

## *If my cholesterol is...then I foresee...: patient accounts of uncertainty*

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### ABSTRACT

The author examines the talk of patients with high cholesterol as they discuss their experiences of adding a statin to their treatment regimen. The primary objective was to understand patients' expectations of statins, and their beliefs and feelings as they continued or discontinued use, and to better understand why adherence to a statin regimen is particularly low. While numerous studies report reasons for nonadherence, few apply theory to provide plausible explanations. Analysis of the focus group data revealed three major themes. First, patients do not view high cholesterol as serious in light of other major health problems like diabetes and cancer within the household. Second, patients believe statins are effective in lowering cholesterol but risky. Third, many patients do not understand how high levels of cholesterol are produced in the body and how statins interrupt that process. Problematic integration theory is used to explain the uncertainty patients experience when given a diagnosis of high cholesterol, the use of statins to control it, and the quality of information received about both cholesterol and statins.

### Introduction

Cardiovascular disease is the leading cause of death in the United States followed closely by stroke.<sup>1,2</sup> In 2010, the direct and indirect costs of the two together were estimated to be over three-hundred billion dollars.<sup>2</sup> Cardiovascular disease and stroke are often caused by too much buildup of cholesterol in the blood. The excessive buildup of cholesterol in the blood is called high cholesterol. Some uncontrollable factors that increase one's risk

for high cholesterol are heredity, age, and sex; but patients can reduce their risk by eating a healthy diet, exercising more, maintaining a healthy weight, not smoking, managing chronic illnesses if present, and taking medication when prescribed. Nevertheless, 73 million Americans live with high cholesterol. One out of three has it under control and less than half are getting any treatment at all in the form of diet modification, increased physical activity or the use of medications.<sup>3</sup> However, Aggarwal and Mosca<sup>4</sup> suggest the failure of patients to change their behavior as part of a treatment regimen is not due to a lack of knowledge about high cholesterol.

As one form of treatment, statins control the rate of cholesterol produced in the body while increasing the liver's ability to remove excess from the blood.<sup>5</sup> These medications (known by popular brand names like Lipitor and Crestor) are effective in decreasing morbidity and mortality rates associated with cardiovascular disease, so physicians often prescribe them.<sup>6</sup> However in the United States, 40 to 60 percent of patients fail to take them.<sup>7</sup> In addition to never taking a statin, a patient may discontinue its use against medical advice, take more or less than prescribed, use it with other drugs it negatively interacts, and disregard recommendations to diet and exercise to maintain a healthy weight.<sup>8</sup> Poor adherence is common within 3 to 6 months.<sup>9</sup> Even the ability to accurately foresee one's risk of heart attack within ten years with or without a statin does not result in the likelihood that a statin will be taken as prescribed.<sup>10</sup> Patients cite muscle pain as the primary reason for discontinuation, followed by cost and a perceived lack of efficacy. Those with low household incomes, who have experienced some muscle pain while on statin therapy, and take other medications for cardiovascular disease are at the highest risk for nonadherence.<sup>11,12</sup> Patients living in neighborhoods with a high density of Hispanics, African Americans, or immigrants and females

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not males are more likely to be nonadherent.<sup>11</sup> Discontinuers admit that they fail to regularly monitor their cholesterol, are not satisfied with their physicians' explanation of cholesterol treatment, and feel the need to use the internet to research statins for themselves.<sup>12</sup>

Medical researchers are not oblivious to the concerns of patients and seek to confirm or disconfirm claims of the adverse effects of statins. A few meta-analyses conclude that some adverse effects include muscular toxicity and/or myopathy,<sup>13,14</sup> cataracts,<sup>13</sup> raised liver enzymes,<sup>14</sup> and diabetes.<sup>13,15,16</sup> However, most argue that these effects are small compared to the beneficial effects of statins on major cardiovascular events.<sup>14,15</sup> The Cholesterol Treatment Trialists' (CTT) Collaboration<sup>17</sup> asserts statins reduce the risk of major vascular events irrespective of age, sex, baseline LDL cholesterol, previous vascular disease or the presence of other diseases. The continued use of statins with at least eighty percent or greater adherence over time is associated with progressively increasing survival rates.<sup>18</sup> Statins are associated also with lower risks of dementia, cognitive impairment, fractures and pneumonia.<sup>14</sup> To date, there is no evidence that connects statins to an increased risk of cognitive decline or to cancer,<sup>16,17</sup> to renal disorders, arthritis, depression<sup>5</sup> or to adverse effects on mood, sleep, and physical functioning.<sup>19,20</sup>

In addition to establishing the lack of adherence to statin therapy, discerning the reasons for nonadherence, and investigating the adverse effects of statins, researchers seek to understand the thought process involved in statin nonadherence. Chakraborty<sup>21</sup> applied the mental models approach to understand lay perceptions in relation to existing scientific information on the risk of nonadherence. He found statin-nonadherent patients negatively perceive the healthcare system, the Food and Drug Administration, the drug industry, government, and insurance companies, and consequentially believe statins are too risky. He concluded that these patients do not trust the information they receive from major stakeholders in the fight against cardiovascular disease. Although insightful, these findings seem incomplete. We still do not understand the patient's thought process when a statin is added as part of the treatment plan, or how she or he evaluates its worth and continued use. We do not fully understand why statin adherence is low.

To me, distrust signals misgivings, questions, doubts, suspicions or uncertainties about something or someone. Problematic integration theory suggests we orient to our world based not solely on our beliefs but consider what issues are associated with those beliefs and the evaluative meanings those associations hold for us.<sup>22-24</sup> It proposes that illness involves the endless experience of the problematic integration of one's beliefs or expectations with one's desires.<sup>25</sup> The theory organizes types of uncertainty into a coherent framework and asserts that we are often uncertain about how to integrate a particular belief with other beliefs.<sup>24</sup> My objective was to ascertain the percep-

tions, beliefs, understandings, and uncertainties of patients about high cholesterol and the use of a statin, and then discuss those findings using problematic integration theory. A clearer understanding of this thought-process may assist physicians in devising more effective ways in addressing high cholesterol with their patients.

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## Materials and Methods

My study draws upon existing data from a previous investigation (sponsored by a major drug company) that consisted of focus-group interviews conducted with high-cholesterol patients and their spouses residing within 20 miles of a focus-group facility in the Southeastern region of the United States.<sup>26</sup> All procedures were approved by an institutional review board. In that previous investigation, I served as a focus-group facilitator. Statin adherent and non-adherent participants were recruited from the claims database of a major health insurance company via telephone and prepared script. The health insurance company designated a patient as non-adherent when he or she ceased using a statin for at least 3 months after a minimum of six months of therapy. The majority of patients were white, middle-class, and between the ages of 45-78. A total of thirty-two patient-spouse dyads were assigned to four primary focus groups based on the patient's statin-adherence status. This resulted in two adherent and two nonadherent groups. After interviews were conducted with the patient-spouse dyads, we placed each individual into a patient-only or spouse-only group for additional interviewing.

Utilizing a semi-structured interview format, participants were asked about their reactions to a high-cholesterol diagnosis, treatment plans, and how these issues impacted their relationships. The sessions were videotaped and professionally transcribed. I analyzed the transcriptions utilizing McCracken's<sup>27</sup> five-step guideline for qualitative analysis and Owen's<sup>28</sup> framework of identifying key terms. First, I sorted responses addressing a high-cholesterol diagnosis, statins, and adherence. Then examined the transcripts within and across focus groups based on adherence status to identify any logical relationships and contradictions. Third, I re-read the transcripts to confirm or disconfirm emerging reasons for adherence or nonadherence within specific contexts. Then I reviewed themes to determine connections between and across various contexts. Finally in using McCracken's<sup>27</sup> guidelines, I examined the resulting themes within a framework of published research on statin adherence and problematic integration theory. In addition, I looked for the repetition of key words that were significant in describing a certain experience or feeling; examined meanings threaded throughout the text, and identified important words or phrases displayed through the use of vocal inflection, volume, or emphasis.<sup>28</sup> Three major themes emerged. First, patients do not view HC as serious in light of other major health problems within the household. Second, patients

believe statins are effective in lowering cholesterol but risky. Third, many patients do not understand the disease process and how statins interrupt that process.

## Results

### High cholesterol is not serious

Whether adherent or not, patients believe the best way to manage high cholesterol is with a combination of healthy eating, exercising and taking a statin. However, as indicated in the following comments, they do not view a diagnosis of high cholesterol as significant especially if genetic or in comparison to other health problems that exist within the household. (Note. AF=adherent female, AM=adherent male, NF=nonadherent female, NM=non-adherent male).

AF1: *It's not like you have cancer or something.*

AM1: *That's true. My father died at 87. He smoked 3 packs of Camel a day and died from lung cancer.*

AF2: *I don't think about my cholesterol at all! Who thinks about cholesterol when you are going to be operated on and be in a brace?*

NF: *Does cholesterol have symptoms? I don't know of any! [Laughing]*

NF: *My mom's first five siblings died of Parkinson's. That's what I'm worried about!*

NM: *It's not a priority item. It's not something that I think is going to affect me immediately, or that is going to create a problem that can't be taken care of.*

NF: *Families have lived with it through generations. That's part of their body make up and it may not be a concern although doctors are focused in on that.*

Most of the patients and their spouses have multiple health problems. Therefore for them, a diagnosis of high cholesterol fits into a complex hierarchy of health issues in which immediate pain and perceived vulnerability are the criteria governing how serious an illness is judged. Cancer, diabetes, other chronic illnesses, and trauma are often viewed as much more important than a high-cholesterol diagnosis. These illnesses have visible symptoms and consequences, unlike high cholesterol. Some patients view cholesterol simply as a natural component of body functioning. They do not connect directly or indirectly the deaths of any loved ones to a diagnosis of high cholesterol. They have witnessed others *live with it* for years and do not view or speak of high cholesterol as a precursor to cardiovascular disease or stroke. It is believed to be inconsequential.

### Statins are safe but risky

In the transcripts, patients talk about statins available on the market, side effects, prescription plans and cost. They acknowledge they are blessed to have health insurance that keeps costs down. Adherent patients expressed concerns about side-effects, and with the support of their

physicians, some switched to another medication. They interpreted the results of blood tests indicating lowered cholesterol levels as evidence of the positive effect of statins. However, some thought they would eventually learn something unfavorable about statins. Notice in the following exchange how these patients seem aware of the importance of a healthy diet, but are also cognizant of how difficult it is to maintain one. They see taking a statin as the quickest and easiest solution to the problem, although they have lingering thoughts in the back of their minds of the possibility of receiving bad news about the negative effects of statin use based on current mediated reports of other drugs. Regardless, statin-adherent patients are willing to take the risk. (Note. M=male, and F=female).

M1: *I think a lot of times we take these medications thinking we can eat anything because my cholesterol's going to start coming down.*

M2: *Practically speaking, I'm not always going to eat right. I'm happy that I'm losing weight and maybe in ten years I could be down to the weight that I'm supposed to be. It doesn't bother me at all to say that in ten years I'm going to be taking the same pills, because for me it's genetic anyway. It's a small price to pay. It doesn't hurt, so I take the pill.*

F: *It's definitely the easier way out than discipline.*

M3: *It's out of my mind unless I see something in the media that makes me think, "Maybe this stuff is going to turn out to be bad news one day like Vioxx." I'll be thinking "God, I took that stuff for years no wonder I'm screwed up!"*

Both adherent and nonadherent patients alike do not believe the healthcare system and science will ever have a comprehensible explanation for high cholesterol or a definitive answer about the most effective way to treat it. If adherent, patients hold on to the hope that they are doing the right thing by taking a statin, and if nonadherent, patients are comfortable questioning the motives of corporations as illustrated in the following. (Note: AM=adherent male, NM=nonadherent male, and NF=nonadherent female).

AM: *If I'm still taking the medicine I'm hoping it's not going to be a problem. I think cholesterol might be a big hoax from the medical industry. Plenty of people live to be old with HC. If I find out it's a hoax I'm going to be really mad!*

NM: *Companies are selling these pills and they're making a fortune. They want everybody on it.*

NF: *Yes, it's just business. It's about the medical association getting us to buy drugs.*

A few nonadherent patients chose to concentrate on diet and exercise and did not take a statin especially if this was their first chronic disease medication. Others took an *and if* stance. These nonadherent patients declared that they would use a statin *only* under the following conditions: i) their high cholesterol was proven to be genetic and ii) maintenance of a healthy diet did not work. As one man stated:

*If my cholesterol is caused by genetics, then I foresee myself in ten years taking whatever the new or the prescribed medication to control cholesterol. If, in ten years, medical science says, "We're on the same path. We do believe the same things we believed ten years ago." And if it isn't my diet. And if I decide to really do something about my diet, where as I become – this is it, I'm going to try and stay within a completely healthy diet, and if it doesn't change, I absolutely foresee in ten years me taking Lipitor.*

In addition to simply choosing not to take a statin, many patients connected their nonadherence directly to the negative side effects they experienced when taking one. These nonadherent patients suffered muscle aches and in some instances excruciating pain when using a statin. Some worked with their doctor to find another statin that did not cause any pain. Alternatively, doctors successfully reduced the dosage of the undesirable statin for some patients, while other patients were instructed to take in addition to the undesirable statin, another cholesterol-lowering drug, ezetimibe (Zetia) to address adverse effects. A few took matters into their own hands and reduced the dosage of the offending drug before consulting a doctor. The angst of finding the right statin without side effects is clear in the following exchange. (Note. NM=nonadherent male, and NF=nonadherent female).

NM: *Yes, I've tried Crestor and Zocor; every one of them. With every one I've had some muscle distress. Some worse than others. There is a percentage of the population they say that cannot take this medication because you are one of the two percent that has this thing, and I'm probably part of that two percent. But maybe I'm not. So then what do you do?*

NF: *I thought, "Well, I don't want liver disease." And my mother had died of liver disease, so I was really unhappy with my doctor. I really didn't want to take it but he insisted that I take it. I took what he gave me and cut it in half, and took that. I think doctors overmedicate, so I self-adjusted. It really did not agree with me. Subsequently, I was switched to another one. I was on Zocor and switched to Lipitor, and I did feel better.*

In sum, both adherent and nonadherent patients question the ability and desire of the healthcare system and science to find a cure for high cholesterol. Patients living with high cholesterol believe statins work but question whether or not the benefits outweigh the risks. Many are nonadherent during a drug switching process due to muscle-pain side effects. A few nonadherent patients do not want to take a statin at all while other nonadherent patients take an *and if* stance where a decision to take a statin is based on i) discovering their high cholesterol is genetic and ii) whether they have the ability to sustain lifestyle changes involving diet. Statin-adherent patients view a statin as the quickest and easiest solution in comparison to lifestyle modification requiring a change in diet.

## Ignorance is bliss

Patients do not understand the biochemistry at work with cholesterol lowering drugs or the influence of cholesterol on the formation of plaque. The relationship between high cholesterol, heart attacks and stroke are rarely mentioned. In other words, there is a serious gap in the understanding of the disease process at work and how statins interfere with that disease process, as follows. (Note. F=female, and M=male).

F: *I was more concerned about my liver than cholesterol. Maybe because I'm not too informed about cholesterol. I don't know.*

M: *I have the same question she had, like really I don't know the seriousness of cholesterol. Nobody ever explained it to me. I really don't know the symptoms either. I figured I'd take the pills for six months and be alright.*

Many patients with high cholesterol do not know their numbers or keep good records as we see in the comments of F below.

M: *What's HDL in cholesterol?*

F: *I don't know.*

M: *How high is your HDL?*

F: *I don't know. I can't remember. They're written down somewhere. It's not the kind of thing you know unless it's bad.*

This lack of understanding leads to an overreliance on statins and a mindset that seems to value dietary change but does not result in behavior change. Instead, patients resort to blaming their physicians for not providing them with information or answers to their questions, as in the following:

F1: *It would be nice to have a paper diet or something.*

F2: *I wish that they had sent me to a nutritionist.*

F3: *I have never been recommended to a nutritionist by any doctor ever.*

M1: *I've had three heart attacks – one in 1986, in 1990, and in 2005. My cholesterol had been around 300. I've used Mevacor, Lipitor and now I'm on Vytorin. They all brought my numbers down and I've had no side effects, but the doctors never gave me a nutritional system.*

M2: *I discussed sending me to a nutritionist with my doctor and he poo poed it! So now I've had eight bypasses.*

F2: *They had ice cream on the hospital tray after my bypass surgery and justified it!*

Nevertheless, some patients wanted to know more about cholesterol. When a more knowledgeable person in the group spoke, people paid attention. Several acknowledged that simply engaging in the focus group process encouraged them to seek out more information and in some cases, consider changing their behavior. The following is an example of the types of explanations of cholesterol shared:

F: *Clots stop your arteries. Image a greasy buildup like in a hose. You turn on the faucet and have the water go through the hose. Well, suppose there is an obstruction in the hose. The water may flow through or not with the force that you want it to. Well, that's going to happen with cholesterol. It's like a greasy or fat buildup inside the vein. It clogs up the vein, and then there's problems with blood flowing through and it's scary, because it can easily cause a heart attack or stroke.*

In sum, ignorance may be bliss. Many living with high cholesterol do not understand what it is, how it effects the body, how it causes or is an agent in the development of other chronic illnesses. They do not understand the role of a statin beyond its ability to lower cholesterol. As long as one feels good and does not experience negative side effects of a statin, the conclusion is that things are okay. If things are not going well, then the fault lies with physicians who fail to provide the specific information needed to affect change.

### What if, either-or, both-and, according to whom?

High-cholesterol patients live with uncertainty. Uncertainty is apparent in their communication with one another indicating the substance of their cognitive and emotional processing. Their talk serves to construct, illuminate, confuse, confront, and alter probabilistic and evaluative orientations as a productive endeavor through which they come to understand their experiences as problematic.<sup>22</sup>

One type of uncertainty that patients experience, has to do with the complexity at the core of the illness itself.<sup>25</sup> Some patients do not understand what high cholesterol is and how it effects the body. Most have an expectation that illnesses have symptoms, and therefore cannot take a high-cholesterol diagnosis seriously in comparison to other illnesses experienced within the household with visible symptoms. Families tend to prioritize the treatment of illnesses based on the degree of pain experienced and evidence of physical deterioration that interferes with quality of life.<sup>29-31</sup> Sells *et al.*<sup>30</sup> label this behavior *a virtual cascade of crises* (p. 95). For these high-cholesterol patients, the nonexistence of symptoms is positively associated with the evaluation of high cholesterol as nothing to be truly concerned.

The probabilistic orientation experienced by high-cholesterol patients as a certainty that high cholesterol is not serious is further complicated by another type of uncertainty. This type of uncertainty relates to the nature of one's judgment about the likelihood of particular outcomes.<sup>24,25</sup> Evaluative orientations address whether or not an object or outcome is good or bad.<sup>22</sup> In this case, the object of focus is the statin prescribed. First, the patient determines the likelihood that he or she is at risk of experiencing some negative outcome like a stroke due to a diagnosis of high cholesterol. If at risk, then one must decide to take a statin to lower one's cholesterol level or engage in lifestyle modification through diet and exercise.

This is an *either-or* not a *both-and* situation. Specific causes reasoned as crucial precedents to certain outcomes are at the heart of risk assessment.<sup>32</sup> Therefore, if the outcome of taking a statin results in lowering cholesterol then one must have had high cholesterol and in some cases that high cholesterol was caused by genetics. If no side effects are experienced then there is no perceived need for lifestyle changes. However, if taking a statin causes excruciating muscle pain that is not resolvable through switching or dosage modification, then a statin may be assessed as too risky and the focus becomes the less desirable alternative of lifestyle modification. Improved cholesterol numbers satisfy the expectations of the patient while simultaneously fulfilling one's desire to continue with one's current lifestyle. Patients are creating cognitive maps based on a variety of cause-and-effect beliefs and their evaluations of links between beliefs.

Concerns about the accuracy, sufficiency, reliability and validity of information also lead to uncertainty.<sup>22,24,25</sup> Individuals selectively evaluate, bracket, integrate, and compare information from a variety of sources.<sup>32</sup> For these high-cholesterol patients key sources of information include the media, one's physician, one another and key stakeholders in the healthcare system. Media in the form of direct-to-consumer advertising promotes over-diagnosis of high cholesterol and over-treatment for those who the use of a statin presents more risks than benefits.<sup>33</sup> These advertisements portray statins as miracle drugs in lowering cholesterol while simultaneously casting doubt on the efficacy of lifestyle changes as sustainable. As a result, patients tend to view diet and exercise as less important.<sup>21,33,34</sup> Such mixed messaging conflict with common wisdom resulting in uncertainty and questions about the reliability of mediated messages.

As previously noted, Aggarwal and Mosca<sup>4</sup> suggest that nonadherence is not due to a lack of knowledge about high cholesterol. I argue however, that these patients do not understand the relationship between high cholesterol and its comorbidities and feel it is the responsibility of physicians to make sure they do. Because physicians fail to provide sufficient information, patients believe it is not important to know the specifics of high cholesterol. This belief is positively associated with the belief that high cholesterol is not serious anyway. This probabilistic orientation experienced as certainty is then challenged by knowledge acquired through learning more about high cholesterol and statins from listening to other patients resulting in a quandary of how to evaluate and organize incoming messages.<sup>24</sup> Additionally, many high-cholesterol patients, as in other studies<sup>21,33</sup> believe insurance companies are greedy and profit driven; and that the healthcare system is ineffective. Such distrust of the government, drug industry and science increases perceptions of risk associated with statin adherence. Questions then arise about the credibility of these sources and whether one should view as valid any information from them.

## Conclusions

My findings support those of other studies<sup>9,10,12</sup> that the side effect of muscle pain from the use of statins is a major reason for nonadherence. However, Aggarwal and Mosca's<sup>4</sup> assertion that a lack of knowledge about high cholesterol is not linked to statin-nonadherence was not supported. Unlike the conclusions drawn in previous works<sup>4,9,10,12</sup> my findings suggest that the major problem for the high-cholesterol patient is the probabilistic orientation that high cholesterol is not serious. This initial belief held by patients complicates the formation and maintenance of other positive probabilistic and evaluative orientations toward believing that sustained behavior modification consisting of eating healthier, increasing physical activity, and taking a statin consistently over time are worth the effort. As a result, high cholesterol patients live with uncertainty that is not necessarily experienced as bad. At times, they may actively seek to reduce or manage it, but are not likely to see it resolved through more information. They are more likely to use what Babrow<sup>24</sup> refers to as *piecemeal coping strategies* (p. 563) through reappraisal and accepting things as they are, or by reframing as an opportunity for self-exploration. These findings suggest that physicians may have the greatest impact on high-cholesterol patients' understanding and beliefs at initial diagnosis. More attention should be given to sharing information about its link to cardiovascular disease, stroke and other comorbidities to foreground its threat. Patients must see high cholesterol as serious as they view cancer.

This study should be viewed in light of a few limitations. Findings reflect primarily the experiences of White middle-class women with health insurance. Personality factors such as introversion, extroversion, degree of optimism or pessimism, were not taken into consideration. In addition, demographic factors such as, level of education, religion, race, and gender were not considered.

In future studies exploring statin adherence and non-adherence in the context of living with high cholesterol, researchers should consider the aforementioned personality and demographic factors. We must identify the rhetorical strategies used by physicians with patients who do view a diagnosis of high cholesterol seriously. What is the structure and specific content of these persuasive messages? Discourse analyses of actual sessions in which physician diagnose high cholesterol may be the most enlightening. How did patients process these messages? One-on-one in-depth interviews with patients should provide even more insight into relevant thought processes.

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