

# Effect of Nurse Case Management Compared With Usual Care on Controlling Cardiovascular Risk Factors in Patients With Diabetes

A randomized controlled trial

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**OBJECTIVE**—To determine whether nurse case management with a therapeutic algorithm could effectively improve rates of control for hypertension, hyperglycemia, and hyperlipidemia compared with usual care among veterans with diabetes.

**RESEARCH DESIGN AND METHODS**—A randomized controlled trial of diabetic patients that had blood pressure (BP) >140/90 mmHg, hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) >9.0%, or LDL >100 mg/dL. Intervention patients received case management (*n* = 278) versus usual care (*n* = 278) over a 1-year period. The primary outcome was the percentage of patients achieving simultaneous control of all three parameters (defined by BP <130/80 mmHg, HbA<sub>1c</sub> <8.0%, and LDL <100 mg/dL) at 1 year. Secondary outcomes included improvements within each individual component of the composite primary outcome. Differences between groups were analyzed using *t* tests, Pearson  $\chi^2$  tests, and linear and logistic regression.

**RESULTS**—A greater number of individuals assigned to case management achieved the primary study outcome of having all three outcome measures under control (61 [21.9%] compared with 28 [10.1%] in the usual care group [*P* < 0.01]). In addition, a greater number of individuals assigned to the intervention group achieved the individual treatment goals of HbA<sub>1c</sub> <8.0% (73.7 vs. 65.8%, *P* = 0.04) and BP <130/80 mmHg (45.0 vs. 25.4%, *P* < 0.01), but not for LDL <100 mg/dL (57.6 vs. 55.4%, *P* = 0.61), compared with those in the usual care group.

**CONCLUSIONS**—In patients with diabetes, nurse case managers using a treatment algorithm can effectively improve the number of individuals with control of multiple cardiovascular risk factors at 1 year.

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Cardiovascular risk factors are common and poorly controlled in patients with diabetes (1). Recent data from the National Health and Nutrition Examination Survey (NHANES) 2003–2006 suggest that only 12.2% of individuals

with diabetes achieve simultaneous control of their blood pressure (BP), glycemia, and lipids. A method that has previously been used to improve risk factor control is case management using physician extenders (nurses, pharmacists, etc.) (2).

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Previous studies have attempted to improve control of an isolated risk factor such as glycemia or BP. We aimed to determine in a randomized controlled trial whether nurse case management could effectively improve simultaneous rates of control for hypertension, hyperglycemia, and hyperlipidemia compared with usual care among veterans with diabetes.

## RESEARCH DESIGN AND METHODS

This randomized, unblinded trial was conducted at the Minneapolis VA Health Care System (MVAHCS) in Minneapolis, MN, and was supported by Veterans Integrated Service Network 23. The trial was registered at ClinicalTrials.gov with the identifier NCT00569556. The Institutional Review Board at the MVAHCS approved the study.

## Study population and randomization

The MVAHCS maintains a registry of all patients with a diagnosis of diabetes who receive primary care through the VA Medical Center or one of the affiliated outpatient clinics. Between September 2006 and April 2008, we identified patients for potential study recruitment from this registry based on hypertension (BP), hyperlipidemia, or hyperglycemia. We mailed potential study patients a brief description of the study and followed the mailing with a telephone invitation to attend a group-screening visit at the MVAHCS. Overall, 3,392 individuals were mailed an invitation to attend a group randomization class.

At the group screening visit we determined HbA<sub>1c</sub>, LDL, and BP values. BP was measured using standardized procedures after the patient was seated for 5 min (3). We recorded three readings and calculated the average of the second and third readings. Individuals who consented to randomization and had one or more of their measures for HbA<sub>1c</sub>, LDL, or BP within the study inclusion criteria (HbA<sub>1c</sub> >9.0%, LDL >100 mg/dL, and

BP >140/90 mmHg) were eligible for study participation. We also obtained the following information at the baseline visit: demographics, self report of comorbidities, smoking status, alcohol use, physical activity, medication use, height, weight, waist circumference, and additional laboratory values. In addition, all patients received information about diabetes, related complications, target values for BP, cholesterol, and glycemia, and medications used to treat these conditions. A registered dietitian presented information on dietary choices for diabetes and hypertension including carbohydrate counting, label reading, and the Dietary Approaches to Stop Hypertension (DASH) low-sodium diet (4).

We excluded patients from study participation if they had a life expectancy of less than 1 year, had a severe mental health condition or active substance abuse, were pregnant or planning on becoming pregnant, were living in an assisted living facility, or were unable to give consent.

After completion of the group-screening visit, we individually randomized participants to either the intervention (case management) group or the control (usual care) group according to a computer-generated randomization schedule with a block size of six. The study case managers were blinded to the randomization schedule.

### Intervention and follow-up

Patients randomized to the intervention group met with their assigned nurse case manager after the initial study visit. Patients, in collaboration with the study nurses, established lifestyle modification goals (including goals for weight loss, dietary changes, physical activity, and smoking cessation, as appropriate) and developed personal action plans. We provided all patients in the intervention group with a validated home BP monitor and instructions on its use. The case manager reviewed diabetes, BP, and lipid medications and made adjustments to those medications according to protocols established for the study (Supplementary Data). The goal was for case managers to contact patients every 2 weeks initially and for the frequency of contact to decrease as the patient achieved home BP and glucose goals. During telephone contacts the case managers reviewed the following: self-monitoring values for blood glucose and BP, difficulties experienced in measuring home blood glucose or BP,

progress toward achieving lifestyle modification goals, and any adverse events associated with therapy. The study case managers also made adjustments to the patients' medications according to the study protocol (Supplementary Data). We notified the primary care provider of any medication changes using the electronic medical record system. For providers outside the VA medical system, we sent a letter informing them of medication changes.

We asked patients randomized to the usual care group to continue managing their diabetes, BP, and lipids under the direction of their primary care provider.

The study duration was 12 months. At the end of the study, we asked all patients to return for a final study visit. At this visit, we reviewed medications and repeated the formal BP, fasting lipids, and HbA<sub>1c</sub> measurements. For patients who could not be contacted (death, withdrawal, or loss to follow-up), we obtained final outcome data from their electronic medical record using the values recorded closest to the 12-month follow-up date.

### Outcome measures

The primary outcome measure was the percentage of patients with control of all three cardiovascular risk factors, defined as: BP <130/80 mmHg, LDL <100 mg/dL, and HbA<sub>1c</sub> <8.0%. Secondary outcome measures were the percentage of individuals achieving individual treatment goals and the change in absolute values for BP, LDL, and HbA<sub>1c</sub> between the intervention and usual care groups at 1 year.

### Sample size and power calculations

Based on existing MVAHCS diabetes registry data, we anticipated that 10% of the usual care participants would achieve control of all three measures at 12 months. We determined that a clinically significant increase in control would be a doubling of the control rate (i.e., a control rate of 20% in the intervention group vs. 10% in the usual care group). To detect an absolute difference of 10% with at least 80% power using a two-sided test with  $\alpha = 0.05$ , a total sample size of 440 participants (220 per group) would be required. We speculated that up to 20% of the randomized participants might either drop out of the study or become lost to follow-up and increased the final sample size to 550 participants.

### Statistical analysis

Characteristics of patients by treatment group were compared using a two-sided Pearson  $\chi^2$  test and ANOVA for categorical

and continuous variables, respectively. To account for baseline imbalances in randomization, linear and logistic regression analyses were performed adjusting for variables that were different at baseline. All analyses conducted were on an intent-to-treat basis. Patients who were unable to complete the final visit at 1 year were assumed to have failed all measures for the primary outcome. Analyses were also conducted in which their last value was carried forward. We also performed a sensitivity analysis in which patients who were inappropriately randomized were removed; results did not change for any outcome (not shown). Finally, we conducted analyses based on subgroups of individuals with particular abnormalities at baseline. For example, we determined the influence of case management on glycemia and the number of diabetes medications in the subgroup of individuals who were included in the trial as a result of an HbA<sub>1c</sub> >9.0%.

**RESULTS**—We invited 3,392 patients to participate in the study. Of those, 729 individuals attended a group visit with 147 of those subsequently determined to be ineligible, because they did not have any intervention measure (BP, LDL, or HbA<sub>1c</sub>) beyond the threshold value. Twenty-six individuals chose not to participate, leaving 556 individuals randomized, with 278 to each group. Of randomized individuals, 7 withdrew (4 intervention vs. 3 usual care) and 10 died (5 intervention vs. 5 usual care). Nineteen individuals were randomized in error; they did not meet any of the entry criteria. These individuals all entered as they had a value at the cutoff for entry criteria but did not exceed the threshold (i.e., LDL = 100). We report results including these individuals. The final visit was completed in person by 431 patients (223 intervention vs. 208 control subjects,  $P = 0.13$ ).

Among randomized patients 53 had an isolated elevated HbA<sub>1c</sub>, 143 had an isolated elevated LDL, 164 had an isolated elevated BP, 151 had two measures beyond the threshold values, and 26 had abnormalities in all three measures.

In general, the randomized population represents a typical VA population, because the majority of individuals were older, male, and Caucasian. Baseline characteristics of randomized individuals by treatment assignment are outlined in Table 1. The baseline characteristics were similar for both treatment groups. The only statistically significant differences

Table 1—Baseline characteristics by intervention group

Baseline characteristic	Case management	Usual care	P value
n	278	278	
Mean age (years)	64.9 (8.9)	65.8 (9.1)	0.23
Race (%)			0.67
Black	14 (5.0)	11 (4.0)	
White	259 (93.2)	259 (93.2)	
Other	4 (1.4)	5 (1.8)	
Male (%)	277 (99.6)	271 (97.5)	0.03
Comorbidities (%)			
Congestive heart failure	38 (13.7)	16 (5.8)	<0.01
Neuropathy	163 (58.6)	149 (53.6)	0.23
Stroke	35 (12.6)	29 (10.4)	0.43
Retinopathy	67 (24.1)	53 (19.1)	0.15
Current smoker	33 (11.9)	38 (13.7)	0.81
Examination			
Mean waist circumference (cm)	46.3 (6.2)	45.7 (5.7)	0.31
Mean weight (pounds)	233.3 (49.7)	230.2 (48.4)	0.46
Mean BMI (kg/m <sup>2</sup> )	33.5 (6.7)	33.2 (6.2)	0.56
Mean pulse rate (bpm)	75.3 (14.1)	75.5 (14.0)	0.88
Mean systolic BP (mmHg)	142.5 (18.8)	142.1 (18.8)	0.82
Mean diastolic BP (mmHg)	76.6 (11.0)	76.7 (9.8)	0.90
Laboratory studies			
Mean HbA <sub>1c</sub> (%)	8.0 (1.6)	7.8 (1.5)	0.20
Mean LDL (mg/dL)	102.8 (32.4)	103.7 (34.3)	0.77

between randomized groups were that patients in the usual care group were more likely to be male (99.6 vs. 97.5%) and to have self-reported congestive heart failure (13.7 vs. 5.8%).

A median of 15 (interquartile range [IQR] 10–21) case manager phone calls were attempted over the 1-year study period, of which 10 (IQR 6–14) were successful. There was no difference between groups in the number of VA primary care visits over the course of the study, as assessed through the medical record (median of three visits in both the intervention and control groups, Wilcoxon test  $P =$

0.96). At the end of the study a greater number of patients assigned to the intervention group achieved the primary study outcome of having all three intervention measures under control (61 [21.9%] compared with 28 [10.1%] in the usual care group,  $P < 0.01$ ) (Table 2). When compared with the usual care group, a greater number of patients assigned to the intervention group achieved the individual treatment goals of HbA<sub>1c</sub> <8.0% (73.7 vs. 65.8%,  $P = 0.04$ ) and BP <130/80 mmHg (45.0 vs. 25.5%,  $P < 0.01$ ), but not LDL <100 mg/dL (57.6 vs. 55.4%,  $P = 0.61$ ). In multivariate analysis,

adjusting for imbalances in baseline characteristics, patients randomized to the intervention group had 2.1 greater odds of achieving control of all three risk factors compared with those randomized to usual care (95% CI 1.4–3.2).

A secondary objective of the study was to determine whether the intervention lead to an improvement in each of the individual components included in the primary end point, among patients with an elevated baseline value for the component. Among participants who entered the study with an HbA<sub>1c</sub> greater than 9.0% ( $n = 139$ ), a greater percentage of patients achieved the goal HbA<sub>1c</sub> in the intervention group, 30 (40.5%), compared with 16 (24.6%) in the usual care group ( $P = 0.047$ ) (Table 2). Similarly, among those randomized with an elevated LDL concentration ( $n = 290$ ), a greater percentage of patients in the intervention group achieved the goal LDL of <100 mg/dL compared with the usual care group (40.9 vs. 27.7%,  $P = 0.02$ ). Finally, among those with an elevated BP at study entry ( $n = 311$ ), a greater percentage of patients also achieved the goal BP at 1 year in the intervention group compared with the usual care group (40.6 vs. 15.9%,  $P < 0.01$ ).

Using mean values for the individual components attenuated differences between groups. Among participants who entered the study with an elevated HbA<sub>1c</sub>, there was a modest, nonsignificant difference in HbA<sub>1c</sub> at 1 year (8.6% intervention vs. 9.1% usual care,  $P = 0.12$ ). Similarly, there was a modest clinical difference in LDL concentration at 1 year among those entering the study with an elevated LDL (107.3 mg/dL intervention vs. 118.4 mg/dL usual care,  $P = 0.005$ ). Finally, there was a significant difference in systolic BP among participants entering the study with an elevated systolic BP (133.7 mmHg intervention vs. 144.4 mmHg usual care,  $P < 0.001$ ).

Participants in the intervention group were more likely to achieve the prespecified targets for blood glucose, lipids, and BP likely as a result of greater use of medications (Table 3).

Adverse events were similar between groups. No participant withdrew from the study as a result of an adverse event. There was no difference in the rate of hospitalization or death between groups.

**CONCLUSIONS**—Our results demonstrate that involving a nurse case manager in the care of patients with diabetes can

Table 2—Outcomes by intervention: Primary and secondary outcome results

	n	Case management		Usual care	P value
Primary outcome (%)					
Patients with BP <130/80 mmHg, HbA <sub>1c</sub> <8.0%, and LDL <100 mg/dL	556	21.9	10.1		<0.001
Secondary outcomes (%)					
HbA <sub>1c</sub> <8.0% in those with baseline HbA <sub>1c</sub> >9.0%	139	40.5	24.6		0.047
LDL <100 mg/dL in those with baseline LDL >100 mg/dL	290	40.9	27.7		0.017
BP <130/80 mmHg in those with baseline BP >140/90 mmHg	311	40.6	15.9		<0.001

Table 3—Medication use at the end of the trial by intervention group among those who entered with a particular abnormality

	n	Case management (%)	Usual care (%)	P value*
Number of BP medications at 1 year in those with an entry BP >140/90 mmHg	311			0.03
0		1.9	4.6	
1		15.6	20.5	
2		24.4	23.8	
3		23.1	18.5	
4		20.0	8.0	
≥5		15.0	9.3	
Number of cholesterol medications at 1 year in those with an entry LDL >100 mg/dL	290			0.01
0		11.4	23.4	
1		58.4	53.2	
2		22.2	19.2	
≥3		8.1	4.3	
Number of diabetes medications at 1 year in those with an entry HbA <sub>1c</sub> >9.0%	139			0.01
1		13.5	23.1	
2		43.2	49.2	
3		31.1	18.5	
4		10.8	4.6	

\*P value from Mantel-Haenszel  $\chi^2$  with 1 degree of freedom.

significantly improve the number of individuals simultaneously achieving target values for glycemia, lipids, and BP compared with the standard practice of provider-driven care. Patients working with nurse case managers were more likely to achieve individual goals for glycemia, lipids, and BP compared with the usual care patients. Although the improvements in glycemia and lipids were modest, the biggest difference was observed in BP management. The observed differences were likely mediated both by enhanced lifestyle changes and a greater intensity of pharmacological treatment among those in the intervention group.

Our results are in keeping with other studies that have examined the influence of physician extenders (nurses, pharmacists, or others) on improving risk factors for adverse outcomes among individuals with diabetes (5–13). Shojania et al. (14) demonstrated in a meta-analysis involving 58 trials that case managers were more effective at improving glycemic control (mean decrease in HbA<sub>1c</sub> 0.42%) compared with usual care. This effect was particularly evident among individuals with baseline HbA<sub>1c</sub> >8.0% (decrease in HbA<sub>1c</sub> 0.54%). The effect of case management appears to be greater in studies where case managers directly altered medications (decrease in HbA<sub>1c</sub> 0.96%).

A recent study suggested that telemonitoring of patients in addition to case management offered greater control of HbA<sub>1c</sub> compared with case management only (15). This may be the result of improved efficiency at contacting patients. Anecdotally, case managers reported difficulties in contacting patients to obtain self-monitoring data (i.e., BP or glucose values), which may be overcome with periodic, automated transmission of data to the case managers (16).

Similar benefits to case management have been demonstrated for hypertension control among patients with and without diabetes. A recent meta-analysis suggested that case management was associated with greater odds of having controlled hypertension (17). Similar to studies targeting hyperglycemia, the magnitude of the benefit associated with case management was greater when a treatment algorithm was used (additional reduction of systolic BP of 9.4 mmHg).

Overall, previous studies suggest that case management with a physician extender is effective at reducing either HbA<sub>1c</sub> or BP. Few studies have used case managers to control LDL, all with generally modest effects, similar to our study results. It is unclear why our study had only a modest effect on lipids, but one possibility is that individuals recruited

for study participation because of an LDL >100 mg/dL had previously failed statin therapy because of adverse effects and refused reintroduction of a statin. A post hoc review of the electronic medical record suggested that 44/275 (16%) patients with a baseline LDL >100 mg/dL had a documented adverse reaction to previous use of statins. The available evidence suggests that use of a treatment algorithm with direct modification of therapy by the physician extenders is more effective than having the extender recommend changes to the primary care provider, likely overcoming the clinical inertia often experienced by clinicians (18).

Individuals with diabetes do not typically have an abnormality in only glycemic control, but also frequently have hypertension and hyperlipidemia. Data from NHANES 2003–2006 suggest that 76% also have hypertension and 55% have hyperlipidemia (1). In the most recent NHANES survey, rates of control for hypertension (BP <130/80 mmHg), hyperlipidemia (LDL <100 mg/dL), and hyperglycemia (HbA<sub>1c</sub> <7.0%) were 45.2, 46.6, and 57%. However, simultaneous control of all three measures was poor at only 12.2%. Although previous studies have suggested that case management is effective at improving control of individual risk factors, case management of isolated abnormalities is likely not sufficient, given the common occurrence of multiple cardiovascular risk factor abnormalities in patients with diabetes. Very few studies have used case managers to target more than one risk factor in patients with diabetes (19). The Informatics for Diabetes Education and Telemedicine (IDEATel) study was a large randomized controlled trial that tested an intervention consisting of case management and telemonitoring against usual care in 1,665 individuals with diabetes (16,20). This study demonstrated a small benefit to case management on three domains (HbA<sub>1c</sub>, –0.29%; LDL, –3.84 mg/dL; systolic BP, –4.32 mmHg). A possible reason for the small effect sizes observed in this study was that the case managers were not able to change medications directly but had to notify primary care providers about abnormalities, which may have delayed therapy as a result of clinical inertia. Our study was similar to that of the IDEATel, but with a significantly greater treatment effect, which is likely a result of direct intervention by the physician extenders through the use of a treatment algorithm.

Given that the majority of individuals with diabetes have multiple cardiovascular risk factors, strategies that target single factors are likely to have reduced benefit compared with those that target multiple risk factors. It is likely unfeasible for patients with diabetes to have multiple case managers because this would likely lead to confusion and extra costs and be onerous for both the patients and the primary care providers. Our results suggest that nurse case managers can effectively enhance the rate of control among individuals with diabetes for three cardiovascular risk factors combined and individually.

Our study has a number of limitations. First, we inadvertently randomized a number of individuals inappropriately because they were at the threshold of our inclusion criteria, but did not formally meet our criteria for inclusion (i.e., systolic BP equal to 140 mmHg, not greater than 140 mmHg). We performed intent-to-treat analysis where these individuals were maintained in all outcome measures—preserving randomization. We also conducted sensitivity analyses, in which these individuals were excluded, with no change in any of our results. Although our overall intervention demonstrated a benefit, it is unclear what component of our intervention resulted in the benefit, because we could not evaluate each component separately as designed. It appears that after 1 year, individuals in the intervention group who had baseline hypertension, hyperglycemia, or hyperlipidemia were on a greater number of medications for these disorders compared with usual care patients. We did not assess medication adherence or changes in dietary patterns, although these were reinforced at every nurse call over the course of the year. As such, we can only conclude that the strategy of case management, including frequent contact, lifestyle modification encouragement, and medication intensification, leads to improved outcomes at 1 year compared with usual care. Other limitations to our study include the few women and minorities enrolled, typical of the VA population. Finally, although our primary outcome was improved, the outcomes we chose are all surrogate measures, and it is unclear if case management would reduce the number of clinical adverse outcomes.

There are a number of strengths to our study. First, we had a fairly large sample size of individuals with minimal exclusion criteria, enhancing the generalizability of

our study. Our study was powered to detect a difference in achieving three cardiovascular risk factors as opposed to just a single factor, enhancing acceptability of the intervention by patients and likely reducing the overall cost of the intervention, although we did not conduct a formal cost effectiveness analysis.

Overall, our results demonstrate that nurse case managers can enhance the care provided to individuals with diabetes. Specifically, use of nurse case managers can improve the percentage of individuals with diabetes attaining control of hyperglycemia, hyperlipidemia, and hypertension. Case management appears to be effective in managing a number of cardiovascular risk factors concurrently in patients with diabetes.

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A.I. designed and conducted the study, analyzed the results, and wrote the manuscript. A.I. had full access to all data in the study and takes responsibility for the integrity of data and the accuracy of data analysis. N.G. conducted the study, analyzed the results, and reviewed and edited the manuscript. B.C.T. performed the statistical analysis and reviewed and edited the manuscript. L.K., P.C., and M.A. obtained data and reviewed and edited the manuscript. B.C. performed the statistical analysis and reviewed and edited the manuscript. N.E.-F. designed and conducted the study, analyzed the results, and reviewed and edited the manuscript.

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