

Medicare Star Excludes Diabetes Patients With Poor CVD Risk Factor Control

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The Medicare Star rating system was designed by CMS to monitor healthcare quality in health plans with Medicare enrollees.^{1,2} The Affordable Care Act (ACA) authorized CMS to provide significant monetary and enrollment incentives to Medicare Advantage plans that perform well on these Medicare Star measures, covering such areas as clinical outcomes and patient-reported quality of life.^{1,2}

In 2012, CMS introduced 3 new metrics to the Medicare Star portfolio: medication adherence to angiotensin-converting enzyme inhibitors or angiotensin receptor blockers (ACE inhibitors/ARBs) to control hypertension, statins to control low-density lipoprotein cholesterol (LDL-C), and oral antihyperglycemics to control glycated hemoglobin (A1C) levels. These novel quality measures emphasize the responsibility of healthcare plans to monitor and improve medication adherence among their patients²; prior to 2012, most health plans did not systematically measure medication adherence at the population level or report adherence externally. Since patients with diabetes account for most antihyperglycemic use and encompass a significant portion of patients prescribed antihypertensives and statins,^{3,5} it is important to understand the impact of this new quality measurement initiative on the diabetes population.

The CMS-defined specifications for the Medicare Star adherence metric explicitly require at least 2 prescription fills in the measurement year to calculate adherence.⁶ Patients who never fill an ordered prescription or obtain only a single fill in the measurement year are therefore excluded from the Star metric. These excluded patients, who are exhibiting evidence of “early nonadherence” to medications,^{7,9} may be at high risk of failure to attain treatment goals and optimal clinical outcomes.^{7,9} The Medicare Star oral antihyperglycemic adherence measure also excludes all patients who are taking oral antihyperglycemic medications if they are also taking insulin. These patients who are intensively treated with both oral and injected medications may also be at high risk for poor cardiovascular (CVD) outcomes.¹⁰ Since CMS has not

ABSTRACT

Objectives

CMS recently added medication adherence to antihypertensives, antihyperlipidemics, and oral antihyperglycemics to its Medicare Star quality measures. These CMS metrics exclude patients with <2 medication fills (ie, “early nonadherence”) and patients concurrently taking insulin. This study examined the proportion of patients with diabetes prescribed cardiovascular disease (CVD) medications excluded from Star adherence metrics and assessed the relationship of both Star-defined adherence and exclusion from Star metrics with CVD risk factor control.

Study Design

Cross-sectional, population-based analysis of 129,040 patients with diabetes aged ≥65 years in 2010 from 3 Kaiser Permanente regions.

Methods

We estimated adjusted risk ratios to assess the relationship between achieving Star adherence and being excluded from Star adherence metrics, with CVD risk factor control (glycated hemoglobin [A1C] <8.0%, low-density lipoprotein cholesterol [LDL-C] <100 mg/dL, and systolic blood pressure [SBP] <130 mm Hg) in patients with diabetes.

Results

Star metrics excluded 27% of patients with diabetes prescribed oral medications. Star-defined nonadherence was negatively associated with CVD risk factor control (risk ratio [RR], 0.95, 0.84, 0.96 for A1C, LDL-C, and SBP control, respectively; $P < .001$). Exclusion from Star metrics due to early nonadherence was also strongly associated with poor control (RR, 0.83, 0.56, 0.87 for A1C, LDL-C, and SBP control, respectively; $P < .001$). Exclusion for insulin use was negatively associated with A1C control (RR, 0.78; $P < .0001$).

Conclusions

Medicare Star adherence measures underestimate the prevalence of medication nonadherence in diabetes and exclude patients at high risk for poor CVD outcomes. Up to 3 million elderly patients with diabetes may be excluded from these measures nationally. Quality measures designed to encourage effective medication use should focus on all patients treated for CVD risk.

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Take-Away Points

CMS recently added cardiovascular disease (CVD) risk factor medication adherence to its Medicare Star program quality measures. These measures exclude patients with <2 medication fills, and patients concurrently taking insulin. We found:

- 27% of patients with diabetes prescribed oral medications were excluded from the measures.
- Excluded patients with diabetes were significantly likely to have poor CVD risk factor control.
- 3 million elderly patients with diabetes may be excluded from these measures nationally.
- Medicare Star adherence measures underestimate nonadherence in diabetes.
- Quality measures designed to encourage effective medication use should focus on all patients treated for CVD risk.

published the specific justifications for these exclusions, it is important to understand the ramifications for both quality measurement and quality improvement.

While some studies have linked higher adherence to cardiometabolic medications with improved CVD risk factor control and clinical outcomes in diabetes patients,^{7,8,11-19} these studies are largely based on younger populations. The relationship between performance on the new Star adherence metrics and risk factor control in the Medicare population, and the relationship between exclusion from the Star metrics and CVD risk factor control, is unknown.

This study is designed to improve our understanding of these novel CMS quality measures by assessing the proportion of Medicare patients with diabetes who are excluded from the Medicare Star medication adherence metrics due to early nonadherence and insulin use, and by quantifying the relationship between Medicare Star adherence, early nonadherence, and concurrent insulin use with CVD risk factor control.

METHODS

Study Setting and Population

The population for this study was derived from the Surveillance, Prevention, and Management of Diabetes Mellitus (SUPREME-DM) study, a multicenter project meant to create a data resource for comparative effectiveness, epidemiology, and health services research.²⁰ The current study utilized data from 3 SUPREME-DM sites: Kaiser Permanente (KP) Northern California, KP Colorado, and KP Northwest. These KPs are nonprofit, integrated, group-model healthcare delivery systems collectively serving 4.1 million members in 3 areas: a 13-county region of northern California, the state of Colorado, and northwest Oregon / southwest Washington. The SUPREME-DM DataLink accesses electronic health record (EHR) data

as well as other clinical and administrative database information from participating sites.²⁰ Data include patient age, birth year, sex, race/ethnicity, census block group socioeconomic status data, enrollment data, laboratory results (including A1C and LDL-C levels), prescription data (including medication orders, fills, dose, days' supply, National Drug Code, and if the medication order was written for an outside-KP pharmacy), and systolic blood pressure (SBP) measurements from 2005 to 2011. Patients were eligible for the current

study if they had diabetes in 2010 and were eligible for Medicare (65 years or older as of January 1, 2010). Patients were defined as having diabetes if they had 2 or more outpatient diabetes *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* diagnosis codes (250.xx) within a 2-year window since the start of 2000.²¹⁻²³ The small number of patients who had prescription orders for medications to be filled outside of KP in 2010 (~1%) were excluded from the analysis.

Medicare Star Medication Adherence

We calculated the Medicare Star adherence metrics following exact CMS specifications to obtain the Medicare Star Proportion of Days Covered (PDC) adherence measure in 2010 for all diabetes patients for each of the 3 therapeutic groups covered by the measures: ACE inhibitors/ARBs, statins, and oral diabetes medications.⁶ These therapeutic groupings are specified for use in calculating the CMS Star adherence measure, following recommendations made by the Pharmacy Quality Alliance.⁶ Per CMS specifications, all patients taking these medications are potentially eligible to be included in the measures, with no upper age limit or restrictions due to health status (eg, nursing home residence). CMS bases the Medicare Star adherence measures on the PDC method for calculating adherence,^{6,24} defined as the percent of days in the measurement period "covered" by prescription fills for the same medication or medications in the same therapeutic category.

CMS specifies that the measurement period for 2010 begins with patients' first fill in 2010, and continues through December 31, 2010. As outlined above, the PDC is only calculated for patients with 2 or more fills in the measurement period: those with less than 2 fills in that period are excluded by CMS, and therefore by our calculations as well. This "2-or-more-fills" criteria within a therapeutic grouping to treat a CVD risk factor captures

patients who switched medications to address that risk factor within that year, and excludes those who discontinue medications to treat a risk factor after only 1 fill. The PDC can range from 0% to 100%; the Medicare Star adherence measure considers patients to be “adherent” if their PDC is $\geq 80\%$.

Medicare Star Exclusions From the Adherence Metrics

The KP pharmacy ordering and refill systems were used to identify patients who had a prescription ordered by their clinician in 1 of the 3 therapeutic groups in 2010, but who never filled it (0 fills) or obtained only a single fill. We then assessed the prevalence of these patients excluded by CMS from the Star measure due to “early nonadherence”: those with an order but no fills were considered “primary nonadherent,” and those with 1 fill but no subsequent fills were considered “early nonpersistent.”⁷ We also created a category for the additional patients excluded from the Medicare Star oral antihyperglycemic medication category who had 2 or more fills of an oral antihyperglycemic during the measurement period, but were excluded by CMS specifications due to concurrent insulin use.

Statistical Analyses

To assess the relationship of poor adherence based on the Medicare Star adherence metric with CVD risk factor control—adjusting for differences in age, race/ethnicity, and other confounding factors also associated with CVD risk factor control—we performed 3 separate Poisson regression models²⁵ using being in good control for A1C, LDL-C, and SBP (defined as A1C $< 8.0\%$, LDL-C < 100 mg/dL, and SBP < 130 mm Hg) at the last recorded measurement in 2010 as the dependent variable, and nonadherence of PDC $< 80\%$ (compared with PDC $\geq 80\%$) as the main independent variable. Modified Poisson regressions directly estimate risk ratios when outcomes are common. In these cases, it is not appropriate to report odds ratios from logistic regressions.²⁵⁻²⁷

To assess the relationship between early nonadherence (ie, patients excluded by Medicare Star adherence measures) and CVD risk factor control, we performed 3 separate Poisson regression models using being in

■ **Table 1.** Patient Characteristics

	N	%
Total patients, N	129,040	100%
Age, years		
65-69	38,298	29.7%
70-74	32,823	25.4%
75-79	26,475	20.5%
80-84	18,442	14.3%
85+	13,002	10.1%
Female	63,689	49.4%
Race/ethnicity		
American Indian/Alaska Native	444	0.3%
Asian	13,306	10.3%
Black	10,063	7.8%
Hispanic	16,492	12.8%
Native Hawaiian/Pacific Islander	633	0.5%
White	75,880	58.8%
Race missing/unknown	12,222	9.5%
Enrolled for 12 months	119,777	92.8%
Anxiety	6295	4.9%
Arthritis	31,650	24.5%
Atrial fibrillation	13,114	10.2%
COPD	11,879	9.2%
Depression	16,655	12.9%
Heart failure	15,309	11.9%
Poorly controlled hyperlipidemia (LDL ≥ 100)	23,104	17.9%
Poorly controlled hypertension (SBP ≥ 130)	47,611	36.9%
Poorly controlled hyperglycemia (A1C $\geq 8\%$)	14,539	11.3%
Insulin use	27,945	21.7%
Fills or orders in 2010 for ACE inhibitor/ARB	95,395	73.9%
Fills or orders in 2010 for statin	103,808	80.4%
Fills or orders in 2010 for oral diabetes drug	78,743	61.0%
Mean number of medications at study start (SD)	5.32 (3.49)	
Mean days supply of ACE inhibitor/ARB (SD)	91.28 (17.91)	
Mean days supply of statins (SD)	89.15 (17.22)	
Mean days supply of oral DM drugs (SD)	89.83 (18.82)	

A1C indicates glycated hemoglobin; ACEI/ARB, angiotensin-converting enzyme inhibitor/angiotensin receptor blocker; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; LDL, low-density lipoprotein; SBP, systolic blood pressure; y, years.

good control for A1C, LDL-C, and SBP at the last recorded measurement in 2010 as the dependent variable, and excluded patients with 0 fills or 1 fill (compared with patients with PDC $\geq 80\%$) as the main independent variable. We examined the relationship between A1C control and exclusion from the oral antihyperglycemic measure based on insulin use concurrent with 2 or more

Table 2. Patient Characteristics by Whether Included in Medicare Star Medication Adherence Metric

	Patients With ACE inhibitor/ARB Fills or Orders in 2010 (n = 95,395)			Patients With Oral Diabetes Drug Fills or Orders in 2010 (n = 78,743)			Patients With Statin Fills or Orders in 2010 (n = 103,808)		
	Adherent: PDC ≥80%	Non- adherent: PDC <80%	Excluded	Adherent: PDC ≥80%	Non- adherent: PDC <80%	Excluded	Adherent: PDC ≥80%	Non- adherent: PDC <80%	Excluded
n (%)	69,402 (73%)	16,718 (17%)	9275 (10%)	46,406 (59%)	10,223 (13%)	22,114 (28%)	73,582 (71%)	19,694 (19%)	10,532 (10%)
Age, years									
65-69	32%	30% ^c	30% ^c	33%	31% ^a	35% ^c	30%	32% ^c	31%
70-74	27%	26% ^b	24% ^c	27%	25% ^c	27%	27%	26%	25% ^c
75-79	21%	20%	20%	20%	20%	19% ^b	21%	20% ^c	19% ^c
80-84	13%	14% ^c	14% ^c	13%	14% ^c	12% ^c	14%	14%	14%
85+	7%	10% ^c	12% ^c	7%	10% ^c	7% ^a	8%	9% ^b	11% ^c
Race/ethnicity									
White	60%	56% ^c	55% ^c	56%	52% ^c	59% ^c	61%	54% ^c	52% ^c
Hispanic	12%	15% ^c	14% ^c	13%	15% ^c	15% ^c	12%	15% ^c	15% ^c
Asian	11%	11%	12% ^a	13%	11% ^c	10% ^c	11%	11%	12%
Race missing/ unknown	10%	9% ^b	10%	11%	11%	8% ^c	9%	10%	11% ^c
Black	7%	9% ^c	9% ^c	7%	10% ^c	8% ^c	7%	10% ^c	10% ^c
American Indian/ Alaska Native	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1% ^a	<1% ^a
Female	49%	51% ^b	48% ^b	48%	51% ^c	48%	48%	52% ^c	51% ^c
Anxiety	4%	5% ^c	5% ^b	4%	5% ^c	4% ^b	4%	6% ^c	5% ^c
Arthritis	24%	25%	23% ^c	23%	24% ^a	23%	25%	25%	23% ^c
Atrial fibrillation	9%	10% ^b	11% ^c	8%	8%	10% ^c	10%	9% ^b	9% ^b
COPD	8%	10% ^c	11% ^c	7%	9% ^c	10% ^c	9%	10% ^c	9%
Depression	12%	14% ^c	14% ^c	10%	12% ^c	15% ^c	12%	15% ^c	13% ^c
Heart failure	10%	14% ^c	15% ^c	8%	9% ^c	14% ^c	11%	13% ^c	13% ^c

ACE inhibitor/ARB indicates angiotensin-converting enzyme inhibitor/angiotensin receptor blocker; COPD, chronic obstructive pulmonary disease; PDC, proportion of days covered.

^aP < .05.
^bP < .01.
^cP < .001.

fills of oral diabetes medications (compared with patients who were not using insulin, and a PDC ≥80% for their diabetes medications) using a separate, similar Poisson regression model. These regression analyses controlled for patient age, gender, race/ethnicity, medication burden (as measured by the overall number of medications a patient was taking at the start of 2010), length of enrollment in the health plan during 2010, and mean days' supply of medications in each therapeutic grouping corresponding to the risk factor control of interest as predictor variables.

All analyses were performed using Stata version 10.1 (College Station, Texas). This study was approved by each KP region's Institutional Review Board.

RESULTS

Of the 129,040 eligible patients in the sample, close to 25% were 80 years and older, 49.4% were female, and 58.8% were white (Table 1). In 2010, 73.9% of patients had at least 1 ACE inhibitor/ARB prescription order or fill, 80.4% had an order or fill for a statin, and 61% had an order or

fill for an oral diabetes medication. In general, patients excluded from the Star metrics were older, less likely to be non-Hispanic white, and had a higher level of comorbidity burden (Table 2).

Figure 1 shows the percent of patients who were adherent based on the Medicare Star metric, and those with evidence of a cardiometabolic medication prescription in 2010 who were excluded from the Medicare Star adherence metric based on the CMS measurement specifications.

Among all individuals receiving an order or prescription, 73%, 71%, and 59% of patients were adherent based on Star criteria to ACE inhibitors/ARBs, statins, and oral diabetes medications, respectively. When the patients excluded by Medicare Star are not included in the adherence calculations, 80.6%, 78.9%, and 81.9% of patients were adherent to ACE inhibitors/ARBs, statins, and oral diabetes medications, respectively (data not shown).

A total of 9% of patients prescribed a medication in the ACE inhibitor/ARB therapeutic grouping were considered “primary nonadherent” and did not fill their medication at all (2%), or were “early nonpersistent” and filled only once (7%), and therefore were excluded by CMS. Among those patients on a statin, 10% were excluded (2% for having 0 fills of an ordered medication, and 8% for having 1 fill). Twenty-eight percent of patients who were ordered an oral diabetes medication were excluded: 2% due to never filling an ordered medication, 7% for filling only once, and 19% because they filled the oral medication at least twice in 2010, but also had at least 1 fill for insulin. A total of 34,514 (27%) of the patients in our diabetes cohort were excluded from all medication adherence monitoring by the Star measures, based on CMS criteria.

Patients who were adherent to medications based on the Medicare Star metric had higher CVD risk factor control than those who were nonadherent based on the Star metric and those who were excluded from the Star metric, in all 3 therapeutic groupings of CVD risk factor medications (Table 3). After adjustment, nonadherence based on the Star metric was associated with suboptimal CVD risk factor control: A1C (risk ratio [RR], 0.95; 95% CI,

Table 3. Risk Factor Control Rates^a for Patients With Medication Fills or Orders in Relevant Therapeutic Category (TC) in 2010

	SBP <130 (TC = ACE inhibitor/ ARB)	A1C <8% (TC = Oral DM)	LDL <100 (TC = Statins)
Included in Medicare STAR Adherence Metric:			
Adherent (PDC ≥80%)	64%	87%	87%
Nonadherent (PDC <80%)	60%	80%	71%
Excluded from Medicare STAR Adherence Metric:			
0 fills (primary nonadherent)	52%	69%	43%
1 fill (early nonpersistent)	55%	69%	48%
2+ fills, on insulin	N/A	69%	N/A
A1C indicates glycated hemoglobin; ACE Inhibitor/ARB, angiotensin-converting enzyme inhibitor/angiotensin receptor blocker; LDL, low-density lipoprotein; N/A, not applicable; PDC, proportion of days covered; SBP, systolic blood pressure.			
^a Based on last recorded measurement in 2010.			

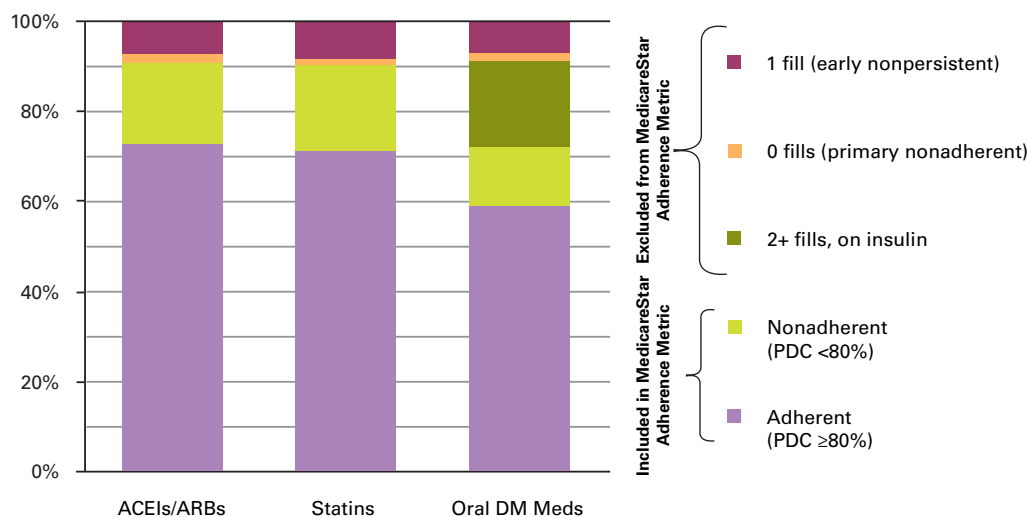
0.94-0.96), LDL-C (RR, 0.84; 95% CI, 0.83-0.85), and SBP control (RR, 0.96; 95% CI, 0.95-0.96), respectively (Figure 2). Exclusion from the Star metric based on early nonadherence was also negatively associated with risk factor control: A1C (RR, 0.83; 95% CI, 0.82-0.85), LDL-C (RR, 0.56; 95% CI, 0.55-0.58), and SBP control (RR, 0.87; 95% CI, 0.86-0.89), respectively. Exclusion from the Star metric for concurrent insulin use was negatively associated with A1C control among patients ordered or filling oral diabetes medications: RR, 0.78; 95% CI, 0.77-0.79.

DISCUSSION

This study is the first to examine levels of medication adherence among Medicare beneficiaries with diabetes based on the new CMS Medicare Star adherence metrics, and to assess the proportion of patients excluded from these metrics. In a cohort of 129,040 patients 65 years or older, we found that 59% to 71% of patients who had evidence their physician had put them on a medication were considered adherent by the CMS metric, depending on therapeutic grouping. However, between 9% and 28% of these patients were excluded from the Star adherence measures by CMS.

The CMS specifications excluded 27% of our overall diabetes cohort of patients 65 years and older from being covered by any of these measures. Since current government estimates find that up to 11 million Americans 65 years and older have diabetes,²⁸⁻²⁹ our study suggests that up to 2.93 million Medicare-age patients with diabetes may be excluded from these measures nationally. It is unclear why CMS chose these particular exclusion

■ **Figure 1.** Patients With Medication Fills or Orders in 2010



ACE inhibitors/ARBs indicates angiotensin-converting enzyme inhibitors/angiotensin receptor blockers; DM, diabetes mellitus.

criteria: for example, while measuring insulin adherence might require different data and methods, the oral diabetes medication adherence for those patients concurrently taking insulin can be measured using the current PDC-based methodology. Further discussion with CMS as to the rationale for excluding these patients, and finding a path toward monitoring the quality of CVD risk factor management in these excluded patients has the potential to improve care for millions of diabetes patients.

Adherence to medications is a process measure for assessing the quality of healthcare, since it does not measure clinical outcomes directly.³⁰ The most meaningful process measures of healthcare quality should be tightly linked to clinical outcomes.³¹ In this case, attempts to measure the process of taking CVD risk factor medications appropriately should be strongly correlated with CVD risk factor control. Our study shows that the Medicare Star adherence metrics achieve this linkage with CVD risk factor control among patients covered by the measure. However, our study also demonstrates that exclusion from the metric based on early nonadherence is also strongly associated with poor CVD risk factor control. These findings suggest that the underuse of cardiometabolic medications is a significant barrier to CVD risk factor control in diabetes patients,³² and suggest that the current Star measures underestimate medication nonadherence in the diabetes population.

Currently, the difference between a 5-star rating for adherence to oral antidiabetes medications and a 3-star rat-

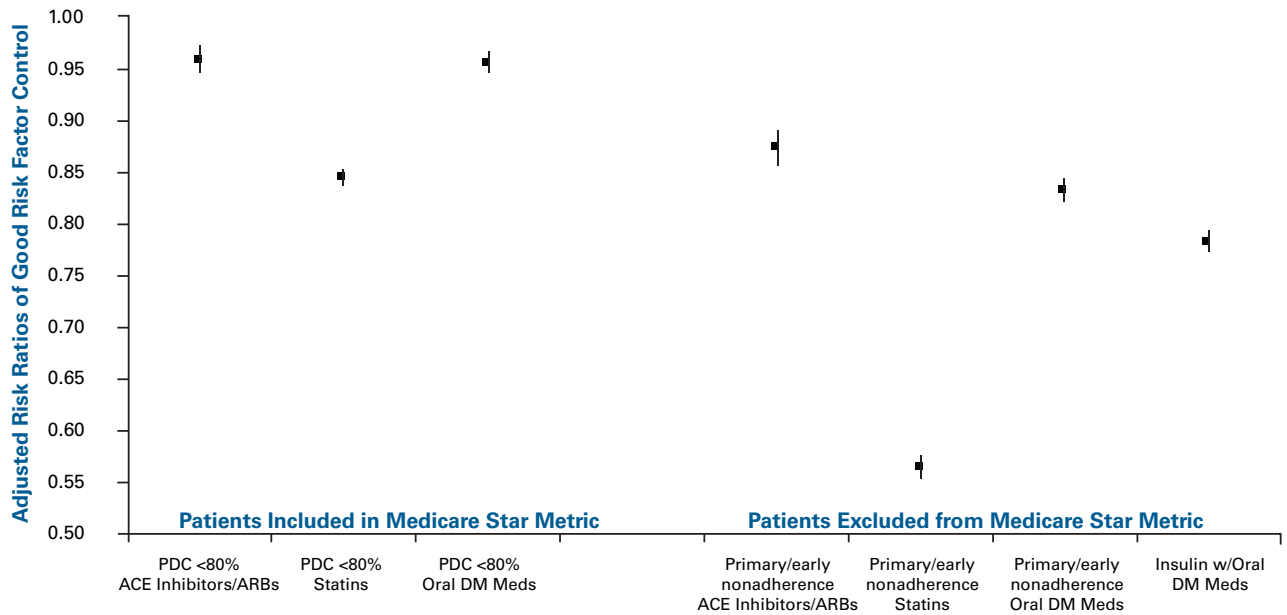
ing for Medicare Advantage plans is less than 5% ($\geq 79\%$ adherent vs $< 75.7\%$ adherent).⁶ While changes to the way CMS measures adherence that would account for early nonadherence could temporarily lower health plan ratings on these measures, considering the importance of high Star ratings to health plans³³ these changes would likely encourage plans to address early non-adherence among their enrollees. Quality measures focused on adherence should also account for underuse of medications due to not starting or not refilling a prescribed medication.

The new Star adherence metrics place an important and innovative emphasis on holding health plans accountable for appropriate medication adherence. As a response to this mandate, CMS and health plans caring for Medicare enrollees should focus on implementing and disseminating system-level interventions to help patients successfully start medications, as well as encourage ongoing medication persistence in those who have achieved 2 fills or more.^{2,8,17,34} Research suggests that effective interventions to improve medication starts and ongoing adherence are available. For example, one recent study showed that automated outreach to early nonadherent patients can successfully improve statin starts and refill rates.³⁵ These types of interventions, when cost-effective, have great potential as healthcare systems move toward greater integration and meaningful use of electronic health information.³⁶⁻³⁸

Limitations

This analysis has a few limitations worth noting: all

Figure 2. Good Risk Factor Control Least Likely Among Patients Excluded From Medicare Star Metric



ACE inhibitors/ARBs indicates angiotensin-converting enzyme inhibitors/angiotensin receptor blockers; DM, diabetes mellitus.

patients in this study had diabetes. The Medicare Star adherence measures are also be applied to patients with hypertension or hyperlipidemia who do not have diabetes. The level of adherence based on Medicare Star measure specifications in these large, integrated delivery systems was generally high, and these systems also achieve consistently high scores on other Medicare Star metrics³⁹; the level of Medicare Star adherence and early nonadherence to medications may be different in other healthcare settings. In addition, not all health plans currently engaged in reporting to CMS have access to EHR prescription data. However, since KP system characteristics, such as integration and meaningful use of electronic healthcare data, are put forth as models of care by the ACA and other recent legislation,³⁶⁻³⁸ and health plans will be moving to EHRs based on these requirements, these findings provide a significant benchmark for medication adherence standards moving forward. In addition, we do not have data on why patients may have discontinued medications after only 1 fill, and were therefore excluded from the Medicare Star metric.

We were unable to measure medication adherence for a substantial proportion of patients with diabetes because they had no evidence they were placed on a CVD risk factor control medication by their physician (ie, no prescription orders or fills in 2010). As shown in Table 1, 19.6% of diabetes patients had no evidence they

were prescribed statins, 26.1% had no evidence they were prescribed ACE inhibitors/ARBs, and 39% showed no evidence they were prescribed oral diabetes medications. Medication adherence metrics would not be appropriate for monitoring quality of care in these patients; however, whether risk factors in these patients were being managed through lifestyle interventions alone, or whether due to age or other comorbidities these medicines were not indicated for CVD risk factor control, is unknown. Future research should focus on developing quality metrics that monitor quality for a wide range of CVD risk factor control efforts in Medicare-aged patients with diabetes that take the needs of older patients with multiple comorbidities into account.

CONCLUSIONS

While higher Star-defined adherence is associated with CVD risk factor control, this new measure excludes a significant number of diabetes patients prescribed cardiometabolic medications that are at high risk for poor CVD outcomes. Healthcare policies that encourage system-level efforts to address the underuse of medications in diabetes patients should focus on decreasing CVD risk for the entire population of Medicare patients, including those presently excluded from the new Star adherence metrics.

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