



Assessing Changes in Statin Prescribing Patterns Surrounding the 2013 American College of Cardiology/American Heart Association Lipid Guidelines

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ABSTRACT

Purpose: The American College of Cardiology (ACC) and the American Heart Association (AHA) introduced new lipid guidelines in late 2013 that were a vast departure from older guidelines. Concerns were raised regarding the likely increase in the number of adults who would be eligible for lipid-lowering therapy, namely moderate to high intensity statins. We sought to determine whether, in the first year after the ACC/AHA guideline release, more patients were prescribed statins, prescribed moderate- to high-intensity statins, and eligible for statins compared with the previous year.

Methods: This study was a retrospective, cross-sectional, observational analysis of National Ambulatory Medical Care Survey collected by the Centers for Disease Control and Prevention during the years 2013 and 2014. Survey participants who were younger than 40 years or older than 75 years, were pregnant, or had triglyceride levels ≥ 400 mg/dL were excluded. Descriptive analyses and χ^2 tests of homogeneity (and associated odds ratios [ORs] and CIs) were constructed and reported.

Findings: Compared with 2013, a higher percentage of patients in 2014 were prescribed a statin and were eligible to receive a statin. In fact, patients in 2014 were significantly more likely to be prescribed a statin (OR = 1.22; 95% CI, 1.00–1.48) and to be eligible for a statin (OR = 9.26, 95% CI 7.54–11.37) compared with 2013. Although a higher percentage of patients in 2014 were prescribed a higher-intensity statin, the difference was not statistically significant (OR = 1.17; 95% CI, 0.90–1.52).

Implications: In the first year after the ACC/AHA guideline introduction, more patients in the United States were prescribed a statin. However, it is unclear whether the new guidelines were strictly adhered to regarding intensity of statin therapy. (*Clin Ther.* 2019;41:314–321) © 2019 Elsevier Inc. All rights reserved.

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INTRODUCTION

In 2013, the American College of Cardiology (ACC) and the American Heart Association (AHA) introduced new guidelines to guide lipid-lowering therapy.¹ These guidelines were the first new guideline recommendations for the use of lipid-lowering therapy in 11 years. The previous guidelines, The Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, used target LDL-C levels for specific patient populations as well as the Framingham risk calculator to further stratify patients into specific LDL-C target groups.² The ACC/AHA guidelines challenge the notion that specific LDL-C targets are essential for primary or secondary prevention of cardiovascular events. Instead, the guidelines focus on statin intensity based on patient risk. The 4 statin benefit groups that are

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described in the guidelines are (1) patients with clinical atherosclerotic cardiovascular disease (ASCVD), (2) patients with an LDL-C level >190 mg/dL, (3) patients aged 40–75 years with diabetes mellitus and LDL-C levels of 70–189 mg/dL, and (4) patients without clinical ASCVD or diabetes with an estimated 10-year ASCVD risk of $\geq 7.5\%$ and LDL-C levels of 70–189 mg/dL. On the basis of these new criteria, these ACC/AHA guidelines expand the potential eligibility of those who would be prescribed statin therapy. The largest driver of increased eligibility is the fourth statin benefit group basing eligibility for lipid-lowering therapy on an increased 10-year risk of ASCVD.¹

At the time of the guidelines' release, it was estimated that the ACC/AHA guidelines may cause a 25% increase in the proportion of the overall population that is treated with statins during the subsequent 3 years, increasing from 3,909,407 patients (27.7%) to 4,892,668 patients (34.7%), with the estimated largest proportion of increased utilization to be for primary prevention in patients aged 40–75 years who were not already receiving a lipid-lowering therapy.³

Historically, dissemination and adoption of new guidelines, especially ones that are as drastic as the departure the ACC/AHA guidelines made from the previous guidelines, have been slow because of a variety of barriers.^{4–6} Recent studies in the literature have compared pre- and post-statin use since the ACC/AHA guideline institution using either insurance claims data or smaller data sets from specific health care systems.^{7,8} When using insurance claims for the retrospective cohort, statin use remained fairly consistent between 1 year before and after the ACC/AHA guideline institution at 32% and 31%, respectively.⁷ However, when using a single-center cohort, investigators found a modest increase of high-intensity statin use of 4% at 1 year after the 2013 guideline institution.⁸ Recent studies have also used publicly available Centers for Disease Control and Prevention (CDC) data sets, such as the National Health and Nutrition Examination Survey (NHANES), to compare the eligibility criteria for patients based on the 2013 AHA criteria to the newer US preventative task force guidelines.⁹ To our knowledge, this is the first study that uses the National Ambulatory Medical Care Survey (NAMCS) to determine eligibility of statin use before

and after the ACC/AHA guideline release. The use of another publicly available, nationally representative CDC survey to assess statin eligibility and utilization before and after the updated 2013 ACC/AHA statin guidelines will provide additional evidence for practicing clinicians to evaluate the effect of the 2013 guidelines.⁹ Furthermore, although the data collected in NHANES is patient reported, the NAMCS-collected data is physician reported. Having analyses of both patient and physician reported data in the literature is particularly important given how recently the ACC/AHA statin guidelines have been implemented and the departure in recommendations from the long-standing Adult Treatment Panel (ATP) III guidelines.

METHODS

This study was a retrospective, cross-sectional, observational analysis of deidentified data collected by the CDC (and available to the public) in the NAMCS during the years 2013 and 2014.^{10,11} Survey participants who were younger than 40 or older than 75 years, were pregnant, or had triglyceride levels ≥ 400 mg/dL were excluded. This study was given exempt status by Campbell University's Institutional Review Board.

In both 2013 and 2014, the NAMCS survey used a stratified 2-stage sample, with physicians included in the first stage and visits in the second. The survey is designed to allow analysis results to be extrapolated to generate national estimates. However, the data collected at the physician's offices included in the survey cannot be guaranteed to reflect the population of “non–federally employed office-based physicians who are primarily engaged in direct patient care” that it is designed to represent. To improve the representativeness of the survey sample, weighting, clustering, and stratification variables are generated by the National Center for Health Statistics (NCHS). Taking these variables into account in the data analysis allows accurate national estimates to be generated. Thus, the survey data were analyzed using these variables as recommended by the NCHS.¹² In addition, the sampling weights have been adjusted by the NCHS for survey nonresponse as appropriate, yielding unbiased national estimates of visit occurrences, percentages, and characteristics.¹³ The sampling weights were divided by the number of survey years included in this study (2013–2014) to

arrive at mean annual estimates. The analysis of the survey, as designed, allows the generation of national mean annual total visits to non–federally employed office-based physicians who are primarily engaged in direct patient care by extrapolation of the survey sample ($n = 9373$). Because of the complex survey design, the appropriate SAS procedures/options to address missing data and use domains to determine accurate variance estimates were implemented in the analyses as recommended by the NCHS.^{12,14} For further details, the authors recommend review of the provided Refs.^{12,13}.

The outcome variables of interest were prescription of a statin (yes vs no), statin intensity (low-moderate vs moderate-high), and statin eligibility (yes vs no), where the denominator was the number of survey visits that met the inclusion and exclusion criteria. Statin doses were not provided in the NAMCS database; thus, atorvastatin, atorvastatin/amlodipine, atorvastatin/ezetimibe, rosuvastatin, and ezetimibe/simvastatin were categorized as moderate-high intensity, and simvastatin, simvastatin/niacin, pravastatin, lovastatin, lovastatin/niacin, fluvastatin, and pitavastatin were categorized as moderate-low intensity. Statin eligibility was determined by the date of survey completion. However, the NAMCS database does not include data on the family history of CVD, and as such it was not included in the calculation of the Framingham risk score for statin eligibility using the ATP III guidelines and therefore may underestimate the total number of patients eligible for statin therapy. Because the ACC/AHA statin guidelines were updated in November 2013, the eligibility of those completing the survey in November 2013 or earlier was determined relative to the original ACC/AHA statin guidelines, whereas the eligibility of those completing the survey in December 2013 or later were determined relative to the updated ACC/AHA statin guidelines.

Demographic and patient characteristics, including 10-year risk score, were summarized. Rao-Scott χ^2 tests of homogeneity were used to analyze the following: (1) whether the proportion of visits with a statin prescription differs by time frame relative to the statin guideline change (January through November 2013 [preguideline change] vs December 2013 through December 2014 [postguideline change]); (2) whether the proportion of visits with a moderate-high statin intensity differs by time frame

relative to the statin guideline change (January through November 2013 [preguideline change] vs December 2013 through December 2014 [postguideline change]); and (3) whether the proportion of visits eligible for a statin differs by time frame relative to the statin guideline change (January through November 2013 [preguideline change] vs December 2013 through December 2014 [postguideline change]).

Odds ratios (ORs), corresponding 95% CIs, and p values for these tests were reported. For each study year, a contingency table of statin prescription versus eligibility and a listing of the percentage of visits at which each statin was prescribed was generated, in addition to descriptive statistics of demographic and patient characteristics of interest.

RESULTS

A total of 9373 visits were identified for patients meeting the study inclusion and exclusion criteria in the NAMCS for the years 2013 and 2014. Most patient visits were by women (54.7%) (mean [SE] age of 59.8 [0.20] years) and white people (82.9%). Twenty-seven percent of visits included patients with diabetes, and 15.3% were current tobacco users, whereas 35.2% and 11.8% had CVD as defined by the ATP III and ACC/AHA guidelines, respectively. Fifty-seven percent had hypertension, with a mean (SE) systolic blood pressure of 128 (0.35) mm Hg, whereas only 50.7% of patients had been treated. Mean (SE) lipid panel results were as follows: total cholesterol 185 (0.72) mg/dL; HDL-C, 54 (0.35) mg/dL; LDL-C, 106 (0.58) mg/dL; and triglycerides, 134 (1.12) mg/dL. Fifty percent of patients had an ASCVD risk score $\geq 7.5\%$, whereas 3.3% of patients had a Framingham 10-year risk $>20\%$, and 28.5% had a 10-year risk of 10%–20%. Interestingly, 66.9% of the patients had ≥ 2 major risk factors that modify LDL-C goals according to the ATP III guidelines, but as previously stated the mean (SE) LDL-C level was only 106 (0.58) mg/dL (Table I).

Per the guidelines, patients at 51.3% of visits in 2014 were eligible to receive a statin, whereas patients at 10.2% of visits in 2013 were eligible (OR = 9.26; 95% CI, 7.54–11.37; $p < 0.0001$). This finding corresponds to an estimated increase nationwide of >25 million physician visits annually at which patients were eligible to receive a statin. In addition, patients at 38.4% of visits were prescribed

Table I. Demographic and patient characteristics.^a

| Characteristic | No. (%) of Patient visits (<i>n</i> = 9373) ^b |
|---|--|
| Survey year | |
| 2014 | 58,893,012 (54.1) |
| 2013 | 50,053,711 (45.9) |
| Age, mean (SE), y | 59.8 (0.20) |
| Sex | |
| Female | 59,559,964 (54.7) |
| Male | 49,386,760 (45.3) |
| Race | |
| Other ^c | 6,021,329 (7.3) |
| Black | 8,063,470 (9.8) |
| White | 68,325,504 (82.9) |
| Diabetes | |
| Yes | 29,845,505 (27.4) |
| No | 79,101,219 (72.6) |
| SBP, mean (SE), mm Hg | 127.8 (0.35) |
| Hypertension | |
| Yes | 62,091,751 (57.0) |
| No | 46,854,973 (43.0) |
| Hypertension management | |
| Treated | 55,223,206 (50.7) |
| Untreated | 53,723,518 (49.3) |
| ATP III cardiovascular disease definition | |
| Yes | 38,315,341 (35.2) |
| No | 70,631,383 (64.8) |
| ACC/AHA cardiovascular disease definition | |
| Yes | 12,837,001 (11.8) |
| No | 96,109,723 (88.2) |
| Tobacco use | |
| Current | 14,077,065 (15.3) |
| Not current | 78,198,052 (84.7) |
| Cholesterol, mean (SE), mg/dL | |
| Total | 184.8 ± 0.72 |
| HDL-C | 53.7 ± 0.35 |
| LDL-C | 105.6 ± 0.58 |
| TG | 133.9 ± 1.12 |
| Framingham 10-year risk, % ^d | |
| >20 | 1,664,251 (3.3) |
| 10-20 | 14,383,288 (28.5) |
| <10 | 34,466,083 (68.2) |
| ASCVD 10-year risk % ^d | |
| ≥7.5 | 30,769,152 (50.2) |

Table I. (Continued)

| Characteristic | No. (%) of Patient visits (<i>n</i> = 9373) ^b |
|---------------------------------|--|
| 5-<7.5 | 7,612,285 (12.4) |
| <5 | 22,907,840 (37.4) |
| Major risk factors ^e | |
| 0 | 7,150,252 (7.7) |
| 1 | 23,468,196 (25.4) |
| 2 | 42,690,097 (46.3) |
| 3 | 16,391,077 (17.8) |
| 4 | 2,575,495 (2.8) |

ACC = American College of Cardiology; AHA = American Heart Association; ASCVD = atherosclerotic cardiovascular disease; ATP, Adult Treatment Panel; SBP = Systolic Blood Pressure; TG = triglycerides.

^aSurvey weighting and clusters accounted for reflecting unbiased, national annual estimates of visit occurrences for the portion of the population who met the study inclusion and exclusion criteria.

^bRaw, unweighted survey sample size from which the weighted estimates included in this table were extrapolated. Data are presented as number (percentage) unless otherwise indicated.

^cOther race group includes Asian, Native Hawaiian/Other Pacific Islander, American Indian/Alaska Native, and more than 1 race reported.

^dThe Framingham scores and ASCVD scores were calculated for survey participants in both 2013 and 2014.

^eMajor risk factors that modify LDL-C goals as defined by the ATP III guidelines. Counts and percentages were calculated for survey participants in both 2013 and 2014.

a statin in 2014 compared with 33.9% in 2013 (OR = 1.22; 95% CI, 1.00–1.48; *p* = 0.0473). This corresponds to an estimated increase nationwide of >5.6 million physician visits annually at which patients were prescribed a statin. Fifty-one percent of patients prescribed a statin were prescribed moderate to high intensity in 2014 versus 47% in 2013 (OR = 1.17; 95% CI, 0.90–1.52; *p* = 0.2340) (Table II).

Of those who were eligible to receive a statin in 2013, 33.1% of patients were prescribed a statin versus 47.4% in 2014 under the new guidelines, corresponding to an estimated increase nationwide of >12.6 million physician visits annually at which

Table II. Statin prescription, intensity and eligibility results by survey year in the National Ambulatory Medical Care Survey, 2013–2014.^a

| Variable | No. (%) of visits | | OR (95% CI) | P |
|----------------------------------|-------------------|-------------------|-------------------|---------|
| | 2014 | 2013 | | |
| Prescribed a statin ^b | | | | |
| Yes | 22,638,561 (38.4) | 16,971,820 (33.9) | 1.22 (1.00–1.48) | 0.0473 |
| No | 36,254,452 (61.6) | 33,081,891 (66.1) | | |
| Statin intensity ^b | | | | |
| Moderate-high | 11,426,262 (50.5) | 7,902,674 (46.6) | 1.17 (0.90–1.52) | 0.2340 |
| Low-moderate | 11,212,299 (49.5) | 9,069,146 (53.4) | | |
| Statin eligibility ^c | | | | |
| Yes | 30,186,835 (51.3) | 5,104,371 (10.2) | 9.26 (7.54–11.37) | <0.0001 |
| No | 28,706,178 (48.7) | 44,949,340 (89.8) | | |

OR = odds ratio.

^a Survey weighting and clusters accounted for reflecting unbiased, national annual estimates of visit occurrences for the portion of the population meeting the study inclusion and exclusion criteria.

^b Determination of statin prescription and intensity was the same for both years.

^c Determination of statin eligibility per the Adult Treatment Panel III guidelines for 2013 and per the atherosclerotic cardiovascular disease guidelines for 2014.

those eligible to receive a statin were prescribed a statin. Furthermore, of those who were not eligible to receive a statin in 2013, 34.0% of patients were still prescribed a statin versus 29.0% in 2014 under the new guidelines, corresponding to an estimated decrease nationwide of nearly 7 million physician visits annually at which those not eligible to receive a statin were prescribed a statin (Table III).

A larger percentage of patients were prescribed moderate-high intensity statin therapy based on the ACC/AHA guidelines; however, the result was not statistically significant (50.5 vs 46.6%; OR = 1.17; 95% CI, 0.90–1.52) (Table II). Although the dose of statin therapy is not reported in the NAMCS database, the number of prescriptions for all statins was summarized. Atorvastatin and rosuvastatin are considered a moderate- or high-intensity statin. A net increase in atorvastatin and rosuvastatin prescriptions was observed between 2013 and 2014 (31.5% vs 35.7% and 11.9% vs 13.0%, respectively). In addition, a decrease in low- to moderate-intensity statins, such as simvastatin and lovastatin, was observed (35.2% vs 29.3% and 6.1% vs 5.3%, respectively) (Table IV).

DISCUSSION

Our study highlights the disparity between those who are eligible to receive a statin based on the ACC/AHA guidelines versus the ATP III guidelines (51.3% vs 10.2%). A second significant disparity was noted between those eligible to receive a statin and those who were prescribed a statin under the ACC/AHA guidelines (51.3% vs 38.4%). It is interesting that the disparity between those who were prescribed a statin, yet ineligible for statin therapy, also decreased under the new guidelines (34% vs 29%); however, this could be attributable to the increased eligibility criteria from the ACC/AHA guidelines. The data from this study indicate that in the first year after the new guidelines were released, there was a 13.3% relative increase in statin prescribing from the previous year (33.9% vs 38.4%). This is a substantial difference from the 1% decrease that has been reported in other recent literature as well as the 25% increase Over 3 years after the ACC/AHA guidelines release that was originally hypothesized.^{3,7} Because uptake to guidelines typically requires time for providers to be made aware and fully adherent, with only 1 year of data postguideline available, we would expect statin prescribing to increase even

Table III. Statin prescription versus eligibility results by survey year in the National Ambulatory Medical Care Survey, 2013–2014.^a

| Statin eligibility ^b | No. (%) prescribed a statin ^c | |
|---------------------------------|--|-------------------|
| | Yes ^d | No ^d |
| 2013 | | |
| Yes | 1,687,342 (33.1) | 3,417,029 (66.9) |
| No | 15,284,478 (34.0) | 29,664,862 (66.0) |
| 2014 | | |
| Yes | 14,323,016 (47.4) | 15,863,818 (52.6) |
| No | 8,315,545 (29.0) | 20,390,633 (71.0) |

^a Survey weighting and clusters accounted for reflecting unbiased, national annual estimates of visit occurrences for the portion of the population meeting the study inclusion/exclusion criteria.

^b Determination of statin eligibility per the Adult Treatment Panel III guidelines for 2013 and per the atherosclerotic cardiovascular disease guidelines for 2014.

^c Determination of statin prescription was the same for both years.

^d The reported percentages are row percentages, totaling 100% in each row.

further as more providers embrace change and comply with the most recent guidelines.

Another major difference between the ATP III guidelines and the ACC/AHA guidelines is the use of LDL-C levels in determining patient ineligibility for a statin, a criterion that is incorporated into the ATP III guidelines but was largely absent from the more recent ACC/AHA guidelines. The ACC/AHA guidelines algorithm that does not rely on a specific LDL-C target or goal level but instead on the percentage of reduction of LDL-C allows significantly more patients to be eligible to receive a statin. Alarming, our study found there were approximately 6 times more patients who were eligible for statin therapy based on the 2013 ACC/AHA guidelines using the 4 statin benefit groups (extrapolated national annual estimate of 30,186,835) compared with the ATP III guidelines (estimate of 5,104,371). We also found that the extrapolated national annual estimate of the number of patients eligible to receive a statin based on the ATP III guidelines ($n = 5,104,371$) was much lower than those who were indeed prescribed a statin ($n = 16,971,820$) under the same guideline. We hypothesize that perhaps many patients may have reached their LDL-C goal, thereby making them ineligible to receive a statin based on the ATP III

guidelines. However, the topic of LDL-C level and the intensity to which we lower a patient's LDL-C has been debated for years, and there were likely some early adopters of dosing based on risk assessment.¹⁵ The question of how low we can effectively lower a patient's LDL-C level has yet to be definitively answered.¹⁶ Moreover, we hypothesize that many eligible patients did not receive a statin based on the ACC/AHA guidelines in 2014 because of low to normal LDL-C values. This finding may also account for the lack of a significant difference seen between years in statin intensity because patients with lower LDL-C values may have been prescribed a low-moderate intensity statin even if they qualified for a high-intensity statin. Having prescribed medication dose data available would have enabled us to determine the effect of provider preference on statin prescribing. Unfortunately, dose data are not available within the NAMCS database, which is why we split statin intensity into low-moderate and moderate-high groupings.

There are a few other limitations with our study worth mentioning. Unfortunately, the NAMCS does not include statin doses, which makes it difficult to tease out the difference between high-, moderate-, and low-intensity statins. Although statin doses are not available, the increase in both atorvastatin and

Table IV. Statin prescriptions by survey year in the National Ambulatory Medical Care Survey, 2013–2014.^a

| Statin | No. (%) of visits | |
|-------------------------|--------------------|--------------------|
| | 2014 | 2013 |
| Atorvastatin | 8,259,384 (35.7) | 5,442,755 (31.5) |
| Simvastatin | 6,759,989 (29.3) | 6,081,859 (35.2) |
| Pravastatin | 3,451,480 (14.9) | 2,075,688 (12.0) |
| Rosuvastatin | 3,004,952 (13.0) | 2,060,245 (11.9) |
| Lovastatin | 1,222,917 (5.3) | 1,048,957 (6.1) |
| Ezetimibe-simvastatin | 214,388 (0.9) | 343,054 (2.0) |
| Pitavastatin | 61,375 (0.3) | 104,743 (0.6) |
| Amlodipine-atorvastatin | 60,411 (0.3) | 95,797 (0.6) |
| Niacin-simvastatin | 38,294 (0.2) | 27,518 (0.2) |
| Fluvastatin | 20,093 (<0.1) | 10,563 (<0.1) |
| Lovastatin-niacin | 14,926 (<0.1) | 10,725 (<0.1) |
| Atorvastatin-ezetimibe | 0 (0.0) | 0 (0.0) |
| Total ^b | 23,108,209 (100.0) | 17,301,904 (100.0) |

^a Survey weighting and clusters accounted for reflecting unbiased, national annual estimates of visit occurrences for the portion of the population meeting the study inclusion/exclusion criteria.

^b Prescription totals are greater than those given in Table II (22,638,561 for 2014 and 16,971,820 for 2013, respectively) because some individuals in the survey were prescribed >1 statin. Such individuals were counted in the relevant multiple rows to reflect all statins prescribed in each year.

rosuvastatin prescriptions from 2013 to 2014 and the decrease in simvastatin and lovastatin prescriptions in the same time frame led us to believe that there was a net increase in moderate- to high-dose statin prescribing nationwide. Although the NAMCS is designed to be nationally representative for the years included among those who meet the study inclusion and exclusion criteria, most of study population was white. However, there is a well-established increased risk of CVD in the African American population as well as a potential overestimated risk of CVD in Hispanic patients.^{17,18} Thus, one could hypothesize that the increase in patient eligibility for a statin is even larger in these specific ethnic groups, leading to an overall higher increase than we report here. In addition, although our patient population met the criteria for each set of guidelines, the population was generally healthy, save for the number of patients with untreated hypertension. Although it could be argued that this study population is not truly representative of the population of the United States as a whole in terms of general health and well-being, the study population that we have studied is perhaps

more likely to engage in typical office-based ambulatory care clinics.

CONCLUSION

Our study found that when using nationally representative, CDC designed and executed survey data, more patients were eligible for and then prescribed a statin after the introduction of the ACC/AHA guidelines in late 2013. No significant difference was found in regard to statin intensity, but it is unclear whether the new guidelines were strictly adhered to in the 1 year after their establishment because adherence to new guidelines typically requires an extended period. Future studies are needed to assess statin use and the subsequent benefits long term as more current data during a longer period become available.

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CONFLICTS OF INTEREST

The authors have indicated that they have no conflicts of interest regarding the content of this article.

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