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Original article

Statins utilization trends and expenditures in the U.S. before and after the implementation of the 2013 ACC/AHA guidelines

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ABSTRACT

Importance: Statins are drugs of choice in treating hyperlipidemia and preventing or reducing cardiovascular diseases.
Purpose: Explore statins utilization and expenditure trends in the United States before and after the publication of the 2013 ACC/AHA guidelines.
Method: A retrospective, cross-sectional study of US noninstitutionalized civilians was conducted using MEPS data from 2008 to 2019. Adults who were ≥ 40 years old and who reported taking statins were included in the study.
Primary outcomes: Statins use patterns, total cost, and out-of-pocket spending in the general adults who reported taking statins medications. Expenditures were expressed in 2019 US dollars.
Results: In this study, 409,804 individuals were eligible to be included (mean age [SE], 59 [0.1] years; 54% female). Of those participants, 22% reported taking statin therapy, and 11% of them filled only one statin prescription. The number of individuals in the general population who reported taking any statin climbed from 31 million (12%) in 2008–2009 to 92 million (35%) in 2018–2019, representing a 197% increase. After 2013, the number of individuals who used statins increased by 149%, from 37 million in 2012–2013 to 92 million users in 2018–2019. The annual number of statins prescriptions increased from 461 million to 818 million (77%; p = 0.000) between 2008 and 2019. Atorvastatin was the most prescribed medication in the statins class (36%), followed by simvastatin (34%). The moderate-intensity statins were the most used by the participants (60%). The total statins cost in 2013 was $8 billion and increased to $10 billion in 2019 (25%; p = 0.000). The total OOP expenditure trend sloped from $4.0 billion in the 2008–2009 cycle to $3.1 billion in 2018–2019. The average OOP paid by Asians was higher than that of other races at $141.
Conclusion: The proportion of individuals who used statins significantly increased following the adoption of the 2013 ACC/AHA guidelines. The findings, however, demonstrated suboptimal prescribing trends of high-intensity statins, which need to be addressed by the stakeholders to maximize medication outcomes. Statins expenditures, especially the co-payments, significantly decreased. The results have shown that revised or new regulations have a substantial impact on the healthcare industry.

1. Introduction

Statins are the drugs of choice in treating hyperlipidemia and preventing or reducing heart diseases (Salami et al. 2017). In 2013, the American College of Cardiology (ACC) and the American Heart Association (AHA) revised the Adult Treatment Panel III (ATP-III) guidelines to minimize the risk of cardiovascular diseases (CVD), which dramatically have increased the number of people eligible to take statins (Davies et al. 2016). The previous protocols targeted patients diagnosed with CVD or diabetes and low-density lipoprotein (LDL) cholesterol level of ≥ 100 mg/dL (Pencina et al. 2014). In addition, the ATP-III protocols indicated statins for primary prevention in individuals based on LDL cholesterol profile and the 10-year risk of coronary heart disease (CHD) using the Framingham risk formula (Ardern et al. 2005). Moreover, the outdated guidelines recognized the importance of a patient's lifestyle in the prevention and treatment of heart disease. Regardless of cholesterol levels, the new protocols focus on preventing

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cardiovascular events using specific statin intensities (Pokharel et al. 2017). The 2013 guidelines recommend statin therapy for those diagnosed with atherosclerotic cardiovascular disease (ASCVD) (Egan et al., 2016). Moreover, the newly-released recommendations target patients aged 40 to 75 years old diagnosed with diabetes and their low-density lipoprotein cholesterol (LDL-C) blood concentration is 70–189 mg/dL (Okerson et al. 2017). And those with an estimated 10-year ASCVD risk of $\geq$ 7.5% and LDL-C levels of 70–189 mg/dL will also be eligible to start statin therapy (Sidebottom et al., 2020).

Statins are among the most prescribed medicines in the United States (U.S.), and their utilization has increased significantly in recent years (Salami et al. 2017). Following the implementation of the revised protocols, it was anticipated that the use of these medications would grow due to broadened eligibility criteria. The 2013-updated guidelines raised the number of statin users in the U.S. by 80%, from 22 million individuals in 2002–2003 to 40 million users in 2012–2013 (Pursnani et al. 2014). The high prescribing rates of statins were also associated with increased statin-related expenditures. In the 2012–2013 period, approximately 220 million statins prescriptions were filled with a total cost of $16.9 billion, whereas out-of-pocket spending constituted $3.9 billion (Salami et al. 2017). In markets, there are many statin brands and generics with a wide range of prices, such as lovastatin, which costs $21 per day, while pravastatin's daily cost is $1.16 (Davies et al. 2016). Patients' financial status, prescribed statin costs, and the limitations of healthcare plans may lead to a considerable financial burden. Between 2007 and 2011, the annual sales of the brand name atorvastatin alone in the U.S. was more than $7 billion (Luo et al. 2016). These expenditures are also expected to increase in the future for several reasons, including inflation, a higher number of patients with CVD, or further regulatory updates or changes in the guidelines.

Due to the inconsistencies of previous studies and given that little has been done recently to explore the trends of statins prescribing patterns and expenditure. To our knowledge, the most recent study that covers this area was published in 2017 by Salami and colleagues, and the authors analyzed data between 2002 and 2013. However, in this study, we utilized the Medical Expenditure Panel Survey (MEPS) data (2008–2019) to search statins use patterns and spending. The research results will provide significant and updated data that may assist the healthcare sector, and stakeholders track prescribing models and the cost of such essential medications. Additionally, the findings might reflect the impact of newly adopted guidelines on clinical practice.

2. Methodology

2.1. Study design and population

A retrospective, cross-sectional study of U.S. noninstitutionalized civilians using MEPS files of full-year consolidated data, medical conditions, and prescribed medicines from 2008 to 2019 was conducted. MEPS is a group of large-scale national surveys of individuals and families and their medical providers and employers (Agency for Healthcare Research, 2019). It is the only national source that measures how noninstitutionalized American civilians utilize and pay for medical services, health insurance, and out-of-pocket expenditure. These surveys are conducted annually by the Agency for Healthcare Research and Quality (AHRQ) to provide nationally representative estimates about medical conditions, the utilization of healthcare services, charges, insurance, and customer satisfaction. Moreover, the MEPS Household Component (H.C.) evaluates respondents' health conditions, demographic and socioeconomic characteristics, employment status, access to care, and level of satisfaction with health care services. These estimates cover individuals, families, and population subgroups. The survey panel design includes five rounds of interviews over two full calendar years, presenting information for examining person-level changes in variables of interest such as costs, medical insurance coverage, and health status. MEPS uses a computer-assisted personal interviewing (CAPI) technology to collect information about each household, and then the survey structures on these data through several interviews. Then, all data are reported by a single respondent for a sample household (Agency for Healthcare Research, 2019).

Only adults $\geq$ 40 years who reported taking statins were included in the study. Sociodemographic data such as (age, gender, race/ethnicity), medical history, and prescribed medications were extracted from the MEPS HC files. Chronic conditions such as hypertension, coronary heart disease, angina, heart attack, stroke, high cholesterol level, diabetes, and other conditions data were extracted from the medical history files. In addition, the medication data file captured the source of payment, including out-of-pocket, Medicare and Medicaid, private insurance, and the total spending. Drug prices and expenditures were expressed in U.S. dollars. The dollar value was adjusted for inflation using the consumer price index to be constant with the 2019 dollar value (U.S. Bureau of Labor Statistics 2021). The International Classification of Diseases, Clinical Modification ninth and tenth revision (ICD-9-CM and ICD-10-CM) were used to identify individuals diagnosed with particular conditions, including hypertension, heart failure, high cholesterol levels, and diabetes (Centers for Disease Control and Prevention 2020). These chronic conditions were assumed to be the indication for statin use among the study population.

2.2. Statistical analysis

All statistical analyses were carried out using Stata software (version 15.1) and Microsoft Excel (version 2112). The study combined the 12-year data into one file for ease of analysis. Baseline characteristics of the participants were reported in frequencies and proportions for categorical variables, and continuous data were summarized as mean, standard deviation (S.D.), and standard error (S.E.). The study applied the final person-weight adjusted for the 12-year-period and utilized the *svy: prop* command to estimate the proportion of the population taking statins, the intensity of statins prescribed, the total number of prescriptions, OOP, and the total expenditures pre and post-the adoption of the ACC/AHA new protocols. The trend analysis before and after 2013 was conducted using descriptive analysis to explore the statins prescribing behaviors and associated expenditures. Also, a one-way ANOVA analysis was done to measure the trends of total spending and OOP costs. Moreover, a Chi-square test was performed to examine the association between the categorical observations. In this study, 95% confidence intervals (C.I.s), standard error (S.E.), and standard deviation (S.D.) were reported in some analyses, and a P-value < 0.05 was considered statistically significant.

3. Results

In this study, 409,804 individuals were eligible to be included (mean age [S.E.], 59 [0.1] years; 54% female). Of those participants, 22% reported taking statin therapy, and 11% of those patients filled only one statin prescription. Table 1 demonstrates the study population characteristics. The majority of the study population were non-Hispanic White females, most of whom were between 50 and 59 years old. Moreover, individuals who reported taking statins were diagnosed with several chronic diseases, such as hypertension (50%), hyperlipidemia (47%), and diabetes (18%).

Table 1
Characteristics of Statin Users, MEPS 2008 to 2019.

MEPS Cycle	2008–2009	2010–2011	2012–2013	2014–2015	2016–2017	2018–2019	Total	P-value**
Total Number of Statin Users (Unweighted)	6,662	4,945	7,740	7,544	7,999	8,631	**43,521**	
Total Number of Statin Users* (Weighted)	31	24	37	38	41	92	**266**	
Characteristics								
Mean age[SE], years	57.7[0.2]	58.3[0.2]	58.7[0.2]	59.2[0.2]	59.6[0.2]	62.9[0.2]	**59[0.1]**	**0.000**
Age category (%)								
40–49	32	32	32	28	27	15	**27**	
50–59	29	29	30	30	28	21	**28**	**0.000**
60–69	19	20	21	22	22	28	**23**	
≥70	18	18	16	19	21	35	**22**	
Gender (%)								
Male	47	45	46	45	45	48	**46**	**0.000**
Female	53	54	53	55	55	52	**54**	
Race/ethnicity (%)								
Whites	75	55	43	44	47	63	**41**	
Black	10	18	21	21	19	13	**15**	
Hispanics	10	19	25	24	25	15	**21**	**0.000**
Asians	4	7	8	8	7	5	**20**	
Other	0	0	2	2	2	3	**2**	
Medical history (%)								
Hypertension	46	47	47	49	48	59	**50**	**0.000**
CHD	10	8	7	9	8	13	**9**	**0.000**
High lipids	44	42	41	45	43	65	**47**	**0.000**
Stroke	6	5	5	7	6	9	**7**	**0.000**
Heart attack	6	5	5	6	6	10	**6**	**0.000**
Angina	5	4	3	4	3	5	**4**	**0.000**
Diabetes	13	15	15	17	17	26	**18**	**0.000**
Insurance status (%)								
Any private	55	58	54	54	56	53	**55**	**0.000**
Public only	27	26	28	27	27	28	**27**	**0.000**
Uninsured	17	16	17	18	16	18	**17**	**0.000**
Education level (%)	**Hispanic**	**Whites**	**Blacks**	**Asians**	**Others**	**P-value**		
No degree	50	22	11	15	1	**0.000**		
GED	26	36	21	16	2			
High school	15	42	13	28	1			
Bachelor	13	44	15	25	1			
Master's	10	50	15	21	2			
Doctorate	12	50	14	22	2			
Prescriptions filled	600*	3 billion	437*	1.4 billion	85*			
95% CI	536–655	2.5–2.9	399–476	1.3–1.5	66–100			

3.1. Trends in statins utilization

Overall, the number of individuals in the general population who reported taking any statin climbed gradually from 31 million (12%) in 2008–2009 to 92 million (35%) in 2018–2019, representing a 197% increase (Fig. 1).

After 2013, the number of individuals who used statins increased 149% from 37 million in 2012–2013 period to 92 million users in 2018–2019. Moreover, the size of statins users sharply increased in the 2018–2019 period (122%). The annual number of statins prescriptions increased from 461 million to 818 million (77%; p = 0.000) between 2008 and 2019 (Fig. 2).

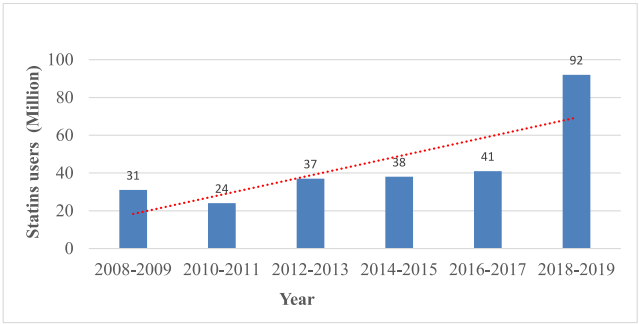

Fig. 1. Trends in Statins Utilization, MEPS 2008–2019.

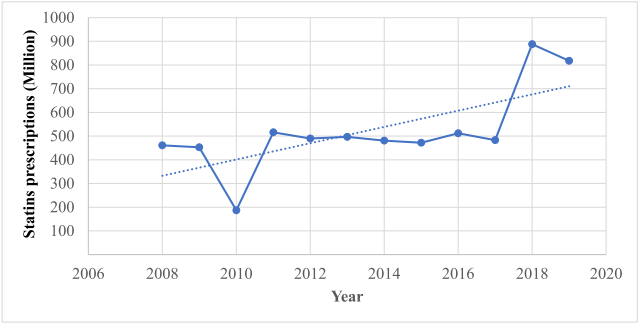

Fig. 2. Number of Statins Prescriptions, MEPS 2008–2019.

The study found disparities in the number of stains prescriptions among racial minorities and age groups. The lowest number of statins prescriptions was observed in the non-Hispanic Blacks with 437 million prescriptions, while the Hispanics minority purchased approximately 600 million prescriptions. Although Asians accounted for only 20% of the study population, they highly utilized statins, with 1.4 billion prescriptions filled throughout the study period (Table 1). Among age groups, the highest number of statins prescriptions were utilized by patients who aged between 50 and 59 years, with 1.7 billion filled prescriptions, while the lowest number of statins prescriptions was observed in individuals who were 60–69 years old (Fig. 3).

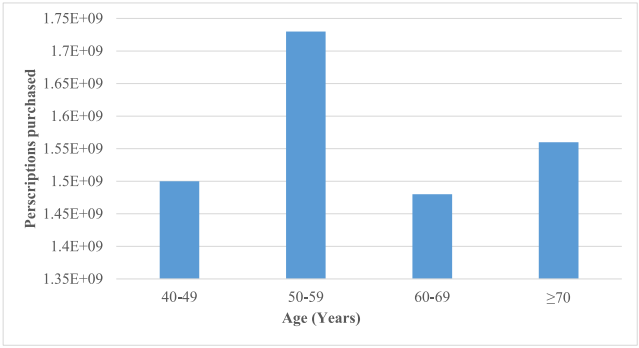

Fig. 3. Statins Prescription Purchase based on Age Groups, MEPS 2008–2019.

The utilization of different statins shifted over the study period. In general, atorvastatin was the most prescribed medication in the statins class (36%), followed by simvastatin (34%). On the other hand, pitavastatin and fluvastatin were the least utilized statins between 2008 and 2019. In 2013, after the publication of the updated recommendations, however, the percentage of atorvastatin prescriptions began to grow regularly from 26% until it reached the highest point at 52% (p = 0.000) in 2019 (Fig. 4). Statins intensity prescribing patterns also changed slightly during the study period, and moderate-intensity statins were the most used by the participants. 60% of the administered statins were moderate strength vs. 20% high-intensity statins (p = 0.000). The percentage of prescribed statins as high-intensity dose grew significantly after the revised protocols were published, from 15% in 2013 to 30% in 2019 (p = 0.000), peaking at 31% in 2018 (Fig. 5).

3.2. Statins expenditures trend

In 2008, the total cost for statins was $11 billion (95% CI $9.80-$11.6), and the highest annual total expenditure was $22.9 billion in the 2018–2019 period (Fig. 6). More importantly, the total statins expenditure gradually increased after 2013, when the guidelines were implemented. The total statins cost in 2013 was $8 billion and increased to $10 billion in 2019 (25%; p = 0.000) (Fig. 6). On the other hand, the total OOP expenditure trend sloped from $4.0 billion in the 2008–2009 cycle to $3.1 billion in 2018–2019, and the lowest spending was seen in the 2016–2017 period at $1.8 billion.

Available statins in the market are offered at varying prices. Among the U.S. adult population, the mean annual OOP of statins expenditures per user decreased from $175 in 2008 to $131 in 2009 before it sharply increased to $348 in 2010. However, in 2011 the OOP descended fast to $117 and continued to fall until it reached an all-time low at $30 in 2019.

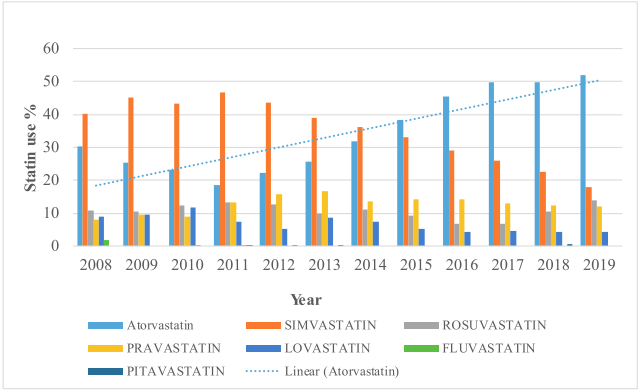

Fig. 4. Utilization of Statins by Type, MEPS 2008–2019.

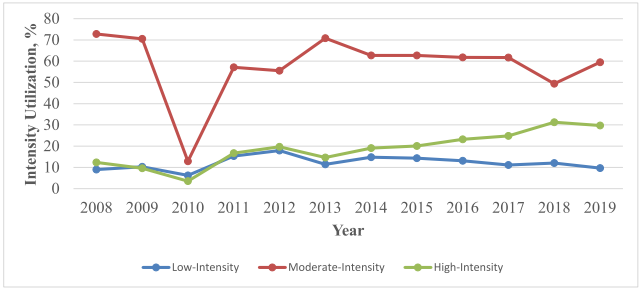

Fig. 5. Statins Utilization Trend by Intensity, MEPS 2008–2019.

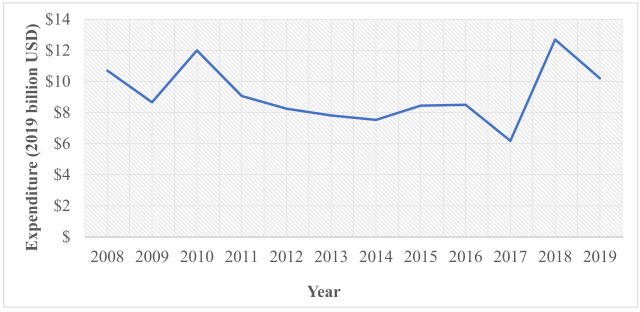

Fig. 6. Annual Total Expenditures Trend of Statins, MEPS 2008–2019.

In the subgroup analysis, the average OOP in different races varied widely. For example, the study found that Asians paid higher OOP than other races at $141.3, while Whites spent the lowest at $55. Additionally, the mean OOP that Hispanics and Blacks paid was $71.3 and $61.8, respectively (P < 0.000). Furthermore, the mean OOP among age groups was the highest in individuals who were 40–49 years old at $83 (p = 0.000).

Medical insurance covered a significant part of statins expenditure over the study period. For instance, Medicare paid more than $5 billion in 2008–2009, which was also the lowest amount paid by the program over the study period. As statins utilization increased after 2013, the cost paid by Medicare also expanded to $5 billion in 2019 (95% CI $4.3-$5.5). Medicaid, on the other hand, paid less than what Medicare spent. The total statins expenditures covered by Medicaid were $8.7 billion from 2008 until 2019. In addition, private insurance played an important role in covering some statins expenses. The sum of statins expenditures paid by private insurance was $32.7 billion between 2008 and 2019, representing 29% of statins cost coverage.

4. Discussion

This study aimed to explore statins use and expenditure trends before and after the 2013 ACC/AHA guidelines changes to manage high cholesterol concentration and reduce cardiovascular events. It is one of few studies that recently investigated statins utilization and cost patterns. This study showed that statins utilization significantly increased after 2013, the year in which the updated guidelines were published. However, despite the increase in statins use, OOP costs decreased over the study period. The results also showed that some statins were dominant and became dominated by other medications in the same class over time. Moreover, although the use of statins increased, this study found considerable disparities among subgroups such as racial/ethnic minorities and in different age groups.

The population of statins users expanded between 2013 and 2019, with a slight decrease in the 2010–2011 cycle. Additionally, the number of statins prescriptions increased 65% after 2013, peaking in 2018 at 888 million fills. Similarly, a previous study found an 80% increase in statin use among U.S. adults 40-year-old and older from 2002 to 2013 (Salami et al. 2017). The expansion in statins utilization is more likely due to the updated ACC/AHA guidelines released in 2013, which broadened the proportion of individuals eligible to take these medications (Patel et al. 2019). Another possible reason that led to excessive lipid-lowering medication use might be the increase in CVD cases and population size. In a study conducted by Gregory et al. to assess the global burden of cardiovascular diseases and risk factors, they concluded that CVD cases almost doubled from 271 million in 1990 to 523 million in 2019 (Roth et al. 2020).

This study also assessed the prescribing patterns of different statins over 12 years period. The results showed that atorvastatin and simvastatin were the most prescribed lipid-lowering medications between 2008 and 2019. However, the simvastatin prescribing trend was steady at around 40% of all statins prescriptions until it started to drop in 2013. In the same year, atorvastatin prescriptions shifted to an ascending trend and surpassed simvastatin in 2015. These findings are consistent with recent results from a study conducted in the U.S. reporting that the simvastatin prescribing trend declined in 2013, while atorvastatin prescriptions started to rise in the same year (Salami et al. 2017).

There are possible causes of that switch argued in the literature. First of all, the efficacy and effectiveness of atorvastatin over simvastatin in lowering LDL-C. A group of researchers conducted a systematic review and *meta*-analyses to compare the efficacy of different statins in patients diagnosed with dyslipidemia, CVD, or diabetes mellitus. Their study concluded that atorvastatin was more effective than simvastatin in lowering LDL-C (Zhang et al. 2020). Moreover, another study found that atorvastatin was associated with lower cardiovascular events (7.5% vs. 8.2%) and fewer medical-related absenteeism days compared to simvastatin (Simpson et al. 2009). Also, the 2013 ACC/AHA guidelines recommend initiating high-intensity statin as a first-choice therapy in individuals $\leq$ 75 years old who are diagnosed with ASCVD (Stone et al. 2014). This suggestion could also explain the increase in atorvastatin utilization following the implementation of the updated ACC/AHA protocols.

The findings showed remarkable suboptimal use of high-intensity statins among the study population. Generally, of the study participants, only 20% reported taking high-strength statins, and 60% were on moderate-intensity statin therapy. These results are in line with findings from research showing that only 21% of U.S. adult patients took high-intensity statins in the 2008–2009 period and 30% in the 2012–2013 cycle (Salami et al. 2017). Reason believed to be related to the underuse of high-intensity statins includes that some providers concentrate on LDL-C targets and potential adverse effects associated with potent statins patients may experience (Stone et al. 2014). Also, some studies argued that physicians possibly don't have enough information about revised recommendations. For instance, in a survey conducted among 513 medical providers, 34% were unfamiliar with the 2013 protocols. The results from the same study reported that 51% of trainee providers and 47% of practitioners were aware of the four statin benefit groups as mentioned in the guidelines (Rosenson et al. 2015). Another survey reported that 71% of medical providers did not grasp the definitions of different statin intensities as provided in the updated guidelines (Harrison et al. 2018). Statins utilization is considered a measurement to evaluate health outcomes in patients with ASCVD, and it is imperative not to ignore statin dose intensity to optimize therapeutic effects. The lack of understanding of the ACC/AHA guidelines that was observed in practice might lead to the underutilization of high-intensity statins, which would affect health outcomes (Okerson et al. 2017). Providers need to learn more about the guidelines to prescribe the suggested statin strength to patients at high risk regardless of LDL-C concentrations.

This project also investigated the trends of statins expenditures over a decade in the U.S., which will present valuable data for stakeholders to assist them in forecasting the expense of cardiovascular treatment plans. This study showed that the total expenditure of statins decreased from $10.7 billion in 2008 to $6.1 billion in 2017, followed by a sharp climbing trend in 2018 (12.7 US billion). Additionally, the OOP costs dramatically dropped despite increasing the number of statins prescriptions filled. In 2008, the total OOP cost for statins decreased from $2.2 billion to $1.4 billion in 2019, with the average annual OOP of $175 paid by a patient dropping by 83% ($30) in 2019. These figures are consistent with the findings from a recent study conducted by Salami and colleagues in 2017 (Salami et al. 2017). Their research showed an initial increase in the total statins expenditure in the 2002–2003 period ($17.2 billion), followed by a reducing trend to $16.9 billion in the 2012–2013 cycle. They also reported a 75% drop in the annual mean OOP expenditure per patient from $348 to $94. The observed decrease in statins costs was driven by factors such as the introduction of generic statins. When a drug's patent expires, other equivalent generic substitutions become available in the market with lower prices than the brand. The reports from a recent national study stated that the release of generic statins had an impact on the expenditure of these medications (Salami et al. 2017). Another study also reported a 28% savings in atorvastatin expenditures from 2012 to 2014 after the generic was introduced, despite increasing atorvastatin utilization in the U.S. (Warraich et al. 2018). An additional factor that led the OOP to decrease is the Patient Protection and Affordable Care Act of 2010 (ACA) (Ngo-Metzger et al. 2019). The law requires private insurers to provide first-dollar coverage for medical services and medications of grade "A" or "B" from the United States Preventive Services Task Force (USPSTF) with no co-payments for primary prevention indications (Tolbert 2022). This made some insurance companies to reduce the OOP costs for particular generic statins to zero USD, whatever the indication was.

5. Limitations

The study has some limitations, and the results should be carefully interpreted. Since MEPS data were collected through questionnaires, there is a chance of overestimating medication utilization reported by users and vice versa (survey bias). Moreover, the participants also partially self-reported medical history, which might lead to underestimating the size of individuals with chronic diseases in this study. Also, the study participants were noninstitutionalized civilian adults in the U.S.; therefore, the findings could only be generalized cautiously. Another limitation is that the costs are constant with the 2019 USD value because the consumer price index (CPI) of 2020 and 2021 was not available at the analysis time. Additionally, the analysis of utilization trends of brand-named statins was not feasible because MEPS data did not collect data on brand-named statins for some years.

6. Conclusion

In conclusion, the proportion of individuals who used statins significantly increased following the adoption of the 2013 ACC/AHA guidelines intended to manage blood cholesterol and prevent or reduce CVD events. The findings, however, demonstrated suboptimal prescribing trends of high-intensity statins, which need to be addressed by the stakeholders to maximize medication outcomes.

This study also found substantial differences in prescribing patterns of various statin medications. Furthermore, despite the increase in statins use, the results showed a considerable decline in statins expenditures, especially the co-payments that decreased by 83% over the study period. The findings have shown that revised or new regulations have substantial impacts on the healthcare industry. These results have valuable public health implications that encourage additional research and actions to promote optimal statins utilization and keep track of associated expenditures.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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