>1 diagnosis, %	50	45
Female, %	50	53
White, %	90	91
Speak English at home, %	98	98
Medicaid insurance, %	7	7
High school education or less, %	39	39
No tobacco use, %	84	86
Mean age (SD), y	61.1 (11.3)	60.9 (11.7)
Mean systolic blood pressure (SD), mm Hg	128.8 (16.8)	128.7 (17.1)
Mean diastolic blood pressure (SD), mm Hg	74.5 (11.0)	74.3 (11.6)
Mean HbA$_{1c}$ level (SD), %*	7.4 (1.5)	7.3 (1.5)
Mean LDL cholesterol level (SD)*		
mmol/L	2.23 (0.79)	2.24 (0.78)
mg/dL	86.1 (30.4)	86.4 (30.0)

HbA$_{1c}$ = glycated hemoglobin; LDL = low-density lipoprotein.
* Among patients with diabetes. Results were available for 1365 of 1366 patients with diabetes.

Table 3. Percentage of Goals Met at Baseline and 1 Year

Patient Group	Care Guide					Usual Care					Care Guide Effect	
	Patients, n	Goals Met, %		Absolute Difference, percentage points	Relative Difference, %	Patients, n	Goals Met, %		Absolute Difference, percentage points	Relative Difference, %	Odds Ratio* (95% CI)	P Value
		Baseline	1 y				Baseline	1 y				
All	1423	75.1	82.6	7.5	10.0	702	76.1	79.1	3.0	3.9	1.31 (1.16–1.47)	<0.001
Diabetes mellitus	930	75.5	82.5	7.0	9.3	436	76.3	78.2	1.9	2.5	1.35 (1.22–1.50)	<0.001
Hypertension	1162	75.8	83.2	7.4	9.8	560	77.2	80.2	3.0	3.9	1.29 (1.16–1.44)	<0.001
Congestive heart failure	89	82.5	88.2	5.7	6.9	34	86.6	85.1	−1.5	−1.7	1.58 (1.01–2.48)	0.047
>1 diagnosis	717	77.0	83.6	6.6	8.6	316	78.4	79.7	1.3	1.7	1.37 (1.21–1.55)	<0.001
Clinic 1	239	72.8	80.7	7.9	10.9	119	71.0	79.3	8.3	11.7	1.02 (0.82–1.28)	0.84
Clinic 2	239	81.4	87.6	6.2	7.6	117	84.4	85.2	0.8	0.9	1.33 (0.99–1.77)	0.055
Clinic 3	239	73.8	81.7	7.9	10.7	120	73.6	75.8	2.2	3.0	1.46 (1.19–1.80)	<0.001
Clinic 4	241	75.9	82.1	6.2	8.2	119	77.0	78.9	1.9	2.5	1.31 (1.05–1.64)	0.019
Clinic 5	119	71.4	84.7	13.3	18.6	60	76.6	83.7	7.1	9.3	1.27 (0.88–1.83)	0.195
Clinic 6	346	74.6	81.5	6.9	9.2	167	76.1	76.9	0.8	1.1	1.39 (1.16–1.66)	<0.001

* Refers to difference in percentage of goals met at 1 y (care guide vs. usual care).

Table 4. Achievement of Individual Clinical Goals

Care Goal	Care Guide				
	Patients, n	Goals Met, %		Absolute Difference, percentage points	Relative Difference, %
		Baseline	1 y		
No tobacco use	1423	83.8	86.6	2.8	3.3
Systolic blood pressure					
All patients	1409	63.3	73.0	9.7	15.3
Patients with hypertension only	458	53.1	76.0	22.9	43.1
Patients with diabetes mellitus	930	67.8	71.2	3.4	5.0
Diastolic blood pressure					
All patients	1409	78.5	80.9	2.4	3.1
Patients with hypertension only	458	78.6	86.5	7.9	10.1
Patients with diabetes mellitus	930	78.0	77.7	−0.3	−0.4
HbA$_{1c}$	930	74.6	76.9	2.3	3.1
LDL cholesterol	930	72.9	77.4	4.5	6.2
Retinal examination	722	83.1	90.6	7.5	9.0
Microalbumin test	930	78.7	94.7	16.0	20.3
Pneumonia vaccination	965	63.5	83.6	20.1	31.7
Echocardiography	89	98.9	100.0	1.1	1.1
β-Blocker prescription for patients with congestive heart failure and LVEF <0.40	43 (45)‡	90.7	95.6	4.9	5.4
ACEI or ARB prescription					
Patients with diabetes mellitus and microalbuminuria	279 (333)‡	77.4	83.8	6.4	8.3
Patients with congestive heart failure and LVEF <0.40	43 (45)‡	81.4	82.2	0.8	1.0

ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin-receptor blocker; HbA$_{1c}$ = glycated hemoglobin; LDL = low-density lipoprotein; LVEF = left ventricular ejection fraction.
* Refers to difference in percentage of goals met at 1 y (care guide vs. usual care).
† Could not be calculated.
‡ Data are numbers at baseline (numbers at 1 y). Numbers at 1 y include patients for whom information about urinary albumin or LVEF became available during the study.

original analysis but taking into account the time (quarter of the year) of each goal's final measurement to analyze whether the observed care guide effect was related to when goals were measured.

We evaluated the benefit of working with care guides in demographic subgroups by including an interaction between care guide effect and membership in these subgroups in a model similar to that used in the primary outcome analysis. To evaluate the effect of working with a care guide on patients' perceptions of care before and after the study, we regressed survey response measures on treatment group by time, percentage of goals met at baseline, and time and included random effects for patient and clinic (xtmixed command in Stata). We used Poisson regression (poisson command in Stata) to compare numbers of Allina Health hospitalizations and emergency department visits during the year before and the year after each patient's enrollment. For the analysis of charges, we regressed charges on time by treatment group (glm command in Stata) using log link and γ variance functions, with SEs clustered by clinic.

We collected but do not report outcome comparisons of enrolled patients with matched patients in similar clinics with no exposure to care guides.

Role of the Funding Source

The Robina Foundation had no role in the design or conduct of the study; collection, management, analysis, or interpretation of the data; or preparation, review, or approval of the manuscript.

RESULTS

Patients

Of 2455 patients referred by providers, 2135 enrolled. Ten enrollees who withdrew after allocation are not included in our analyses (**Figure**). **Table 2** shows diagnoses and characteristics of the 2125 included in analyses. About half had more than 1 diagnosis. **Appendix Table 1** (available at www.annals.org) shows characteristics of patients at each site. The median number of patients served by 1 care guide was 120 (range, 92 to 130 patients; interquartile range, 118 to 121 patients). No patients crossed over between groups.

Primary End Point

Patients in both the care guide and usual care groups increased the percentage of goals met at 1 year compared with baseline (relative differences, 10.0% and 3.9%, respectively) (**Table 3**). Care guide patients met a larger percentage of possible care goals at 1 year than usual care patients (82.6% vs. 79.1%; odds ratio, 1.31 [95% CI, 1.16 to 1.47]; $P < 0.001$). Care guide patients reduced unmet goals by 30.1% compared with 12.6% for usual care patients. Numerators (goals met) and denominators (possible goals) for the entire group and for patients in each clinic are shown in **Appendix Table 2** (available at www.annals

Table 4—Continued

Patients, n	Usual Care				Care Guide Effect	
	Goals Met, %		Absolute Difference, percentage points	Relative Difference, %	Odds Ratio* (95% CI)	P Value
	Baseline	1 y				
702	85.2	85.5	0.3	0.4	1.77 (1.09–2.86)	0.021
690	66.7	70.3	3.6	5.4	1.20 (0.98–1.46)	0.077
246	55.3	71.1	15.8	28.6	1.32 (0.97–1.79)	0.078
436	72.7	69.7	−3.0	−4.1	1.15 (0.81–1.63)	0.45
690	80.1	81.7	1.6	2	0.97 (0.66–1.41)	0.87
246	77.6	87.8	10.2	13.1	0.85 (0.59–1.23)	0.39
436	81.2	78.0	−3.2	−3.9	1.03 (0.63–1.68)	0.92
435	75.9	77.9	2.0	2.6	0.97 (0.88–1.06)	0.49
435	74.3	77.9	3.6	4.8	1.00 (0.77–1.31)	0.99
346	76.3	77.2	0.9	1.2	2.70 (1.32–5.54)	0.007
435	81.6	87.1	5.5	6.7	3.16 (2.32–4.31)	<0.001
456	63.8	72.8	9.0	14.1	3.49 (2.37–5.15)	<0.001
34	94.1	100.0	5.9	6.3	†	†
11 (12)‡	90.9	91.7	0.8	0.9	†	†
140 (164)‡	78.6	79.9	1.3	1.7	1.52 (0.93–2.51)	0.097
11 (12)‡	81.8	58.3	−23.5	−28.7	1.19 (0.24–5.87)	0.21

.org). In a post hoc sensitivity analysis, the difference in outcomes between treatment groups was minimally affected by differences in the times of final measurement for each goal (**Appendix Table 3**, available at www.annals.org).

Secondary End Points

The percentage of possible goals met at 1 year for care guide and usual care patients grouped by diagnosis and clinic are shown in **Table 3**. For each diagnosis group, care guide patients met a larger percentage of possible care goals at 1 year than usual care patients ($P < 0.001$ for diabetes and hypertension; $P = 0.047$ for congestive heart failure). Results for achievement of individual clinical goals are shown in **Table 4**. Care guide patients were more likely to meet the goal of not using tobacco ($P = 0.021$) than usual care patients. Care guide patients with diabetes were more likely than usual care patients to meet the goals of having had recent retinal examination ($P = 0.007$), recent microalbuminuria testing ($P < 0.001$), and pneumonia vaccination ($P < 0.001$).

For adherence and effort, the mean number of visits to a patient's primary clinic during the study was similar for care guide and usual care patients (5.1 and 5.0 visits, respectively). Care guides reported a median of 4 provider contacts and 7 patient contacts (2 face-to-face and 5 by telephone) during the study year; these numbers were similar across study sites (**Appendix Table 4**, available at www.annals.org) and study quarters.

The benefit of working with a care guide was not influenced by age, sex, race, language, or education. Patients with Medicaid were more likely to benefit than patients

with other insurance (**Appendix Table 5**, available at www.annals.org). In poststudy surveys, care guide patients reported significantly more positive perceptions of their care than control patients in constructs measuring social support, individualized care, help, reinforcement, and understanding of how to improve their health (**Appendix Tables 6** and **7**, available at www.annals.org).

Full-time care guides served a median of 120 patients. Compensation was $511 176 for 12 care guides ($16/h salary plus benefits) and $116 736 for 2 nurse supervisors. Care guides and supervisors estimated that 63% and 60% of their duties, respectively, were related to patient care rather than research. Modular furniture and equipment for 12 semiprivate workstations within existing clinic space cost $108 000, which could be depreciated over 5 years. Training costs were $3031. Care guides estimated that, without research duties, they could each serve approximately 190 patients; the total cost per patient would be $286 per year.

When the care guide year and the previous year were compared, mean hospitalizations per patient decreased from 0.37 to 0.35 for care guide patients and increased from 0.29 to 0.35 for usual care patients ($P = 0.050$ for a between-group difference over time); emergency department visits were not statistically significantly different (**Appendix Table 8**, available at www.annals.org). Median hospital charges decreased for care guide patients and increased for control patients, but charge data were highly skewed and not statistically significantly different when a log γ distribution was used ($P = 0.157$). There was no statistically significant difference in professional charges

or relative value units (**Appendix Table 9**, available at www.annals.org).

DISCUSSION

In this study, a group of patients with chronic disease in a community setting who met three quarters of recommended treatment goals at baseline reduced unmet goals by 30.1% in 1 year with care guide support; patients in the same clinics who were randomly assigned to usual care reduced unmet goals by 12.6%. These results were achieved using a new and relatively inexpensive care model, which integrates trained laypersons directly into the primary care delivery process. Estimated cost was $286 per patient. There were differences favoring care guide patients in all diagnosis subgroups, in achievement of clinical and process goals (for example, tobacco cessation and retinal examination), in patients' perceptions of care, and in hospitalization rates. Benefits were broadly based across patient demographic categories.

Improving the quality of care for patients with chronic disease is an important goal for the U.S. health care system. The question of how to do this in a practical and efficient way remains. We searched the English-language chronic disease care management literature from 2008 to 2013 using the keywords "chronic disease," "manager," "navigator," "coach," "guide," "trainer," "community health worker," "promotora," "matron," and "peer patient" in PubMed and using Google Scholar. We found several innovative care management models, including the chronic care model and the patient-centered medical home (10, 15, 36–39), the teamlet model (40), and the community health worker model (21–23). Some included peer patients (24–27), family members (41), or surrogate family members (42). Many involved large integrated delivery systems with resources for chronic disease care programs (38, 39); how to fund such activities in other settings is uncertain (12, 37). We were unable to identify another large randomized trial that tested the effectiveness of integrating laypersons into the delivery of primary care for patients with chronic disease. Many studies addressed the needs of underserved patients; in our study, care guides helped a broad range of patients who were meeting many goals at baseline and were treated by providers already receiving regular quality improvement feedback.

What were the key interactions that led to clinical improvements? Care guides used various techniques. With patients, they took time to explain the benefits of meeting goals in lay language, used their nonmedical backgrounds to create an environment where patients felt at ease asking questions, called patients after office visits to ensure instructions were understood, and helped develop specific action plans. With providers and nurses, they gave reminders about unmet goals on the day of an appointment (when this information would be most useful) and supplied such information as, "This patient reports difficulty affording medication" or "This patient seems ready to quit tobacco."

Using their relationships with providers, care guides served as quality improvement advocates integrated into the daily process of providing primary care. This arrangement differs from the common practice of giving providers periodic feedback based on data gleaned from the EHR. The effectiveness of feedback about groups of patients may be limited by differences in numbers of outlier patients in providers' practices, incorrect provider attribution, and rigid guideline targets. As a result, clinicians can become frustrated and ignore feedback perceived as inaccurate (43–46).

Moving the quality improvement process into the primary care office resolves some of these problems. Conversations about care quality and when to deviate from guidelines can occur face-to-face; a sense of teamwork can increase workplace satisfaction (43). In a poststudy survey of 115 providers and nurses (data not shown), 93% believed that care guides improved patient care and 94% believed that care guides were an effective use of resources. Improvements that we saw in usual care patients in some clinics were probably related to the presence of care guides.

Costs were low for several reasons. Most care guides were early in their careers (although 1 was nearing retirement) and accepted entry-level salaries in the Minneapolis–St. Paul market. They were encouraged to concentrate on patients who seemed ready to make changes and to contact others less often. They used brief, focused behavior-change techniques. Each worked with a small number of providers, allowing informal and electronic communication rather than scheduled "huddles."

Improvements associated with care guides did not come at the expense of additional resource use. When the study year was compared with the previous year, rates of hospitalization increased for usual care patients but not for care guide patients. However, because patients could obtain care outside of the Allina Health system and baseline hospital use differed in patient groups, further analysis is needed to determine whether this intervention affected hospital costs.

How do care guides differ from other personnel used as care managers? Care guides can explain the value of meeting standard goals but, unlike nurses, cannot answer clinical questions. They have less training than medical assistants and no competing duties in the clinic. Like community health workers, care guides are culturally similar to the patients they serve, but they are located in the clinic. Care guides were recruited for specific traits and competencies: an outgoing personality; the ability to engage easily with people of different ages and backgrounds; and a second language, where needed (for example, Spanish and Somali in the pilot study) (31).

Generalizability of our findings may be limited because our study sample included few uninsured and non–

English-speaking patients; however, these groups were well-represented in the pilot study, which had similar results. In other locations, it may be difficult to find similarly motivated and low-cost care guides. Other limitations of the study include that the usual care delivered by providers may have been influenced by contact with care guides about other patients. Improvement in usual care patients could be related to their knowledge that they were study participants. The number of care goals met was assessed by using the last available data in the EHR. Poststudy survey responses are subject to response bias and influenced by disease-specific information received before randomization. The study's 1-year time frame limits the ability to assess the durability of the care guide model or long-term effects on resource use. We cannot explain the difference in hospitalizations between patient groups in the year before randomization; studying resource use in a closed system would provide more reliable data.

In conclusion, this study showed that laypersons with relevant skills and training who are located in clinic waiting rooms—where they can meet patients and providers face-to-face—can help patients with chronic disease and their providers improve the quality of care. This approach to care management blends several important elements. It is low in cost, is integrated into existing clinic workflows, explicitly incorporates behavior change theory, and leverages the power inherent in face-to-face relationships. We believe that the care guide model could be used to help other types of patients and be implemented in other settings, including small independent offices, where most primary care in the United States is delivered (12–14, 47).

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Appendix Table 1. **Baseline Patient Characteristics, by Clinic**

Characteristic	All Patients		Clinic 1		Clinic 2		Clinic 3		Clinic 4		Clinic 5		Clinic 6	
	Care Guide (n = 1423)	Usual Care (n = 702)	Care Guide (n = 239)	Usual Care (n = 119)	Care Guide (n = 239)	Usual Care (n = 117)	Care Guide (n = 239)	Usual Care (n = 120)	Care Guide (n = 241)	Usual Care (n = 119)	Care Guide (n = 119)	Usual Care (n = 60)	Care Guide (n = 346)	Usual Care (n = 167)
Diabetes, %	65	62	72	59	56	42	74	70	60	66	62	67	66	68
Hypertension, %	82	80	78	83	94	93	72	73	79	71	78	78	85	80
Heart failure, %	6	5	4	6	7	3	4	6	8	6	9	7	7	4
>1 diagnosis, %	50	45	51	46	54	37	49	45	44	40	46	50	53	51
Female, %	50	53	54	63	51	59	47	38	46	50	45	53	51	52
White, %	90	91	75	76	96	99	86	89	96	97	97	95	94	92
Speak English at home, %	98	98	98	97	99	98	96	98	99	99	100	98	98	98
Medicaid insurance, %	7	7	8	8	2	2	10	9	4	5	8	7	9	9
High school education or less, %	39	39	44	48	13	23	43	34	38	30	45	43	48	51
No tobacco use, %	84	86	85	84	95	96	77	76	83	85	83	82	82	87
Mean age, y	61.1	60.9	60.1	60.8	65	65.7	57.7	56.0	60.7	61.2	63.8	61.6	60.6	60.5
Mean systolic blood pressure, mm Hg	128.8	128.7	130.2	133.7	130.8	131	126.1	126	128	127.2	129.8	128	128.6	127
Mean diastolic blood pressure, mm Hg	74.5	74.3	75.6	76.7	74.1	73.2	74.5	75.4	73.7	71.6	73.6	73.4	74.8	74.7
Mean HbA$_{1c}$ level, %*	7.4	7.3	7.4	7.2	7.3	7	7.5	7.5	7.3	7.1	7.5	7.4	7.3	7.4
Mean LDL cholesterol level*														
mmol/L	2.23	2.24	2.32	2.29	1.95	1.97	2.23	2.13	2.24	2.25	2.22	2.25	2.32	2.40
mg/dL	86.1	86.4	89.7	88.4	75.1	76.0	86.2	82.1	86.4	86.9	85.7	86.8	89.6	92.5

HbA$_{1c}$ = glycated hemoglobin; LDL = low-density lipoprotein.
* Among patients with diabetes.

Patient Group	Care Guide			Usual Care		
	Patients, *n*	Goals Met, n/N* (%)		Patients, *n*	Goals Met, n/N* (%)	
		Baseline	1 y		Baseline	1 y
All	1423	6892/9178 (75.1)	7632/9236 (82.6)	702	3335/4385 (76.1)	3488/4411 (79.1)
Clinic 1	239	1189/1634 (72.8)	1337/1656 (80.7)	119	525/739 (71.0)	586/739 (79.3)
Clinic 2	239	1087/1336 (81.4)	1175/1342 (87.6)	117	477/565 (84.4)	483/567 (85.2)
Clinic 3	239	1241/1682 (73.8)	1383/1692 (81.7)	120	600/815 (73.6)	626/826 (75.8)
Clinic 4	241	1167/1537 (75.9)	1265/1541 (82.1)	119	605/786 (77.0)	624/791 (78.9)
Clinic 5	119	498/697 (71.4)	596/704 (84.7)	60	272/355 (76.6)	302/361 (83.7)
Clinic 6	346	1710/2292 (74.6)	1876/2301 (81.5)	167	856/1125 (76.1)	867/1127 (76.9)

* Goals met out of assigned goals.

Appendix Table 3. Influence of Time of Final Goal Measurement on Care Guide Effect on Goals Met at 1 Year

Care Goal	Care Guide Effect		Care Guide Effect (Including Measurement Time Variable)*	
	Odds Ratio† (95% CI)	*P* Value	Odds Ratio† (95% CI)	*P* Value
No tobacco use	1.77 (1.09–2.86)	0.021	1.77 (1.09–2.86)	0.021
Systolic blood pressure				
All patients	1.20 (0.98–1.46)	0.077	1.20 (0.98–1.46)	0.076
Patients with hypertension	1.32 (0.97–1.79)	0.078	1.32 (0.98–1.78)	0.071
Patients with diabetes mellitus	1.15 (0.81–1.63)	0.45	1.15 (0.81–1.63)	0.45
Diastolic blood pressure				
All patients	0.97 (0.66–1.41)	0.87	0.97 (0.66–1.41)	0.86
Patients with hypertension	0.85 (0.59–1.23)	0.39	0.85 (0.59–1.21)	0.36
Patients with diabetes mellitus	1.03 (0.63–1.68)	0.92	1.03 (0.63–1.67)	0.91
HbA$_{1c}$	0.97 (0.88–1.06)	0.49	0.96 (0.84–1.10)	0.58
LDL cholesterol	1.00 (0.77–1.31)	0.99	0.98 (0.73–1.32)	0.91
Retinal examination	2.70 (1.32–5.54)	0.007	2.62 (1.31–5.23)	0.007
Microalbumin test	3.16 (2.32–4.31)	<0.001	‡	‡
Pneumonia vaccination	3.49 (2.37–5.15)	<0.001	‡	‡
ACEI or ARB prescription				
Patients with diabetes mellitus and microalbuminuria	1.52 (0.93–2.51)	0.097	1.54 (0.96–2.47)	0.071
Patients with congestive heart failure and LVEF <0.40	1.19 (0.24–5.87)	0.83	1.24 (0.32–4.81)	0.75

ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin-receptor blocker; HbA$_{1c}$ = glycated hemoglobin; LDL = low-density lipoprotein; LVEF = left ventricular ejection fraction.
* For this analysis, we determined the quarter of the year in which the final measurement occurred for each goal and repeated the original analysis using Stata's blogit command with this variable added. The care guide effect persisted with minimal differences between the 2 analyses, indicating that the time of goal measurement had little influence on attainment.
† Refers to the difference in percentage of goals met at 1 y (care guide vs. usual care). Odds ratios for echocardiography and β-blocker prescription could not be calculated in the primary analysis (care guide effect), so these goals are not included in the table.
‡ Could not be calculated.

Appendix Table 4. Care Guide Contacts With Patients and Providers*

Clinic	Care Guide–Patient		Care Guide–Provider
	Telephone	In Person	
All	5 (3, 7)	2 (1, 4)	4 (4, 5)
Clinic 1	3 (1, 4)	2 (1, 4)	4 (4, 6)
Clinic 2	4 (2, 7)	1 (1, 3)	4 (4, 5)
Clinic 3	7 (5, 9)	3 (1, 5)	4 (4, 5)
Clinic 4	5 (3, 7)	1 (0, 3)	4 (4, 5)
Clinic 5	6 (4, 8)	2 (1, 4)	4 (4, 5)
Clinic 6	5 (3, 8)	2 (0, 4)	5 (4, 6)

* Data are median (first quartile, third quartile) numbers of contacts during the study year.

Appendix Table 5. Influence of Demographic Variables on Care Guide Effect on Goals Met at 1 Year*

Patient Group	Care Guide Effect	
	Odds Ratio† (95% CI)	P Value
Aged >65 y	0.99 (0.80–1.22)	0.90
Female	0.88 (0.73–1.07)	0.20
White	1.04 (0.76–1.41)	0.82
Speak English at home	0.66 (0.31–1.41)	0.28
Medicaid insurance‡	1.47 (1.05–2.06)	0.027
High school education or less	0.96 (0.80–1.16)	0.64

* Shows the interaction between demographic group and care guide effect by adding the variable "treatment group by demographic group" to the primary end point analysis using Stata's blogit command.
† Refers to care guide effect on percentage of goals met at 1 y in patients with each demographic variable compared with those without it.
‡ Only predictor of increased care guide effect.

Appendix Table 6. Influence of Working With Care Guides on Perceptions of Care: Patient Survey Measures

Component	Cronbach α* (All Patients)		Care Guide				Usual Care			
	Baseline	1 y	Baseline		1 y		Baseline		1 y	
			Patients, n	Mean Score (SD)†	Patients, n	Mean Score (SD)†	Patients, n	Mean Score (SD)†	Patients, n	Mean Score (SD)†
Social support	0.93	0.92	1364	3.97 (0.79)	900	4.25 (0.75)	668	3.95 (0.81)	399	4.09 (0.79)
Help	0.85	0.81	1351	3.82 (1.04)	909	3.53 (0.66)	665	3.91 (1.02)	415	3.41 (0.80)
Individualized care	0.88	0.90	1359	4.18 (0.62)	926	4.31 (0.67)	670	4.18 (0.64)	419	4.22 (0.66)
Reinforcement	0.88	0.91	1310	4.05 (0.67)	897	4.13 (0.73)	655	4.08 (0.70)	401	3.98 (0.80)
Understanding	0.72	0.93	1335	3.28 (0.92)	882	3.39 (1.04)	661	3.35 (0.95)	398	3.29 (0.99)

* Values show measurement reliability at conventionally accepted levels.
† Higher numbers indicate more positive responses.

Component	Treatment Group by Time[†]	*P* Value (Treatment Group by Time)[‡]	Percentage of Goals Met at Baseline[†]	Time[†]	Constant	Observations, *n*	Chi-Square Value	*P* Value (Full Model)
Social support	0.138	0.013	0.251	0.133	3.835	3331	121.01	<0.001
Help	0.202	<0.001	0.282	−0.512	3.791	3340	235.21	<0.001
Individualized care	0.099	0.023	0.208	0.030	4.187	3374	113.7	<0.001
Reinforcement	0.169	<0.001	0.280	−0.100	4.036	3263	85.93	<0.001
Understanding	0.178	0.004	0.206	−0.071	3.464	3276	74.83	<0.001

* We assessed the patient care experience by regressing patient responses on treatment group by time, percentage of goals met at baseline, and time. Because the responses were repeated by patients and patients clustered by clinic, random effects were included for patients and clinics, with patients nested within clinics (Stata command xtmixed).
† Regression coefficients.
‡ In all 5 constructs, the care guide effect (treatment group by time) was associated with significantly improved perceptions of care.

Appendix Table 8. Hospitalizations and Emergency Department Visits*

Patients	Period	Mean Hospitalizations (SD)	Mean Emergency Department Visits (SD)
Care guide	Previous year	0.37 (1.00)	0.50 (1.99)
Care guide	Intervention year	0.35 (1.08)	0.57 (2.82)
Usual care	Previous year	0.29 (0.78)	0.45 (1.79)
Usual care	Intervention year	0.35 (0.93)	0.57 (1.73)

* Numbers of hospitalizations and emergency department visits at Allina Health facilities were manually counted from the electronic health record. "Previous year" was defined as the 365 d before each patient's enrollment; "intervention year" was defined as the following 365 d. Differences were compared using Poisson regression. Hospitalizations showed little change in care guide patients and increased in usual care patients; the difference between groups over time was significant (coefficient, −0.24; *P* = 0.050). Emergency department visits increased less in care guide patients than in usual care patients, but this difference was not significant.

Appendix Table 9. Hospital Charges, Professional Charges, and Relative Value Units*

Patients	Period	Hospital Charges, $		Professional Charges, $		Relative Value Units	
		Mean (Range)	Median (25th, 75th Percentiles)	Mean (Range)	Median (25th, 75th Percentiles)	Mean (Range)	Median (25th, 75th Percentiles)
Care guide	Previous year	30 041 (0–474 400)	6416 (1377, 33 816)	3746 (138–53 538)	2254 (1232, 4358)	15.32 (0–290.37)	9.16 (4.94, 16.95)
Care guide	Intervention year	32 791 (0–1 016 195)	5560 (1301, 35 336)	3812 (0–71 126)	2175 (1122, 4528)	15.29 (0–188.07)	8.5 (4.5, 18.18)
Usual care	Previous year	25 815 (0–502 612)	4484 (1234, 32 497)	3759 (146–185 889)	2152 (1168, 4325)	14.1 (0.97–195.3)	8.28 (4.71, 17.16)
Usual care	Intervention year	32 734 (0–427 657)	8341 (1300, 28 764)	3851 (0–86 292)	2093 (1017, 4115)	14.98 (0–149.07)	8.5 (4.42, 17.11)

* Data on charges were extracted from Allina Health billing data 4 mo after the 1-y anniversary of the last patient enrollment and were modified by mean collection rates. "Previous year" was defined as the 365 d before each patient's enrollment; "intervention year" was defined as the following 365 d. We evaluated these charges using a γ distribution with log link to reduce skewness. Differences by treatment group and year were not significant (*P* = 0.157 for hospital charges; *P* = 0.77 for professional charges; *P* = 0.38 for relative value units).