# Overcoming Inertia: Improvement in Achieving Target Low-density Lipoprotein Cholesterol

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**Objective:** To improve lipid management of highrisk patients in a large academic primary care practice.

**Study Design:** Educational intervention with historical controls.

Methods: We determined the likelihood of providers within an academic Veterans Affairs primary care practice to adjust simvastatin doses before and after a low-cost educational intervention. Study patients were enrolled during a 2-year preintervention period, had an indication to achieve a low-density lipoprotein cholesterol (LDL-C) level of <100 mg/dL, and were taking simvastatin but not at the maximum dose. We explored factors that might affect dose changing, including patient demographics, diabetes, coronary disease, patient medication adherence, and a threshold effect where LDL-C values just above the target might lead to provider inaction.

Results: Initially, 49% of 4048 patients met their LDL-C target. Before the intervention, the simvastatin dose was changed at only 16% of 2103 patient visits where the patient was not at treatment target and was on less than the maximum dose. Providers were more likely to adjust the dose for patients with high LDL-C and those who were compliant, and less likely to adjust it for older or diabetic patients. After the intervention, 62% of 1414 patients met their treatment target. Compared with the preintervention period, providers were more likely to increase the simvastatin dose for patients not yet at their target (P = .023).

**Conclusion:** Following a low-cost intervention, providers more aggressively treated high LDL-C in high-risk patients, and more patients reached their treatment target goal.

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For author information and disclosures, see end of text.

he leading cause of death in the United States is coronary heart disease. Among patients at the greatest risk of death from heart disease, medical interventions that reduce low-density lipoprotein cholesterol (LDL-C) have repeatedly been shown to prolong life. The Report of the Expert Panel of the National Cholesterol Education Panel (NCEP) concluded that the HMG-CoA reductase inhibitor (statin) class of medications are the preferred choice for patients in whom lifestyle modifications either fail or are unlikely to achieve LDL-C targets. Despite widespread dissemination of these guidelines, many patients in general practice settings have not met their treatment targets, even when receiving statin medication. 2-6

Two provider factors, clinical inertia and the presence of a threshold effect, may contribute to poor outcomes. Clinical inertia refers to a provider practice in which the clinician recognizes that a patient is not at the treatment target but nevertheless fails to change therapy. It has been documented in cases of hyperlipidemia, diabetes, and hypertension. We define a threshold effect as the provider's increasing failure to intensify therapy as a patient approaches the treatment target.

We explored these factors and their impact on patients at the highest risk of death from vascular disease in our primary care practice. We studied patients who were taking statin medication but had not reached their LDL-C target. Our goals were: (1) to determine whether an educational intervention overcame clinical inertia and the threshold effect to achieve LDL-C treatment success at follow-up visits, using the failure to increase the statin dose as a metric, and (2) to measure factors associated with such failures.

#### **MFTHODS**

The study took place in the primary care clinics of the Durham Veterans Affairs Health Care system. Providers included physicians (n=38), physician assistants (n=10), nurse practitioners (n=3), and geriatrics fellows (n=15). Our hospital's institutional review board approved this study.

Data were collected from the hospital's clinical information system.<sup>9</sup> We abstracted patient demographics, prescribing records, and laboratory tests for all primary care visits during 2 time

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periods. The first period (January 1, 2003, until December 31, 2004) was used to measure the preintervention determinants of statin dosing changes. The second period (May 1, 2005, until July 31, 2005) was used to measure changes following the intervention.

We identified all primary care patients with an active prescription for simvastatin, the preferred formulary statin, as of December 31, 2004, and each primary care visit for the preceding 2 years at which an LDL-C value was available. We isolated patients identified by providers as having diabetes or coronary artery disease (*International Classification of Diseases*, *Ninth Revision*, *Clinical Modification* 10 codes 250.00-250.93, 410.0-410.92, 411.0-411.89, 412, 413.1, 413.9, and 414.0-414.9), <sup>10</sup> as the LDL-C target for these patients was unequivocally less than 100 mg/dL. The index visit for

each period was the first visit where the patient was prescribed simvastatin at a dose less than the maximum recommended (80 mg/day). We also required that the patient receive at least 1 refill of simvastatin following the index visit.

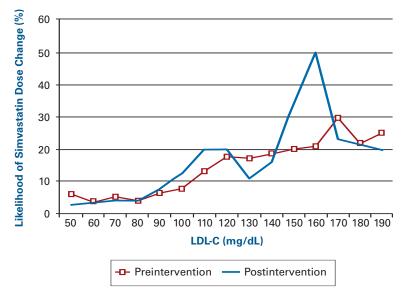
We recorded each patient's simvastatin dose at the time of the index visit and the next prescription issued after that visit to detect changes in dosing. We excluded patients who had concurrent prescriptions for medications that might complicate the dosing of simvastatin.<sup>11</sup> Patients who requested refills consistent with daily usage were considered adherent.

Following the preintervention period, we began a communication and education initiative to increase the chance that providers would take action at each visit for patients who had not met their LDL-C target. The intervention included 1 large group and several smaller group presentations given during staff meetings and a regular series of short educational messages sent through electronic mail.

We continually emphasized that our practice data suggested a threshold effect, whereby providers were getting patients close to but not below the treatment target. We reiterated that success could be reached by either increasing the statin doses or adding nonpharmacologic interventions, but that failure to change practice would lead to continued failure to achieve treatment targets. LDL-C-lowering response can be predicted from statin dose, and we highlighted the expected improvement from a dosage increase by applying information compiled by the Department of Veterans Affairs and the Department of Defense.<sup>12</sup>

The electronic mail intervention consisted of 11 weekly communications. Each communiqué was designed to be no

■ Figure 1. Likelihood of Simvastatin Dose Change During Visit Based on Low-density Lipoprotein Cholesterol (LDL-C)



more than a "screenful" of information and was sent with the ability for each provider to add replies, allowing an online forum for discussion. Of the communications, 2 reviewed non-pharmacologic measures to reduce LDL-C, 2 reinforced the guidelines themselves and provided quantitative feedback on how successful our group was at meeting them, and 3 reviewed pharmacologic strategies in detail. The remaining 4 communications discussed ways to improve practice management and patient communications with regard to cholesterol treatment.

Standard descriptive statistics were used to describe the variables of interest. We used logistic regression to predict the likelihood of a dosing change. To assess for a threshold effect and clinical inertia between study periods (Figure 1 and Figure 2), we compared outcomes curves at each 10-mg/dL LDL-C interval with a  $\chi^2$  test. We also used a  $\chi^2$  test to compare the percentages of patients below the LDL-C target for the preintervention versus the postintervention period. All analyses were performed with Stata statistical software. <sup>13</sup>

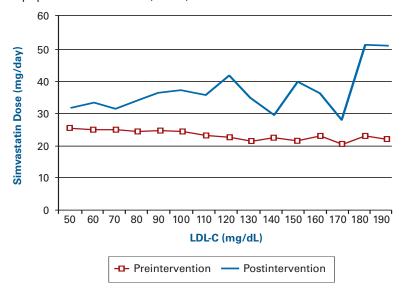
We would expect a high rate of change for all patients above their LDL-C goal of 100 mg/dL. A low overall rate of change suggests provider inertia. A threshold effect, whereby the dose is less likely to be changed for patients near, but still over, their treatment goal would be evidenced by a graph that shows a lower probability of changing the simvastatin dose as the LDL-C nears the treatment target.

# **RESULTS**

We identified 102 981 visits between January 1, 2003, and December 31, 2004, and isolated 35 510 visits by 10 404

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■ Figure 2. Average Simvastatin Dose Based on Low-density Lipoprotein Cholesterol (LDL-C)



unique patients during which the provider entered a diagnosis code of either diabetes or coronary artery disease. Of these patients, 4420 had an active submaximal simvastatin prescription at the time of at least 1 primary care visit and at least 1 simvastatin refill after that visit. A total of 372 patients were excluded because of concurrent prescriptions limiting simvastatin adjustment.

The **Table** provides descriptive information about this cohort of 4048 patients. At 451 (11%) of the visits, the provider

changed the dose of simvastatin. Of those changes, 111 occurred in patients at or below the target LDL-C level of 100 mg/dL. Almost all changes were dose increases. We found that adherence was not associated with the dose of simvastatin (P = .41). The distribution of the likelihood of changing the dose was normal (P = .13 to reject a normal distribution) among 66 different providers, suggesting that the practices of outliers did not obscure the larger trend of the group.

Using univariate analysis from variables shown in the Table, a high preclinic LDL-C level and patient adherence were positively correlated with a likelihood of dose change (P < .001) for both). Older patients (P < .001), those having both diabetes and coronary artery disease (P = .013), and those who were white (P = .002) were less likely to have had their simvastatin

dose increased. In a multivariate analysis, 4 variables predicted dose change: a high preintervention LDL-C level and simvastatin adherence predicted an increased likelihood of dose change, whereas patient age and diabetes predicted a decreased likelihood of dose change. Of those, the LDL-C level is by far the strongest predictor. Although the 4-variable model is statistically significant (P < .001), it explained only 6.9% of observed variation. The Hosmer-Lemeshow goodness-of-fit test<sup>14</sup> confirmed the appropriateness of the logistic model

■ Table. Patient Demographics and Cohort Description\*

Variable	Preintervention (n = 4048)	Postintervention (n = 1414)
Mean age (SD), y <sup>†</sup>	66 (10.7)	66 (10.1)
Sex, n (%) <sup>†</sup>		
Male	4020 (99)	1400 (99)
Female	28 (1)	14 (1)
Indication for LDL-C target of <100 mg/dL, n (%) $^{\dagger}$		
Diabetes alone	1713 (42)	623 (44)
Coronary artery disease alone	1401 (35)	439 (31)
Diabetes and coronary artery disease	934 (23)	352 (25)
Patients who were adherent, n (%)†	3448 (85)	1226 (87)
Mean LDL-C value at index visit (SD), mg/dL <sup>‡</sup>	107 (35)	93 (27)

<sup>\*</sup>A total of 924 patients in the postintervention group (65%) were also in the preintervention group.

 $<sup>^{\</sup>dagger}P$  > .14 for each comparison.

 $<sup>^{\</sup>ddagger}P < .00$ 

LDLC indicates low-density lipoprotein cholesterol.

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(P = .31). The overall accuracy of the model was 69% as measured by the area under the receiver operating characteristic [ROC] curve. Adding variables for the individual providers only increased the explained variation to 9.7% (area under the ROC curve of 73%).

The preintervention line in Figure 1 shows the likelihood of a simvastatin dose change at the index visit. Even at LDL-C levels greater than 160 mg/dL, the probability of making a dose adjustment was no more than 30%. We interpret that low rate of simvastatin dose change regardless of LDL-C level as suggestive of provider inertia. The low rate of dose change becomes even lower as the LDL-C value at the index visit approaches the goal of 100 mg/dL; this suggests a threshold effect.

Providers were overall significantly more likely to adjust the simvastatin dose following the intervention ( $\chi^2 = 19.3$ , P = .023). Among patients not at their treatment goal, 42% were close to the target, with preclinic LDL-C values between 100 and 120 mg/dL. The increased likelihood of dose change among patients close to, but not at, their target suggests that the intervention overcame the threshold effect. Figure 2 even more strikingly suggests clinical inertia, as the preintervention dose of simvastatin remained the same regardless of the patient's LDL-C level. During the postintervention period, patients received higher doses of simvastatin at every cholesterol level  $(\chi^2 = 148, P < .001)$ , and high LDL-C levels became associated with higher simvastatin doses, also suggesting the intervention overcame clinical inertia and threshold effects. LDL-C levels during the postintervention period improved following the intervention (P < .001); 62% of 1414 patients were below their LDL-C target of 100 mg/dL. This percentage is qualitatively similar to the percentage of patients we predicted a priori would reach their target LDL-C level following simvastatin dose intensification (58% for a single stepwise increase in dose, or 68% for changing to the maximal simvastatin dose).<sup>12</sup>

# DISCUSSION

Following a low-cost intervention, our large primary care practice changed its prescribing behavior concerning cholesterol management and achieved a significant improvement in helping patients achieve their target LDL-C level. We evaluated 4048 opportunities for providers to review lipid management with statin therapy in patients from our primary care practice who were at high risk of cardiac events. At these encounters, approximately half the patients were considered to be at target LDL-C levels; this is consistent with rates found in other studies. <sup>15-17</sup> Providers for patients not at the target level were unlikely to change statin doses, even for patients with the highest LDL-C values. Similar results have been found in several set-

tings.<sup>4,5,18</sup> Following our intervention, providers increased simvastatin doses for patients who had not achieved their target cholesterol level, and this behavior change correlated with an improvement in LDL-C values. Improvements following targeted interventions have been noted in highly selected groups,<sup>19</sup> but to our knowledge this is the first such success reported among such a large group of providers and patients.

It is possible that the increased likelihood to change the simvastatin dose was a reflection of larger trends in practice and not related to our intervention. As the guidelines for atrisk patients had not changed in several years before the intervention, and a significant change in behavior across a wide range of providers was noted just 3 months after the start of our intervention, we feel that the intervention itself is the most likely explanation. Only a randomized trial design can address this question definitively.

The NCEP targets are not continuous; they dictate that all patients whose LDL-C level exceeds their target value should undergo an intervention. The key issue is that the patients are above target, not by how much.<sup>1</sup> As all of the subjects in our study were already on a submaximal dose of simvastatin, an obvious intervention would be to increase the dose of lipid-lowering medication. A provider following the guidelines should be as likely to increase a simvastatin dose for a high-risk patient whose LDL-C was 101 mg/dL as for a patient whose LDL-C was 195 mg/dL; this was not what we found (Figure 1). We found not only a problem with clinical inertia, but also a threshold effect where patients close to treatment targets were even less likely to have their doses increased compared with those whose values were higher.

We demonstrated that a low-cost effort prodded primary care providers into action. The likelihood that they would adjust simvastatin doses increased. With this change we noticed an improvement in the lipid profile of our patients at the highest risk of vascular events. From the perspective of a large primary care clinic, the improvement from 49% to 62% in the percentage of patients who reached their LDL-C target only 3 months after the intervention represents a large number of patients who benefited from the intervention.

**Previous Presentation:** Aspects of this study were presented as a poster at the annual Society for General Internal Medicine Meeting, Los Angeles, Calif, April 28, 2006.

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#### **Take-away Points**

Lipid management for high-risk patients within an academic Veterans Affairs primary care practice was improved with a low-cost educational intervention.

- The intervention, consisting of group presentations during staff meetings and weekly e-mail communications, addressed 2 provider factors: clinical inertia and the threshold effect (increasing failure to intensify therapy as the patient approaches treatment goal).
- Before the intervention, the simvastatin dose was changed in only 16% of patients who were not at treatment target and who were taking less than the maximum dose.
- After the intervention, providers more aggressively treated high LDL-C in high-risk patients, and more patients achieved their treatment target of an LDL-C less than 100 mg/dL.

the data analysis. The authors (KCG, SDM, DLS) report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter discussed in this manuscript.

**Authorship Information:** Concept and design (KCG, SDM, DLS); acquisition of data (KCG); analysis and interpretation of data (KCG, SDM, DLS); drafting of the manuscript (KCG, SDM, DLS); critical revision of the manuscript for important intellectual content (KCG, SDM, DLS); statistical analysis (KCG, DLS).

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