Individualized Risk Communication and Outreach for Primary Cardiovascular Disease Prevention in Community Health Centers Randomized Trial

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Background—Many eligible primary cardiovascular disease prevention candidates are not treated with statins. Electronic health record data can identify patients with increased cardiovascular disease risk.

Methods and Results—We performed a pragmatic randomized controlled trial at community health centers in 2 states. Participants were men aged ≥35 years and women ≥45 years, without cardiovascular disease or diabetes mellitus, and with a 10-year risk of coronary heart disease of at least 10%. The intervention group received telephone and mailed outreach, individualized based on patients’ cardiovascular disease risk and uncontrolled risk factors, provided by lay health workers. Main outcomes included: documented discussion of medication treatment for cholesterol with a primary care clinician, receipt of statin prescription within 6 months, and low-density lipoprotein (LDL)-cholesterol repeated and at least 30 mg/dL lower than baseline within 1 year. Six hundred forty-six participants (328 and 318 in the intervention and control groups, respectively) were included. At 6 months, 26.8% of intervention and 11.6% of control patients had discussed cholesterol treatment with a primary care clinician (odds ratio, 2.79; [95% confidence interval, 2.25–3.46]). Statin prescribing occurred for 10.1% in the intervention group and 6.0% in the control group (odds ratio, 1.76; [95% confidence interval, 0.90–3.45]). The cholesterol outcome did not differ, and the majority of patients did not repeat lipid levels during follow-up.

Conclusions—Risk communication and lay outreach increased cholesterol treatment discussions with primary care clinicians. However, most discussions did not result in statin prescribing. For outreach to be successful, it should be combined with interventions to encourage clinicians to follow contemporary risk-based cholesterol treatment guidelines.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01610609.

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Key Words: cardiovascular diseases • case management • cholesterol • randomized controlled trial • risk assessment

The risk of developing cardiovascular disease (CVD) can be greatly reduced through lifestyle and medical therapies that address diet, overweight and obesity, smoking, dyslipidemia, hypertension, and diabetes mellitus. Irrespective of which factors are contributing on an individual’s risk for the development of CVD, treatment with statins safely and effectively reduces morbidity and mortality from CVD.1,2 The recent American College of Cardiology/American Heart Association cholesterol treatment guideline emphasizes identifying and treating individuals at risk for developing CVD.3 However, fewer than half of high-risk individuals are treated with statins.4,5 Statin use is lower among blacks,4,6 Hispanics,5,6 the uninsured,7 and poorer individuals.8,9 Reducing the population burden of CVD and decreasing disparities will require maximizing the use of preventive strategies among all individuals likely to benefit from them.

Statins may be underused for primary prevention for several reasons. Clinicians and patients may not readily appreciate increased CVD risk, particularly when risk comes from factors other than elevated cholesterol.10,11 Patients may also
WHAT IS KNOWN

- Minority populations and persons of lower socioeconomic status face a disproportionally high burden from cardiovascular disease in the United States.
- Moderately high-intensity interventions using clinicians, such as nurse practitioners, can reduce cardiovascular disease risk factors, but widespread implementation may be limited because of cost.

WHAT THE STUDY ADDS

- A telephone and mailed outreach intervention, which was delivered by lay health workers and sought to improve statin uptake for primary prevention among community health center patients with moderately high cardiovascular risk, led to more cholesterol treatment discussions with primary care clinicians but had little impact on statin prescribing.
- This intervention that was predominantly patient directed and focused on statin therapy for primary cardiovascular disease prevention risk did not lead to significantly increased uptake of statins.
- Ways to promote a tailored and targeted risk-based approach to statin prescribing among primary care clinicians should be investigated.

Methods

Design Overview

We conducted a pragmatic single-blind, randomized, controlled trial. The intervention group received telephone and mailed outreach individualized based on patients’ CVD risk and uncontrolled risk factors and was provided by lay health workers. The control group received usual care during the 1-year study. The institutional review board of Northwestern University approved the study and waived informed consent. Participating clinic networks also approved the study protocol. Eligible patients were identified using EHR data. Eligible participants were randomly assigned, in 3 waves, in a 1:1 ratio to each of the 2 groups. The 3 waves of enrollment took place between August 2012 and March 2013. We followed patients in each wave for 1 year after which the control group received the outreach protocol.

Setting and Participants

The study was performed at 3 networks of federally qualified community health centers (CHCs): 1 site that is part of Heartland Health Outreach (Chicago, IL), 8 sites from Near North Health Services Corporation (Chicago, IL), and 2 sites from North Country Healthcare (Flagstaff and Winslow, AZ). At the time of the study, the EHRs at the 3 sites had clinical decision support, which enabled clinicians to automatically calculate the 10-year risk of coronary death or myocardial infarction when they chose to do so based on the Framingham Heart Study equations.16

Patients were identified using structured query language applied to data within the sites’ EHRs. Eligibility and exclusion criteria were based on the cholesterol screening recommendations from US Preventive Services Task Force19 and the recommendations for primary CVD prevention from the National Cholesterol Education Program Adult Treatment Panel III in 2001 and 2004,20,21 which were the contemporaneous guidelines at the time this study was conducted. Eligibility criteria included: (1) men aged ≥55 years and women aged ≥45 years old, (2) LDL-cholesterol measured within in the past 5 years, (3) no lipid-lowering medication on the active medication list, (4) at least 1 face-to-face visit to a study site in the 6 months before the date of a randomization wave, (5) a 10-year risk of coronary death or myocardial infarction (based on Framingham Risk Score) of at least 10%,18,21 and (6) an LDL-cholesterol of ≥100 mg/dL on the most recent test. Exclusion criteria included: (1) diagnosed coronary disease, peripheral arterial disease, abdominal aortic aneurysm, or diabetes mellitus and (2) patients with a primary language recorded other than English or Spanish. We reviewed the lists of eligible patients with patients’ primary care clinicians who could indicate patients they felt should not receive outreach. When no primary clinician could be identified, the clinician who most recently saw the patient, or the practice medical director performed this role. These patients were included in the intention-to-treat analysis.

Randomization and Intervention

A Northwestern investigator (S.P.) who was not aware of patients’ identities, stratified eligible patients by CHC network then randomly assigned patients in a 1:1 ratio within each stratum using a random number generator in SAS 9.3 statistical software (SAS Institute, Cary, NC).

Participants were entered into the study at 3 time points (waves 1, 2, and 3). Deviation from the planned randomization procedure occurred when 14 subjects who were included in the first wave of randomization were mistakenly included in the second wave of randomization; 6 were assigned to the same group both times, and 8 were assigned to different groups. Because individuals assigned to the intervention received outreach during the study year, we included these 8 individuals in the intervention group. A sensitivity analyses demonstrated that excluding the 8 patients randomized to both study arms had little effect on any measured outcome (Appendix I in the Data Supplement).

Care managers fluent in English and Spanish performed the outreach. Care managers received 20 hours of training by Northwestern University investigators. Physicians, nurse practitioners, and physician assistants at the clinics were oriented to the study by e-mail and through announcements at staff meetings.

For each intervention patient, we used EHR data to estimate global CVD risk based on the equations of D’Agostino, et al.22 We chose this outcome (which includes the development of any symptomatic coronary heart disease, cerebrovascular disease, peripheral arterial disease, and heart failure) to emphasize patients’ level of risk. We also determined clinical actions to encourage patients to discuss with their clinician. For all patients, this included the use of medication to lower cholesterol. Additional recommended actions included addressing high blood pressure (when the blood pressure was ≥140/90 mm Hg) and attempting to quit smoking (for current smokers). Care managers
performed outreach by telephone and mail. We chose this outreach approach (rather than in-person counseling sessions with care managers) because: it was a feasible way to deliver the intervention to a fairly large number of patients, it did not require additional clinical office space, and we wanted to promote discussions with primary care clinicians who had the ability to prescribe medication.

On the telephone, care managers informed patients that (1) the patient’s primary clinician wanted them to call to talk about cholesterol (as well as blood pressure and smoking when applicable), (2) they were at a higher than average risk for heart disease, and (3) to encourage an appointment with the clinician to discuss strategies to decrease risk. After the attempted telephone outreach, care managers mailed a summary of the patient’s personal 10-year CVD risk and actions to discuss with their primary clinician (see Appendix for sample print message in the Data Supplement). Mailings also included simple lay language educational material defining cholesterol, heart disease, and statin medications; an explanation of how cholesterol is related to heart disease; and actions they could take to lower risk. We tested these materials with patients with CHC and made modifications to improve patient understanding. Patients who were not reached after 3 call attempts were mailed a letter providing the same content included in the telephone outreach, the personalized patient educational materials, and an encouragement to call the care manager. When outreach was delivered, care managers sent EHR notes to patients’ primary clinicians detailing the patient’s CVD risk level, risk targets discussed, and that the patient was asked to schedule a CVD prevention visit. Care managers delivered a second round of outreach to patients who did not have a CVD office visit within 3 months. For homeless patients, telephone outreach was conducted by the same protocol when possible. If the EHR contained an address for a shelter or transitional home, care managers attempted to reach the patient by calling the general shelter telephone number. Mailed outreach was sent to transitional homes.

Outcomes and Follow-Up
All outcomes were from data collected during routine care. The primary process outcome was whether a discussion about drug treatment for cholesterol occurred during an office visit between the patient and any physician, nurse, or physician assistant in the 6 months after randomization. Care managers printed office notes from this period and redacted patient identifiers. Care manager notes pertaining to the delivery of the intervention were not included. Northwestern investigators reviewed these charts and were blinded to study group assignment. The primary process outcome was met if there was documentation of (1) prescription for a statin, (2) clinician recommendation for drug therapy for cholesterol, (3) patient refusal of drug therapy for cholesterol, or (4) discussion of the use of a drug to lower cholesterol (any free text). A single investigator (S.S. or S.D.P.) classified the chart outcomes. Both reviewers classified 10% of the charts independently, and there was excellent agreement for the primary outcome (κ = 0.90; 95% confidence interval, 0.79–1.0). Secondary outcomes included the individual components of the primary outcome (agreement for these outcomes is included in the Data Supplement). We also examined post hoc the composite outcome of any recommendation of drug treatment for cholesterol, which consisted of the first 3 components of the primary process outcome above.

The primary clinical outcome, collected by EHR query, was an LDL-cholesterol test during the 1-year study period having a value at least 30 mg/dL lower than the baseline value. Other outcomes assessed through automated searches of the EHR included statin prescription and repeat LDL-cholesterol testing at 6 months and 1 year.

Statistical Analysis
We aimed to include at least 488 subjects (244 per group) to provide 90% power to detect an absolute difference in the primary process outcome of 15% across the entire range of possible outcome proportions in the control group with a 2-sided type I error rate of 0.05 using a χ² test. For the primary clinical outcome, we expected that the proportion of patients who would meet this outcome in the control group would be low. A group size of at least 244 would provide 90% power to detect a 10% absolute difference in this outcome if the proportion in the control group was <7.5% and at least 80% power to detect a 10% difference in this outcome if it was <12%. Available resources permitted us to perform a study that included 646 participants. All analyses were by intention-to-treat and used SAS 9.3 statistical software (SAS Institute). To compare primary and secondary outcomes between the 2 groups, we used logistic regression with generalized estimating equations to account for the stratified randomization by health center network (PROC GENMOD). When the number of events in a group was <5, we applied Barnard test to determine if there were changes in statistical significance. Because no significant changes were found, we present the results from the regression models.

Results

Participants
Figure 1 shows the flow of the 646 patients identified as eligible based on EHR queries through the study. All were included in intention-to-treat analysis. Of the 328 patients assigned to the intervention group, 9 were ineligible based on chart review and clinicians indicated 25 should not receive the intervention. Baseline characteristics were similar in both the groups (Table 1). Patient characteristics by health center network are shown in Table I in the Data Supplement.

Intervention Implementation
Of the 294 intervention patients for whom outreach was attempted, care managers spoke with 133 (45.2%) patients by telephone during initial outreach. The mailing was returned as undeliverable for 20 patients. Within 3 months, 129 patients had had an office visit and were ineligible for further outreach, 22 patients refused all further contact during initial outreach, and 5 were no longer receiving care at the CHC. Data for 26 patients for reminder outreach was missing. Repeat outreach was performed for 112 patients; telephone contact was successful for 42 (37.5%).

Six-Month Outcomes
At 6 months, 88 (26.8%) intervention group and 37 (11.6%) control group patients had discussed cholesterol medication treatment with a primary care clinician (odds ratio, 2.79 [95% confidence interval, 2.25–3.46]; P < 0.001). Proportion of patients with a statin prescribed was 10.1% in the intervention group versus 6.0% in the control group (odds ratio, 1.76 [95% confidence interval, 0.90–3.45]); P = 0.098). Patients in the intervention group were also more likely to have documentation of refusing cholesterol-lowering medication, discussions about drug treatment that did not include a clear recommendation, and the combined post hoc outcome of any recommendation for drug treatment for cholesterol (Table 2). More intervention group patients had a clinician office visit within 6 months; 237 (72.3%) versus 192 (60.4%), (odds ratio, 1.69 [95% confidence interval, 1.11–2.55]; P = 0.014).

Twelve-Month EHR Outcomes
The proportions of patients who met the primary clinical outcome (LDL-cholesterol repeated and at least 30 mg/dL lower within 1 year) did not differ significantly between intervention groups (5.2% and 3.8% in the intervention and control groups, respectively, P = 0.57). Other results obtained by automated queries of EHR data are shown in Table 3.
Discussion

We tested an intervention to identify patients at increased risk for developing CVD using EHR data and then deliver individualized outreach by lay care managers to encourage CVD risk reduction discussions with their provider. This intervention increased face-to-face encounters with a primary care clinician at which cholesterol treatment was addressed and the proportion with any office visit within 6 months. This indicates that the population health approach to primary CVD prevention taken here had measurable effects on the care patients obtained. However, when discussions about cholesterol treatment did occur, these visits resulted in a statin being prescribed far less than half the time. There was no significant increase in the proportion of patients who had a clinically important decline in LDL-cholesterol at 1 year. Therefore, if implemented in its current form, we do not expect that this intervention would have a large impact on CVD prevention.

Improving outcomes require multiple steps. Figure 2 shows these steps, the potential missed opportunities at each step, and the targets where future interventions need to focus to achieve greater success. The 2 steps in this sequence that seem to warrant the most attention are increasing the proportion of visits where cholesterol treatment discussions occurred, and increasing the proportion of cholesterol discussions that result in a statin recommendation. Additional downstream drops that were not measured here are also possible: some new prescriptions are never filled, and many individuals who initially start statins discontinue them during the first year.

There are several potential explanations for our findings. Primary care clinicians may not have always been convinced that statin therapy was warranted. We informed these clinicians about the intervention rationale, and care managers sent primary care physicians EHR messages indicating that patients were advised to consider medication to treat cholesterol, but prescribing decisions were left up to the treating clinicians. Although there was substantial published evidence available before the time this study was performed demonstrating benefits of statin treatment for primary prevention across a wide range of baseline cholesterol levels, the contemporary US guidelines did not make particularly strong statements for statin therapy for most primary prevention patients. The National Cholesterol Education Program Adult Treatment Panel III recommended in 2001 to consider drug therapy for individuals with a 10-year Framingham Risk of 10% to 20% with an LDL-cholesterol goal of $\geq 130$ mg/dL. The 2004 update of this guideline indicated that for individuals with this level of risk and a LDL-cholesterol level of 100 to 129 mg/dL, starting drug therapy was considered to be a therapeutic option. The American College of Cardiology/American Heart Association adult cholesterol treatment guideline that became available in November 2013 (after this study took place) provided much more definitive recommendations about the use of statin therapy for primary prevention based on individuals' risk of developing atherosclerotic CVD. Importantly, prescription of a statin for this group is only recommended after a clinician–patient discussion that considers the magnitude of benefit, potential harms, and patient preferences. A new intervention based on this guideline might yield a more significant increase in statin prescribing to individuals at increased CVD risk than what we observed.

Stronger effects may have occurred if we had included more clinician-facing strategies. These practices could automatically calculate the Framingham Risk Score within the EHR when requested by a clinician but did not have decision support rules aimed at influencing treatment decisions for primary prevention of CVD in adults without diabetes.
mellitus, neither did they have performance feedback addressing primary CVD prevention. Clinicians may have chosen to address CVD risk in other ways such as through therapeutic lifestyle changes that addressed dietary changes, exercise, or smoking cessation rather than using statin therapy. Although we think that therapeutic lifestyle change and smoking cessation are crucial aspects of CVD prevention, in moderate-to-high risk populations such as the one studied here, clinicians may need additional encouragement to use statin pharmacotherapy concurrently with attempts to improve CVD-related health behaviors. Further studies should examine the effects of combining clinician-directed and patient-directed improvement modalities.

Alternative strategies for the initial patient contact could be tested to see if they improve intervention effectiveness including individual or group meetings with the care managers to provide explanations about CVD risk, individuals’ risk factor profiles, and recommended actions. Another potential explanation for our observed findings is that this intervention led patients to discuss CVD prevention with clinicians but did not overcome some patients’ reluctance to initiate drug therapy. The increase in patients who refused...
cholesterol-lowering medication among the intervention group supports this notion.

This study takes a CVD risk estimation approach similar to what has been done in previous studies\textsuperscript{12–15} and applies it to an entire population of patients receiving care in CHCs. Previous studies showed that providing individualized CVD risk information to patients has effects on patients’ knowledge, attitudes, and some health behaviors, but the impact on CVD risk factors has been inconsistent, and the impact on health outcomes is not known. A systematic review examined the impact of giving CVD risk information to adults with moderate-to-high CVD risk. The 18 studies identified (including 14 randomized controlled trials) showed that providing patients with their CVD risk information increased accuracy of perceived risk and probably increased the intention to start medication. Studies with repeated exposure to risk messages yielded significant reductions in the predicted CVD risk.\textsuperscript{25} Several studies completed because this review took a CVD risk estimation approach similar to what has been done in previous studies\textsuperscript{12–15} and applies it to an entire population of patients receiving care in CHCs.

Several other limitations should be kept in mind. Because we used a pragmatic design, we relied on data collected in the course of routine care. In particular, we did not perform scheduled measurements of cholesterol. Because statin prescribing was low, we doubt that we would have shown major differences in cholesterol levels even had we done routine scheduled measurements. We used chart review to measure treatment discussions, and there is a possibility that some outcomes were misclassified because not all discussions and treatment recommendations may have been documented or detected by chart reviewers. Our study was conducted at CHCs. It is possible that patient populations with higher socioeconomic status or educational attainment would find the outreach messages more actionable and, therefore, the effects may be larger if this intervention were conducted at clinics serving more affluent patients. Conversely, these CHCs were well-organized networks that had used an EHR for several years. The intervention effects might be smaller if performed at CHCs with less robust information systems. In addition, this intervention did not focus on other important aspects of CVD prevention (ie, smoking cessation that was prevalent in this population). Other benefits to CVD risk reduction may have been observed had we taken a broader approach rather than being focused on promoting the use of statins.

In summary, providing individualized CVD risk communication and lay outreach to a general population of primary prevention candidates at risk for CVD and receiving care at CHCs increased cholesterol treatment discussions with primary care clinicians. However, the majority of discussions did not result in statin prescribing. Future interventions need to more successfully change processes at each step from motivating moderate- and high-risk patients to seek care, to promoting clinician–patient discussions about CVD risk reduction, to overcoming clinicians’ barriers to medication prescribing, and to encouraging patient acceptance of recommended treatment.

\section*{Acknowledgments}

We thank Erin Kaleba, MPH, Regina Knight, and Jonathan Grey for their contributions to this project. We have listed everyone who contributed significantly to the work in the Acknowledgments. The full trial protocol is available from the corresponding author by request.

\section*{Sources of Funding}

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\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|}
\hline
Outcomes Measured by Automated Data Retrieval From Electronic Health Records & Assigned Outreach Intervention, n=328 & Assigned Control Intervention, n=318 & Odds Ratio (95\% CI), P Value \\
\hline
LDL-cholesterol repeated and at least 30 mg/dL lower than baseline at 1 y, n (%)* & 17 (5.2) & 12 (3.8) & 1.39 (0.45–4.31), 0.57 \\
Repeat LDL performed within 1 y, n (%) & 127 (38.7) & 108 (34.0) & 1.86 (0.92–3.62), 0.07 \\
Repeat LDL performed within 6 mo, n (%) & 89 (27.1) & 53 (16.7) & 1.22 (0.92–1.62), 0.07 \\
Statin prescribed within 6 mo, n (%) & 29 (8.8) & 18 (5.7) & 1.62 (0.98–2.67), 0.06 \\
Statin prescribed within 1 y, n (%) & 44 (13.4) & 34 (10.7) & 1.29 (1.01–1.66), 0.04 \\
\hline
\end{tabular}
\caption{Outcomes Measured by Automated Data Retrieval From Electronic Health Records}
\end{table}
Disclosures

Dr Persell receives grant support from Pfizer, Inc. The other authors report no conflicts.

References


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**Supplemental Material**

**Supplemental Table 1. Characteristics of Patients by Community Health Center Network**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Center 1 (N = 196)</th>
<th>Center 2 (N = 173)</th>
<th>Center 3 (N = 277)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD), y</td>
<td>54.7 (5.8)</td>
<td>62.4 (10.2)</td>
<td>61.8 (9.9)</td>
</tr>
<tr>
<td>Male sex, %</td>
<td>187 (95.4)</td>
<td>152 (87.9)</td>
<td>234 (84.5)</td>
</tr>
<tr>
<td>Race, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>119 (60.7)</td>
<td>5 (2.9)</td>
<td>198 (71.5)</td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>54 (27.6)</td>
<td>133 (76.9)</td>
<td>29 (10.5)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>22 (11.2)</td>
<td>29 (16.8)</td>
<td>36 (13.0)</td>
</tr>
<tr>
<td>Other, unknown</td>
<td>1 (0.5)</td>
<td>6 (3.5)</td>
<td>14 (5.1)</td>
</tr>
<tr>
<td>Primary language, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>186 (94.9)</td>
<td>168 (97.1)</td>
<td>236 (85.2)</td>
</tr>
<tr>
<td>Spanish</td>
<td>10 (5.1)</td>
<td>5 (2.9)</td>
<td>30 (10.8)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>11 (4.0)</td>
</tr>
<tr>
<td>Clinic visits in past 12 months, median (IQR)</td>
<td>3.5 (2, 6)</td>
<td>2 (1, 4)</td>
<td>3 (2, 4)</td>
</tr>
<tr>
<td>10-y Framingham CHD risk score (SD)*</td>
<td>13.5 (4.5)</td>
<td>14.7 (9.2)</td>
<td>13.8 (5.3)</td>
</tr>
<tr>
<td>Global cardiovascular risk score (SD)†</td>
<td>21.5 (8.6)</td>
<td>24.3 (9.2)</td>
<td>24.2 (10.9)</td>
</tr>
<tr>
<td>Total cholesterol, mg/dl (SD)</td>
<td>214.4 (29.9)</td>
<td>213.4 (35.9)</td>
<td>208.7 (29.8)</td>
</tr>
<tr>
<td>LDL cholesterol, mg/dl (SD)</td>
<td>132.0 (24.8)</td>
<td>134.0 (27.4)</td>
<td>131.5 (24.1)</td>
</tr>
<tr>
<td>HDL cholesterol, mg/dl (SD)</td>
<td>50.9 (15.7)</td>
<td>48.8 (13.5)</td>
<td>50.2 (13.8)</td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg (SD)</td>
<td>132.7 (18.8)</td>
<td>137.5 (17.5)</td>
<td>138.1 (20.0)</td>
</tr>
<tr>
<td>Diastolic blood pressure, mm Hg (SD)</td>
<td>87.2 (13.3)</td>
<td>83.9 (9.7)</td>
<td>81.7 (11.1)</td>
</tr>
<tr>
<td>Drug treated hypertension, %</td>
<td>41 (20.9)</td>
<td>45 (26.0)</td>
<td>78 (28.2)</td>
</tr>
<tr>
<td>Current smoker, %</td>
<td>159 (81.1)</td>
<td>68 (39.3)</td>
<td>131 (47.3)</td>
</tr>
</tbody>
</table>
## Supplemental Table 2. Outcomes Measured at by Blinded Chart Review at 6 Months Excluding Patients Assigned Both Study Groups

<table>
<thead>
<tr>
<th>Outcome Description</th>
<th>Patients Assigned Outreach Intervention n = 320</th>
<th>Patients Assigned Control Intervention n = 318</th>
<th>Odds Ratio (95% CI), P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office discussion of treatment for cholesterol, n (%)†</td>
<td>88 (27.5)</td>
<td>37 (11.6)</td>
<td>2.89 (2.24-3.73), &lt;0.001</td>
</tr>
<tr>
<td>A) Statin prescribed, n (%)</td>
<td>33 (10.3)</td>
<td>19 (6.0)</td>
<td>1.82 (0.89-3.71), 0.099</td>
</tr>
<tr>
<td>B) Drug treatment for cholesterol recommended (but not prescribed, n (%))</td>
<td>2 (0.6)</td>
<td>0 (0)</td>
<td>--</td>
</tr>
<tr>
<td>C) Patient refusal of drug treatment for cholesterol, n (%)</td>
<td>10 (3.1)</td>
<td>1 (0.3)</td>
<td>11.29 (1.71-74.39), 0.012</td>
</tr>
<tr>
<td>D) Discussion but no clinician recommendation for drug treatment for cholesterol, n (%)</td>
<td>43 (13.4)</td>
<td>17 (5.4)</td>
<td>2.69 (2.20-3.28), &lt;0.001</td>
</tr>
<tr>
<td>Any recommendation of drug treatment for cholesterol, n (%)†</td>
<td>45 (14.1)</td>
<td>20 (6.3)</td>
<td>2.45 (1.35-4.43), 0.0031</td>
</tr>
</tbody>
</table>

* Primary process of care outcome (includes A, B, C and D)

† Post hoc combined process outcome (includes A, B and C)
**Supplemental Table 3. Outcomes Measured by Automated Data Retrieval from Electronic Health Records Excluding Patients Assigned Both Study Groups**

<table>
<thead>
<tr>
<th>Outcome Description</th>
<th>Patients Assigned Outreach Intervention n = 320</th>
<th>Patients Assigned Control Intervention n = 318</th>
<th>Odds Ratio (95% CI), P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL-cholesterol repeated and at least 30 mg/dL lower than baseline at 1 year, n (%)*</td>
<td>17 (5.3)</td>
<td>12 (3.8)</td>
<td>1.44 (0.44-4.67), 0.54</td>
</tr>
<tr>
<td>Repeat LDL performed within 6 months, n (%)</td>
<td>88 (27.5)</td>
<td>53 (16.7)</td>
<td>1.91 (1.38-2.62), &lt;0.0001</td>
</tr>
<tr>
<td>Repeat LDL performed within 1 year, n (%)</td>
<td>124 (38.8)</td>
<td>108 (34.0)</td>
<td>1.23 (0.92-1.65), 0.17</td>
</tr>
<tr>
<td>Statin prescribed within 6 months, n (%)</td>
<td>29 (9.1)</td>
<td>18 (5.7)</td>
<td>1.66 (0.97-2.85), 0.06</td>
</tr>
<tr>
<td>Statin prescribed within 1 year, n (%)</td>
<td>44 (13.8)</td>
<td>34 (10.7)</td>
<td>1.33 (1.00-1.78), 0.051</td>
</tr>
</tbody>
</table>

* Primary clinical outcome
Supplemental Table 4. Inter-Rater Agreement for Chart Review Outcomes of 10% Sample

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Kappa</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office discussion of drug treatment for cholesterol, n (%)*</td>
<td>0.90</td>
<td>0.79-1.00</td>
</tr>
<tr>
<td>- Statin prescribed, n (%)</td>
<td>0.94</td>
<td>0.82-1.00</td>
</tr>
<tr>
<td>- Drug treatment for cholesterol recommended (but not prescribed, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Patient refusal of drug treatment for cholesterol, n (%)</td>
<td>0.90</td>
<td>0.71-1.00</td>
</tr>
<tr>
<td>- Discussion but no clear recommendation for drug treatment for cholesterol, n (%)</td>
<td>0.72</td>
<td>0.45-0.98</td>
</tr>
<tr>
<td>Recommendation of drug treatment for cholesterol, n (%)</td>
<td>0.96</td>
<td>0.88-1.00</td>
</tr>
</tbody>
</table>

* Primary process of care outcome
Supplemental Figure 1. Sample Patient Education Material

Your Risk of Heart Attack or Stroke During the Next 10 Years is High

- Your risk is higher than it should be
- You can lower your risk
- See your doctor to discuss ways to lower your risk of heart attack or stroke
- Diet and exercise can help but you may also need medication
- Discuss medication to lower cholesterol with your doctor

Your risk of having a stroke or heart attack in the next 10 years is about 22 out of 100 (22%).
Supplemental Figure 2. Patient Education Information about Cholesterol

Cholesterol

What is it?

Cholesterol is a type of fat. Cholesterol is found in foods that come from animals. Your body also makes cholesterol in your blood.

Why is it bad?

High cholesterol hurts your body by clogging up your blood vessels. But even if it’s hurting your body, you won’t feel anything until the blood vessels get really blocked up. This can cause you to have a heart attack or stroke.

What can I do about it?

The good news is there are things you can do to lower your cholesterol. You can exercise. You can eat healthy foods. But, your body makes most of the cholesterol in your blood.

Even if you are exercising and eating healthy, you may still need a medicine to lower your cholesterol.

What medicines can help lower cholesterol?

There are medicines that can lower your cholesterol and your chance of having a heart attack. These medicines are called statins.

Statins are very safe and work well. They have been used for a long time by many patients to reduce their risk of having a heart attack.

Call today to make an appointment with your doctor.