Diabetes Care Management Teams Did Not Reduce Utilization When Compared With Traditional Care: A Randomized Cluster Trial

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ABSTRACT

Purpose: Health services research evaluates redesign models for primary care. Care management is one alternative. Evaluation includes resource utilization as a criterion. Compare the impact of care-manager teams on resource utilization. The comparison includes entire panels of patients and the subset of patients with diabetes.

Design: Randomized, prospective, cohort study comparing change in utilization rates between groups, pre- and post-intervention.

Methodology: Ten primary care physician panels in a safety-net setting. Ten physicians were randomized to either a care-management approach (Group 1) or a traditional approach (Group 2). Care managers focused on diabetes and the cardiovascular cluster of diseases.

Analysis compared rates of hospitalization, 30-day readmission, emergency room visits, and urgent care visits. Analysis compared baseline rates to annual rates after a yearlong run-in for entire panels and the subset of patients with diabetes.

Results: Resource utilization showed no statistically significant change between baseline and Year 3 (P=.79). Emergency room visits and hospital readmission increased for both groups (P=.90), while hospital admissions and urgent care visits decreased (P=.73). Similarly, utilization was not significantly different for patients with diabetes (P=.69).

Conclusions: A care-management team approach failed to improve resource utilization rates by entire panels and the subset of diabetic patients compared to traditional care. This reinforces the need for further evidentiary support for the care-management model's hypothesis in the safety net.

Key words: Primary care redesign; managed care; patient-centered care; randomized trial; utilization

INTRODUCTION

Health care redesign identifies new approaches for treating chronic disease to improve outcomes, increase satisfaction, and lower resource utilization (RU) (Berwick 1996). To deliver these improvements, policy makers propose systematic changes to traditional primary care delivery, including institutional disease management, case management, care management (CM), the chronic care model (CCM), guided care, transitional care, personalized care, and the patient-centered medical home (PCMH). Some elements included in these models have been enumerated (Wagner 1998, Boult 2008, Coleman 2006, Coulter 2015, Berenson 2008, Stellefson 2013). They include: 1) registries and information systems, 2) self-management support, 3) decision support, 4) care managers in multidisciplinary teams (CMT), 5) delivery-system redesign, and 6) change in community resources and public policy. Researchers have used randomized controlled trials (RCTs), quasi-randomized studies, and cohort studies to evaluate implementation of specific elements of these models (Peters 1995, Davidson 2007, Shojania 2006). Reviews and policy statements based on these elements propose that deployment of some of these models will lead to quality and utilization benefits (Weingarten 2002). The American College of Physicians website promotes implementation of the CCM (Allweiss 2015) and a PCMH (ACP 2016). A large portion of literature on transforming the delivery of care stresses how these models will improve the care of people with chronic illnesses, and PCMHs have been promoted as benefiting all patients. However, the paucity of high-quality evidence (Shojania 2006, Stokes 2015, Hussey 2009, Kolbasovsky 2011, Solberg 2007) substantiating success in lowering cost, decreasing RU, increasing access, and improving satisfaction and quality should give those eager to implement these models some pause. A review by Jackson (2013) cited several factors needed to create a valid body of literature.

Results of rigorous studies of CMT and elements of that model have shown improved process without showing benefits in clinical outcomes, RU, or costs (Norris 2001, Loveman 2003, Goldman 2014). The large-scale comparison in the Health Disparities Collaboratives demonstrated improved process measures for only two of three disease states within safety-net institutions. No improvement in clinical outcomes, RU, or costs was demonstrated (Landon 2007).

Optimism for the various CM templates stemmed from early studies (Davidson 2007, Wagner 2001, Diabetes 1993). In a 12-month RCT, Aubert showed a statistically significant reduction in HbA_{1c} for patients managed by a CMT versus those receiving standard care (1.7 vs. 0.6 percentage points, P=.001) but did not find reductions in hospital admissions, patient satisfaction, or RU (Aubert 1998). Norris et al. (2001) reviewed 72 studies and found no economic effect. They concluded that external generalization of results for self-management was limited with respect to quality improvement and RU. Typically, evaluations of successful PCMH programs are reports of case-controlled designs (Higgins 2014). In a 15-center Medicare review of care coordination studies, Peikes (2009) reported no benefit in cost or RU with CM and CMT. In a meta-analysis, Stokes (2015) stated, "Current results do not support case management as an effective model, especially concerning reduction of secondary care use or total costs."

Evaluation of the effect of CM is vulnerable to negative and positive spillover effects. This is due to the statistical aberration of clustering. In safety-net institutions, an additional source of misinterpretation is due to diversion of fixed resources to benefit an intervention group while depriving control and nonstudy patients.

This study looks at RU during reorganization of traditional primary care physician (PCP) practices. It compares RU by patients with diabetes who were care managed with those managed traditionally. Additional outcomes include comparison of RU for all patients in these physicians' panels to identify "unintended consequences" as suggested by Jackson (2013). Comparisons required a cluster adjustment, which was also suggested by Jackson. Results reflect overall RU by the panels.

METHODS

Subjects and setting

The study was a prospective RCT in a safety-net institution. The institutional review board (IRB) approved this study as a quality-improvement program based on the planned implementation of an organizational care delivery change. The IRB approved the consent for physicians participating in the study. There were no adjustments to the study protocol during the entirety of the study.

A query of a registry with 16,824 diabetic patients identified 18 PCPs, each caring for >300 patients with diabetes working in one Federally Qualified Health Center. These physicians were included as potential subjects if they were board-certified in internal medicine, practiced at the study site for more than five years, and were willing to participate as members of Group 1 or Group 2 (Figure). The IRB approved a cluster randomization scheme that randomized each PCP by a study coordinator using a computer-generated, random-number scheme in an opaque sealed envelope. After consent was obtained, a blinded study coordinator opened the envelope. The study's principal investigator consented and randomized 12 PCPs to Group 1 or Group 2 depicted in the Figure. The intervention group, Group 1, consisted of 5 PCPs assigned CMTs. The control group, Group 2, consisted of 5 PCPs that continued with traditional care. Each group had one alternate physician randomized in case a physician left similar to the way juries have alternate jurors.

Patients

A system-wide electronic Health Information System (HIS; Invision, Siemens, Malvern, Pa.) maintained a list of all patients with their assigned PCP. Patients diagnosed with diabetes by their PCP had been entered into a proprietary registry (DM, FileMaker Pro v. 6.0) either upon referral for diabetes education or abstraction from a one-time query of the HIS (ICD-9 codes 249.**, 250.**, 357, 362.0*, 366.4, 648.0*). A patient's relationship with a specific PCP determined the patient's group assignment. Prior to and during the baseline year of the study, the PCPs established the approach to diabetes care guided management.

The study lasted three years. Patients maintained their initial group assignment for the duration of the study and for analysis. Patients in both groups had an opportunity to attend a series of standardized self-management educational sessions (Norris 2001) discussing monitoring of blood sugar, adjusting lifestyle and medication based on test results, diet, exercise, and coping with chronic conditions and complications.

Group 1 and D-CMT

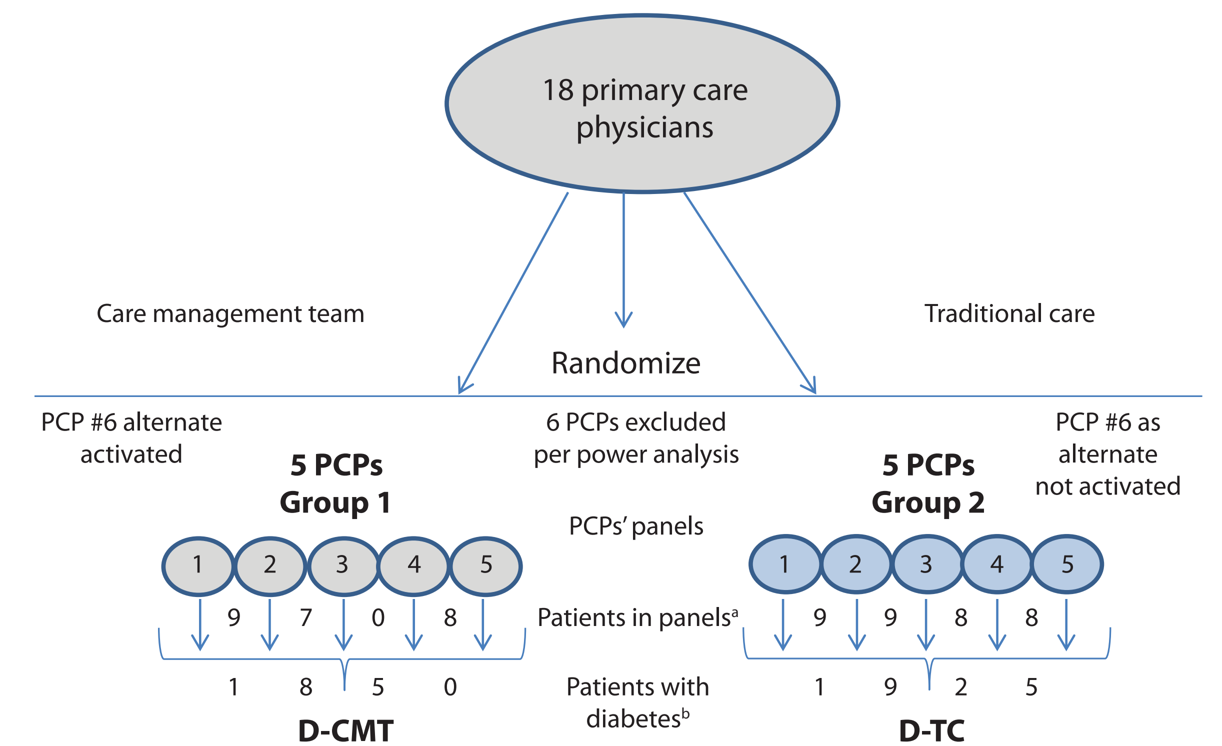
CMTs were formed as part of an operational change of the daily routine of care delivery (Solberg 2007). Three certified diabetic educators (CDEs) from the Diabetes & Metabolism clinic were reassigned to a Group 1 PCP to join a care-manager team (D-CMT). To be assigned, the CDE met specific criteria: 1) a current RN or PharmD license; 2) certification as a diabetes educator; and 3) passing an internal examination certifying familiarity with the protocols for medication adjustment, aspirin use, statin initiation, blood pressure treatment, microalbuminuria screening, and management. A medical assistant (MA) was assigned to worked exclusively with the D-CMT. The team thus consisted of a Group 1 physician, a care manager, and the MA.

D-CMT members assumed extended roles. The PCP authorized the D-CMT to use all the management protocols for their patients with diabetes. D-CMTs implemented elements of the CCM program with emphasis on information technology, patient self-management, practice reorganization, and protocol-driven management. Patients were encouraged to call their PCP first, 24/7, for new problems or questions. The D-CMT worked with coaches from the MacColl Institute for practice facilitation during the study (Coleman 2009). D-CMT met routinely to discuss patients failing to achieve a clinical goal according to regular registry reports. The PCP provided backup for exceptions falling outside the guidelines. Patients agreed to contact by D-CMT to receive recommendations for management of medication and testing. The registry automatically generated reminders, results, and alerts. Medication adjustments followed protocols. D-CMT scheduled patients for follow-up after admission to a hospital, emergency department (ED), or urgent care (UC). The PCPs managed their remaining paneled patients with the assistance of regular clinic staff.

Group 2 and D-TC

The traditional care (D-TC) followed routines, guidelines (ADA 2005), and protocols developed by practice consensus over 10 years with individual variations. Groups 1 and 2 had information systems with read-only access available for demographic information, clinical laboratory, diagnostic radiology, a separate picture archiving system, and access to guidelines and protocols, all through a nonintegrated clinical IT system. The system did not have registry functionality. Although Group 2 shared in the continuing medical education programs presenting the CCM model, there was no proactive effort to provide access to a registry or point of care access to guidelines or to initiate a redistribution of tasks according to skill level, training, aptitude, and interest among staff. A head nurse managed the practice of the 18 physicians. An assistant head nurse worked with 8–10 physicians and was assisted by MAs whose assignment to specific physicians varied through the week.

Group 2 practiced in the same clinic as Group 1. Group 2 physicians



FIGURE

Schematic of study organization

Random selection of 10 participants from among 18 potential physicians

[a]Cumulative number of patients in the respective panels

[b]Total number of diabetic patients in each arm

D-CMT=diabetes care management teams, D-TC=diabetes traditional care worked without a team structure. CDEs reported to a remote Diabetes & Metabolism clinic and provided consultation and self-management educational sessions on an ad hoc basis (Norris 2001). Eight CDEs shared an MA and had no access to the registry. Group 2 received ad hoc laboratory and radiological results per that PCP's routine practice.

Protocols

The divisions of endocrinology and primary care wrote management guidelines and protocols for diabetes and the cardiovascular cluster of diseases. The pharmacy and therapeutics

TABLE 1
Baseline characteristics of Groups 1 and 2

	Group 1	Group 2
N	9,708	9,988
Age, years	55.2 ± 14.9	54.2 ± 15.0
Gender female (male), %	53 (47)	51 (49)
Language, %		
English	74.5	73.6
Spanish	11.3	13.5
Vietnamese	3.4	2.7
Other	10.8	10.2
Financial class, %		
Managed care	61.2	61.2
Medicare	8.5	8.3
FQHC	26.7	26.3
Other	3.6	4.2
Marital status, %		
Single	37.2	37.2
Married	28.8	28.4
Other	25.1	25.3
Divorced	8.9	9.1
RU by panel		
Hospital admission rate (CI), %/yr	12.1 (9.1, 15.1)	11.9 (10.9, 12.9)
Hospital LOS (CI), mean days	3.7 (3.69, 3.71)	3.79 (3.78, 3.80)
Readmission rate (CI), %/yr	15.5 (12.4, 18.6)	14.8 (11.8, 17.8)
Emergency room visits (CI), %/yr	13.3 (10.2, 16.4)	13.4 (13.3, 16.5)
Urgent care visits (CI) , %/yr	15.1 (11.1, 19.1)	12.7 (8.7, 16.7)
	D-CMT	**D-TC**
RU by patients with diabetes, % panel)	18.4	19.7
HbA_{1c}, mean (CI); mmol/mol (SD)	7.8 (7.7, 7.9); 62 (9)	7.7 (7.6, 7.7); 61 (6)
Hospital admission rate (CI), %/yr	10.1 (9.2, 11.0)	10.6 (9.6, 11.5)
Hospital LOS (CI), mean days	3.7 (3.6, 3.7)	3.8 (3.7, 3.8)
Readmission rate (CI), %/yr	21.0 (19.6, 21.9)	20.0 (18.7, 21.1)
Emergency room visits (CI), %/yr	22.3 (20.2, 24.2)	22.9 (21.0, 24.8)
Urgent care visits (CI), %/yr	22.2 (19.9, 24.5)	17.9 (15.6, 20.2)

CI=95% confidence interval, D-CMT=diabetes care management team, D-TC=diabetes traditional care, LOS=length of stay, RU=resource utilization

TABLE 2
Change in visit rates for both groups

Site	Group 1	Group 2	*P* value
Panel size, n	9,708	9,988	
Urgent care visits (CI), % per year	−2.5 (−2.1, −2.9)	−1.7 (−1.3, −2.1)	.73
Emergency room visits (CI), % per year	3.8 (3.5, 4.1)	3.6 (3.3, 3.9)	.90
Hospital admissions (CI), % per year	−1.4 (−3.3, 0.5)	−1.9 (−3.9, 0.0)	.28
Readmission rate (CI), % per year	7.5 (4.4, 10.5)	3.7 (1.5, 5.8)	.31

Percent change in visits to the respective clinical site. A positive number indicates an increase in visits from baseline to Year 3.

committee approved the protocols before implementation. The protocols conformed to national guidelines with annual updates (ADA 2005).

Registry

A mature database (DM, FileMaker Pro, v. 6.0) was available to the D-CMT. The registry included robust query capabilities with algorithms that identified individuals failing to reach goals and in need of management (Peterson 2008). The registry produced lists of patients for D-CMT with clinical details. The D-CMT contacted patients based on these reports. The number of tests performed divided by the number recommended by guidelines determined compliance. Lists identified patients requiring additional assistance in accomplishing their self-management goals. Lists included notification of a patient's admission to the hospital and a monthly update on visits to the ED and UC. D-TC received no reports.

Outcomes and statistical analysis

The primary outcome was the change in RU rates between the two groups during the baseline and Year 3 of the study. RU included panel rates of admissions to the hospital, ED, and UC. An assumed 2% absolute reduction in urgent care visits would be meaningful with an observed UC visit rate of 13 visits per 100 patients per year. An 80% likelihood of detecting a change at the $P<.05$ level required 9,000 paneled patients and 300 diabetic patients per group. Based on historical data, 5 PCPs in each group would achieve this power. After randomizing 12 PCPs, the last two PCPs were designated alternates. The study excluded the remaining six PCP panels.

Effects were calculated using prespecified criteria. Intention-to-treat design included the entire panel of patients in Groups 1 and 2 as well as the subset of patients in the diabetes registry within those panels (D-CMT, D-TC). Statistical comparisons used standard statistical software for Student's t-tests for continuous variables and a chi square for dichotomous values. An intracluster level adjustment used a rho, ρ, value of 0.01 with 10 clusters (Killip 2004). The unit of measure for RU is a rate of visits to a resource annually.

Extended stays due to socioeconomic factors and regional cost idiosyncrasies precluded the usefulness of cost data. Readmission rates were determined for patients readmitted within 30 days of a discharge for any cause. Significance is reported by confidence intervals or $P<.05$.

RESULTS

For the entire group of PCPs, the average practice experience was 14 years (median 13 years) at the same clinic. The average age was 40, and median, 35. Group 1 had two male PCPs and three female PCPs and Group 2 had three male PCPs and two female PCPs, with all boarded in internal medicine. The 10 physicians randomized to Groups 1 and 2 had combined panels of 9,708 and 9,988 patients respectively (Table 1). The panels averaged 1,969 (Group 1=1,941; Group 2=1,998) patients. Baseline characteristics of the patients were similar (Table 1). D-CMT averaged 370 patients with diabetes while D-TC averaged 385 patients.

Panel results

Both Groups 1 and 2 had a decrease in UC visits from Year 1 to Year 3 (Table 2). The within-group decrease was not significantly different for either group (−2.5% [−2.1, −2.9%], −1.7% [−1.3, −2.1%]) (mean ± CI) Groups 1 and 2, respectively (P=.73).

Groups 1 and 2 increased ER utilization, with visits rising by 3.8% (3.5, 4.1%) and 3.6% (3.3, 3.9%), respectively (Table 2). The within-group increase was not statistically significant (P=.11). Combining the UC and ER visits for the respective groups represents the total number of unanticipated visits. The groups had baseline combined ER and UC visit rates of 28.4 and 26.2 visits per 100 patient-years, respectively (P=.61). The combined encounters of Group 1 increased 1.3 visits per 100 patient-years, compared with an increase of 1.9 visits per 100 patient-years for Group 2. The number of visits per 100 patient-years for UC (P=.71) and ER (P=.87) and the combined totals (P=.86) did not differ significantly.

The change in admission rates between baseline and Year 3 for Groups

1 and 2 was similar. Within-group changes in hospital admissions for both groups was an insignificant decrease between baseline and Year 3 (P=.63). This decrease was not statistically significantly different in comparing the 2 groups (Table 2). By Year 3, the length of stay had increased by 1.1 (0.7, 1.5) days for Group 1 and 0.6 (0.5, 0.7) day for Group 2. Group 1 stayed 4.8 (4.7, 4.9) days, with Group 2 staying 4.4 (4.3, 4.5) days (P=.01).

The readmission rate for Groups 1 and 2 increased. The readmission rate did not differ within groups. The difference between the two groups was likewise not statistically significant (P=.79) (Table 2).

D-CMT and D-TC results

The D-CMT group had similar reductions in UC visits to D-TC (Table 3). By contrast, ER visits had a similar increase for both D-CMT and D-TC (Table 3). Admissions to the hospital decreased for D-CMT, with an insignificant difference compared to the reduction seen for D-TC (Table 3). There was a greater than twofold increase in the readmission rate for D-CMT, but this difference was not statistically significant compared with that of D-TC (Table 3). Combining all visits to these sites, there was no statistical difference between the two groups. (P=.69)

TABLE 3
Change in rate of visits for subset of patients with diabetes

Site	Diabetes care management team	Diabetes traditional care	*P* value
Panel size, n	1,850	1,925	
Urgent care visits (CI), % per year	−2.5 (−4.8, −0.2)	−3.0 (−5.3, −0.7)	.54
Emergency room visits (CI), % per year	4.0 (3.1, 4.9)	4.1 (3.2, 5.0)	.48
Hospital admissions (CI), % per year	−1.8 (−5.8 , 2.2)	−1.1 (−4.2, 1.9)	.22
Readmission rate (CI), % per year	5.7 (3.4, 8.0)	2.4 (0.1, 4.7)	.09

Percent change in the rate of visits to the respective clinical site for patients with diabetes.

DISCUSSION

Studies have shown that implementation of a CM model may improve process measures and have variable improvement in intermediate outcomes for patients receiving the intervention (Davidson 2007, Chin 2007). According to several sources (Stokes 2015, Hussey 2009, Kolbasovsky 2011, Holtz-Eakin 2004, Jackson 2013), insufficient evidence exists showing that CM programs reduce overall spending, reduce RU, or improve clinical outcomes. In addition, the body of literature supporting CM has yet to identify essential elements for an effective program (Wasson 2017). Finally, studies evaluating CM ignore the concept of externality (Jackson 2013). In medicine, these are the "unintended consequences." These include consequences affecting nonstudy and control individuals when attention and resources divert to study patients.

This study of a broad comparison of the effects of CM and TC in a large practice includes a simultaneous analysis of effects on the subset of patients with diabetes. This study showed comparable changes in RU for Groups 1 and 2 as well as equivalent changes occurring in RU for D-CMT and D-TC.

This study contributes a randomized evaluation of RU between primary care models across entire panels in an integrated safety net institution. In addition, it demonstrates equivalent RU among diabetic patients actively care managed with appropriate statistical adjustments for cluster randomization.

Failure to demonstrate a benefit is not proof that CM cannot influence RU. As pointed out by Wasson, the typical approach to PCMH and CM is to regulate process and measure compliance. Perhaps this approach misses the essence and value of clinical care, which is doing "what matters to patients" (Wasson 2017). As Rothman (2005) demonstrated, using a similar design, improvement in HbA_{1c} can be observed despite a lack of improvement in RU. Boult's "guided care" approach (Sylvia 2008) relies on

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ClinicalTrials.gov Identifier:
NCT00838825; https://clinicaltrials.gov/ct2/show/NCT00838825

Acknowledgments: The author thanks Jeffry Young, MD, Stanford School of Medicine, Division of Nephrology, for reviewing the manuscript and contributing to the discussion.

Funding: Santa Clara Valley Medical Center's Quality Improvement budget provided funding for the study.

Conflict of interest and data integrity: The author generated the hypothesis, collected and maintained the data, performed the research and analysis, and wrote the manuscript. The author has no conflict of interest in performing the study or publishing the results.

CMT across heterogeneous panels. In this population, preliminary reports, as with other studies noted, were not statistically significant and these findings remain unsubstantiated by independent evaluation. Further rigorous investigations are required.

Without an evidentiary foundation for improved access, quality, or reduced RU, support for the CM hypothesis relies on improvement of process measures and potential benefit to intermediate and surrogate outcomes (Davidson 2007, Norris 2001, Landon 2007, Aubert 1998, Higgins 2014, Peikes 2009, Holtz-Eakin 2004). Even the studies of CM reporting intermediate and clinical outcomes have varying results in different care venues (Weingarten 2002, Diabetes 1993, Rothman 2005, Sylvia 2008, Steiner 2008, Homer 2005).

In order for redesign studies to support generalization of their findings, methodology should include a randomized, controlled study design with intention-to-treat analysis. When randomization employs physician practices, statistical methods require defined adjustments (Killip 2004). Before implementing a reorganization of the national primary care system, policy makers should require evidence levels I and II in demonstrating benefit with minimal adverse effects to access, quality, cost, resource utilization, and satisfaction of patients and providers (Asch 2005, Hayward 2007). An additional goal for future studies will identify the model's elements essential to delivering benefits in the associated care settings (Kahn 2015).

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