

SPECIAL ARTICLE

Health Care Hotspotting — A Randomized, Controlled Trial

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ABSTRACT

BACKGROUND

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There is widespread interest in programs aiming to reduce spending and improve health care quality among “superutilizers,” patients with very high use of health care services. The “hotspotting” program created by the Camden Coalition of Healthcare Providers (hereafter, the Coalition) has received national attention as a promising superutilizer intervention and has been expanded to cities around the country. In the months after hospital discharge, a team of nurses, social workers, and community health workers visits enrolled patients to coordinate outpatient care and link them with social services.

METHODS

We randomly assigned 800 hospitalized patients with medically and socially complex conditions, all with at least one additional hospitalization in the preceding 6 months, to the Coalition’s care-transition program or to usual care. The primary outcome was hospital readmission within 180 days after discharge.

RESULTS

The 180-day readmission rate was 62.3% in the intervention group and 61.7% in the control group. The adjusted between-group difference was not significant (0.82 percentage points; 95% confidence interval, -5.97 to 7.61). In contrast, a comparison of the intervention-group admissions during the 6 months before and after enrollment misleadingly suggested a 38-percentage-point decline in admissions related to the intervention because the comparison did not account for the similar decline in the control group.

CONCLUSIONS

In this randomized, controlled trial involving patients with very high use of health care services, readmission rates were not lower among patients randomly assigned to the Coalition’s program than among those who received usual care. (Funded by the National Institute on Aging and others; ClinicalTrials.gov number, NCT02090426; American Economic Association registry number, AEARCTR-0000329.)

HEALTH CARE SPENDING IN THE UNITED States is heavily concentrated, with 5% of the population accounting for 50% of annual spending and 1% accounting for almost a quarter of annual spending.¹ There is therefore substantial interest in interventions that can reduce spending and improve health care quality by targeting “superutilizers” of the health care system. Such programs have received considerable positive attention from the media²⁻⁷ as well as support from the federal government.^{8,9}

Since being profiled in Atul Gawande’s seminal *New Yorker* article, “The Hot Spotters,”¹⁰ the program created by the Camden Coalition of Healthcare Providers (hereafter, the Coalition) has been a flagship example of a promising superutilizer program. The Coalition’s Camden Core Model uses real-time data on hospital admissions to identify patients who are superutilizers, an approach referred to as “hotspotting.” Focusing on patients with chronic conditions and complex needs, and starting with the premise that navigation of the standard system is difficult for these patients, the program uses an intensive, face-to-face care model to engage patients and connect them with appropriate medical care, government benefits, and community services, with the aim of improving their health and reducing unnecessary health care utilization.

The program has been heralded as a promising, data-driven, relationship-based, intensive care management program for superutilizers, and federal funding has expanded versions of the model for use in cities other than Camden, New Jersey.⁷⁻¹⁶ To date, however, the only evidence of its effect is an analysis of the health care spending of 36 patients before and after the intervention¹⁷ and an evaluation of four expansion sites in which propensity-score matching was used to compare the outcomes for 149 program patients with outcomes for controls.¹⁸ More broadly, there are a number of promising observational studies of other superutilizer programs.^{12,17,19-21} However, regression to the mean — the tendency for patients selected for the exceptionally high cost of their care at a moment in time to move closer to average cost over time — may bias observational studies of superutilizer programs toward spurious results.^{22,23}

Although there is limited rigorous evidence of the effectiveness of superutilizer programs, several randomized trials of care-transition programs —

which, like the Camden Core Model, start with patients in the hospital and work with them after discharge — have shown substantially reduced readmissions.²⁴⁻²⁹ However, the Camden Core Model targets a much more heterogeneous population with greater social and medical complexity and substantially higher health care utilization. Therefore, the Coalition partnered with investigators to design a prospective, randomized evaluation of this nationally recognized program.

METHODS

TRIAL DESIGN

This investigator-initiated, randomized, controlled trial was approved by institutional review boards at Cooper University Hospital, the National Bureau of Economic Research, Kennedy Health, and Our Lady of Lourdes Medical Center. The trial protocol, available with the full text of this article at NEJM.org, and planned analyses were publicly prespecified in March 2014 in consultation with Dr. Jeffrey Brenner, then director of the Coalition. Minor departures from the plan developed before analysis are described in the Supplementary Appendix, available at NEJM.org. The Coalition staff implemented the protocol and administered the intervention for patients in the treatment group but were unaware of the results until the trial was completed.

PROGRAM

Eligibility

The Camden Core Model is a care-transition program designed to improve patient health and reduce hospital use among some of the least healthy and most vulnerable adults in the United States. Eligibility for trial participation was limited to adults 18 to 80 years of age living in Camden, New Jersey, which is one of the most economically depressed cities in the country and has a high rate of violent crime¹⁰; in 2017, 37% of Camden residents lived below the poverty line as compared with 15% of persons in the United States overall.³⁰

The intervention targeted superutilizers of the health care system — persons with medically and socially complex needs who have frequent hospital admissions. The inclusion criteria were at least one hospital admission at any of four Camden-area hospital systems in the 6 months before the index admission, when patients were enrolled; at least two chronic conditions; and at least two of

the following traits or conditions: use of at least five active outpatient medications, difficulty accessing services, lack of social support, a coexisting mental health condition, an active drug habit, and homelessness. Patients were excluded if they were uninsured, had cognitive impairment, or were receiving oncologic care or had been admitted for a surgical procedure for an acute health problem, for mental health care (with no coexisting physical health conditions), or for complications of a progressive chronic disease for which limited treatments were available. The eligible population composed less than 0.5% of the Camden population but accounted for 11% of the city's hospital expenditures (see the Supplementary Appendix).

Intervention

The time-limited intervention had intensive clinical and social components. Patients were enrolled while in the hospital. Once they returned home, patients worked with a multidisciplinary team that included registered nurses, social workers, licensed practical nurses, community health workers, and health coaches. The team conducted home visits, scheduled and accompanied patients to initial primary and specialty care visits, coordinated follow-up care and medication management, measured blood pressure and blood sugar levels, coached patients in disease-specific self-care, and helped patients apply for social services and appropriate behavioral health programs. The intervention contained many characteristics considered important for successful care-transition programs for high-cost, high-need patients.^{31,32} The Supplementary Appendix includes more details on the intervention.

The control group received usual postdischarge care, which may have included home health care services or other forms of outreach. We were unable to measure the postdischarge services received by the control group.

RECRUITMENT AND RANDOMIZATION

Recruitment took place at Cooper University Hospital and Our Lady of Lourdes Hospital. Using the Camden Coalition Health Information Exchange database — which provided daily updates from hospital electronic medical records at these hospitals and the Virtua Health System and the Kennedy Health System (as of July 2014) — staff selected potentially eligible patients, who formed

the triaged population. A Coalition recruiter approached these patients in the hospital, confirmed their eligibility, obtained written informed consent, and conducted a baseline survey. The recruiter then used a tamper-proof and externally recorded randomization process to assign treatment or control status and informed the patient of the assignment. All patients who completed the baseline survey were compensated with \$20 for their time. Details regarding recruitment and randomization are available in the Supplementary Appendix.

The trial population was enrolled from June 2, 2014, through September 13, 2017. Of the 1520 patients triaged, recruiters deemed 1442 eligible for participation; 809 patients consented, and half were randomly assigned to treatment. Subsequently, 5 of the 809 patients were excluded at their request; the last 4 patients enrolled were excluded in order to reach the target trial population of 800 (Fig. 1).

DATA SOURCES

The primary data were hospital discharge data collected through March 31, 2018, from the four Camden hospital systems; these accounted for 98% of New Jersey hospital discharges of Camden residents (see the Supplementary Appendix). The discharge data contained admission and discharge dates, diagnoses, discharge destination, charges and payments received, and patients' identifying information.

We supplemented these data with data from several other sources. The Camden Coalition Health Information Exchange database contained additional demographic information and a record of the patient's index admission (where recruitment occurred). We matched 782 of the patients (98%) in the trial to the discharge record for their index admission; match rates were balanced between the treatment group (98.5%) and the control group (97.0%). The baseline survey provided additional socioeconomic information on patients. The Coalition recorded staff contacts with patients in the treatment group. Administrative data from the state of New Jersey provided information on social services received by trial participants (specifically, the Supplemental Nutrition Assistance Program, Temporary Assistance for Needy Families, and General Assistance), and the National Death Index provided mortality data. (See the Supplementary Appendix for additional details.)

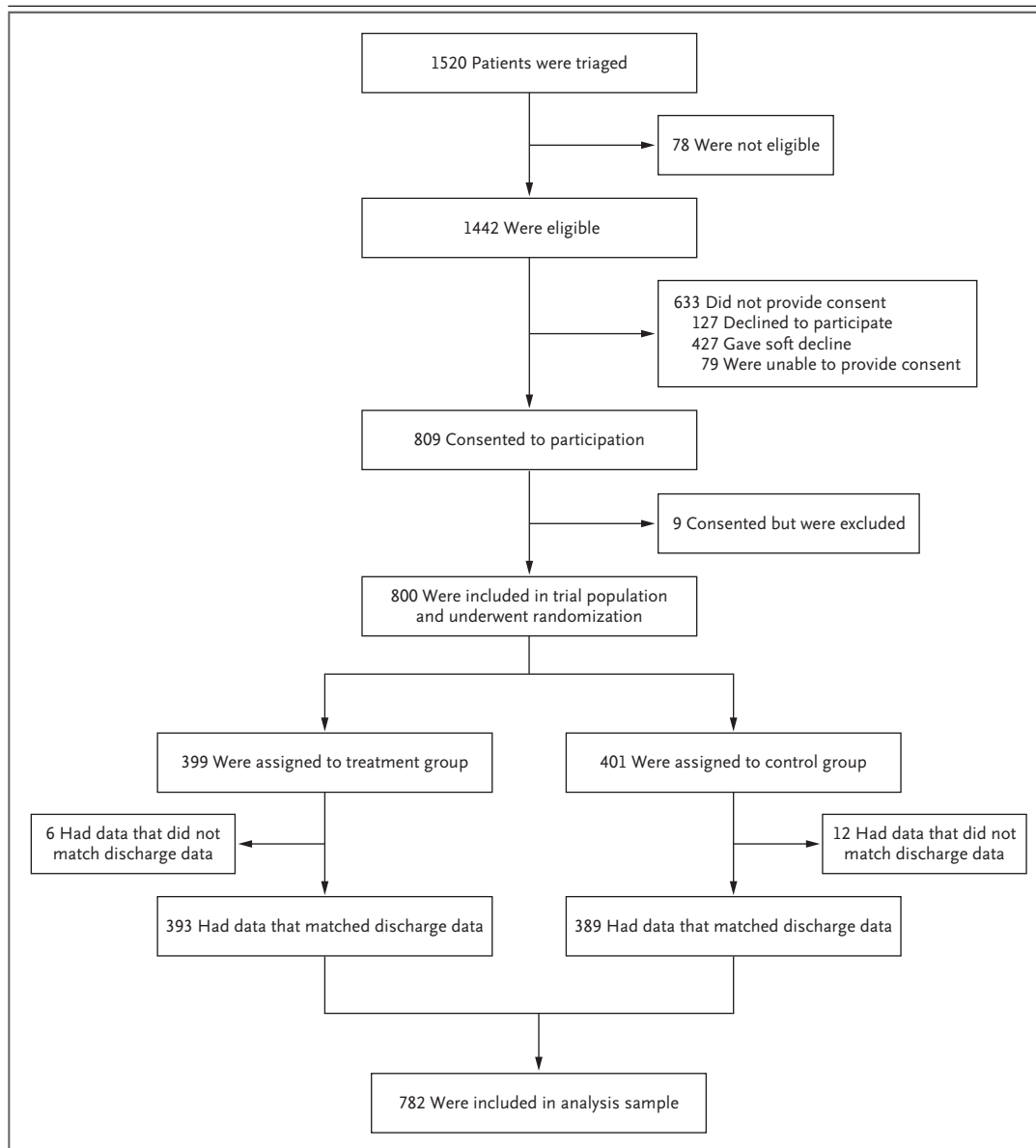


Figure 1. Screening, Randomization, and Analysis.

Data are from the Camden Coalition Health Information Exchange. Patients who declined to participate explicitly said “no” to the offer of randomization. Patients who gave a soft decline did not provide consent when approached but did not decline to participate and could be approached again during future hospitalizations if they were otherwise eligible. Patients who were unable to provide consent were either discharged or died before they could be reached or were unable to consent for reasons such as being asleep. Patients who consented but were excluded included 5 patients who consented and later asked to be removed from the trial and the last 4 patients enrolled in the trial who were excluded to keep the trial population at the target of 800 patients. For patients in the trial population to be included in the analysis sample, a record of their index admission had to have been found in the hospital discharge data. Further information is provided in the Supplementary Appendix.

OUTCOMES

The primary outcome was readmission within 180 days after hospital discharge. Secondary outcomes were the number of readmissions, the pro-

portion of patients with two or more readmissions, hospital days, charges, payments received, and mortality — all measured 180 days after discharge — as well as readmission rates at shorter

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Overall (N=782)	Treatment (N=393)	Control (N=389)
Age at index admission (%)			
≤44 yr	17.1	16.0	18.3
45–64 yr	55.4	55.0	55.8
≥65 yr	27.5	29.0	26.0
Race or ethnic group (%)			
Non-Hispanic black	54.9	57.8	51.9
Hispanic	29.5	26.7	32.4
Non-Hispanic white	15.1	14.8	15.4
Asian, multiracial, or other	0.5	0.8	0.3
Inpatient admissions before index admission (no.)			
0–6 mo before	1.75	1.72	1.78
7–12 mo before	0.74	0.74	0.75
Primary payer (%)			
Medicaid	44.6	43.0	46.3
Medicare	48.2	47.6	48.8
Other	7.0	9.2	4.9
Employment status (%)			
Currently employed	5.5	4.8	6.2
Not employed	94.0	94.9	93.1
No response	0.5	0.3	0.8
Mental health diagnoses at index admission (%)			
Depression	30.2	32.3	28.0
Substance abuse	44.0	41.2	46.8

* Data on age, number of admissions before the index admission, primary payer, and mental health diagnoses were obtained from hospital discharge data, and data on race, ethnic origin, and employment status were obtained from a survey conducted at baseline. The analysis sample (782 patients) excluded 18 patients with missing outcome data because they could not be matched to the discharge record for their index admission. Percentages may not sum to 100 because of rounding.

and longer time horizons. We also analyzed the primary outcome according to prespecified subgroups. With the exception of receipt of social services and mortality, all outcomes were based on hospital discharge data.

STATISTICAL ANALYSIS

We used linear regressions to compare outcomes for patients in the treatment and control groups. To increase precision, we included prespecified covariates for age (with patients grouped in 5-year increments), sex, indicators for non-Hispanic black

and Hispanic origin, and measures of health care utilization less than 6 months and 7 to 12 months before the index admission. We also report differences in means for patients in the treatment and control groups without adjustment for covariates. We conducted a sensitivity analysis with the use of multiple imputation to account for missing outcome data for 18 patients who could not be matched to the discharge record for their index admission.³³

Initially, we determined that a population of 800 would provide 80% power to detect a decrease of 9 percentage points in the 180-day readmission rate (at a two-sided significance level of 0.05). Subsequently, data from the actual study population — whose readmission rate was twice what we had assumed — indicated power to detect a decline of 9.6 percentage points in the primary outcome (see the Supplementary Appendix). There was no prespecified plan to adjust for multiple comparisons; therefore, we report P values only for the primary outcome and report 95% confidence intervals without P values for all secondary outcomes. The confidence intervals have not been adjusted for multiple comparisons, and inferences drawn from them may not be reproducible.

RESULTS

TRIAL POPULATION

The trial population averaged 1.8 hospital admissions in the 6 months before the index admission (Table 1) as compared with less than 0.1 admissions in the general adult Camden population (see the Supplementary Appendix). The trial population was 50% male; 40% were younger than 55 years of age and 30% were older than 65 years of age; 55% were non-Hispanic black, 30% were Hispanic, and 15% were non-Hispanic white. Our prespecified covariates were balanced between the treatment and control groups (Table S2).

Tables S1 and S2 in the Supplementary Appendix show that three quarters of the trial population were unmarried, one half did not have a high school diploma, and three fifths reported needing help with mobility. Nearly the entire population (95%) was not employed, and 40% received a diagnosis of substance abuse during the index admission. Medicare was the primary payer for 48% of the trial population, and Medicaid was the primary payer for 45% of the population.

PROGRAM IMPLEMENTATION

Table 2 shows measures of program implementation. Among patients in the treatment group, 95% had at least three encounters with program staff after enrollment; on average, a patient received 7.6 home visits and 8.8 telephone calls from staff and was accompanied on 2.5 physician visits, and 90% worked with the Coalition for more than 30 days. The median duration of program participation was 92 days. The Coalition set ambitious goals for connecting patients to care quickly after discharge.³⁴ These goals included a home visit from program staff within 5 days after a patient's arrival at home and a provider visit within 7 days after arrival at home; the first goal was met for 60% of patients, the second goal was met for 36% of patients, and both goals were met for 28% of patients. Three quarters of the patients received both a home visit within 14 days and a provider visit within 60 days.

Receipt of government benefits during the 6 months after discharge was the one metric of program implementation observed in both the treatment and control groups (Table 3). Rates of participation in both Temporary Assistance for Needy Families and General Assistance were low and did not significantly change with the intervention; the adjusted difference in participation in the Supplemental Nutrition Assistance Program associated with the intervention was 4.6 percentage points (95% confidence interval [CI], 0.5 to 8.6).

EFFECTS OF THE INTERVENTION

Table 4 shows the effects of the intervention. The 180-day readmission rate was 62.3% in the treatment group and 61.7% in the control group. The intervention had no significant effect on this primary outcome: the adjusted difference in the probability of readmission was 0.82 percentage points higher in the treatment group than in the control group (95% CI, -5.97 to 7.61; $P=0.81$). This finding is robust to the use of multiple imputation to account for missing data (adjusted difference, 0.64 percentage points; 95% CI, -6.12 to 7.40) (see Table S6 for details). The intervention also had no effect on any of the secondary outcomes or within any of the prespecified subgroups (Table 4).

Results for the primary outcome were not sensitive to alternative specifications or measurement over alternative horizons. The intervention had no significant effects when the hazard rate

Table 2. Program Metrics in the Treatment Group.*

Metric	Values
Encounters	
Home visits — mean no. (median)	7.6 (5)
At least one — %	88.8
At least three — %	70.7
Telephone calls — mean no. (median)	8.8 (5)
At least one — %	88.0
At least three — %	65.4
Primary care provider and specialist visits — mean no. (median)	2.5 (2)
At least one — %	84.7
At least three — %	29.5
Other types of visits — mean no. (median)	5.7 (1)
At least one — %	65.1
At least three — %	36.1
Total no. of encounters — mean no. (median)	28.1 (17)
At least one — %	98.7
At least three — %	95.2
Length of intervention, measured from discharge home — %	
>30 days	89.8
>90 days	50.5
>180 days	17.0
Median — days	91.5
Timing of service provided, measured from day of discharge home — %	
Camden Coalition home visit	
Within 5 days	58.6
Within 14 days	83.0
Office visit with PCP or specialist	
Within 7 days	36.0
Within 14 days	60.2
Within 60 days	83.3
Both home visit within 5 days and office visit with PCP or specialist within 7 days	28.0
Both home visit within 14 days and office visit with PCP or specialist within 60 days	76.1

* Data on program metrics are from the records of the Camden Coalition of Health Care Providers and the 393 patients in the treatment group. Data on timing of services are missing for 4 patients, and data on length of intervention are missing for 11 patients.

of readmission (with either a Cox proportional-hazards model or a competing-risks model accounting for mortality), 180-day mortality, or post hoc subgroups were analyzed; results differed slightly according to hospital of index admission,

Table 3. Benefit Participation during 6 Months after Enrollment.*

Metric	Control Group (N=389)	Treatment Group (N = 393)	Unadjusted Difference (95% CI)	Adjusted Difference (95% CI)
	<i>percent</i>			
Participation in supplemental nutrition assistance program	50.13	58.52	8.4 (1.43 to 15.36)	4.59 (0.52 to 8.65)
Receipt of temporary assistance for needy families	1.03	1.78	0.75 (−0.9 to 2.4)	0.69 (−0.34 to 1.71)
Receipt of general assistance	6.94	6.87	−0.07 (−3.63 to 3.49)	0.68 (−1.82 to 3.18)

* Data on benefit participation are from the New Jersey Department of Human Services and consist of the analysis sample (782 patients). Shown are the mean values for each outcome in the control group and the treatment group. Calculation of the unadjusted between-group difference was based on an indicator for the treatment group from an ordinary least-squares regression of the outcome, with no other covariates. Calculation of the adjusted between-group difference was based on an indicator for the treatment group from an ordinary least-squares regression of the outcome with pre-specified covariates. All confidence intervals (CIs) were calculated with the use of heteroskedasticity-robust standard errors. Prespecified covariates included the dependent variable 0 to 6 months before the index admission, the dependent variable 7 to 12 months before the index admission, and indicators for age (grouped in 5-year increments), male sex, black non-Hispanic origin, and Hispanic origin. Measurement of covariates was based on hospital discharge data except for the characteristic of race or ethnic origin, which was reported from data in the baseline survey.

but the estimates were quite imprecise (Tables S6 and S8 and Fig. S5).

BEFORE AND AFTER ANALYSIS OF THE INTERVENTION GROUP

In contrast with the results of the randomized, controlled trial, a comparison of admission rates for the intervention group alone in the 6 months before and after enrollment misleadingly suggested a substantial decline in admissions in response to the intervention because it did not account for the similar decline in the control group. Figure 2 shows the average number of admissions per quarter before and after the index admission. In both the intervention and control groups, admissions rose sharply in the 6 months before the intervention and fell rapidly afterward.

In addition, estimates of the change in hospital admissions before and after the intervention that were based only on the intervention group were very sensitive to the definition of the period before the intervention. There was a 38-percentage-point decrease in the probability of a hospital admission during the 6 months after the intervention as compared with the 6 months preceding the intervention, but there was a 29-percentage-point increase in the probability of a hospital admission in the 6-month period after the intervention as compared with the 12-to-18-month period that preceded the intervention (Table S5).

DISCUSSION

In this randomized evaluation involving 800 trial participants, the Camden Core Model had no significant effect on participants' 180-day readmission rate. The 95% confidence intervals rule out a decrease in readmission rates of more than 6 percentage points as compared with a control mean of 62%; this finding rules out the reductions in readmissions of 15 to 45% in the Medicare population reported in randomized evaluations of other care-transition programs.²⁴⁻²⁹ The Camden model targets a different population: one that was younger, with more diverse medical needs, greater social complexity, and much higher health care utilization; previous hospital use was nearly twice that in most previous successful programs involving care transition.

Our results suggest that there are challenges for superutilizer programs aimed at medically and socially complex populations. They are consistent with the mixed results on hospital admissions from randomized evaluations of care-management programs for chronically ill populations, although those programs, unlike the Camden model, did not focus on the postdischarge transition.^{35,36,37} It is possible that approaches to care management that are designed to connect patients with existing resources are insufficient for these complex cases. The Coalition has continually worked to adapt the model to the needs of

Table 4. Effects of Intervention in the Treatment Group, 180 Days after Discharge.*

Effect	No. of Patients	Control Group	Treatment Group	Unadjusted Between-Group Difference (95% CI)	Adjusted Between-Group Difference (95% CI)
<i>mean</i>					
Readmission in total sample					
Any (%)		61.70	62.34	0.64 (−6.17 to 7.46)	0.82 (−5.97 to 7.61)
No. of readmissions		1.54	1.52	−0.02 (−0.29 to 0.26)	0.01 (−0.25 to 0.27)
≥2 readmissions (%)		36.25	36.39	0.14 (−6.61 to 6.89)	0.27 (−6.22 to 6.77)
Days in hospital		9.95	9.36	−0.59 (−2.49 to 1.31)	−0.32 (−2.17 to 1.53)
Hospital charges (\$)		114,768	116,422	1,654 (−25,523 to 28,831)	3,722 (−23,438 to 30,882)
Hospital payments received (\$)		17,650	18,130	480 (−3,613 to 4,573)	680 (−3,415 to 4,775)
Any readmission according to subgroup (%)					
No. of admissions in previous yr					
2	336	52.12	52.63	0.51 (−10.2 to 11.22)	0.78 (−10.35 to 11.91)
≥3	446	68.75	69.82	1.07 (−7.51 to 9.65)	1.27 (−7.38 to 9.92)
Preferred language					
English	638	63.11	62.61	−0.49 (−8.01 to 7.02)	0.1 (−7.42 to 7.61)
Other	144	56.25	60.94	4.69 (−11.58 to 20.96)	8.49 (−9.08 to 26.06)

* Data consist of the analysis sample (a total of 782 patients), and outcomes are measured with the use of hospital discharge data. For the unadjusted difference, the coefficient and 95% confidence interval are shown on the basis of an indicator for treatment group from an ordinary least-squares regression of the outcome, with no other covariates. For the adjusted difference, the coefficient and the 95% confidence interval are shown on the basis of an indicator for treatment group from an ordinary least-squares regression of the outcome, with prespecified covariates. All confidence intervals were calculated with the use of heteroskedasticity-robust standard errors. Prespecified covariates include the number of admissions less than 6 months before the index admission, the number of admissions 7 through 12 months before the index admission, and indicators for age (grouped in 5-year increments), male sex, black non-Hispanic origin, and Hispanic origin. With the exception of race and ethnic origin, for which data was obtained from the baseline survey, covariates were measured on the basis of hospital discharge data. For three of the outcomes (days in hospital, hospital charges, and hospital payments received), the number of admissions from 0 to 6 months before the index admission and from 7 to 12 months before the index admission were replaced with the values of the dependent variable over those two time periods. The P value for the primary outcome (any readmission) for the adjusted difference was 0.81.

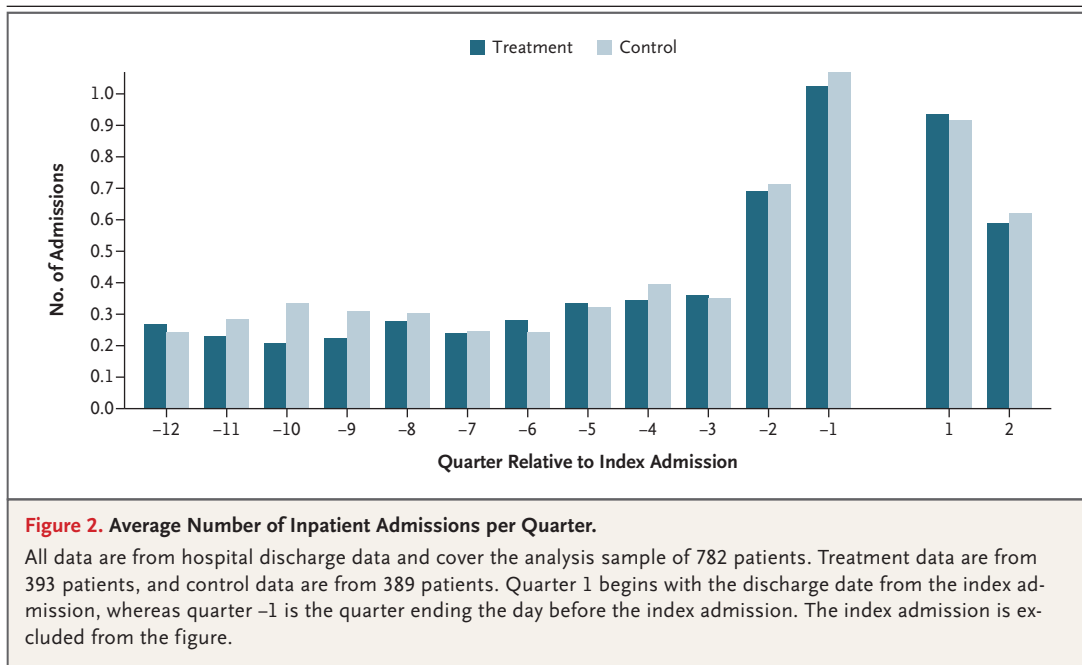
its patient population, and both the Coalition and others are exploring models that involve more complete redesigns of care provision.^{6,38} (See also Comprehensive Care Physician: Integrated Inpatient and Outpatient Care for Patients at High Risk of Hospitalization [ClinicalTrials.gov number, NCT01929005].)

Engagement with the program was high (95% of patients had at least three encounters with program staff), and patients received an intensive intervention (averaging 7.6 home visits), but two program goals related to the timing of services — a home visit within 5 days after hospital discharge and a visit to a provider's office within 7 days after discharge — were achieved less than 30% of the time. Challenges in reaching these goals included patients' lack of stable housing or

a telephone and their behavioral health complexities and providers' few available appointments. The difficulties that this pioneering, data-driven organization had in achieving rapid assistance for patients may portend difficulties in achieving it at scale.

Our findings may also reflect fundamental challenges with the strategy of targeting super-utilizers: many patients whose medical costs are high today will not be as high in the future — and this trend becomes even more pronounced as one goes higher in the cost distribution.^{22,39,40} Moreover, for patients with medical costs that are persistently high, few of those costs may be related to potentially preventable hospitalizations.³⁹⁻⁴¹

Such regression to the mean also underscores the importance of rigorous evaluation through



randomized trials, since observational evaluations of superutilizer programs will be prone to the detection of spurious effects.^{18,22,23} This danger was illustrated in our program by the similar reduction in readmissions in both the treatment and control groups.

Our trial has several limitations. It was powered to detect whether this care-transition program could achieve reductions in readmissions as compared with similar programs focused on patients with less complex health care needs. However, the trial was not powered to detect smaller reductions that could be clinically meaningful, nor was it powered to analyze effects within specific subgroups, where there could be differential effects. The data did not permit evaluation of potential nontangible benefits such as improved relationships with providers.⁴² Nor did the data allow comparison of outpatient care for the treatment and control groups. Usual care in Camden was evolving during the trial period, multiple other care-management programs were starting,⁴³⁻⁴⁶ and the Coalition was leading a city-wide campaign to connect patients with primary care within 7 days after hospital discharge.⁴⁷

Despite these limitations, the trial provides rigorous evidence of the effect of a nationally recognized program aimed at superutilizers of the health care system that has been expanded to

other cities. The results suggest both the challenges of reducing readmissions in a medically and socially complex superutilizer population and the importance of conducting randomized evaluation of interventions such as this one, which, because they target high-cost patients, are likely to show substantial regression to the mean in observational studies.

The findings and conclusions expressed are solely those of the authors and do not represent the views of their funders.

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A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

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