

# Primary Nonadherence to Statin Therapy: Patients' Perceptions

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**C**ardiovascular disease (CVD) is the primary cause of death in the United States.<sup>1</sup> Furthermore, the total estimated direct and indirect costs of CVD and stroke in the United States were \$286 billion for 2007.<sup>2</sup> Hypercholesterolemia is a well-known risk factor for CVD; the estimated prevalence of elevated low-density lipoprotein cholesterol (LDL-C) levels among adults in the United States aged 20 years or more was 32% in 2008.<sup>2</sup> Hydroxymethylglutaryl-coenzyme A reductase inhibitors (statins) are widely used for management of elevated cholesterol levels and have been shown to be effective at preventing fatal and non-fatal cardiovascular events<sup>3-7</sup> and potentially reducing healthcare costs.<sup>8-10</sup>

The potential public health benefits of statin use are limited if there are patients who never fill newly ordered medication (primary nonadherence). While most of the available evidence on nonadherence to statin therapy has focused on refill rates (secondary nonadherence), recent studies have shown that primary adherence to statin therapy is suboptimal across a variety of populations.<sup>11-17</sup> For example, among a large, diverse cohort of managed care patients in Southern California, 20% of patients failed to fill their initial statin prescription.<sup>18</sup> An evaluation of a community-based electronic prescribing initiative found that 28% of initial prescriptions for lipid-lowering agents were never filled.<sup>11</sup> A prospective study among military veterans given a new statin prescription found that 10% of the cohort reported having never started their medication.<sup>14</sup>

In addition to measuring the prevalence of primary nonadherence to statin therapy, understanding self-reported factors that result in unclaimed prescriptions is important for developing patient-focused interventions aimed at improving adherence and ultimately reducing adverse CVD events. While previous studies have assessed sociodemographic, medical, and healthcare utilization characteristics associated with nonadherence to statins,<sup>19</sup> to our knowledge, only 1 published study has explored patients' perceptions of statin therapy that contribute to primary nonadherence.<sup>15</sup> Three additional studies assessed patients' perceptions of statin therapy with respect to nonadherence but these analyses combined patients who never filled their statin prescription and patients

who discontinued their medication.<sup>14,20,21</sup> The aim of our study was to explore self-reported reasons for primary nonadherence among patients with a newly prescribed

**Objectives:** To identify self-reported reasons for not filling a new prescription for statin therapy.

**Study Design:** A cross-sectional telephone survey.

**Methods:** Potential participants were identified from a randomized, controlled trial among Kaiser Permanente Southern California (KPSC) members aged ≥24 years with no record of redeeming a new statin medication, defined as primary nonadherence. Among 1158 eligible patients, 98 were randomly selected and participated in a semi-structured telephone interview that included questions on whether the respondent redeemed their statin prescription, why the patient may have chosen not to use a KPSC pharmacy, reasons for not filling the prescription, use of non-prescription products for elevated cholesterol levels, and questions to assess health literacy.

**Results:** At 12 weeks post-index prescription date, 75% of 98 respondents reported not filling their new statin prescription, 20% reported picking it up from a non-KPSC pharmacy, 4% had already picked up the prescription at a KPSC pharmacy, and 1% did not know if it had been filled. The 3 most commonly cited reasons for primary nonadherence were general concerns about taking the medication (63%), a decision to try lifestyle modifications (63%), and fear of side effects (53%). A substantial proportion (33%) of respondents reported inadequate health literacy.

**Conclusions:** These data suggest the need for interventions that address patients' negative perceptions of statins while emphasizing the benefits of statin therapy for reducing cardiovascular morbidity and mortality in formats accessible to those with limited health literacy.

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### Take-Away Points

This study highlights patients' concerns about statins and a preference for lifestyle modifications among those who do not fill their first statin prescription.

- Reasons for primary nonadherence to statin therapy are multifactorial; therefore, individualized interventions may be warranted.
- Further research is needed to explore patient–physician communication about statin therapy, and the most appropriate communication methods and formats for different audiences.

statin medication, thus contributing to the scant literature on this topic.

## METHODS

### Setting

This study was conducted at Kaiser Permanente Southern California (KPSC), an integrated health delivery system which provides comprehensive care to more than 3.4 million members at 14 medical centers and 197 medical offices. KPSC clinical practice guidelines for adult cholesterol management recommend statin treatment among all people with established coronary artery disease (CAD), diabetes mellitus (40 years or older), ischemic stroke or trans-ischemic stroke, abdominal aortic aneurysm, peripheral artery disease, or carotid artery stenosis (>50%). In these patients, statins are recommended regardless of baseline LDL-C, and LDL-C goal is less than 100 mg/dL with an optional goal of less than 70 mg/dL. For patients with diabetes aged 39 years or under, patients with chronic kidney disease stages 4 or 5, and those with a 10-year CAD risk greater than 20%, statins are recommended with an LDL-C goal less than 100 mg/dL. For primary prevention patients who have a 10-year CAD risk less than 20%, the LDL-C goal is less than 130 mg/dL. Simvastatin was the preferred first-line statin for both primary and secondary prevention patients within KPSC during the study. In addition, KPSC guidelines recommend lifestyle modifications in the management of adults with dyslipidemia.

### Study Population

The sample for this study was derived from KPSC members enrolled in a randomized controlled trial evaluating an automated system to increase adherence to newly prescribed statins using telephone messaging and follow-up letters. The trial's inclusion criteria are described in detail elsewhere.<sup>22</sup> In brief, KPSC members were eligible for the trial if they were at least 24 years of age, had a new statin prescription that had not been filled at a KPSC pharmacy within 1 to 2 weeks of being ordered, had 12 months of continuous KPSC membership prior to the statin order, and did not have a statin

or statin combination drug dispensed within 365 days prior to the index prescription date. A total of 5216 members were equally randomized to the intervention arm and a usual care arm. Members in the intervention arm received an automated telephone call followed up 1 week later by a letter for those who had not redeemed their statin medication at KPSC.

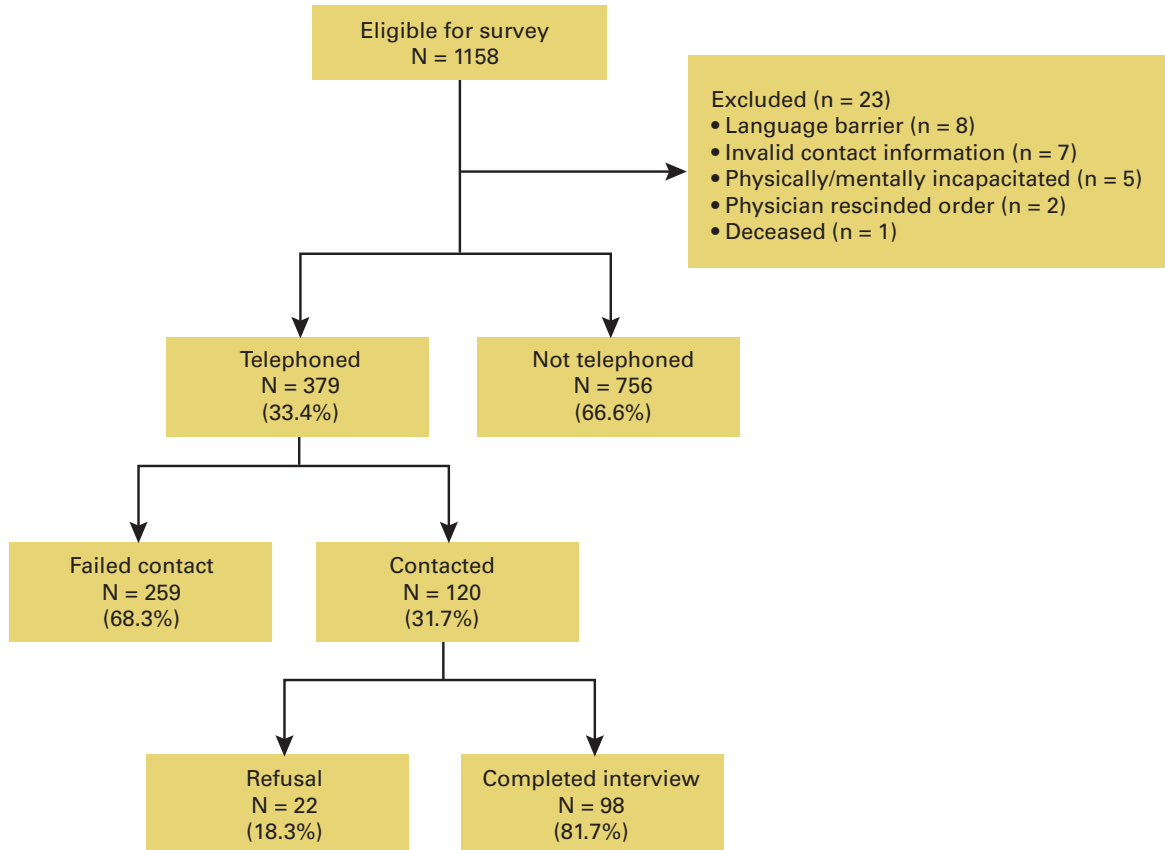
Members were randomly selected for this study from the 1158 participants in both arms of the randomized trial who had a new statin prescription ordered between May 10 and June 14, 2010, who had no record of redeeming their statin medication 12 weeks after the prescription date and whose preferred language, according to administrative records, was English. Members could have, however, redeemed their statin prescription between study selection and recruitment (a maximum of 5 days). Participants' demographic characteristics were captured through structured administrative databases. LDL-C measurements were obtained from electronic medical records closest to the date each member was prescribed the new statin medication.

### Recruitment

Between June 23 and July 30, 2010, we attempted to contact eligible members on a rolling basis for a brief telephone interview. Due to budget considerations, we aimed to complete 100 interviews. We made a maximum of 2 attempts over 5 days to contact each potential participant.

Two trained research staff used a survey instrument consisting of scripted questions to assess 1) whether respondents redeemed their statin prescription, 2) why the patient may have chosen not to use a KPSC pharmacy, 3) reasons for not filling the prescription, 4) use of non-prescription products for cholesterol reduction, and 5) respondents' health literacy ([Appendix](#)). To explore factors that may have contributed to primary nonadherence, interviewers read a series of statements derived from the published literature<sup>23</sup> about concerns with side effects, safety, effectiveness, and affordability, and asked respondents to indicate whether or not (yes/no) each reason applied to them. Responses to open-ended questions were recorded verbatim. Poor health literacy has been associated with low medication adherence,<sup>24</sup> therefore we measured self-reported health literacy using a previously validated 3-item instrument that assesses problems due to reading, understanding, and filling out medical forms.<sup>25</sup> The study protocol was approved by the Institutional Review Board of Kaiser Permanente Southern California and informed consent was obtained by the telephone interviewer prior to the start of each interview.

■ **Figure.** Recruitment Flow Chart



**Statistical Analysis**

Summary statistics (means and proportions) were calculated for demographic characteristics (age, gender, race/ethnicity, education, and income), LDL-C, redemption of statin prescription, reasons for nonadherence, and use of non-prescription products to lower cholesterol. Responses to open-ended questions about reasons for primary nonadherence were reported qualitatively.

Responses to each of the validated health literacy screening questions were scored on a scale of 1 to 5 and summed to create an overall score that ranged from 1 to 15, with higher values representing better health literacy.<sup>25</sup> The overall health literacy score was dichotomized as “adequate” (score = 15), defined as the respondent reporting no problems, and “inadequate” (score ≤14).<sup>26</sup> All analyses were performed using SAS statistical software version 9.2 (SAS Institute, Cary, North Carolina).

**RESULTS**

Among 1158 members eligible for interview, 23 were excluded during recruitment: 8 did not speak fluent English, 7 had a non-working telephone number, 5 were physically or

mentally incapacitated, 2 had the statin prescription canceled by their physician, and 1 was deceased (Figure). We telephoned 379 eligible members, making 120 contacts. Of the 120 contacts, 22 refused to participate and 98 completed an interview. The overall response rate was 81.7%.

Demographic and clinical characteristics of the participants are provided in Table 1. The mean age among all survey respondents was 59.3 years (range: 29-97 years) and 46.9% were female. Nearly half of respondents were white, the large majority had at least a high school diploma, and approximately one-third had an annual household income of \$50,000 or less. The mean (SD) LDL-C level closest to the date of enrollment in the randomized trial was 151 (36) mg/dL.

Twelve weeks post-index date, 74.5% of respondents reported that they had not filled their statin prescription, while 20.4% reported filling the prescription at a non-KPSC pharmacy. A small proportion of respondents claimed that they filled the statin prescription at a KPSC pharmacy or did not know whether the prescription was filled (Table 2).

Among the 73 respondents who reported not filling their statin prescription at any pharmacy, the most commonly cited reasons for not filling the prescription were general concerns about taking the medication (63.0%), a decision

■ **Table 1.** Demographic Characteristics of Survey Respondents (n = 98)

Characteristic	Mean (SD) or %
Age, y <sup>a</sup>	59.3 (13.4)
Female, %	46.9
<b>Race/ethnicity, %<sup>a</sup></b>	
Asian	8.2
Black	7.1
Hispanic	21.4
White	49.0
Other	14.3
≥High school graduate, % <sup>b</sup>	81.1
<b>Household income, %<sup>b</sup></b>	
≤\$24,999	14.8
\$25,000-\$49,999	20.8
\$50,000-\$99,999	34.3
≥\$100,000	30.1
<b>Most recent LDL, mg/dL<sup>a</sup></b>	151 (36)

KPSC indicates Kaiser Permanente Southern California; LDL, low-density lipoprotein; SD, standard deviation.  
<sup>a</sup>Data obtained from KPSC electronic data sources.  
<sup>b</sup>Data are based on Census 2000 data geocoded at the block level.

to try lifestyle modifications, such as diet and exercise, instead of taking the medication (63.0%), and fear of side effects (53.4%) (Table 3). Thirty-nine percent of respondents perceived the statin medication as unnecessary while 34.7% did not believe their condition to be life-threatening. The same proportion of respondents were concerned about drug interactions (16.4%) and perceived they already took too many medications and did not want to take any more (16.4%). Financial hardship was cited by 12.3% of respondents. When respondents were asked to qualitatively identify additional reasons they did not pick up their statin medication, 9 reported not being aware their physician prescribed the medication, 6 had a previous supply of the medication (>365 days old), 6 preferred to take a “natural product,” and 3 did not like taking medication. One-third of respondents who left their statin prescription unfilled reported taking non-prescription products, including supplements or herbs, to lower their cholesterol.

Among the 20 respondents who reported obtaining their statin prescription at a non-KPSC pharmacy, 8 did not have a KPSC pharmacy benefit, 5 generally purchased their prescriptions from an outside pharmacy (non-specific reason), 5 had a pharmacy benefit through another provider (eg, Veterans Affairs, Indian Health Service, workers’ compensation), and 2 preferred a non-formulary product (data not shown).

Overall, 32.9% of respondents reported inadequate health literacy. More specifically, 16.9% reported needing help reading medical material, 17.1% reported having problems learning about their medical condition, and 29.6% were not confident completing health forms alone (data not shown).

## DISCUSSION AND CONCLUSIONS

Most respondents in our study who were nonadherent with their initial statin prescription had general concerns about the medication and a preference for lifestyle modifications. To a lesser extent, respondents expressed concerns about side effects, drug interactions, and polypharmacy, and did not perceive a need for statin therapy. Cost of the statin prescription was not reported as a primary factor for respondents’ failure to redeem their prescription.

Interestingly, general concerns and a decision to try diet and exercise instead of taking statin therapy were each reported by the same proportion of respondents. The former reason may have facilitated respondents’ decision to take an alternative approach to reducing their cholesterol level, including the use of non-prescription products. Despite the concerns about adverse effects of statin therapy, the evidence among people with preexisting CVD suggests that any possible negative outcomes are outweighed by the benefits of treatment.<sup>27</sup> The findings from this study regarding safety concerns and a preference for lifestyle modification are similar to other published assessments of self-reported factors that contribute to primary non-adherence to statin therapy. For example, a study that explored beliefs about diet control found that 79% of patients preferred to change their diet before taking a statin compared with 63% in our sample.<sup>14</sup> Among participants of an Internet-based study who self-identified as not having filled a new statin prescription, 65% and 43% reported fear of side effects and general concerns about taking the medication, respectively.<sup>15</sup> While 44% of respondents in that study perceived cost as a barrier to filling their statin prescription, only 12% of primary non-adherent participants in our study held this perception. This difference could be influenced by the fact that more than 90% of KPSC members have a pharmacy benefit that covers all or a large portion of medication costs.

The majority of respondents in our study who redeemed their prescription at a non-KPSC pharmacy did not have a KPSC drug benefit. This finding suggests that some patients without a pharmacy benefit may actually redeem their statin prescription, particularly if they perceive a need for the medication.<sup>15</sup> Moreover, studies relying solely on electronic medical records to assess primary nonadherence should exclude patients without a drug benefit to avoid potentially overestimating prevalence of primary nonadherence.

## Primary Nonadherence to Statin Therapy

A small but noteworthy number of respondents reported not being aware of their physician having prescribed the statin medication, which suggests a need for improved patient–physician communication. At least 4 published studies of self-reported reasons for primary nonadherence to medications have found a similar experience.<sup>28-31</sup> These studies analyzed prescriptions electronically transmitted to the pharmacy, which is also the primary method of ordering prescriptions utilized by our health plan. In health systems where prescriptions are ordered electronically, providers may be able to improve primary nonadherence by giving patients verbal and written information about the statin prescription that was ordered.

One-third of respondents in our study had inadequate health literacy. This finding is somewhat surprising given the relatively high income and education levels of the respondents and because we only included English speakers in the sample. Using the same 3-item instrument, a study with a large, ethnically diverse cohort of diabetes patients in Northern California found that 62% of enrollees reported inadequate health literacy.<sup>26</sup> With socioeconomically diverse health plan memberships, clinicians and pharmacists should consider employing low-literacy, pictorial and audio-visual education materials to decrease primary nonadherence to statin therapy.<sup>24</sup>

Our study has several limitations. First, self-reported data are subject to social desirability bias. For example, respondents may have over-reported their choice to make lifestyle changes or to report a lapse in memory rather than admit that they did not follow the physician’s advice. Second, our small sample size and study design did not allow for meaningful statistical comparisons. Third, although KPSC membership is socioeconomically diverse, we only sampled English speakers of 1 integrated health plan and in 1 geographic region, thus the results may differ from those in other regions and other types of managed care organizations. Fourth, we did not directly measure health literacy, nor did we assess the relationship between health literacy and lipid management. The main strengths of our study are the focus on primary nonadherence to statin therapy and the use of self-reported data. Only 2 of the 4 previously published studies that assessed self-reported reasons for nonadherence to

■ **Table 2.** Self-Reported Location of Statin Prescription Fill (n = 98)

Response	% (n)
Did not fill prescription at any pharmacy	74.5 (73)
Filled prescription at non-KPSC pharmacy	20.4 (20)
Filled prescription at KPSC pharmacy	4.1 (4)
Does not know whether medication was filled	1.0 (1)
KPSC indicates Kaiser Permanente Southern California.	

■ **Table 3.** Self-Reported Reasons for Primary Nonadherence (n = 73)

Did not pick up cholesterol medication due to/because...	% Yes (n)
General concerns about medication	63.0 (46)
Decided to try lifestyle modification	63.0 (46)
Fear of side effects	53.4 (39)
Did not think medication was needed	38.9 (28)
Did not believe condition was life threatening	34.7 (25)
Fear of drug interactions	16.4 (12)
Already took too many medications and did not want to take any more	16.4 (12)
Financial hardship	12.3 (9)
Did not understand why provider prescribed medication	11.0 (8)
Did not understand purpose of medication	8.2 (6)
Did not think medication would be effective for condition	6.9 (5)
Inconvenient dosing regimen	4.1 (3)
Change in health insurance/drug benefit	2.7 (2)

statin therapy exclusively analyzed patients who did not fill their prescription.<sup>15,21</sup> Furthermore, most studies have relied on medical records and pharmacy data rather than self-reported barriers to primary nonadherence. Our study also provided respondents with the opportunity to qualitatively cite reasons for not redeeming their prescription, which allowed us to explore potentially unidentified self-reported reasons for primary nonadherence.

Respondents’ reasons for primary nonadherence to statin therapy are multifactorial; therefore, individualized interventions aimed at improving primary nonadherence may be warranted. For example, it may be helpful to institute interventions at the time of the initial prescription that address patients’ negative perceptions of statins while emphasizing the benefits of statin therapy for reducing cardiovascular morbidity and mortality. A variety of methods, formats, and styles should be explored to help tailor patient–physician communication for different audiences. These interventions and methods should be examined in a larger population and across different health plan types to ensure the greatest impact.



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## Primary Nonadherence to Statin Therapy

### ■ Appendix. Survey of Patients Who Did Not Fill a New Prescription for Cholesterol-Lowering Medication

A doctor from Kaiser Permanente prescribed a medication for you on [date] to lower your cholesterol and help prevent a heart attack or stroke. Our records show that you have not picked up the medication from a Kaiser Permanente pharmacy.

1. Have you picked up the medication from a Kaiser Permanente pharmacy?	Yes/No/Don't know
2. Have you picked up the medication from a different pharmacy?	Yes/No/Don't know
3. Would you share with me why you chose not to pick up the medication from a Kaiser Permanente pharmacy?	Open-ended
4. I did not pick up my prescription cholesterol medication...	Yes/No/Don't know
a) Due to a change in health insurance or drug benefits	Yes/No/Don't know
b) Due to a fear of side effects	Yes/No/Don't know
c) Due to an inconvenient/complex dosing regimen	Yes/No/Don't know
d) Because paying for the prescription medication was a financial hardship for me	Yes/No/Don't know
e) Due to general concerns about taking the prescription medication	Yes/No/Don't know
f) Due to fear of drug interactions	Yes/No/Don't know
g) Because I did not think the drug would work for me/be effective for my condition	Yes/No/Don't know
h) Because I did not understand the purpose of the prescription medication	Yes/No/Don't know
i) Because I did not believe that my condition was life threatening	Yes/No/Don't know
j) Because I did not think that I needed the prescription medication	Yes/No/Don't know
k) Because I did not understand why my provider prescribed the medication for me	Yes/No/Don't know
l) Because I decided to try life-style modification instead of taking prescription medications	Yes/No/Don't know
m) Because I felt like I already took too many medications and did not want to take any more	Yes/No/Don't know
5. Are there any other reasons that you did not pick up the medication from the pharmacy?	Open-ended
6. Are you currently taking any over-the-counter or non-prescription products, including dietary supplements or herbs to lower your cholesterol?	Yes/No/Don't know
7. How often do you...	None of the time/ A little of the time/ Some of the time/ Most of the time/ All of the time
a) Have someone (like a family member, friend, hospital clinic worker, or caregiver) help you read hospital or other medical materials?	
b) Have problems learning about your medical condition because of difficulty understanding written information?	
8. How confident are you filling out health forms by yourself?	Extremely/ Quite a bit/ Somewhat/ A little bit/ Not at all