

ORIGINAL RESEARCH & CONTRIBUTIONS

Patients' Perspectives on Nonadherence to Statin Therapy: A Focus-Group Study

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Abstract

Context: Nonadherence to statin therapy is associated with poor cardiovascular outcomes.

Objective: We explored factors and perceptions that contribute to statin therapy nonadherence.

Design: We conducted a qualitative study that was based on three patient focus groups using a structured discussion guide to explore factors related to statin therapy nonadherence, information sources, perceptions of statins and cardiovascular risks factors, and suggestions for improving adherence.

Participants: We enrolled 18 adult patients of an integrated delivery system who had been newly prescribed a statin between November 2006 and August 2007, with a subsequent one- to six-month gap in drug supply as documented by automated pharmacy data.

Measures: We performed content analysis of verbatim focus-group transcripts to assess themes within each domain.

Results: Study participants identified many factors that contributed to their statin therapy nonadherence, including concerns or experiences with adverse effects, uncertainty about the benefits or importance of statins for their overall health, and lack of convenience. Concerns about the adverse effects of statins were a dominant theme. Although most participants believed that having a high cholesterol level is unsafe, many were unsure about their personal need for statins if they were making other lifestyle changes or had only borderline high cholesterol levels. Participants suggested that systematic follow-up, as well as greater information about the risks and benefits of statins and the merits of alternative approaches for lowering cholesterol, could have improved their adherence to therapy.

Conclusions: Many patients reduced statin use because of concerns about adverse effects and desire for more information about statins. Effective interventions that address patients' underlying concerns and perceptions are needed to improve statin therapy adherence.

Introduction

Hydroxymethylglutaryl-coenzyme A reductase inhibitors (statins) are the most commonly prescribed medications for decreasing lipid levels. In 2005, 29.7 million individuals in the US were prescribed statin therapy.¹ There is considerable trial evidence that statins are effective medication therapy for reducing cardiac and cerebrovascular morbidity and mortality.²⁻⁵ Studies also suggest, however, that patients' adherence to statin therapy is suboptimal and that persistence among those newly prescribed statins is poor.⁶⁻⁹ For example,

one study found that 40% of elderly patients lacked adequate statin supply three months after receiving a prescription, and 60% lacked adequate supply after one year.⁷ Poor adherence to statin therapy is associated with adverse health outcomes, including higher hospitalization rates and increased nonpharmacy medical costs.¹⁰⁻¹⁴

Earlier studies have identified patient characteristics associated with statin therapy nonadherence, such as younger age, female sex, fewer comorbidities, and greater out-of-pocket costs.^{8,13,15-17} Few studies, howev-

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er, have examined underlying patient perceptions or attitudes that contribute to differential therapy adherence levels. A survey study reported in 2007 suggested that patients who were concerned about the adverse effects of statins or uncertain about the potential benefits were more likely to discontinue statin use.¹⁸ Gaining a better understanding of the range of underlying motivations for discontinuing therapy is critical for designing effective interventions. Identifying the types and sources of information patients use to learn about statins and their perceptions of cardiovascular risk factors could also improve clinician–patient communication about statins.

We conducted focus groups with patients of an integrated delivery system to examine these factors and to elicit suggestions for what could improve patients' adherence to statin therapy. We focused on adult patients who had a gap of one month or longer in drug supply within the first six months of receiving a new statin prescription.

Methods

Setting

Kaiser Permanente Northern California (KPNC) is an integrated delivery system that provides comprehensive care, including inpatient, outpatient, and pharmacy services, to more than three million members. KPNC guidelines for adult cholesterol management recommend medication therapy for patients with low-density lipoprotein cholesterol levels >130 mg/dL, without established coronary artery disease (CAD). Medication treatment for dyslipidemia is also recommended for all patients with CAD or CAD risk equivalents, including cerebrovascular disease, peripheral arterial disease, abdominal aortic aneurysm, diabetes mellitus (age 40 years or older), and chronic kidney disease (stages 4 and 5). Simvastatin is recommended as first-line drug therapy and is available at the generic drug copayment level. The guidelines are available to all KPNC physicians and serve as recommendations but not requirements for clinical practice. Before the approval of generic simvastatin in June 2006, lovastatin was the preferred statin in the KPNC formulary; patients had generally low copayments for generic drugs (\$0–\$35 for a 100-day supply).

Study Population

We conducted focus groups with KPNC patients who received a new statin prescription and had a subsequent gap in drug supply. The target population included patients who received an index statin prescription between November 1, 2006, and August 15,

2007, with no statin dispensed during the preceding 24 months and drug supply gap of one to six months after the index prescription and the date of selection for the study population (August 15, 2007), allowing for carryover of remaining drug supply from month to month. All study participants were 18 years or older, with continuous membership and pharmacy benefits for 24 months before the index prescription and through the selection date (n = 7700).

Recruitment and Focus-Group Protocol

We contacted the clinicians of 1500 randomly selected patients from the target population for approval to phone their patients to invite participation. We confirmed that patients had not been taking statins as prescribed during the recruitment phone call. Patients could elect to participate in one of three focus groups that were conducted in two different locations, and they received a \$50 gift card for participation. Recruitment for each group ended after 12 patients per group agreed to participate; this decision was based on our goal of including approximately 6 to 10 patients per focus group and estimated no-show rates that were based on the moderator's previous experience with the KPNC membership. The protocol and informed-consent forms for participants were approved by the Kaiser Foundation Research Institute's institutional review board.

All focus groups were conducted by a professional moderator in English, using a detailed discussion guide developed by the research team. We examined four main areas: 1) patients' experiences with statins, including how they took or take them and reasons for not taking them as prescribed; 2) information patients received about statins from their physician, pharmacists, or other sources; 3) patients' perceptions about statins, including the potential benefits and risks of statins; and 4) suggestions for what could have helped them take their statins and improved their adherence to therapy.

Each group was asked the same set of open-ended questions, and each focus-group session lasted two hours. Participants gave opinions on a voluntary basis, but all were asked to state why they stopped taking statins. The moderator also used probes included in the discussion guide to ask specific questions as needed, particularly about potential barriers to therapy adherence.

Content Analysis

The focus groups were audiotaped, and their discussions were transcribed verbatim. The study team identified major themes, and two researchers independently coded relevant passages into one or more of the themes;

... underlying patient perceptions or attitudes contribute to differential therapy adherence levels.

new themes were added if appropriate. The rate of agreement between the two coders was 91%; cases of disagreement were discussed by a larger group and resolved by consensus.

Results

The majority of eligible study participants were prescribed lovastatin and had copayments of ≤\$15 for generic and ≤\$35 for brand-name medications (Table 1). The focus groups were conducted with a total of 18 participants with a mean age of 61 years; 14 participants were prescribed lovastatin and four were prescribed simvastatin. Seven participants were members of the health system's hypertension registry, and three were members of the diabetes registry.

Statin Use

Patterns of statin therapy nonadherence varied across the focus-group participants: four patients did not take any statins after receiving the initial prescription; five took the statin for less than two weeks; six took their initially prescribed statin for a longer period of time (eg, more than two weeks) before stopping use; two participants took statins intermittently or at a lower dose

than prescribed; and one participant did not provide this information. Seven participants reported that they told their physicians about the change in their statin use.

Reasons for Therapy Nonadherence

The participants identified a total of 15 reasons they did not take statins as prescribed (Table 2), which fall into four major categories: 1) concerns or experiences with adverse effects, 2) uncertainty about the benefits or importance of statins, 3) lack of convenience, and 4) other (being too ill to take statins; wanting to drink grapefruit juice, which they were instructed to avoid because it inhibits the metabolism of statins; and preferring to take a brand-name statin instead of the prescribed generic statin).

Concerns About Adverse Effects—Many participants expressed concerns about potential long-term effects of statins, including specific concerns such as liver and kidney damage and depletion of coenzyme (co) Q₁₀. In each of the focus groups, the participants talked extensively about the potential adverse effects of statins, and for many, these concerns were the primary reason they stopped taking statins. For example, one respondent expressed her specific concerns, whereas another noted his general fears about statins:

"If you could get a cholesterol drug that didn't degrade the muscles and didn't endanger my kidneys or my liver, I think I would take it in a second."

"I didn't really like taking [lovastatin] because I had heard some negative things about it before. It was hard on your system in some ways. ... It wasn't good to take a lot of it for a long time. I can't remember specifics; I just heard that it was kind of a powerful thing and better not to take it if you can avoid it."

In conjunction with their concerns about the adverse effects of statins, some patients expressed a preference for controlling their cholesterol via lifestyle changes, such as exercise and diet, or alternative therapies, including herbal remedies:

"The pamphlet they gave me with the medication gave me all of the after effects, and I didn't like those effects. One of them was [that] once I start taking [statins], I have to continue them ... so I did not take it. I went on the oatmeal diet four to five days a week. I'm still on it."

A number of patients noted that they would like their physicians to discuss these options with them before prescribing statins:

"I wanted options: A and B. Healthier options like work out, lose weight—those types of things—instead of just heading off to drugs."

Characteristic	Percentage
Age (years)	
<35	2.9
35–44	12.3
45–54	26.4
55–64	27.3
65+	31.0
Sex	
Women	49.4
Men	50.6
Generic name of statin on index prescription	
Lovastatin	69.8
Simvastatin	28.1
Atorvastatin calcium	1.5
Pravastatin sodium	0.6
Rosuvastatin calcium	0.1
Fluvastatin	0.0
Copayment	
Generic, \$0–\$7; brand, \$0–\$20	30.3
Generic, \$10–\$15; brand \$10–\$35	51.3
Generic, \$30–\$35; brand \$60–\$120	14.8
Other	3.6

Note: All study participants were dispensed a new statin prescription between November 2006 and August 2007 (n = 7700). Age was calculated as of August 15, 2007, and copayment amounts are for a 100-day supply as of January 2007. Information was abstracted from automated pharmacy databases.

Table 2. Patient-identified reasons for nonadherence to statin therapy
Concerns or experiences with adverse effects
Faced immediate problems with adverse effects (eg, nausea)
Concerned about long-term adverse effects
Dislike taking medications in general because of concerns about risks
Preferred to use alternative methods (eg, lifestyle changes, herbal remedies)
Concerned about long-term use (ie, did not want to take the statin for rest of their life)
Uncertainty about the benefits or importance of statins
Believed statins to be unnecessary for their health
Uncertain whether statin should be continued, because of lack of clinician follow-up
Distrusted physician's instructions
Lack of convenience
Inconvenient to get laboratory testing done
Inconvenient to take the medication
Did not want to wait at the pharmacy for a prescription to be filled
Forgot to take medication
Other
Wanted to drink grapefruit juice, which they were instructed to avoid
Too ill to take statins
Preferred to take a brand-name statin instead of the generic statin prescribed

Note: list is based on content analysis of focus-group transcripts.

In addition, a number of participants noted that they dislike taking medications in general. For example, one said:

"It's not just statins. I hate taking any drugs. You hear this stuff on the TV and the radio, and they pull it off the shelf, and you say, 'Gee, am I killing myself?'"

Fewer than half of the participants noted that they stopped taking statins because of immediate adverse or side effects, including nausea, muscle pain, and allergic reactions. About half of these participants reported that they discussed these problems with their physicians, and many eventually resumed statin therapy. Notably, among participants who reported other primary barriers to therapy adherence (eg, concerns about long-term adverse effects, uncertainty about benefits of statins, inconvenience), none reported resuming statin therapy after their initial discontinuation. In addition, a number of participants who faced immediate problems with adverse or side effects decided to stop taking statins on their own, as this patient did:

"[Statin] made my heart race. I was suddenly agitated. I tried taking [them] at bedtime, and then I

tried taking them in the morning instead of bedtime for the second week. I didn't feel right taking them. I said, 'I can do this on my own. I can lower my own cholesterol.'"

Uncertainty About Importance and Benefits of Statins—Some participants did not take statins as prescribed because they were unsure about the importance of statins for their health. Uncertainty about the need for statins was related to a number of factors, including the absence of obvious symptoms and lack of follow-up by their physicians.

"You have high cholesterol, but that doesn't really manifest itself into anything tangible. You don't have severe headaches or your vision isn't necessarily blurred. There isn't anything really that makes you stop and say, 'Hey, I have to take my medication; this is serious.'"

"I had no side effects. I took it as prescribed, and I was never asked to come back to do a cholesterol check, so I never went back. ... I didn't get anything saying I needed to come back or I needed to follow-up or I needed to continue taking that drug."

Lack of Convenience—A few participants noted that it was inconvenient to take the drug or obtain follow-up laboratory testing; however, this reason was uncommon. One respondent noted: "Initially I was prescribed to cut the tablet in half, and for some reason that just became so inconvenient, I would just put it off and just never took it." In this insured population, no participants cited out-of-pocket drug costs as a barrier.

Sources of Information

Participants were asked to describe the kinds of information they received from their physician, pharmacist, or other sources. The majority of participants noted that they did not receive detailed information about statins from their physicians. One said:

"[The physician] just said, 'I'm going to prescribe it. Go get the medication.' He didn't give me much details about it."

The majority of patients noted that they were told by their physician that statins were prescribed to lower cholesterol levels but that they were not given information on the possible side effects, risks, or benefits of statins. Participants also described the information they received from pharmacists as limited and mainly focused on basic information about administration:

"I don't remember anything about lovastatin that [the pharmacist] told me except just to take it once a day with food. Don't take grapefruit, maybe."

In addition, a number of participants commented that

the pharmacy handout containing information on their prescribed statin raised concerns for them:

"If you read those sheets they give you, you wouldn't take anything. It's scary."

Most participants noted that they received or sought information on statins from sources other than their physician or pharmacist. The most common sources were the experiences of family and friends, and lay sources, including the Internet and television programs. A number of participants sought information on alternative remedies for high cholesterol levels, including herbal treatments and dietary changes. Many participants also noted that they learned information on the risks of taking statins, but not information on the potential benefits of statins, from these sources.

"I read these herbal catalogs. ... In one of them, it said that taking statins cut down the amount of co-Q₁₀ in your body. ... co-Q₁₀ is very important because the doctor said you should take supplements. This doctor on Channel 9 ... said you should take supplemental co-Q₁₀ when you get older."

"I went on the Internet, and it turns out statin drugs scatter the Q₁₀ away from your kidneys, and there's a lot of information out there that Q₁₀ is one of the best things you can do for your kidneys, and that's one of the reasons I decided to try exercise."

Table 3. Patients' suggestions for how to improve patient adherence to statin therapy

Provide additional or more detailed information about statins
Allow more time with the clinician to discuss the medication
Provide more information about the reason statins were prescribed and about the benefits and risks of statins
Provide written information about statins to describe risks, side effects, and medication administration
Provide classes to describe risks, side effects, and medication administration
Advise about possible drug interactions
Inform about or try alternative approaches first
Inform about the risks of drinking grapefruit juice while taking statins
Improve follow-up after initial prescription
Provide follow-up reminders (eg, mailing)
Provide follow-up by clinician
Improve convenience
Mail statins to patients

Note: list is based on content analysis of focus-group transcripts.

Perceptions of Statins and High Cholesterol Levels

We asked participants about their perceptions about statins and high cholesterol levels. When asked by the focus-group moderator, the majority said that they felt that it is unsafe to have high cholesterol levels (eg, "high cholesterol means diabetes, stroke, heart attack—all the really bad stuff") and believed that statins were effective at lowering cholesterol. However, a number also questioned their personal need for statins and appeared to have limited awareness of other cardiovascular risk factors. For example, some participants were unsure if they needed statins if their cholesterol was only borderline high:

"[Statins] seem to help some people that have really bad cholesterol. I think of mine as not that high. I'm suspicious that that's the best way to fix the problem."

Participants' views on whether other risk factors, such as family history of heart disease, were important reasons to take statins were mixed. Some stated that these factors did not affect their perceived need for statins:

"No doctor said to me that it was that important."

They didn't make it seem important. So ... do I really need [statins]?"

Other patients noted that these factors concerned them, but many also felt that the potential risks of taking statins outweighed the potential benefits.

Suggestions for Improving Therapy Adherence

Participants were also asked what might have helped them take their statins as prescribed (Table 3). The participants' suggestions were closely related to their reasons for not adhering to statins, and many centered on the need for more information about statins or high cholesterol levels. One participant noted:

"Sometimes doctors say, 'This is what you have to do.' ... Tell me why. Tell me what's going to be good for me, what the possible side effects are."

Although most participants preferred to have more time to discuss statins with their physician or suggested discussions with other health care professionals (eg, nurse practitioners), a few noted that providing additional information in written format might have also helped them understand the need for statins or helped them remember what was discussed during the appointment.

Others suggested that more systematic follow-up by clinicians or reminder systems might have helped them adhere to statin therapy. One participant compared the lack of follow-up regarding her statin pre-

scription with the systematic reminders she receives for other preventive care:

"If it's important, I think it would be nice if there was a follow-up system. I get a card that tells me it's time for my [Papanicolaou] test. I get a card that tells me it's time for my mammogram. It might not be a bad idea ... [if] the doctor follows up in a certain amount of time, or sends you a preprinted card that says, 'Contact me if you have any questions.' It would trigger your memory and make you think about it."

Discussion

We conducted focus groups to validate existing hypotheses and identify additional reasons for nonadherence to new statin therapy. Patients identified a wide range of factors that contributed to their discontinuation of statins; the majority cited concerns about the risks of taking statins and uncertainty about the benefits or importance of statins as primary reasons for stopping. Patients expressed a strong desire for more information about statins, to better understand the risks and benefits of the medication, and also suggested that systematic follow-up after receiving the prescription could have improved their therapy adherence.

Most patients believed that statins effectively reduce cholesterol levels and that having a high cholesterol level is unsafe; however, many also questioned their personal need for statins. A number of participants felt that their cholesterol levels were close enough to target thresholds that statins might not be of much benefit to them. In addition, many patients had unfavorable perceptions of the safety profile of statins and noted that concerns about potential long-term harms were a primary factor in their decision to discontinue therapy. Although some patients cited specific concerns, such as liver and kidney damage, many also expressed general fears about taking statins and other medications. Of concern, most participants did not discuss these fears with their physician or a pharmacist. These findings agree with those of other studies that have examined underlying perceptions that contribute to poor statin therapy adherence,^{18,19} as well as other chronic drug therapies,²⁰⁻²² and further highlight an important need to identify effective and efficient ways of providing patients with more information about statins.

Dissatisfaction with the amount of information received about statins from physicians and pharmacists was a dominant theme in the focus groups. A recent study found that some physicians hesitate to discuss potential side effects with their patients because they worry about contributing to patient fears and therapy

nonadherence.²³ The patients in our focus groups, however, sought this information from alternate sources, such as the Internet and television. The information gathered from these sources might not be clinically reputable and appeared to focus on the risks of statins rather than the benefits of statins or of lowering cholesterol levels. Stressing the benefits of statin therapy at time of prescribing, as well as discussing potential adverse or side effects, the likelihood of experiencing them, and their seriousness, may improve how patients filter information they receive from other sources. In patients with more moderate cholesterol levels but with other risk factors for cardiovascular disease, such as diabetes mellitus, it may be particularly valuable to explain in detail why the statin is being prescribed.

Because the time available to discuss statins with patients may be limited, providing clinically accurate and easily accessible written information online, as handouts, or in health education classes may also present important counterpoints to other sources patients might consult. Work is needed to determine the most effective ways of delivering this information. Patients also suggested that receiving simple postcard or telephone reminders after they began statin therapy would reinforce the importance of therapy and improve their adherence to it.

This was a qualitative study with a small sample size. Although we identified a wide range of patient-reported reasons for therapy nonadherence and found similar themes repeated throughout each focus group, there might have been unidentified barriers. Patients might have had incomplete or inaccurate recall of their experiences with statins or the information they received. In addition, patients who were not able to participate in the focus groups (because of, for example, illness, cognitive impairment, or language barriers) likely face additional barriers to adherence.^{7,22,24} We did not assess the clinical appropriateness of the statin prescription for each participant, nor did we collect information about why patients were prescribed statins. This study was conducted within a single integrated delivery system, and all study participants had a pharmacy benefit with modest copayments. No participants cited costs as a concern, and the impact of costs on statin therapy adherence is likely to be greater in other settings or for patients prescribed brand-name statins.^{12,13} With the approval of the generic statin simvastatin in 2006, however, cost barriers to statin use are likely to decrease. In addition, concerns such as the inconvenience of filling a prescription or obtaining laboratory work may be greater in nonintegrated settings.

... the majority of patients cited concerns about the risks. Patients suggested systematic follow-up after receiving the prescription ...

Conclusion

Patients identified a wide range of reasons for stopping their statin therapy, and most emphasized concerns about adverse effects or uncertainty about the benefits of statins. They expressed a desire for more information about the benefits and risks of statins and believed that such information might have helped them take their statins as prescribed. These factors should be systematically assessed in a larger population to identify the most effective strategies for improving statin therapy adherence. ❖

Disclosure Statement

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