

The Effectiveness of Diabetes Care Management in Managed Care

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The chronic care model highlights delivery system design as a key element in providing quality care to patients with chronic illness.¹ One system design innovation that has taken hold in the past decade is the use of nonphysician care managers for selected patients with chronic illnesses such as diabetes mellitus. Clinical trials have examined the effect of care management (CM) programs^{2,3} (often led by nurses) on diabetes care quality and outcomes. Most have found positive associations between CM interventions and improved process measures (such as glycosylated hemoglobin [A1C] level testing rates) and patient satisfaction.^{2,4-7} It is controversial whether CM improves critical outcomes such as blood pressure and glycemic and lipid control.^{2,4,6,8-14} A recent effectiveness evaluation of CM found no association between the intensity of CM use and A1C level, blood pressure, or low-density lipoprotein cholesterol (LDL-C) level in the diabetic populations of 10 health plans and 71 provider groups.¹⁵

Almost all evaluations of CM to date have been randomized controlled trials.^{8,12,16,17} There have been few studies of how nurse CM programs and protocols from these trials translate into everyday care delivery settings¹⁸ or how they affect patient outcomes after implementation on a wide scale. Chronic condition CM usually is designed to target a small segment of higher-risk patients; however, there is little published information on the extent to which CM programs appropriately succeed in reaching their intended population.

Kaiser Permanente Northern California (KPNC) implemented a large-scale primarily nurse-led diabetes CM program beginning in 1999. More than 150 diabetes nurse care managers offered intensive counseling on medication management (including appropriate titration) and adherence, diet, and lifestyle to patients with diabetes referred to CM by their primary care physician. Care management was designed to help provide additional individualized patient support beyond primary care for improving self-management and cardiovascular disease (CVD) risk factor control. Control of glycemia was a central focus from the program's inception; emphasis on blood pressure and lipid control was added in later years. This program was designed to treat patients for 3 to 6 months and then to place the patients back into the primary care

system once (ideally) CVD risk factors and self-management behaviors had improved.

The objectives of this study were 3-fold: (1) to describe the population

Objectives: To evaluate the effectiveness of the diabetes care management (CM) program in Kaiser Permanente Northern California (KPNC) by determining the proportion of enrollees that met program entry criteria and by comparing intermediate outcomes trajectories of enrollees versus similar patients who did not receive CM.

Study Design: Observational study with propensity score matching of CM patients to control subjects.

Methods: Care management program entry criteria were assessed for 179,249 adult patients with diabetes mellitus in 2003 and were compared between CM and non-CM patients in that year. Propensity score matching was used to match CM patients with comparable non-CM controls. Preprogram and postprogram glycosylated hemoglobin (A1C), low-density lipoprotein cholesterol (LDL-C), and systolic blood pressure levels, as well as medication adherence, and treatment intensification rates of CM patients, were compared for enrollees versus controls.

Results: Sixteen percent of CM patients were ineligible by program entry criteria. Small but statistically significant differences in A1C and LDL-C levels favoring CM patients were observed during 15 months of postprogram follow-up. Care management patients were more likely to receive treatment intensification for poorly controlled hyperglycemia, hyperlipidemia, and hypertension. Improvements in all 3 cardiovascular risk factor levels were observed for all KPNC patients with diabetes regardless of CM participation.

Conclusions: Eligibility guidelines for diabetes CM were not strictly adhered to in this program. Nevertheless, in a population with improving risk factor control, patients entering CM experienced slightly greater improvement.

(*Am J Manag Care.* 2009;15(5):295-301)

In this issue

Take-Away Points / p296

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**For author information and disclosures,
see end of text.**

Take-Away Points

This study of the diabetes care management program in Kaiser Permanente Northern California examined fidelity to program entry criteria and compared intermediate outcomes trajectories of program enrollees versus similar patients who did not receive care management. Findings include the following:

- Sixteen percent of care management patients in 2003 did not meet program eligibility criteria.
- Thirty-three percent of patients who did not receive care management met program eligibility criteria.
- Care management patients showed small improvements in control of glycosylated hemoglobin and low-density lipoprotein cholesterol levels compared with matched controls.
- Significant improvements in all cardiovascular disease risk factor levels were observed for all patients with diabetes regardless of participation in care management.

Matching CM Patients to Control Subjects

To assess program effectiveness for improving SBP and A1C and LDL-C levels, as well as medication adherence and treatment intensification rates, the study included all CM patients who had been identified as having diabetes since at least December 2001 and who had been enrolled continuously with an active drug benefit from January 2002 through

of patients enrolled in this program, (2) to assess correspondence of program enrollment with stated entry criteria, and (3) to evaluate program effectiveness for improving A1C level, LDL-C level, systolic blood pressure (SBP), medication adherence, and appropriate treatment intensification.

METHODS

Study Population

This study was developed and approved by the steering committee of the Translating Research in Action for Diabetes (TRIAD) study¹⁵ and was conducted in KPNC, which is 1 of 6 TRIAD translational research centers. As an integrated healthcare delivery system, KPNC provides comprehensive medical care to a diverse population of approximately 3.2 million members in Northern California. Patients with diabetes were selected for the study from the KPNC diabetes registry¹⁹ if they were identified as having diabetes before December 31, 2002; were aged 20 to 85 years as of January 2003; and were continuously enrolled with an active drug benefit in January 2003. A small number of patients ($n = 2609$) who were likely to have type 1 diabetes mellitus (age <40 years as of January 1, 2003, and taking insulin only) were excluded. Initial SBP and A1C, LDL-C, and albumin levels for CM patients and for patients with diabetes not in CM were compared using the first value for 2003 found in the registry database. Patients were identified as CM participants if they had a diabetes CM entry date between January 1, 2003, and December 31, 2003, in the automated "Alert Note" CM database and had at least 1 day of enrollment in the program. Official eligibility criteria for the KPNC CM program state that patients entering diabetes CM should meet 1 or more of the following criteria: (1) an A1C level of at least 8.5%, (2) an albumin level exceeding 3.0 g/dL, or (3) a diabetes-related hospitalization or emergency department (ED) visit. All patients with diabetes were assessed for whether they met CM program entry criteria between July 1, 2002, and December 31, 2003.

December 2005. These selection criteria allowed assessment of long-term intermediate outcomes and medication adherence before entering and after leaving CM. Because program participants could potentially differ from nonparticipants on a number of patient-level characteristics such as age or disease burden (as well as possibly the characteristics of their referring primary care physicians), the study used propensity score matching.²⁰ This matching allowed for comparison of CM patients' outcomes with those of similar patients who did not enter CM, while effectively controlling for differences in their baseline characteristics.²⁰ Matched control subjects were selected from registry members who met the diabetes duration, health plan membership, and benefit criteria but who did not enter CM during 2003. For matching, all eligible patients were first assigned a propensity score (probability range, 0-1) for entering CM using logistic regression analysis and including the following predictors: age, sex, race/ethnicity, A1C level, albumin level, whether the patient had a diabetes-related hospitalization or ED visit in the prior year, comorbidity score (DxCg, Inc, Boston, Massachusetts) derived from hospital and ambulatory diagnoses during 2002,²¹ use of insulin, number of primary care visits in 2003, number of patients with diabetes in the patient's primary care physician panel in 2003, and percentage of patients with diabetes in a primary care physician's panel referred to CM in 2003. These variables were chosen because they reflected the official entry criteria for entering CM (and were likely to influence whether patients were referred into the program) or because they measured patient-level or physician-level characteristics that were likely to influence program entry. Each CM patient was matched to the control having the closest propensity score possible who also had an A1C reading during the quarter of 2003 in which the CM patient entered the program.

Adherence to Medication Regimens

Adherence to diabetes, hypertension, and hyperlipidemia medication regimens for 12 months before and after CM was calculated separately for each condition among CM patients

and matched controls using KPNC prescription databases. For each medication class, the proportion of days between first and last prescription fills in the 12-month periods for which the patient did not have medication available was determined.^{22,23} Adherence was first calculated separately for each medication class and then was combined across all medications prescribed for a single condition, weighing each by the interval from first to last prescription fill in the period. Consistent with prior findings in this setting,²⁴ poor adherence for each condition was defined as a weighted nonadherence measure of at least 20% across all medications prescribed for the condition.

Treatment Intensification

Treatment intensification during 12 months following the start of CM was assessed for each CM patient and his or her matched control using prescription fills during 3 months before and 3 months after the first above target measurement in the period. Intensification was defined as any 1 of the following 3 occurrences: (1) an increase in the number of drug classes, (2) an increase in the daily dose of at least 1 ongoing drug class, or (3) a switch to a medication in a different drug class. A new insulin regimen was considered treatment intensification for hyperglycemia; titration of insulin dosages after insulin initiation could not be observed in the pharmacy database. Details on this method are available elsewhere.²⁴

Statistical Analysis

Systolic blood pressures and A1C and LDL-C levels obtained during 15 months after exiting from the program were compared between CM patients and their matched controls using hierarchical linear regression analysis adjusting for facility as a random effect and adjusting for baseline risk factor values as fixed effects. The latest available readings during the 15-month period were used as dependent variables in separate models for each CVD risk factor. In these models, CM versus control was the independent variable. Similar hierarchical logistic regression models were used to assess the effect of CM on good versus poor adherence to medication regimens for hyperglycemia, hyperlipidemia, and hypertension. Adherence to each regimen in the 12 months starting with the date of CM entry was modeled as a dependent variable, with CM versus control as the independent variable and with adjustments for medication adherence during the 12 months before CM entry as fixed effects. Hierarchical logistic regression analysis was used to model the probability of receiving treatment intensification for hyperglycemia, hyperlipidemia, and hypertension during the 12 months following CM entry, with CM versus control as the independent variable. All models

adjusted for propensity score as a fixed effect and for facility as a random effect.

All analyses were performed using SAS version 9.1 (SAS Institute Inc, Cary, NC). This study was reviewed and approved by the institutional review board of Kaiser Permanente.

RESULTS

A total of 179,249 patients with diabetes met the criteria for inclusion in the study (Table). Eight percent of these patients entered the CM program in 2003. There were modest differences between CM patients and patients who did not enter CM in terms of age, sex, and LDL-C levels; SBP differences were not significantly different between the 2 groups. The greatest differences between patients entering CM and those who did not were related to program entry criteria, including the mean A1C level (9.0% and 7.0%, respectively), the prevalence of microalbuminuria (17% and 9%, respectively), and diabetes-related hospitalizations or ED visits (13% and 6%, respectively).

Among patients who entered CM, 84% (Table) met at least 1 of the specified entry criteria into the program. Thirty-three percent of patients who did not enter CM met at least 1 of the specified entry criteria. Patients who were in CM stayed in the program for a mean of 8 months.

A total of 3579 CM patients were matched on the basis of propensity scores to 3579 controls who had not received CM. The multivariate logistic regression model that created the propensity scores used for matching showed that the following were significant positive predictors ($P < .05$) of entering CM (data not shown): younger age, female sex, higher A1C level, higher degree of microalbuminuria, presence of a diabetes-related hospitalization or ED visit, higher DxCG score, adherence to an insulin regimen, and annual number of primary care visits. The propensity score logistic regression model had a C statistic of 0.89. After matching, CM patients and their controls were similar on all characteristics in the propensity score models ($P > .05$ for all differences [data not shown]).

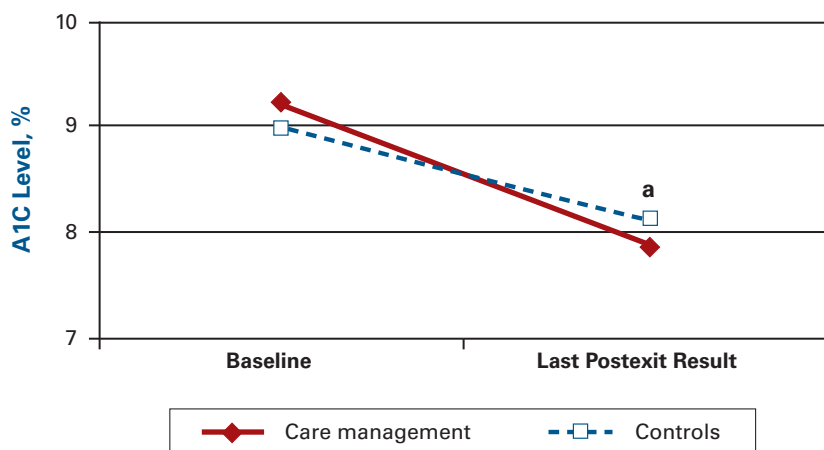
For CVD risk factors, small but statistically significant postprogram differences favoring CM patients were observed for A1C and LDL-C and SBP levels (Figure 1 and Figure 2). For A1C level, patients who had been enrolled in CM had levels that were 0.3% lower than those of their controls after multivariate adjustment. In a subanalysis conducted in patients with baseline A1C levels of at least 9.0%, CM patients had postprogram A1C levels that were 0.5% lower than those of their controls after multivariate adjustment (data not shown). The adjusted postprogram difference in LDL-C level was 3 mg/dL lower in CM patients than in their controls. Improvements in control of all 3 CVD risk factors over time were substantial for

■ **Table.** Characteristics of Adult Diabetes Patients in 2003

Characteristic	All Patients With Diabetes (N = 179,249)	CM in 2003 (n = 14,685)	Not in CM in 2003 (n = 164,564)
Age, mean (SD), y	60.7 (12.9)	58.1 (12.2)	61.0 (12.9) ^a
Female sex, %	47.0	50.0	46.8 ^a
Race/ethnicity, %			
White	46.2	43.4	46.4 ^a
African American	10.2	11.6	10.0
Hispanic	10.9	14.2	10.6
Asian	13.4	12.4	13.5
Native American	0.7	0.9	0.7
Pacific Islander	0.1	0.3	0.1
Multiple	5.3	6.1	5.3
Missing	13.1	11.0	13.3
A1C level, mean (SD), %	7.5 (1.8)	9.1 (2.1)	7.3 (1.6) ^a
LDL-C level, mean (SD), mg/dL	113.9 (34.6)	115.8 (36.3)	113.6 (34.4) ^a
SBP, mean (SD), mm Hg	138.2 (16.5)	138.2 (16.7)	138.2 (16.5)
Albumin level >3.0 g/dL, %	9.6	16.6	9.0 ^a
Having diabetes-related hospitalization or ED visit, %	6.7	13.1	6.1 ^a
Meeting at least 1 CM entry criteria, %	36.8	84.1	32.6 ^a
Duration in CM, mean (SD), mo	NA	7.7 (5.1)	NA

A1C indicates glycosylated hemoglobin; CM, care management; LDL-C, low-density lipoprotein cholesterol; NA, not applicable; SBP, systolic blood pressure.
^aP < .001 difference between CM and non-CM groups.

■ **Figure 1.** Glycosylated Hemoglobin (A1C) Level in Care Management Patients Versus Matched Controls



^aPostexit difference significant ($P < .01$) in multivariate models adjusting for baseline values and propensity score as fixed effects and for facility as a random effect.

both control and CM patients. Models that also adjusted for potential clustering at the physician level exhibited similar results (data not shown).

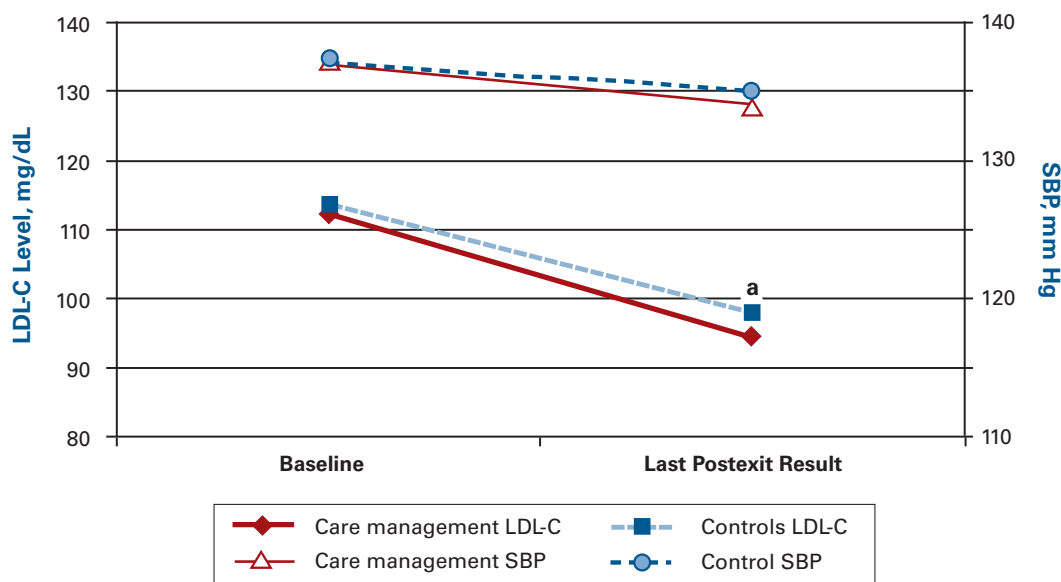
percent of enrollees did not meet any enrollment criteria, and the reach of the CM program (calculated as the number of eligible patients enrolled divided by the number of eligible pa-

Care management was not associated with changes in medication adherence (Figure 3). However, CM patients were more likely than controls to have received treatment intensification for hyperglycemia, hyperlipidemia, and hypertension during 12 months after program entry (Figure 4).

DISCUSSION

This study is one of the first to examine a large-scale fully implemented CM program and to assess its effectiveness at reaching its target population and in improving care quality and outcomes. The findings suggest that this CM program did not always follow specified guidelines in enrolling patients. Sixteen

■ **Figure 2.** Low-Density Lipoprotein Cholesterol (LDL-C) Level and Systolic Blood Pressure (SBP) in Care Management Patients Versus Matched Controls



^aPostexit difference significant ($P < .01$) in multivariate models adjusting for baseline values and propensity score as fixed effects and for facility as a random effect.

tients in the population during the year) was 18.7%. Patients who enrolled remained in the program longer than originally anticipated; while the program goal was to discharge patients after 6 months, the mean enrollment in the program was 8 months. Although it is possible that this additional time with patients facilitated care managers in achieving favorable outcomes, it also likely resulted in the program reaching fewer patients than anticipated. Because fidelity to intended implementation strategies and program reach are important factors in the success of clinical programs for patients with chronic conditions,²⁵⁻²⁷ each of these factors would likely diminish the expected effectiveness of this program from the population perspective.

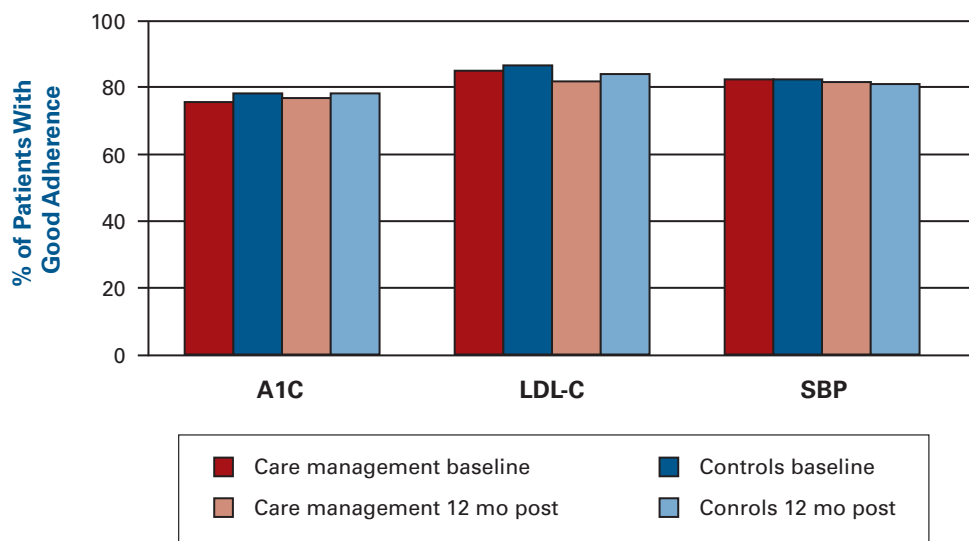
Nevertheless, for those patients who were reached by the program, CM seemed to have clinically modest but statistically significant effects on intermediate outcomes, with greater improvements in A1C level (and to a lesser extent in LDL-C level) after CM. Most important, CM patients were more likely to have received treatment intensification than their matched controls, particularly for elevated A1C levels. For lipid and SBP control, treatment intensification levels were lower, as were the differences between CM and usual care. These findings suggest that the program was able to effect needed intensification of pharmacotherapy for CM patients.

A striking result in this study is that CM patients and controls showed significant improvements in CVD risk factor levels over time. This finding is consistent with other

evidence of improvements in CVD factor levels over time in managed care settings.²⁸ There are a number of reasons specific to KPNC that might explain this overall improvement in the population within the organization. During 2003, KPNC had a facility-level performance feedback and quality incentive system that included rewards for hypertension and LDL-C control, as well as for A1C control in patients with diabetes. These feedback and reward systems may have helped drive the organization toward CVD risk factor control improvement in the diabetes population regardless of whether patients were managed in primary care or in a CM program.

Whether the small incremental benefits of these population management programs can be justified in systems where quality is improving dramatically for most patients is an important question. Our data suggest that the general care system for patients with diabetes was able to improve CVD risk factor control for a broad group of patients. Our finding that the benefits of CM were somewhat greater in patients with baseline A1C levels of at least 9.0% suggests that a smaller target population might have been more appropriate and more effective. The UK Prospective Diabetes Study²⁹ has recently reported long-term follow-up data suggesting that A1C improvements of 0.3% to 0.5% (the range of observed outcome differences in CM patients compared with their matched controls) are associated with reductions in CVD mortality and morbidity. While a detailed cost-effectiveness analysis was outside of the scope of the present study, changes in guidelines that could focus CM

■ **Figure 3.** Medication Adherence in Care Management Patients Versus Matched Controls

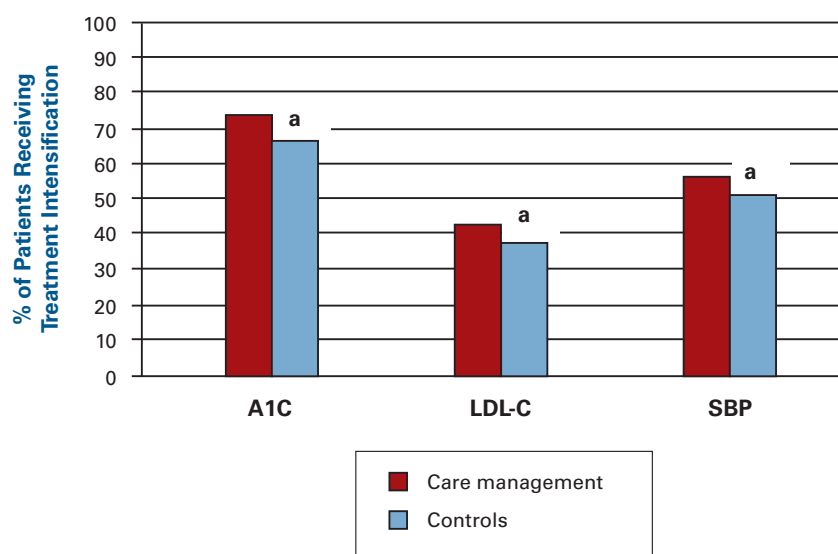


Postcare management medical adherence differences not significant in multivariate models adjusting for baseline adherence and propensity score as fixed effects and for facility as a random effect. A1C indicates glycosylated hemoglobin; LDL-C, low-density lipoprotein cholesterol; SBP, systolic blood pressure.

on a smaller target population with greater likelihood of benefit would likely be more cost-effective and potentially would help the program provide a return on investment. In recent years, KPNC has begun to emphasize population management programs in diabetes that attempt to outreach to all patients with poor control of CVD risk factors and to provide medication initiation and titration as appropriate. As the number of poorly controlled patients in managed care populations decreases, it

KPNC during the study period, these risk factor levels represent an important metric of program success. Other limitations include that few patients who were exposed to CM had sufficient program and postprogram follow-up time and laboratory values to be considered in the matched control study of the effect of CM and that the one-to-one matching process further reduced the sample size. To address this potential concern, a sensitivity analysis was conducted that used multivariate

■ **Figure 4.** Treatment Intensification in Care Management Patients Versus Matched Controls



A1C indicates glycosylated hemoglobin; LDL-C, low-density lipoprotein cholesterol; SBP, systolic blood pressure.

^aDifferences between care management patients and controls significant ($P < .01$) in multivariate models adjusting for propensity score as a fixed effect and for facility as a random effect for all conditions.

may also become more feasible and more appropriate to devote additional resources such as CM to these smaller groups of patients.

There are limitations to this study that should be noted. This study did not look at outcomes of CM outside of CVD risk factor levels; it is possible that CM had a positive effect on patient satisfaction, patient self-efficacy, and other measures that were not available in this analysis. However, because improving CVD risk factors was a primary goal of the CM program and of

regression analysis to examine the effect of CM exposure on almost 70,000 patients in the 2003 diabetes population with follow-up laboratory values after 2003. This analysis, which used the propensity score model predictors as covariates, yielded identical differences in A1C, LDL-C, and SBP values between CM patients and their controls as those in the propensity score-matched analysis. These results help validate the robustness of the study findings.

Finally, it is possible that a certain amount of the CVD risk factor improvements in the CM and non-CM populations may be due to regression to the mean. However, the fact that this study finds high rates of treatment intensification in both groups suggests that active and aggressive treatment is likely the cause of a significant portion of the observed improvements.

This study of diabetes CM in KPNC suggests that, although the program did not optimally reach its target population, it provided small but significant benefits in CVD risk factor control. These benefits were seen alongside improvements in CVD risk factor control in all KPNC patients with diabetes over time. Future CM program implementations may benefit from careful patient targeting and from a focus on methods to increase patient adherence.

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Funding Source: This study was funded by grant U58/CCU923527-04-1 from the Centers for Disease Control and Prevention. Dr Schmittiel is supported by Women's Health K12 Career Development Award K12HD052163 from the Office of Research in Women's Health Building Interdisciplinary Careers.

Author Disclosure: The authors (JAS, CSU, BHF, JVS) report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

Authorship Information: Concept and design (JAS, BHF, JVS); acquisition of data (JAS, CSU); analysis and interpretation of data (JAS, CSU, BHF, JVS); drafting of the manuscript (JAS); critical revision of the manuscript for important intellectual content (CSU, JVS); statistical analysis (CSU, BHF, JVS); obtaining funding (JVS); administrative, technical, or logistic support (JAS); and supervision (JVS).

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