

HEALTH CARE REFORM

Team-Based Care Approach to Cholesterol Management in Diabetes Mellitus

Two-Year Cluster Randomized Controlled Trial

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Background: Creative, cost-effective interventions to improve the quality of care of chronic illnesses are needed. This study was designed to evaluate the impact of remote physician-pharmacist team-based care on cholesterol levels in patients with diabetes mellitus (DM).

Methods: This 2-year prospective, cluster randomized controlled trial was conducted within the Providence Primary Care Research Network in Oregon. Participants at least 18 years of age were identified by a diagnosis of DM. The intervention included remote physician-pharmacist team-based care focused on cholesterol management in DM. All clinicians in the study had access to the health information technology tool CareManager, which provided automated DM-related point-of-care prompts, a Web-based registry, and performance feedback with benchmarking. Study outcomes included the difference in low-density lipoprotein cholesterol (LDL-C) goal attainment, mean LDL-C, prescribed lipid-lowering therapy, and patient satisfaction between the intervention and control arms.

Results: A total of 6963 patients with DM cared for by 68 physicians in 9 clinics were evaluated. Patients in the intervention arm were more likely to achieve their target LDL-C levels compared with controls (78% vs 50%; $P = .003$). The mean LDL-C level was 12 mg/dL lower in the intervention arm compared with the control arm ($P < .001$). The rate of LDL-C testing was significantly higher in the intervention arm compared with the control arm. Patients in the intervention arm were also 15% more likely to receive a prescription for a lipid-lowering medication ($P = .008$). There was no significant difference in patient satisfaction between study arms ($P = .15$).

Conclusion: Remotely located physician-pharmacist team-based care resulted in significantly improved LDL-C levels and goal attainment among patients with DM.

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PATIENT-CENTERED MEDICAL home (PCMH) is a well-described framework endorsed by the American Academy of Family Physicians and 6 other medical associations.¹ The PCMH is promoted as a component of the required changes needed to address the health care quality, access, continuity, and cost shortfalls in the United

States.² The recently passed healthcare reform bill, the American Recovery and Reinvestment Act of 2009,³ and specifically Title XIII of the bill offer primary care practices the promise of financial incentives to effectively adopt health information technology and redesign care processes. The PCMH framework and financial incentives around meaningful use of electronic health record technology provide clear direction for practices to adopt a certified electronic health record and to have registrylike capabilities.⁴ There is less specific guidance from these sources or published literature to assist practices in decisions regarding care process redesign following implementation of health information technology (IT). How do busy practices best redesign care so that the right work is delegated to the right team member at the right time to provide the most effective outcomes at the lowest cost?

This study evaluates the incremental impact of team-based care in the setting of a fully implemented and adopted electronic medical record (EMR) and disease registry in a community-based primary care setting. We studied cholesterol management in patients with diabetes mellitus (DM), selected as the target population for the study based on DM's high prevalence, available treatment options,

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States.² The recently passed healthcare reform bill, the American Recovery and Reinvestment Act of 2009,³ and specifically Title XIII of the bill offer primary care practices the promise of financial incentives to effectively adopt health information technology and redesign care processes.

The PCMH framework and financial incentives around meaningful use of elec-

poor disease control, and impact on cardiovascular disease profile.

METHODS

This study was a 24-month prospective, cluster randomized controlled trial (RCT) approved by the local institutional review board.

SETTING AND PARTICIPANTS

The study was conducted within the Providence Primary Care Research Network (PPCRN) in Oregon within a not-for-profit integrated delivery system. At the time of the study, PPCRN clinics comprised approximately 110 internal medicine and family practice physicians caring for 182 534 patients in 16 clinics. The PPCRN uses clinical pharmacists to provide direct patient care services and consultation for patients with chronic conditions as well as to facilitate evidence-based, safe, and cost-effective prescribing.

All clinics used Centricity EMR (General Electric Co, Fairfield, Connecticut) to facilitate and document patient care activities, and pharmacists, physicians, and staff had access to a Web-based disease management software system, CareManager (Kryptiq Corp, Beaverton, Oregon), which had been fully implemented prior to study start. As described in the literature, these health IT systems provide practices with integrated point-of-care- and population-based decision support with automated patient outreach capabilities.⁵

For this study, all community-based PPCRN clinics with experience embedding a pharmacy practitioner in the 9-member care team were eligible to participate (**Figure**). Participants within the eligible practices were identified from query of the EMR based on a problem list entry of DM (*International Classification of Diseases, Ninth Revision* codes 250.xx) and an age of 18 years or older. Participants were excluded if they had no evidence of medical chart activity (ie, documentation of an office visit, prescription refill, or telephone contact) within the past 3 years.

ALLOCATION AND CONSENT

Clinics were randomized in a 1:2 intervention-to-control schedule using secure cluster allocation.⁶ Unequal allocation was used to accommodate pharmacist workload capacity, not to exceed 1 full-time practitioner. Clinics were matched based on the panel size of patients with DM, mean age of the DM panel, and proportion of patients with commercial insurance.

Consent to participate in this study was provided by PPCRN medical and administrative leadership. Although there is precedence for informed consent at the community decision-maker level for cluster randomized studies, it remains controversial.⁷ To meet a stricter ethical standard and facilitate improved buy-in,^{8,9} practitioner consent was sought following Zelen's "single consent" design.^{10,11} Accordingly, written consent to participate was sought *after* randomization from only those practitioners assigned to the intervention arm. Finally, individual patient participants contacted in the course of the intervention also had the option to decline therapy. In accordance with Zelen's design, however, data for all physician and patient participants were analyzed by intention-to-treat based on the original randomization allocation.

INTERVENTION

Clinics allocated to the control arm had access to the CareManager disease management program providing auto-

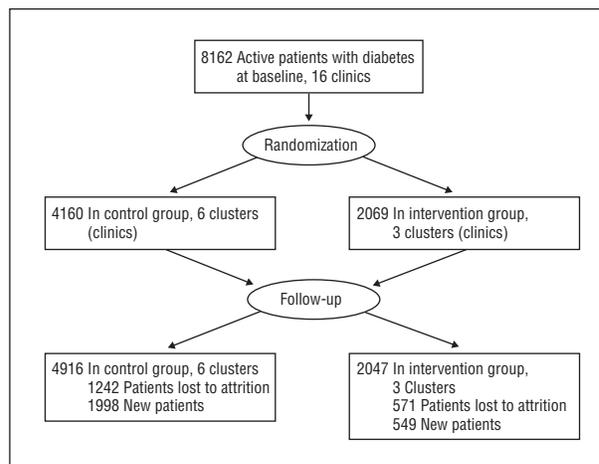


Figure. Study population flowchart.

mated quality reporting, benchmarking, and robust care opportunity decision support for their panel of patients with DM.¹² All physicians and staff received 2 hours of training on software capabilities and workflow best practices. Clinics were encouraged to discuss progress and quality improvement strategies at their weekly practice meetings.

In addition to health IT resources, intervention clinics implemented a team-based care approach for the management of cholesterol in patients with DM. This intervention was analogous to physician-pharmacist team-based care previously used for management of other chronic conditions.^{13,14} For this study, the team-based care approach was modified similar to the model reported by Olson et al,¹⁵ in which a pharmacist is stationed at a remote site serving multiple clinic locations. This more efficient model is enabled by an EMR, which allows for remote access to patients' medical record and electronic communication between the pharmacist and physician.

According to protocol, the pharmacy practitioner reviewed the medical charts of patients with an elevated LDL-C level. Based on patients' medical conditions and medication history, the pharmacist developed individualized, evidence-based treatment recommendations to include medication therapy and follow-up laboratory monitoring. The proposed treatment plan was electronically sent to the physician for review. The physician had the option to ignore the recommendation, act on the recommendation, or approve intervention by the pharmacist.

In the case in which the intervention was approved, the pharmacist would contact the patient by telephone. The telephonic intervention included an introduction of the pharmacist's role on the care team, confirmation of medication history and previous adverse reactions, and identification of barriers to adherence. Education was provided to support a shared decision-making process regarding the treatment plan. All patient communication and care was documented in the patient's medical chart and cosigned by the physician. The pharmacist was supported by a medical assistant who triaged laboratory results, ordered overdue laboratories, scheduled appointments, and facilitated mailings according to protocol.

OUTCOME MEASURES

The primary study outcome was the proportion of participants in each arm achieving a target LDL-C level of 100 mg/dL or lower (to convert LDL-C to millimoles per liter, multiply by 0.0259). The difference in mean LDL-C levels between the

Table 1. Results of Patient Satisfaction Survey

Survey Question ^a	Control Arm, %	Intervention Arm, %	P Value
1. How satisfied are you with PMG in terms of overall care of your diabetes?	80 (403 of 500)	84 (189 of 226)	.25
2. How satisfied are you with the way your questions about your diabetes were answered?	81 (411 of 505)	85 (203 of 238)	.29
3. How satisfied are you with the ease of reaching someone at PMG in an emergency?	77 (358 of 462)	84 (180 of 214)	.04
4. How satisfied are you with the way your test and laboratory results were reviewed and explained?	79 (403 of 510)	84 (199 of 236)	.15
5. How satisfied with the quality of diabetes related information you received.	75 (379 of 502)	80 (182 of 227)	.22
6. How satisfied are you with PMG in terms of concern, courtesy, respect, and sensitivity shown to you?	87 (448 of 514)	90 (217 of 241)	.38
7. How satisfied are you with the ease of scheduling?	87 (445 of 512)	90 (216 of 241)	.12
8. How satisfied you with the way the staff at PMG coordinate the team effort?	84 (419 of 499)	85 (199 of 235)	.82
9. Would you recommend PMG to your family and friends?	84 (423 of 502)	85 (199 of 235)	.92

Abbreviation: PMG, Providence Medical Group.

^a Questions were regarding the past 12 months. The 2 top responses were combined to evaluate the percentage of patients that were mostly satisfied with their DM care

intervention and control arms at the study end was also measured. Process measures included the proportion of patients with a LDL-C laboratory test performed within the last 12 months and the proportion of patients prescribed lipid-lowering medication. The secondary outcomes included glycemic and blood pressure control.

As part of a larger PPCRN study, patient satisfaction with DM care was assessed using the American Diabetes Association and the National Committee for Quality Assurance Provider Recognition Program Modified Patient Satisfaction Survey.¹⁶ The survey included 8 items measuring patient satisfaction with DM care in primary care (**Table 1**). The survey was administered to a random selection of study participants at baseline and study end. Overall satisfaction was evaluated by calculating the mean satisfaction per participant across all components. The 2 top responses were combined to evaluate the percentage of patients who were mostly satisfied with their DM care.

The incremental costs associated with delivering the intervention were recorded in a study database on a weekly basis.

Eligible costs included those directly related to the care delivery process beyond usual primary care. The initial time investment to develop the intervention workflow was not included in the cost assessment because it was considered a nonrecurring expense.

SAMPLE SIZE

Assuming that the active nature of the control used in this study would result in LDL-C goal attainment in 50% of patients, it was estimated that 1898 participants per study arm would be required for 80% power to detect a 10% difference in LDL-C goal attainment, with a 2-sided significance level of $P=.05$. Based on a power calculation for cluster RCTs involving a binary study outcome,^{8,9} a minimum of 2.9 clinics was required for each study arm. This sample size was based on an intracluster correlation coefficient of 0.005, calculated from existing data on variation in LDL-C goal attainment across the PPCRN, resulting in a design effect of 4.7. An average cluster size (number of patients with DM per clinic) was assumed to be 630 patients.

STATISTICAL ANALYSIS

Using descriptive statistics, proportions, means (SDs), and ranges, the demographic characteristics of physicians and their patients with DM were examined. A patient's success in achieving an LDL-C target of a level lower than 100 mg/dL was coded as a binary variable. Study outcomes were measured at the individual patient level, adjusting for clustering effect. The Rao-Scott χ^2 test, a design-adjusted version of the Pearson χ^2 test, was used to evaluate the difference between the study arms for dichotomous variables. The SAS SURVEYFREQ procedure (SAS Institute Inc, Cary, North Carolina) was used to complete this analysis. The SAS SURVEYREG procedure was used to evaluate an intervention effect for continuous variables while allowing an adjustment for a clustering effect.

Analyses were conducted by intention-to-treat such that patients were considered to have been exposed to the intervention regardless of the consent of patients or physicians. The primary study analysis included all active patients with DM. The analysis allowed for any new patients joining the practice during the 2 years to be included in the results (open cohort). A second analysis was completed for patients with DM who were continuously active within the practice for the entire 24-month study period (closed cohort). Analyses were conducted on the primary outcome using 2 methods: the principal analysis assumed that those patients without an LDL-C level within the past 12 months had missed their target, while the alternative method included only those patients with an available LDL-C result. Furthermore, analysis was completed for patients with comorbid coronary heart disease (CHD). All results were adjusted for clustering effect. The significance level was set at 0.05. Statistical analyses were performed using SAS, version 9.1 (SAS Institute Inc).¹⁷

A logistic regression model was built in an attempt to control for potential imbalances between the groups with respect to certain baseline characteristics. The variables with $P < .25$ were considered for inclusion.

RESULTS

A total of 6963 patients with DM cared for by 68 physicians in 9 clinics were evaluated (Figure). Baseline characteristics of physicians and patients by study arm are displayed in **Table 2**. Of the 23 physicians randomized to the intervention arm, 96% consented to participate at

Table 2. Baseline Characteristics of Physicians and Patients^a

Physicians and Patients	Control Arm	Intervention Arm	P Value
Primary Care Physicians (PCPs)			
Clinics, No.	6	3	
Physicians, No.	45	23	
Physician FTEs	38	19	
Part-time physicians, %	48	28	.12
Specialty, %			
Family practice	36	43	.57
Internal medicine	64	57	
PCPs per clinic, mean (SD)	9 (0.5)	8 (0.6)	.80
Women, %	56	54	.56
Years since graduation from medical school, mean (SD)	14 (7)	18 (9)	.31
Years employed at PPCRN, mean (SD)	6 (3)	8 (3)	.43
Overall panel size per physician FTE, mean (SD)	2091 (901)	2335 (884)	.31
DM panel size per physician FTE, mean (SD)	105 (62)	105 (52)	.98
DM panel size per clinic, mean (SD)	693 (254)	690 (256)	.20
Patients With DM, Age >18 y			
Patients, No.	4160	2069	
Sex, %			
Women	55	53	.69
Age, mean (SD), y	62 (14)	65 (14)	.11
Documented smoking, %	11	11	.92
BMI, mean (SD)	33 (12)	32 (13)	.23
Hypertension, %	61	59	.47
Serum creatinine level, mean (SD), mg/dL	1.05 (0.56)	1.09 (0.56)	.14
Creatinine clearance rate, mean (SD)	98 (48)	91 (47)	.11
Any microvascular complication, %			
Documented retinopathy	3	3	.82
Documented neuropathy	9	11	.21
CHD comorbidity	22	23	.90
Insurance status, %			
Commercial	46	39	.02
Medicare	46	55	
Medicaid	4.2	3	
Other	3.4	2.6	
Office visit within the past 12 mo, %	93	95	.10
LDL-C			
LDL-C goal attainment, <100 mg/dL, %	29	33	.10
LDL-C level, mean (SD), mg/dL	107 (33)	104 (32)	.17
LDL-C test within past 12 mo, %	63	68	.04
Any lipid-lowering medication, %	45	46	.79
Statin prescription, %	50	46	.24

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CHD, coronary heart disease; DM, diabetes mellitus; FTE, full-time equivalent; LDL-C, low-density lipoprotein cholesterol; PPCRN, Providence Primary Care Research Network.

SI conversion factors: To convert creatinine to micromoles per liter, multiply by 88.4; to convert low-density lipoprotein cholesterol to millimoles per liter, multiply by 0.0259.

^aData are given as numbers except where noted.

the study start with the remaining 1 physician consenting by midstudy. The patient populations in each study arm were comparable with respect to demographic and clinical characteristics with the exception of insurance status ($P = .02$) and frequency of LDL-C testing ($P = .04$). Patients allocated to the intervention arm were more likely to be enrolled in Medicare and to have had an LDL-C test completed in the past year. Of the 6963 total patients, 4424 were continuously enrolled during the study period: 2928 (60%) from the control arm and 1496 (73%) from the intervention arm.

In the intervention arm, the pharmacist identified 1527 patients with an elevated LDL-C level. Of those, 11% (163) were considered not appropriate for aggressive LDL-C management. In the 1364 patients for whom LDL-C management was deemed appropriate by the team, the phy-

sician enlisted telephonic management by the pharmacist in 514 of 1364 patients (38%). The remaining 62% were addressed by the physician following electronic consultation by the pharmacist as well as follow-up patient-tracking support. Among the 514 patients contacted telephonically by the pharmacist, 37 (7%) declined the treatment recommendation of the pharmacist following a shared decision-making process or preferred to discuss the recommendation further with their physician prior to action.

At the 24-month follow-up, considerable improvements were observed in all outcome and process measures in both groups compared with baseline (**Table 3**). Overall, 78% of the patients in the intervention arm achieved their target LDL-C level compared with 50% of the controls ($P = .003$). Furthermore, the LDL-C goal at-

Table 3. Outcome and Process Measures by Study Group

Outcome or Measure	Control Arm (n = 4916)	Intervention Arm (n = 2047)	Adjusted P Value
LDL-C			
LDL-C level at target, <100 mg/dL, % ^a	50	78	.003
Presence of CHD	65	86	.004
Absence of CHD	48	77	.003
LDL-C level, mean (95% CI), mg/dL	95 (91-97)	83 (82-85)	<.001
LDL-C test within the past 12 mo, %	82	95	.004
LDL-C level at target for closed cohort patients, %	56	79	<.001
LDL-C level at target among patients that were not at goal at baseline	48	74	.001
Any lipid-lowering medication, %	63	77	.04
Prescription for statin medication, %	60	75	.01
HgA _{1c}			
HbA _{1c} test within the past 12 mo, %	85	96	.004
HbA _{1c} level, mean (95% CI)	7.1 (7.0-7.3)	7.2 (6.9-7.5)	.57
HbA _{1c} level at target, <7%, %	49	51	.31
BP, mm Hg			
Systolic BP, mean (95% CI)	127 (126-129)	128 (125-131)	.61
Diastolic BP, mean (95% CI)	73 (71-74)	73 (72-74)	.81
BP at target goal, <130/80 mm Hg, %	49	55	.22

Abbreviations: BP, blood pressure; CHD, coronary heart disease; CI, confidence interval; HbA_{1c}, hemoglobin A_{1c}; LDL-C, low-density lipoprotein cholesterol. SI conversion factors: To convert HbA_{1c} to proportion of total hemoglobin, multiply by 0.01; to convert low-density lipoprotein cholesterol to millimoles per liter, multiply by 0.0259.

^aThe post hoc intracluster correlation coefficient was 0.08.

tainment in the intervention group was statistically higher than among controls after LDL-C goal attainment was stratified by the presence or absence of comorbid CHD ($P < .001$). The mean LDL-C level was 12 mg/dL lower in the intervention arm compared with the control arm ($P < .001$), and LDL-C testing was significantly higher in the intervention arm compared with the control arm. When the analysis was limited to patients with an LDL-C test performed in the past 12 months, 82% of the intervention group and 63% of the control group reached their LDL-C goal ($P = .009$). Nearly 3 of every 4 patients with an LDL-C level higher than the target goal at the baseline achieved their target goal at the follow-up compared with 48% in the control group ($P = .001$). Patients in the intervention arm were also 15% more likely to receive a prescription for a lipid-lowering medication ($P = .008$). There was no difference between the study arms with respect to secondary outcomes with the exception of an hemoglobin A_{1c} test performed in the past 12 months ($P = .004$).

The following variables were included in the logistic regression model: physician full-time equivalent (FTE) status (part-time vs full-time), years since a physician graduated from medical school, the clinic's DM panel size, patient age, body mass index (BMI), primary insurance, number of office visits within the past 12 months, baseline LDL-C goal attainment, and prescription for a statin medication. This analysis was completed for closed cohort patients. Of all variables that were considered, patient age, BMI, statin prescription, and baseline LDL-C goal attainment were kept in the model as statistically significant covariates. After adjusting for statistically significant covariates, the odds of LDL-C goal attainment in the intervention group was still 2.8 times higher than the odds of the LDL-C goal attainment in the control group (95% confidence interval, 2.2-3.7).

Of the total 4000 satisfaction surveys mailed to patients with DM as part of another study, 2614 were sent to participants in this study (Table 1). The overall survey response rate was 29% (27% for the intervention arm vs 30% for the control arm). When overall satisfaction was evaluated, the mean (SD) was high in both groups (5.2 [1.1] for the control arm and 5.4 [0.9] for intervention arm) and not significantly different between the groups ($P = .15$). The only statistically different response between the study arms was regarding satisfaction with reaching someone in an emergency (the rate for the control arm was 77% vs 84% for the intervention arm; $P = .04$).

Over the 24-month course of the study, 1 pharmacist spent a quarter (0.24 FTE) of his or her time fulfilling the role as outlined in the intervention. In addition, 0.44 medical assistant FTE was used to support the scheduling of laboratories and appointments, triaging laboratory results, and patient notification. Nonpersonnel costs included \$3400 per year for office space and \$550 per year for office supplies and postage.

COMMENT

This RCT demonstrated the incremental impact of physician-pharmacist team-based care on LDL-C management in patients with DM in a community primary care setting. In this study, 78% of participants exposed to the intervention achieved their LDL-C goal of a level lower than 100 mg/dL, compared with 50% of participants randomized to control. Among high-risk patients with DM and comorbid CHD, LDL-C goal attainment rate in the intervention arm reached 86%. Translating this impact to long-term patient outcomes based on published evidence, a 3% absolute reduction in cardiovascular (CV)

event risk over 10 years through sustained achievement of lower lipid values was estimated. This reduction is expected to translate into 61 CV events avoided in the intervention population of 2047 with an opportunity to avoid 640 CV events if applied to our entire population of patients with DM (21 000 participants) in the future.

This study is of particular interest because it was conducted in an environment with a fully implemented, robust electronic disease management system. In the absence of an active control, one might hypothesize that the intervention effect resulted from the pharmacist simply notifying the physician of their patients with elevated cholesterol. This hypothesis is reinforced by the frequency with which physicians chose to forgo pharmacist direct action in favor of acting on their own. However, control arm physicians received patient-specific information in the form of color-coded prompts signaling elevated cholesterol in an automated EMR-based point-of-care prompt, as well as continuously updated Web-based views for each physician's panel of patients with DM. The significant improvement in LDL-C management from baseline to study end observed in the control arm (29%-50% LDL-C goal attainment) suggests that physicians actively used this system. Blood pressure and glucose level control too improved across all study clinics. This again is likely due to the electronic disease management prompts that were implemented prior to the study and were available to both study arms. There was not, however, a significant difference in goal attainment for blood pressure or glucose level between arms after the 2-year study period. We assume from our results that this is because the intervention—the pharmacist-physician collaboration and the telephonic patient management by the pharmacist—was focused specifically on cholesterol management.

There were unanticipated findings based on the relocation of existing pharmacist staff from the local clinic setting to a central location. First, the intervention workflow was redesigned to require prospective electronic communication between the physician and pharmacist prior to contact with the patient. Second, pharmacists intervened only telephonically with approximately one-third of the patients with an elevated LDL-C level, with physicians assuming a more active role in responding to pharmacist recommendations than observed in other studies of similar design.¹⁵ As a result, considerably less pharmacist time was used in this care model than was projected (0.24 FTE vs 1.0 FTE). The overall impact of intervention cost is unknown because physician time was not quantified as part of the study. Our observation is that in development of remotely located teams, there is a balance between model efficiency and effective team dynamics, communication, and trust that must be consciously nurtured.

The intervention seemed to have little impact on patient satisfaction, and relatively few patients contacted by the pharmacist declined or delayed therapy decisions. This finding is noteworthy, given the telephonic nature of the pharmacist-patient interaction. The intervention required the pharmacist to establish a trusting relationship, facilitate shared decision-making regarding the need for LDL-C-lowering therapy, and in many

cases, initiate therapy—all telephonically. These results seem to assuage the notion that introducing another health care professional into the physician-patient relationship jeopardizes patient satisfaction.

Use of the prospective, randomized design in this trial adds scientific rigor to related observational research. In a prestudy and poststudy conducted at Kaiser Permanente (Denver, Colorado), 8014 patients with preexisting cardiovascular disease were enrolled in a pharmacist-led telephonic cholesterol management intervention. In just over 2 years, the intervention achieved 73% LDL-C goal attainment with follow-up reductions in cardiac events and mortality.¹⁵ Our study used a similar intervention, deployed over a similar timeframe, and found a consistent magnitude of effect. However, the use of an active control arm helps to eliminate potential confounders, such as the impact of progressive standards of care, physician education, financial incentives, and transparency of clinical performance measures. Notable characteristics of the current study that also enhance the potential generalizability of the intervention include enrollment of patients with DM with and without CHD, as well as the inclusion of patients with mixed insurance status cared for in community-based clinics.

Cluster randomization was used to minimize confusion on the part of physicians and staff and to limit contamination bias. Zelen's^{10,11} consent method was chosen to mimic "real-world" implementation by allowing physicians randomized to the intervention to opt out of participation but still including their information in intention-to-treat analyses.

Despite a moratorium on referrals for collaborative management of DM during this 2-year period, there was the limited possibility of contamination bias because the clinics randomized to the control group had established preexisting clinical pharmacy services and may have continued to request and receive educational and consultation services from PPCRN pharmacists. In addition, this study was limited in its assessment of cost implications, including direct delivery cost and cost avoidance from longer-term health impact.

Multiple publications have evaluated the impact of pharmacist-physician collaboration on cholesterol management.¹⁸⁻²² This study builds on these prior successes by applying a rigorous study design to an innovative mode of intervention with the patient and a novel method of clinical collaboration with the physician. By using a population approach to identification of care opportunities, telephonic patient visits, and electronic collaboration, the team was able to achieve a 28% difference between study arms. These results far exceed the mean difference of -6.3 mg/dL noted in a meta-analysis¹³ of previously published trials highlighting pharmacists direct patient care interventions.

Although physician-pharmacist team-based care accomplished superior outcomes in this study, health care provider organizations may question the business justification for the associated costs in the environment of unclear reimbursement changes. Continuing to evolve the model for team-based care for DM care is important. However, considerable improvements in health and health care delivery efficiency that require a more global expansion

of the team-based model to encompass other chronic disease conditions will also likely need to occur.

In conclusion, physician-pharmacist team-based care resulted in considerably improved LDL-C levels and goal attainment among patients with DM. These results were achieved in an environment with a fully implemented electronic disease management system. The active nature of the control arm bolsters confidence that the model of physician-pharmacist team-based care represents an effective quality improvement strategy that remains relevant with advancing health information technology and evolving health care strategies aimed at improving management of chronic illnesses.

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REFERENCES

1. Running a practice: patient-centered medical home (PCMH). American Academy of Family Practice Web site. <http://www.aafp.org/online/en/home/membership/initiatives/pcmh.html>. Accessed April 21, 2010.
2. AAFP Initiatives: health care system reform: principles for reform of the US health care system. American Academy of Family Practice Web site. <http://www.aafp.org/online/en/home/membership/initiatives/hrsprinciples.html>. Accessed April 21, 2010.
3. American Recovery and Reinvestment Act of 2009, HR 1, 111th Cong, 1st Sess (2009).
4. Cusak C, Knudson A, Kronstadt J, Singer R, Brown A. *Practice-Based Population Health: Information Technology to Support Transformation to Proactive Primary Care* (Prepared for the AHRQ National Resource Center for Health Information Technology under Contract No. 290-04-0016). Rockville, MD: Agency for Healthcare; 2010:24-25. AHRQ Pub No. 10-0092-EF.
5. Population-wide chronic care management. <http://www.kryptiq.com/solutions/patient-engagement/caremanager/>. Kryptiq Corp Web site. Accessed May 2010.
6. Puffer S, Torgerson D, Watson J. Evidence for risk of bias in cluster randomised trials: review of recent trials published in three general medical journals. *BMJ*. 2003;327(7418):785-789.
7. Edwards SJ, Braunholtz DA, Lilford RJ, Stevens AJ. Ethical issues in the design and conduct of cluster randomised controlled trials. *BMJ*. 1999;318(7195):1407-1409.
8. Donner A, Klar N. *Design and Analysis of Cluster Randomization Trials in Health Research*. London, England: Hodder Arnold Pub; 2000.
9. London A. Deprivation, disease, and the ethics of international research. *Bioeth Exam*. 2000;4(1):1-4.
10. Zelen M. A new design for randomized clinical trials. *N Engl J Med*. 1979;300(22):1242-1245.
11. Zelen M. Strategy and alternate randomized designs in cancer clinical trials. *Cancer Treat Rep*. 1982;66(5):1095-1100.
12. Hunt JS, Siemieniczuk J, Gillanders W, et al. The impact of a physician-directed health information technology system on diabetes outcomes in primary care: a pre- and post-implementation study. *Inform Prim Care*. 2009;17(3):165-174.
13. Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analyses. *Med Care*. 2010;48(10):923-933.
14. Hunt JS, Siemieniczuk J, Pape G, et al. A randomized controlled trial of team-based care: impact of physician-pharmacist collaboration on uncontrolled hypertension. *J Gen Intern Med*. 2008;23(12):1966-1972.
15. Olson KL, Rasmussen J, Sandhoff BG, Merenich JA; Clinical Pharmacy Cardiac Risk Service Study Group. Lipid management in patients with coronary artery disease by a clinical pharmacy service in a group model health maintenance organization. *Arch Intern Med*. 2005;165(1):49-54.
16. Montori VM, Bjornsen SS, Green EM, et al. Performance of the provider recognition program's survey to assess patient satisfaction with the provision of diabetes care in primary care. *Am J Manag Care*. 2002;8(4):365-372.
17. SAS Institute Inc. SAS/STAT User's Guide, Version 9.1. Cary, NC: SAS Institute Inc; 2003.
18. Merenich JA, Olson KL, Delate T, Rasmussen J, Helling DK, Ward DG; Clinical Pharmacy Cardiac Risk Service Study Group. Mortality reduction benefits of a comprehensive cardiac care program for patients with occlusive coronary artery disease. *Pharmacotherapy*. 2007;27(10):1370-1378.
19. Straka RJ, Taheri R, Cooper SL, Smith JC. Achieving cholesterol target in a managed care organization (ACTION) trial. *Pharmacotherapy*. 2005;25(3):360-371.
20. Bogden PE, Koontz LM, Williamson P, Abbott RD. The physician and pharmacist team: an effective approach to cholesterol reduction. *J Gen Intern Med*. 1997;12(3):158-164.
21. Mazzolini TA, Irons BK, Schell EC, Seifert CF. Lipid levels and use of lipid-lowering drugs for patients in pharmacist-managed lipid clinics versus usual care in 2 VA Medical Centers. *J Manag Care Pharm*. 2005;11(9):763-771.
22. Fabbio KL, Bradley M, Chrymko M. Evaluation of a pharmacist-managed telephone lipid clinic at a Veterans Affairs Medical Center. *Ann Pharmacother*. 2010;44(1):50-56.