Examination of physicians’ adherence to the 2013 ACC/AHA statin/cholesterol guidelines using a framework of awareness to adherence: A cross-sectional study

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Abstract

Background: Currently, limited data exists regarding primary care physicians’ awareness and implementation of the 2013 cholesterol guidelines.

Objectives: To evaluate primary care physicians’ adherence to the 2013 ACC/AHA cholesterol management guidelines using the framework of the awareness-to-adherence model.

Methods: The study was a cross-sectional pre-post survey design based on the constructs of the awareness-to-adherence model to capture physicians’ awareness of, agreement with, adoption of, and adherence to the 2013 ACC/AHA guidelines for cholesterol treatment and statin and cholesterol management software applications. Physicians with a Medicare Advantage organization in Texas were surveyed before and after educational interventions.

Results: A total of 170 responses were considered usable (post-survey). A significant difference was observed when physicians were divided into 2 groups (any intervention vs no intervention) ($P=0.027$). Physicians with a higher level of agreement were 4.8 times more likely to be adherent to the guidelines ($P=0.011$), compared with those with a lower level of agreement. Also, physicians practicing in the Rio Grande Valley area were 4.7 times more likely to be adherent to the guidelines ($P=0.001$) compared with those from the Greater Houston area.

Conclusion: A high level of awareness, but a lower level of adherence to the guidelines was reported among responding physicians. The awareness-to-adherence model was useful in examining physicians’ level of adherence to the cholesterol guidelines and the utilization of statin and cholesterol management cellular apps and online websites. Future studies are required to examine physicians’ adoption and adherence of new guidelines.

Keywords

Cholesterol, management, adherence, clinical practice guidelines, cardiovascular drugs

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Background

Cardiovascular disease remains one of the leading causes of death in the USA. Hypercholesterolemia is a primary risk factor for developing atherosclerotic cardiovascular disease (ASCVD). ASCVD often develops due to increased levels of low-density lipoprotein cholesterol (LDL-C). Statins are used as pharmacotherapy for primary as well as secondary prevention and treatment of ASCVD and have been shown to
reduce cardiovascular-related morbidity and mortality. The 2013 American College of Cardiology (ACC)/American Heart Association (AHA) cholesterol guidelines recommend statins over other lipid-lowering agents for reducing ASCVD risk. These guidelines consider statin therapy in four statin-benefit groups: patients with ASCVD; patients with LDL-C levels \( \geq 190 \text{mg/dL} \); patients with diabetes mellitus aged 40–75 years; and patients with estimated 10-year ASCVD risk \( \geq 7.5\% \) on the basis of an ASCVD risk estimator derived from the pooled-cohort risk equation.

Moderate-to-high intensity statin therapy is a recommendation for patients within the four benefit groups. Steen and colleagues examined a large US managed care database and found that only 11.4% of the total cohort filled prescriptions for high-intensity statin therapy. The most recent cholesterol management guidelines were released in 2018 that include recommendations for more personalized assessment of risks and new drug options for patients who are at the highest risk for ASCVD. Similar to 2013 guidelines, the recent guidelines focus on identifying and addressing lifetime risks for cardiovascular disease and reinforce the importance of healthy living, lifestyle modification and prevention.

Past research shows that less than half of adults with an elevated LDL-C received pharmacotherapy treatment as primary prevention, and only a third has a desired LDL-C target level. Even when statins are prescribed, the drug therapy may be discontinued or dosages lowered, particularly among older adults; this is often related to patients’ complaints of side effects such as muscle pain. Although guidelines recommend halting statin therapy to determine the cause of muscle pain, therapy is often not reinstated following a rest period, even if the side effects are determined to be unrelated to the statin. This demonstrates a deviation from guideline recommendations for cholesterol management and statin use.

Awareness of new guidelines, which are published periodically, does not necessarily lead to adoption and implementation. Guideline adoption often requires the acquisition of specific knowledge and skills, as well as procedures to facilitate the incorporation of these recommendations into daily practice. For patient care to be in accordance with guideline recommendations, physicians must be aware of the guidelines and consciously decide to adopt them in their clinical practice, as well as adhere to the recommendations when clinically appropriate. Additionally, a prior study specifically noted that physicians were unable to appropriately identify the four statin benefit groups.

This study employed the awareness-to-adherence model theoretical framework, which postulates that several cognitive, sequential, and behavioral steps are required of physicians before they comply with recommended guidelines (Figure 1). These steps include awareness (awareness is operationalized as physician’s knowledge of the existing guidelines [this does not imply that they read the guidelines]). Subsequent steps in the model include agreement (intellectual agreement) in other words physicians must accept the guidelines, adoption (decision to adopt and incorporate in their practice), and adherence to guideline recommendations (consistently following the recommendations). Furthermore, the model postulates that progression among the steps can halt at any point for varied reasons, resulting in non-adherence. Currently, limited data exists regarding primary care physicians’ awareness and implementation of the 2013 cholesterol guidelines. A better understanding of primary care physicians’ concerns, needs, and barriers adhering to these guidelines is crucial to ensuring proper cholesterol management. For this reason, it was important to identify gaps in care to better inform future interventions and thereby improve patient outcomes regarding statin therapy.

In an effort to understand statin prescribing, the study objective was to evaluate primary care physicians’ adherence to cholesterol management guidelines and examine if their behavior was consistent with the framework of the awareness-to-adherence model.

**Methods**

**Study design**

A repeated cross-sectional study (pre-post) was conducted to examine physicians’ awareness of, agreement with, adoption of, and adherence to the 2013 ACC/AHA cholesterol management guidelines.

**Pre-survey instrument and intervention development**

The survey instrument used in the pre-test phase of this study was based on the constructs of the awareness-to-adherence model and included 16 items measured using a 5-point Likert scale from 1-Strongly Disagree to 5-Strongly Agree. The awareness-to-adherence model theoretical framework is a tool used to evaluate physicians’ compliance with clinical guidelines (Figure 1). Awareness-to-adherence module requires several cognitive, sequential (subsequent, concomitant), and behavioral steps taken by the physician before implementing recommended guidelines into practice. Additionally, the model suggests that physicians may abandon clinical guidelines during the progression of treatment, resulting in nonadherence.

The survey instrument was developed to capture physicians’ awareness of, agreement with, adoption
of, and adherence to the guidelines, as well as their demographic and practice characteristics. The primary outcome variable of interest was accessed by physicians' self-reported prescribing of moderate to high statins among the four benefit groups. Further, the survey instrument was reviewed for content and face validity by pharmacists working in a managed care environment, and a cardiologist. Physician demographic information was captured using their national provider identifier. The survey instrument was divided into different sections, which were designed to evaluate: 1) physicians' awareness regarding the four statin benefit groups; 2) physicians' awareness of available statin web applications (e.g., online or by phone app) related to cholesterol clinical management; 3) physicians' agreement with recommendations to prescribe moderate-to-high intensity statin therapy; 4) physicians' adherence to guidelines; and 5) the frequency at which physicians rechallenged patients who were suspected to be statin intolerant.

**Educational interventions**

Based on the information obtained from the pre-survey, a live educational webinar was developed and led by a cardiologist. The webinar was recorded and made available for one month to physicians contracted with the collaborating managed care plan pharmaceutical educators. Previous research has indicated a gap in physicians' understanding with regards to patient anxiety about adverse events, desire for more information, and uncertainty about the benefits of statins. Hence, the webinar was primarily developed to address the four benefit groups. An Amazon gift card ($150) was provided as an incentive to physicians who participated in the educational webinar. Additionally, to reach those unable to attend the live webinar or view the recorded webinar, an E-newsletter was sent in February 2017 by the managed care pharmacy team to physicians contracted with the managed care organization. The aforementioned newsletter highlighted the four benefit groups and the ACC Statin Intolerance App.

**Statin and cholesterol management apps**

The study considered three apps related to statins and cholesterol management (ACC/AHA ASCVD Risk Estimator App, ACC Statin Intolerance App, and ACC Guideline Clinical App). The ACC/AHA ASCVD Risk Estimator App uses the most recent ACC/AHA guidelines to determine patient's 10-year ASCVD risk and develop a customized treatment plan. The ACC Statin Intolerance App provides...
alternative therapy recommendations for patients reporting statin-related adverse effects, such as myopathy. Based upon 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults and statin prescribing information, this app allows the clinician to effectively evaluate best therapy alternatives to reduce LDL.20 The ACC Guideline Clinical App offers an easily, accessible method of obtaining clinical guidelines summaries, treatment algorithms and cardiovascular risk calculators.21 These Apps are downloadable on cellular phones and there are also online computer versions.

Post-survey

The survey instrument used in the post intervention assessment phase contained the same constructs and questions as the pre-test questionnaire, with additional questions about whether physicians attended the webinar and/or read the E-newsletter related to the ACC statin guidelines.

Study sample and data collection

At both phases of the study, the survey instruments were administered to physicians contracted with a Medicare Advantage organization who attended meetings held in large metropolitan cities in the Southwestern US and in the Rio Grande Valley area of Texas (e.g., Edinburg, TX). The survey instrument was distributed via the pharmacy care team to physicians, also the pre-survey and post-survey and educational interventions (e.g., webinar and E-newsletter). The pre-survey was administered during August 2016 and the post-survey was administered during August 2017.

Informed consent was obtained from physicians prior to their participation in the study. Approval from the University of Houston’s Institutional Review Board was obtained prior to conducting the study.

Data analysis

Data was coded initially using a Microsoft Excel spreadsheet. Descriptive statistics were performed to describe the characteristics of respondent physicians and measures of the awareness-to-adherence items. Reliability analysis was conducted using Cronbach’s alpha to assess the internal consistency of construct item scales. The level of physicians’ adherence (binary variable coded as 0/1) was the dependent variable of interest. Physicians having an adherence level of ≥4 were considered adherent to the guidelines while graded <4 were considered non-adherent. The cutoff was chosen based on the awareness-to-adherence model, and a higher score of 4 and above is indicative of a greater level of adherence. The levels of agreement, awareness, and adoption were used as independent variables and coded in the same way (≥4 indicating agreement, awareness, and adoption and <4 indicating non-agreement, unawareness, and non-adoption). A student’s t-test (independent sample) was performed in assessing the adherence level for binary groups. An analysis of variance (ANOVA) was performed in assessing adherence level with more than 2 groups. A paired t-test was used to determine the change in physicians’ level of awareness for the various statin apps. A logistic regression analysis was conducted to examine the influence of covariates on physicians’ reported level of adherence to the guidelines. Statistical significance was set at an alpha level of $P < .05$. SAS® Version 9.4 statistical software (SAS Institute, Cary, NC, USA) was used for data analyses.

Results

Pre-survey

A total of 215 responses were obtained and 197 were considered usable for analysis, due to missing values. Most physicians were white (62.1%), non-Hispanic (64.02%), family practice specialists (60.4%), based in the Greater Houston area (66.5%), and saw patients who were predominantly indigent (50.25%). The majority of physicians (69%) were aware of the 2013 ACC/AHA guideline; however, 79.9% had yet to adopt some facets (e.g., using LDL-C as the target of therapy). Approximately 31% of respondents were aware of the ACC Statin Intolerance App and 58.4% were aware of the ACC Guideline Clinical App. Most physicians asked their patients about statin adherence (93.9%), initiated high-intensity statin therapy (70.1%), and rechallenged statin intolerant patients (59.9%). Overall adoption was significantly different across physician practice location (higher in Houston compared to the Rio Grande Valley; $P = .024$), and guideline adherence was significantly different across race (highest among whites; $P = .008$). Most physicians were aware of the guidelines; however, many primary care physicians were not aware of the Statin Intolerance App.

Post-survey

A total of 170 responses were used for analysis. Table 1 shows the characteristics of physicians who participated in the post-survey. Most physicians were white (66.4%), non-Hispanic (42.28%), specializing in family practice (63.53%), based in the Greater Houston area (57.06%), and saw patients who were
predominantly indigent (54.12%). Also, 6.47% of physicians only attended the webinar and 34.71% only read the E-newsletter; while 11.76% attended both the webinar and read the E-newsletter, and 47.06% were not exposed to either educational intervention. The Cronbach’s alpha score was 0.73 for the awareness construct, 0.88 for the agreement construct, and 0.85 for adherence, demonstrating internal consistency.

Descriptive measures for all variables can be found in Supplementary Table 1. Most physicians were moderately aware (52.94%) of the major recommendations associated with the four statin benefit groups in the guidelines. Approximately 74.71% were aware of the ACC/AHA ASCVD Risk Estimator App, 45.3% were aware of the Statin Intolerance App, and 65.29% were aware of the ACC Clinical Guideline App. Almost half (46.47%) of responding physicians always asked patients about their statin medication adherence. Also, 53.53% of physicians often initiated high-intensity statin therapy as well as rechallenged patients who were statin-intolerant.

Physicians’ level of adherence to statin guidelines

Level of adherence based on various groups (those who only attended the webinar, those who only read the E-newsletter, those who attended the webinar as well as read the E-newsletter, and those were not exposed to either) are shown in Table 2. When physicians were divided into 2 groups (any intervention vs no intervention), a significant difference (based on t-test) was observed between them ($P = .027$). The mean level of adherence for any-intervention group ($n = 90$) was 3.83, while that for the non-intervention group ($n = 80$) was 3.53. An ANOVA showed that there was no significant difference among the four groups.

The level of adherence based on physician characteristics (e.g., physician race, physician ethnicity, physician practice location, and physician specialty) was also assessed using an ANOVA and t-test. A significant difference was observed in the level of adherence across race ($P = .031$) and physician practice location ($P < .0001$) at a significance level of 0.05.

Table 3 shows the results of the logistic regression regarding level of adherence. Physicians with a higher level of agreement were 4.8 times more likely to be adherent to the guidelines (95% confidence interval [CI] 1.43, 16.37; $P = .011$) compared with those with a lower level of agreement. Also, physicians practicing in the Rio Grande Valley area were 4.7 times more likely to be adherent to the guidelines (95% CI 1.85, 11.96; $P = .001$) compared with those from the Greater Houston area.

Physicians’ level of awareness of statin apps

The change in physicians’ level of awareness for the statin apps was assessed using a paired t-test among physicians who completed both the pre and post-surveys ($n = 106$). It was observed that there was a significant difference in the level of awareness of the ACC/AHA ASCVD Risk Estimator App between the pre and post-surveys ($P = .0002$).

Discussion

This is the first known study to access the awareness-to-adherence model among primary care physicians’
managing cholesterol. Utilizing the awareness-to-adherence model, is one strength of this study. However, self-reporting may result in overestimation due to recall or social desirability bias. Previous studies have also shown that physicians report a high level of awareness regarding guidelines developed for diseases such as diabetes, although adoption and adherence may be lacking.22 Our study observed a high level of awareness of, but a lower level of adherence to the guidelines among physicians. Another study purports that the length and complexity of the guidelines. 23 Additionally, the calculation of the ASCVD risk estimator presents a time burden in a busy primary care practice. Our findings correlate to a prior study that evaluated physicians’ understanding of the guidelines, which observed that most providers did not completely understand these guidelines.18 It was observed that only half of responding providers had read guidelines, and about half could correctly identify the four statin-benefit groups; there were significant gaps in understanding noted for both specialty and non-specialty providers.

This study evaluated the effect of educational interventions on the level of physicians’ adherence to the guidelines. A statistically significant difference was observed between the any-intervention vs the non-intervention group. This may be indicative of a positive impact based on the webinar as well as the E-newsletter influencing physicians’ level of adherence to the guidelines. A previous study by Miller et al. used a multi-faceted intervention approach in order to improve physician adherence to the 2013 ACC/AHA statin guidelines by evaluating the change in statin prescription pre and post intervention; however they only reported a slight increase in percentage of statin prescriptions post-intervention, and this was not statistically significant. 24 In our study, adherence, which was access by physicians’ self-reported prescribing of moderate to high statins among the four benefit groups, showed a statistically significant difference across physician race and practice location. However, findings may have limited generalizability as physician recruitment was not randomized.

The logistic regression showed that agreement was a statistically significant predictor of adherence; however, adoption, and awareness were not. Among physician characteristics, physician practice location was also a statistically significant predictor of adherence. Physician race and intervention groups were no longer statistically significant when adjusted for other

| Variable                        | Odds ratio | 95% CI       | P-value |
|--------------------------------|-----------|--------------|---------|
| Awareness*                     | 1.69      | 0.80, 3.56   | 0.167   |
| Agreement*                     | 4.83      | 1.43, 16.37  | 0.011   |
| Adoption*                      | 3.25      | 0.66, 15.95  | 0.147   |
| Intervention group             |           |              |         |
| Any                            | 0.52      | 0.24, 1.12   | 0.094   |
| None                           | Reference |              |         |
| Physician race                 |           |              |         |
| White                          | 1.62      | 0.39, 6.71   | 0.948   |
| Black                          | 1.13      | 0.18, 7.15   | 0.566   |
| Asian                          | 4.15      | 0.64, 26.71  | 0.114   |
| Other                          | Reference |              |         |
| Physician ethnicity            |           |              |         |
| Hispanic                       | 0.34      | 0.07, 1.69   | 0.271   |
| Non-Hispanic                   | 0.25      | 0.05, 1.29   | 0.922   |
| Other                          | Reference |              |         |
| Physician specialty            |           |              |         |
| Internal medicine              | 0.92      | 0.41, 2.07   | 0.838   |
| Family medicine                | Reference |              |         |
| Physician practice location    |           |              |         |
| Rio Grande Valley              | 4.7       | 1.85, 11.96  | 0.001   |
| Houston                        | Reference |              |         |
| Patient socioeconomic status   |           |              |         |
| Middle class                   | 1.84      | 0.83, 4.05   | 0.131   |
| Indigent                       | Reference |              |         |

CI: confidence interval.
*The levels of agreement, awareness, and adoption were coded as binary variables (≥4 indicating agreement, awareness, and adoption and <4 indicating non-agreement, unawareness, and non-adoption).
variables. A study by Beaulieu et al., which used the awareness-to-adherence model to examine physicians' attitudes toward the pharmacological treatment of patients with stable angina pectoris, found similar results where awareness, agreement, and adoption were the strongest predictors of adherence. However, physician demographics and practice characteristics did not predict adherence. 25

Our study also found that there was an increase in the level of awareness of the ACC/AHA ASCVD Risk Estimator App after administration of educational interventions. Thus, the use of these apps may help clinicians managing cholesterol in the patients with ASCVD. Continuous efforts are needed to implement different educational interventions and strategies to increase awareness and adherence of these apps. Additionally, prescribers could benefit from providing patients with the Statin Experience Assessment Questionnaire (SEAQ) to assess statin intolerance.26 Moreover, findings from this study help identify gaps in implementation and adherence to the cholesterol management guidelines and can inform clinicians to help increase the adoption and understanding of the newer 2018 guidelines.

**Conclusion and relevance**

Educational interventions were beneficial in improving the level of adherence; however, future studies employing the awareness-to-adherence model are needed to further evaluate adoption of cholesterol management guidelines. Improving adherence to treatment guidelines should result in improved quality of care among patients with ASCVD and lead to positive patient outcomes. As guidelines are newly developed and updated, understanding how interventions improve awareness-to-adherence is necessary to ensure evidenced-based practices are implemented across a spectrum of medical conditions.

**Contributorship**

MLF contributed to the study conception and design as well as drafted and critically reviewed the manuscript. SR drafted the manuscript and contributed to analysis. MLJ contributed to statistical analysis and interpretation and critically revised the manuscript. Both OS and TE contributed to data acquisition and critically reviewed the manuscript. JC assisted with study conception. SMA contributed to study design and critically reviewed the manuscript. All authors provided final approval of the manuscript.

**Declaration of conflicting interests**

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Fleming was a professor at the University of Houston, and is currently a professor at the University of North Texas System College of Pharmacy. Rege is a graduate student at the University of Houston. Johnson is a professor at the University of Houston. Serna and. Esse were employees of Cigna Health Spring and are currently employees of CareAllies. Choi was an employee and has stock options with Sanofi. Abughosh is a professor at the University of Houston.

**Ethical approval**

Informed consent was obtained from physicians prior to their participation in the study. Approval from the University of Houston’s Institutional Review Board was obtained prior to conducting the study.

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