

## Opinion

# A Framework to Assess the Financial and Clinical Impacts of the Newly Updated 2016 HEDIS Measures about Statin Use

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Starting in 2016, health plans in the US have been held accountable to report additional Healthcare Effectiveness Data and Information Set Measures (HEDIS) about statin use among patients with cardiovascular disease and diabetes patients without atherosclerotic cardiovascular disease. Given the under-use of statin and its beneficial impact on CVD prevention on general population, implementation of the new metrics might represent a new opportunity for quality improvement. However, it is also important for health plans to be aware of the factors they might compromise the quality of care and thus impose additional costs while making efforts to achieved high compliance with the new HEDIS measures. The article aims to draw attention from health plans and other stakeholders in HEDIS implementation to the factors: the possible new onset of diabetes and ineffective control of A1C among diabetes patients associated with statin use, additional burden associated with more frequent screening for diabetes, the need to train physicians/providers about statin therapy adjustment, challenge associated with predicting the statin prices, and lack of consistent data and guidelines for statin therapy adjustment in case of ineffective A1C control. In sum, the new HEDIS measures of percentage of patients receiving statin therapy and adherence rates should be interpreted carefully in those contexts before important policies implications can be drawn from those data reported.

## Introduction to the Newly Added 2016 HEDIS Measure of Statin Use

The National Committee for Quality Assurance (NCQA) has recently incorporated a new measure for statin use for diabetes patients in the Healthcare Effectiveness Data and Information Set (HEDIS) 2016 quality improvement index. Health plans are hold accountable on the two measures: 1) the percentage of patients with Cardiovascular disease receiving statin therapy with at least adherence of 80% of the treatment period; 2) the percentage of Diabetes Mellitus (DM) patients aged 40-75 who do not have Atherosclerotic Cardiovascular Disease (ASCVD) receiving statin therapy with at least 80 percent of the treatment period [1].

In other words, having diabetes is identified as a risk factor ASCVD and is an indication for statin therapy in the new HEDIS measure.

This change largely reflects the practices recommended by the 2013 American College of Cardiology and the American Heart Association (ACC/AHA) Cholesterol Guidelines and the American Diabetes Association (ADA) Standards of Medical Care in Diabetes 2016 [2,3]. These guidelines represented a departure from previous recommendations, most notably for downplaying the role of Low-Density Lipoprotein (LDL) cholesterol thresholds and focusing on total Atherosclerotic Cardiovascular Disease (ASCVD) risk.

The development process of HEDIS metrics is a rigorous one with inputs largely from NCQA's committee on performance

measurement, which includes representation from purchasers, consumers, health plans, health care providers and policy makers. The evolution of the measurement set is also overseen by multiple measurement advisory panels that provide clinical and technical knowledge [4]. Since its introduction to NCQA in the early 1990s, HEDIS has evolved into a standardized performance tracking system targeted at the plan level as a necessary part of a quality improvement process. Part of the goal of implementing HEDIS is also to educate physicians/providers about new ways of practice through HEDIS compliance. We believe this compliance with the new metric at health plan levels will significantly affect the prescribing pattern of statin. Our aim in this article is to present the various factors that health plan should consider in estimating the potential clinical and economic outcomes as a result of implementing the new metrics.

## The Potential Impact of the New HEDIS Metric on Health Outcomes

### A welcome change to improve the underuse of statin

Researchers throughout the world have raised the concern about under-treatment using stain among patients with Cardiovascular Disease (CVD) risk for primary and secondary prevention in the past decade. Using data obtained by self-administered questionnaire from a population-based sample in Oslo residents, researchers found that the rates of statin use for subjects with a heart attack, angina, stroke or diabetes is 45% for men and 35% for women [5]. In a current study using population-based cohort that includes 30,239 adults ≥45 years of age from all 48 continental U.S. states and the District

of Columbia, the use of statins was found to be particularly low among adults with coronary heart disease risk equivalents (stroke, AAA, and/or diabetes) [6]. There is relatively scarce research about statin use focused exclusively on diabetes patients without ASCVD as recommended by HEDIS. However, similar low rate use of statin among diabetes patients was also found. Another study found that only 52.0% (95% CI, 49.4%-54.6%) of individuals with diabetes in a representative national sample aged older than 40 years were statin users in 2010. They believed the under treatment appears to be related to placing too much emphasis on hyperlipidemia and not enough on cardiovascular risk for cardiovascular events [7].

Therefore, it seems that inclusion of the new HEDIS metric targeted at ASCVD patients and diabetes patients will represent a new opportunity for improvement quality of care. If plans were fully compliant with new requirements, one could imagine that the statin utilization rate would have been doubled given the current low utilization rate mentioned above. Nowadays, HEDIS is used by more than 90 percent of America's health plans to measure performance on important dimensions of care and service [8]. An essential step toward improving HEDIS scores is for plans to ensure that providers and clinicians are held accountable for improving prescribing of statin among diabetes patients by following accepted guidelines for treatment. Some plans might have implemented reimbursement strategies that are tied to the metrics, which will serve as a strong impetus to improve HEDIS compliance in this regard [9]. Therefore, we shall be optimistic that the problem of under treatment of statin in diabetes patients will be improved as a result of the new metric in the near future.

### **Concern about the overtreatment related to diabetes risk associated with statin use**

We can't deny the fact that many HEDIS measures have been useful in promoting population health, such as rate of beta-blocker use after myocardial infarction or rate of cervical cancer screening. However, significant health outcomes gain associated with reduction in cardiovascular events among diabetes patients might not be realized in a degree as expected. Part of the concern has to do with 1) the risk of new onset of diabetes associated with statin use and 2) the possible association between statin use and in effective control of hemoglobin A1C among diabetes patients as revealed in the recently emerging literature. It has been recognized that statin use is found to be associated with a modest increase in risk (10%-12%) for new-onset type 2 diabetes, compared with placebo or usual care [10]. During the 6 years follow-up period in a study using Tricare claims data base, healthy statin users are showed to have significantly higher odds of developing diabetes and diabetic complications that persisted throughout follow-up (Odds Ratio [OR] 1.93, 95 % Confidence Interval [CI] 1.55-2.41 and OR 2.15, 95 % CI 1.20-3.86, respectively) [11]. Unfortunately, the second factor was not addressed when NCQA was soliciting public comments about HEDIS 2016 new metric of statin use among diabetes patients in 2015 [12]. Therefore, it is high time for plans and other stakeholders in implementing the metric to be aware of this new line of evidence. There are relatively few results regarding the effects of statin therapy on glycemic control in patients with diabetes mellitus. In a retrospective study among Japanese population, the use of high-potency statins significantly increased HbA1C levels in patients both with and without diabetes,

compared with the baseline value [13]. A recent meta-analysis also found that statin treatment was associated with a modest increase in hemoglobin A1C in patients with diabetes [14]. It seems further research is needed to determine the tradeoff between CVD benefits from statin and the potential risk on HbA1C control. It is also unknown if discontinuation of statin should lead to better outcomes after statin-associated deterioration in glycemia was detected [10].

Given the potential side effects of statin and unfilled research gap, physicians need to be educated about the potential risk of overtreatment, which is likely to occur if health plans emphasize strict and aggressive compliance with the two HEDIS measures. In addition, it can be foreseen that physicians and other providers will likely face additional challenges associated with close monitoring of the diabetes complications and the problem of adherence with statin among some patients with worsening glycemia control. To deal with this challenge, more frequent diabetes screening might be necessary for those patients on statin without diabetes but with major diabetes risk factors than those not on statin [10]. This would ensure appropriate statin therapy adjustment for the two groups indicated for statin according to the HEDIS.

### **The Potential Financial Impacts of HEDIS Statin Measure on Health Plans**

A recent study using simulation model populated at US population based parameters found that statin treatment is likely a cost effective strategy for general population at CVD risk [15]. Assuming a blended generic and branded market for generic statin (91% and 9%); the study derived a weighted estimate of annual drug cost of \$68 per year in 2013 dollars [15]. Based on this baseline estimate, they found statin is likely to be cost effective from the payers' perspective if it was limited to patients with the ASCVD risk thresholds of 4.0% or higher. Allowing for a certain range of variation of statin price, they did find that the population to be treated should be further limited to higher ASCVD threshold if the costs of statin increase. A few pharmacoeconomics studies conducted outside of US among diabetes population also reached similar conclusion and found that the drug price and efficacy of statin in reducing CVD risk as an influential factor [16-18].

However, those findings should be taken with a grain of salt for health plans aiming to estimate the financial impact of implementing the two metrics. First, there is lack of data to predict the price changes for statin in the near future. Although the drug market of statin has quite a few generic options, increasing statin use might not present to payers as a budget issue as the other blockbuster drugs such as cancer therapy and other specialty drug. However, generic drug prices have been soaring at a striking rate and investigation at the federal level has been trying to identify the causes since 2013 [19]. The suspected reasons proposed included manufacturers and market consolidation, informal collusion, and price-fixing on the supply side [20,21]. Health plans might not be the best position to predict whether statin will face another price hike. However, the potential dynamic around statin pricing is no small thing for health plans to overlook given the increasing demand driven by HEDIS statin measures. With the expanded indication for statin therapy proposed by 2013 guidelines of ACC/AHA, a few researchers estimated that there would be an increase of eligible statin users from 43.2 million to

56.0 million using NHANS data [22]. Admittedly, it is hard to tell the actual increased users without the data about the current rate of statin use among diabetes patients recommended by HEDIS new metric. Suffice to say that the pressure to comply with HEDIS might translate to higher use rate of statin this, and this, combined with an expected 80% adherence rate by HEDIS, will lead to an increasing demand for statin. The demand for statin will also be magnified by the increasing prevalence of diabetes. Economic theory holds that demand might drive up higher prices while holding everything else constant in the market. Therefore, health plans should keep alert to the dynamics of generic drug pricing when it comes to estimation the overall budget impact of statin use. Otherwise, they might mistakenly overestimate or underestimate the impact of statin use on the drug and medical expenses.

Second, only minimum adverse effects of statin use have been addressed in those cost effectiveness studies such as new onset of type 2 diabetes, muscle aches, myalgia or myopathy and rhabdomyolysis. Driving use of statin high levels in order to achieve compliance with the HEDIS measure may potentially lead to overtreatment of statin. Given the previous discussion about the concern about statin use among diabetes patients and diabetes risk in CVD patients, overuse of statin might place patients at increased risk of diabetes complications. As a result, this might pose an additional cost when the savings associated with CVD risk control is not sufficient to offset the higher ED/hospital utilization driven by poor A1C control. However, there is no solid data currently available about the financial impact of regular screening, monitoring treatment outcomes for diabetes patients, and lack of HBA1C control for patients placed on statin.

### Cautions about Implementing and Reporting the HEDIS Metrics on Statin

Overall, the correlation between the compliance with the HEDIS statin measure with the financial and clinical outcomes might be more complicated to predict than expected.

Previous research found that higher compliance with HEDIS measures don't necessary reflect higher quality of care. For example, a study revealed that there is no correlation between compliance with the HEDIS medication management measures for people with asthma and improvement in the asthma outcomes examined. Specifically, patients compliant with those measures do not have improvements in asthma-related ED visits, hospitalizations, or rescue medications compared with noncompliant patients [23]. The authors ascribed the lack of correlation partly to the complex treatment process for asthma and partly to the flaw of HEDIS using claims data to measure adherence.

Therefore, caution should be exercised when implementing the HEDIS measurement and reporting the data. Low rate of patients receiving statin use among diabetes patients might indicate that physicians have gone through additional screening of diabetes risk to avoid over-treatment. On the other hand, high percentage of patients on statin does not necessarily mean that patients have experienced overall improvement in quality of life if the side effects are under-reported. Similarly, a reasonable discontinuation rate for statin use might be taken as a positive signal for close monitoring if the discontinuation was justified by the provider aiming to refine-tune the therapy of statin. Therefore, it might involve additional inputs

from the community of outcomes research to help NCQA identify the ideal numerator to calculate the percentage of patients receiving statin.

To avoid overtreatment of statin through HEDIS performance incentives, future research are needed to fill the knowledge gap by identifying whether compliance with the HEDIS statin measure correlates with reduced medical resources utilization associated with CVD events or more intensive use of diabetes-related medical resources. Once more diabetes patients and CVD patients are treated with statin, plans might be able to leverage the accumulated database to further investigate the impacts of statin use on diabetes treatment outcomes. The longitudinal data from those plans, which have longer periods of enrollment will prove more valuable than plans that face high churn rate. Those new evidence will prove of significant value for HEDIS to ensure the quality of design of those performance metrics on statin.

In sum, the new HEDIS metric is a tool for health plan to identify opportunities for improvement. The interpretation of the data of performance reported against such measures has to be put in specific contexts before meaningful policy implications can be drawn from those data.

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