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Assessing Appropriateness of Lipid Management Among Patients With Diabetes Mellitus Moving From Target to Treatment

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Background—Performance measures that emphasize only a treat-to-target approach may motivate overtreatment with high-dose statins, potentially leading to adverse events and unnecessary costs. We developed a clinical action performance measure for lipid management in patients with diabetes mellitus that is designed to encourage appropriate treatment with moderate-dose statins while minimizing overtreatment.

Methods and Results—We examined data from July 2010 to June 2011 for 964 818 active Veterans Affairs primary care patients ≥ 18 years of age with diabetes mellitus. We defined 3 conditions as successfully meeting the clinical action measure for patients 50 to 75 years old: (1) having a low-density lipoprotein (LDL) < 100 mg/dL, (2) taking a moderate-dose statin regardless of LDL level or measurement, or (3) receiving appropriate clinical action (starting, switching, or intensifying statin therapy) if LDL is ≥ 100 mg/dL. We examined possible overtreatment for patients ≥ 18 years of age by examining the proportion of patients without ischemic heart disease who were on a high-dose statin. We then examined variability in measure attainment across 881 facilities using 2-level hierarchical multivariable logistic models. Of 668 209 patients with diabetes mellitus who were 50 to 75 years of age, 84.6% passed the clinical action measure: 67.2% with LDL < 100 mg/dL, 13.0% with LDL ≥ 100 mg/dL and either on a moderate-dose statin (7.5%) or with appropriate clinical action (5.5%), and 4.4% with no index LDL on at least a moderate-dose statin. Of the entire cohort ≥ 18 years of age, 13.7% were potentially overtreated. Facilities with higher rates of meeting the current threshold measure (LDL < 100 mg/dL) had higher rates of potential overtreatment ($P < 0.001$).

Conclusions—Use of a performance measure that credits appropriate clinical action indicates that almost 85% of diabetic veterans 50 to 75 years of age are receiving appropriate dyslipidemia management. However, many patients are potentially overtreated with high-dose statins. (*Circ Cardiovasc Qual Outcomes*. 2013;6:66-74.)

Key Words: cholesterol ■ performance measures ■ quality of care ■ diabetes mellitus ■ lipids

Extensive research has demonstrated that statins reduce the risk of macrovascular complications in patients with diabetes mellitus.¹⁻³ Although the mantra "lower is better" for low-density lipoprotein (LDL) levels is commonly quoted and is the basis of much of our quality measurement, there are reasons to question this belief. First, most available evidence of benefit in reduction of cardiovascular events resulting from lipid therapy focuses on treatment with fixed-dose statins, not treatment to achieve particular LDL targets or progressive intensification of therapy to meet targets.²⁻¹⁵ Second, existing experimental evidence of cardiovascular event reduction is

strongest for use of moderate-dose statins in patients with diabetes mellitus.^{2,3,11,16} Despite the design of the studies and the evidence pointing to the benefit of moderate-dose statins, most national guidelines and performance measures stress achievement of a dichotomous, threshold LDL target (eg, LDL < 100 mg/dL [< 2.59 mmol/L]),¹⁷⁻²¹ and more patients are being treated and achieving these LDL targets than ever before.²²⁻²⁶

Recent analyses of cardiovascular prevention studies,⁶ as well as recognition that high-dose statins have significant toxicities, raise concerns about the appropriateness of focusing on LDL targets rather than on appropriate treatment. Indeed,

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WHAT IS KNOWN

- Treatment of dyslipidemia with moderate-dose statins leads to improved outcomes for patients with diabetes mellitus and high to moderate cardiovascular risk.
- Previous performance measures focused on attainment of low-density lipoprotein levels rather than appropriate treatment with statins.

WHAT THE STUDY ADDS

- Such performance measures could lead to overtreatment with high-dose statins.
- Use of a performance measure that credits appropriate clinical treatment rather than only low-density lipoprotein attainment shows that almost 85% of veterans 50 to 75 years of age are receiving appropriate dyslipidemia management.
- However, nearly 14% of patients with diabetes mellitus but without ischemic heart disease were potentially overtreated with high dose statins.

beyond the design of the statin studies, striving for low LDL values in all patients may not be an appropriate goal. Although higher doses of statins are associated with greater absolute LDL reductions,⁹ higher doses also are more likely to cause adverse events, including myopathy and rhabdomyolysis.^{27–32} The significance of these adverse events was underscored by the recent Food and Drug Administration Drug Safety Communication limiting use of the highest simvastatin dose (80 mg) because of increased risk of muscle damage.³³ Yet, the treat-to-target approach promotes the use of high-dose statins in all patients who do not achieve targets with lower doses. Furthermore, attempting to achieve stated targets will often require the use of nonstatin LDL-lowering therapy (eg, fibrates, ezetimibe, or niacin) that have not been shown to benefit outcomes, particularly when combined with statins.^{34–36}

If the ultimate goal of performance measurement is to improve the quality of patient care, then quality measures for dyslipidemia should focus on motivating evidence-based strategies for reducing cardiovascular risk. Indeed, professional societies, including the American College of Cardiology and American Heart Association, now recommend that the adequacy of lipid management be judged by the appropriateness of the therapy and not solely by LDL value.³⁷ We have previously described and validated such measures, called clinical action measures, which give credit for clinical processes that are strongly associated with important outcomes such as prescription of moderate-dose statins, even when thresholds are not met.^{38–42} Clinical action performance measures are increasingly being recommended to help make performance measurement more clinically meaningful.^{37,40,43}

As part of an effort to refine performance measurement for patients with diabetes mellitus, we collaborated with Department of Veterans Affairs (VA) clinical and measurement experts to develop a clinical action performance measure for lipid management in patients with diabetes mellitus focused on measuring and promoting appropriate use of statins. We examined performance on this proposed measure among

patients with diabetes mellitus receiving primary care in the VA during 2010 to 2011 to assess what proportion would have been receiving appropriate lipid management according to this new clinical action measure compared with the treat-to-target measure of LDL <100 mg/dL performance measure that was then in place. In addition, we examined the use of high-dose statins for patients without documented ischemic heart disease (IHD) to assess the degree of potential overtreatment. Finally, we examined whether achievement of current treat-to-target thresholds was associated with potential overtreatment.

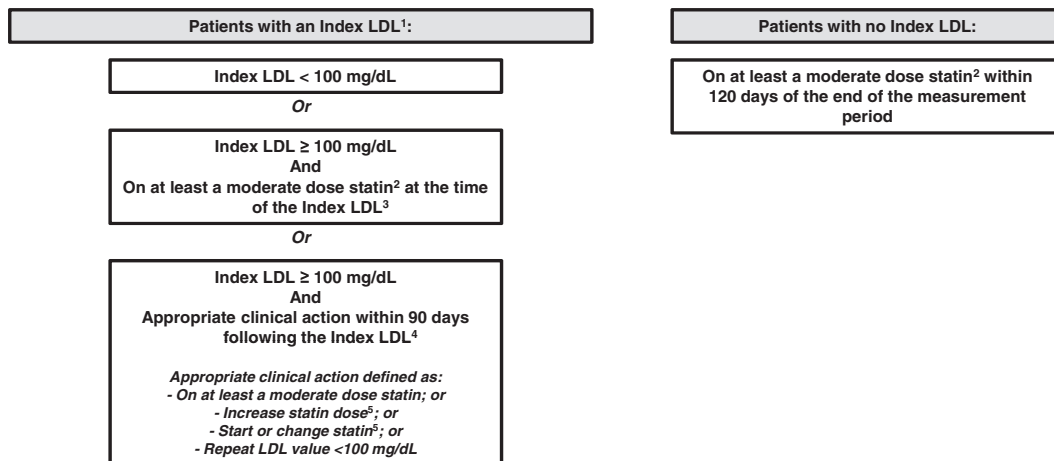
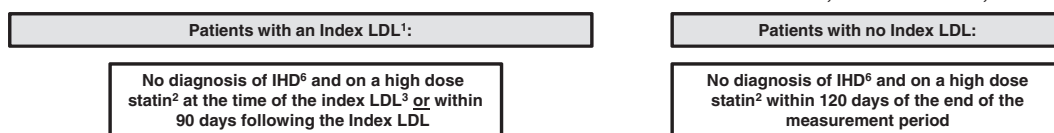
Methods

Measure Development and Construction

In consultation with clinical and measurement experts, we specified a clinical action performance measure for lipid management in patients with diabetes mellitus (Figure 1A). The performance measure focused only on patients of age 50 to 75 years because cardiovascular disease risk for both men and women with diabetes mellitus increases rapidly beyond 50 years of age^{44,45} and limited favorable patient-centered clinical outcome evidence (eg, reduced myocardial infarction, reduced stroke) is available in patients with diabetes mellitus <50 and >75 years of age. Although some guidelines have considered diabetes mellitus an IHD equivalent,¹⁹ suggesting that all patients with diabetes mellitus should be treated with a statin regardless of risk, intervention trial data are lacking except in the 50- to 75-year age range.^{2,3} Indeed, a 40-year-old woman with diabetes mellitus but no other risk factors has a cardiovascular risk <4%. However, by 50 years of age, even most women without other risk factors will have cardiovascular risk >5%. We specified that the clinical action measure could be met either by achieving the target threshold of LDL <100 mg/dL (either at baseline or, because of measurement variation, a repeat measure within 90 days)^{17,19,20} or by appropriate treatment with at least moderate-dose statins when LDL was ≥100 mg/dL or not tested (Figure 1A for measure specification). Moderate-dose statins were defined as statin daily doses capable of producing a 30% to 40% reduction in LDL. The following were considered moderate-dose statins: atorvastatin (≥10–<40 mg/dL), fluvastatin (≥80 mg/dL), lovastatin and pravastatin (≥40 mg/dL), rosuvastatin (≥5–<10 mg/dL), and simvastatin (≥20–≤40 mg/dL, see Methods 1 in the online-only Data Supplement). Additionally, the measure gave credit for appropriate action (ie, starting, switching, or intensifying statin therapy) even when the statin dose did not yet reach moderate-dosing criteria to focus on moving toward moderate doses among patients who might not tolerate higher doses.

We also specified a marker of potential overtreatment that assessed the use of high-dose statins among diabetic patients ≥18 years old without diagnosed IHD (Figure 1B). The following were considered high-dose statins (mg/dL): atorvastatin (≥40 mg/dL), rosuvastatin (≥10 mg/dL), and simvastatin (>40 mg/dL). Routine high-dose statin use may be appropriate among patients with acute coronary syndrome.^{46–50} Although we had complete data on diagnoses of acute coronary syndrome and other IHD-related inpatient and outpatient diagnoses within the VA system, we did not have data on acute hospitalizations outside the VA. When patients hospitalized outside the VA for an acute event are seen back in VA primary or specialty clinics, their IHD diagnosis is captured, but not necessarily the diagnosis of their acute event. To be conservative, therefore, we assumed that all patients with any diagnosis related to IHD (and not just those with acute coronary syndrome) may be appropriately treated with high-dose statins.

We looked at potential overtreatment among all patients with diabetes mellitus, not only those 50 to 75 years old, because there is no age threshold for toxicity from statins. Therefore, the marker of potential overtreatment examined the proportion of patients with diabetes mellitus but without IHD who were on high-dose statins during the measurement period and were therefore exposed to additional risk of treatment side effects without strong evidence for benefit beyond that received from moderate-dose statins.

A THE CLINICAL ACTION PERFORMANCE MEASURE IS MET FOR PATIENTS WITH DIABETES, 50-75 YEARS OLD, WHEN:**B THE MARKER OF POTENTIAL OVERTREATMENT IS MET FOR PATIENTS WITH DIABETES, 18+ YEARS OLD, WHEN:**

1. Index LDL values were determined based on the last recorded value from July 1, 2010 to June 30, 2011; 2. See online-only Data Supplement Methods for definition of moderate dose statin and high dose statin; 3. Patients were considered to already be on a statin if they had a medication fill within 100 days prior to the Index LDL; 4. The period examined for clinical action could be outside of the measurement period (For example, clinical action would be examined from July 2011-Sept 2011 [i.e., a 90 day period] for a patient whose index LDL occurred on June 30th, 2011) 5. At a dose lower than moderate dose; 6. IHD defined as the presence of ICD-9 codes 410, 411, 412, 413, or 414 (or presence of procedure codes for CABG or PCI)

Figure 1. The clinical action measure and the marker of potential overtreatment among patients with diabetes mellitus. LDL indicates low-density lipoprotein; IHD, ischemic heart disease; ICD, *International Classification of Diseases*; CABG, coronary artery bypass graft; and PCI, percutaneous coronary intervention.

Cohort Construction and Setting

We performed a retrospective cohort study in the 12-month period from July 1, 2010, to June 30, 2011 (the measurement period) of active VA primary care patients ≥ 18 years of age with an established diagnosis of diabetes mellitus in the 24 months before the measurement period (Methods 2 in online-only Data Supplement). The index LDL was defined as the last LDL value recorded in the measurement period. All VA clinics in which primary care type services are delivered were included. Only prescriptions filled in the VA were assessed. Data came from 881 facilities (medical centers or freestanding community-based outpatient clinics) in the VA National Corporate Data Warehouse. During this assessment period, the VA performance measure for lipid management among patients with diabetes mellitus was a treat-to-target measure of LDL < 100 mg/dL.

Statistical Analysis

We determined the number of patients (50–75 years old) who passed the clinical action performance measure and identified the reasons for meeting the measure. We also examined use of high-dose statins among the full diabetes mellitus cohort and among the potentially overtreated subgroup without IHD. We used 2 multilevel models in the analysis, one predicting meeting the performance measure and the other predicting overtreatment. A random intercept for facility was used in both models. An empty model with no other covariates was used to calculate the probability of meeting the performance measure and the probability of overtreatment. To assess the potential relationship of cardiovascular risk and intensive treatment, we also estimated a model including age and systolic blood pressure (SBP) as fixed effects. The predicted rates are empirical Bayes estimates that account for the instability of the estimates for small facilities.⁵¹ For illustrative purposes, we calculated the predicted rate of overtreatment in the entire diabetes mellitus cohort for a 40-year-old patient with an SBP of 130 mm Hg (low cardiovascular risk) and a 60-year-old patient with an SBP of 150 mm Hg (high cardiovascular risk).

Finally, we calculated the correlation between the predicted facility proportion of meeting the LDL < 100 mg/dL measure (the current threshold performance measure in VA) and the proportion meeting the overtreatment marker. To further illustrate the relationship between these 2 measures, we divided the 881 facilities into quartiles based on meeting the currently used dichotomous threshold measure of LDL < 100 mg/dL. We then examined the association between facility quartile of meeting the current LDL < 100 mg/dL measure and overtreatment using a multilevel logistic regression model.

All analyses were conducted with Stata, version 11.2 (Stata, College Station, TX). The Subcommittee on Human Studies of the VA Ann Arbor Healthcare System approved this study.

Results

There were 964 818 patients in the full diabetes mellitus cohort. Of these, 668 209 were between 50 and 75 years of age and thus were eligible for the clinical action measure. Table 1 details the baseline characteristics and statin use. In the cohort examined for the clinical action measure, the mean LDL in the year before the measurement period was 89.3 mg/dL, and 27.2% had a diagnosis of IHD. During the 120 days before the start of the measurement period, 24.9% patients were on a high-dose statin, 32.3% on a moderate-dose statin, 7.3% on a low-dose statin, and 35.4% not on any statin.

Clinical Action Performance Measure

Among diabetic patients 50 to 75 years old, 67.2% had an LDL < 100 mg/dL and thus met both the standard treat-to-target performance measure and the clinical action performance measure. (Of those with an LDL < 100 mg/dL, 22.9% were not

Table 1. Characteristics of the Cohort Examined for the Lipid Management Clinical Action Performance Measure (Age 50–75 Years) and for the Marker of Potential Overtreatment (Age ≥18 Years)

Characteristic	Clinical Action Performance Measure (50–75 years old only)		Marker of Potential Overtreatment (≥18 years)	
	Value	Sample, n	Value	Sample, n
n		668 209		964 818
Age, mean (SD), y	63.8 (6.1)	668 209	67.4 (10.8)	964 818
Male, %	96.7	646 429	96.9	934 431
Most recent hemoglobin A _{1c} , mean (SD), %*	7.3 (1.4)	597 364	7.2 (1.4)	844 999
Systolic blood pressure, mean (SD), mm Hg*	132.1 (13.6)	632 492	132.2 (13.8)	911 098
Diastolic blood pressure, mean (SD), mm Hg*	74.7 (9.0)	632 492	73.3 (9.5)	911 098
Low-density lipoprotein, mean (SD), mg/dL*	89.3 (29.3)	591 802	88.4 (29.1)	834 862
Ischemic heart disease, %*	27.2	181 937	29.3	282 538
On a moderate-dose statin at start of measurement period, %†	32.3	216 117	33.0	318 691
On a high-dose statin at start of measurement period, %†	24.9	166 366	22.7	218 807

*Time period examined: 365 days before the start of the measurement period.

†A patient was considered to be on a moderate- or high-dose statin (see Table I in the online-only Data Supplement-Methods 1 for dose ranges defined as moderate or high) if they had medication filled within the 120 days before the start of the measurement period. The highest dose filled during that time period was considered the medication dose.

on any statin, 8.2% were on a low-dose statin, 38.0% were on a moderate-dose statin, and 30.8% were on a high-dose statin.) Another 17.4% met the clinical action measure because of appropriate actions, for a total of 84.6% (n=564 998; Figure 2A and Table 2). Of this latter group, 11.9% had an LDL >100 mg/dL but were on a moderate-dose statin at the time of the index LDL measurement or within 90 days; 1.0% had a statin started or increased; 0.1% had a repeat LDL <100 mg/dL within 90 days; and 4.4% had no LDL measured but were on a moderate-dose statin.

Of note, overall 62.6% of patients 50 to 75 years old (n=418 375) were on at least a moderate-dose statin (28.5% of these [n=190 616] were on a high dose) during the measurement period. Of the remaining patients, 7.7% were on a low-dose statin and 29.7% were not on any statin. Of those not on a statin, 51.9% had an index LDL <100 mg/dL. There was substantial variation across the facilities in predicted probability of meeting the clinical action measure, ranging from 72.2% to 90.2% for a facility at the 5th percentile to the 95th percentile in pass rates ($\chi^2=9454.64$; $P<0.001$ for the likelihood ratio test of the effect of facility on probability of meeting the test).

Approximately 15.4% of the cohort did not meet the clinical action measure (n=103 211). We found that 8.1% of the cohort (n=54 371) had an LDL >100 mg/dL but were not on any statin; 6.0% (n=40 360) had no LDL measurement and were not on a statin; and 1.3% (n=8480) were only on a low-dose statin. Patients who did not meet the clinical action measure had fewer primary care visits on average during the measurement period than patients who did meet the measure (4.7 versus 6.3 visits; $P<0.0001$, 2-group mean comparison (*t*) test).

Use of High-Dose Statins and Potential Overtreatment

The percentage of diabetes mellitus patients ≥18 years of age who were on statins during the measurement period was

68.3% compared with 70.3% of diabetes mellitus patients 50 to 75 years old. Among the 68.3% on statins (n=658 950), 37.7% were prescribed a high dose, 50.5% were prescribed a moderate dose, and 11.8% were prescribed a low dose. Simvastatin, the preferred formulary agent during the entire measurement period, was the most frequently prescribed statin (73.0%). Furthermore, 13.7% of all diabetic patients were on high-dose statins but had no diagnosis of IHD either during or before the measurement period (n=131 772) and were potentially overtreated (Figure 2B). We conducted a sensitivity analysis, also excluding patients with cerebrovascular disease and peripheral vascular disease (in addition to patients with IHD), and the percentage of patients with potential overtreatment decreased from 13.7% to 11.5%.

Facilities varied substantially in high-dose statin use among patients without IHD, with predicted rates of potential overtreatment ranging from 8.5% to 18.4% ($\chi^2=6780.18$; $P<0.001$ for the likelihood ratio test of the effect of facility on probability of meeting the test). Predicted probabilities using a 2-level model that included age and mean SBP in the year before the measurement period showed that, at a facility with median rates of overtreatment, the predicted probability of overtreatment for a 40-year-old patient with an SBP of 130 mm Hg was 17.6% (confidence interval [CI] 17.3–18.0) versus 14.0% (CI, 13.7–14.3) for a 60-year-old patient with an SBP of 150 mm Hg. The expected direction of these variables would be for higher levels of age and blood pressure (which confer a higher level of cardiovascular risk) to predict a higher probability of intensive treatment. Instead, we found a paradoxical inverse relationship between cardiovascular risk and likelihood of intensive treatment.

Association Between Current Threshold Performance Measure and Overtreatment

The facility-level correlation between the proportion of patients meeting the current official VA treat-to-target threshold performance measure (LDL <100 mg/dL) and

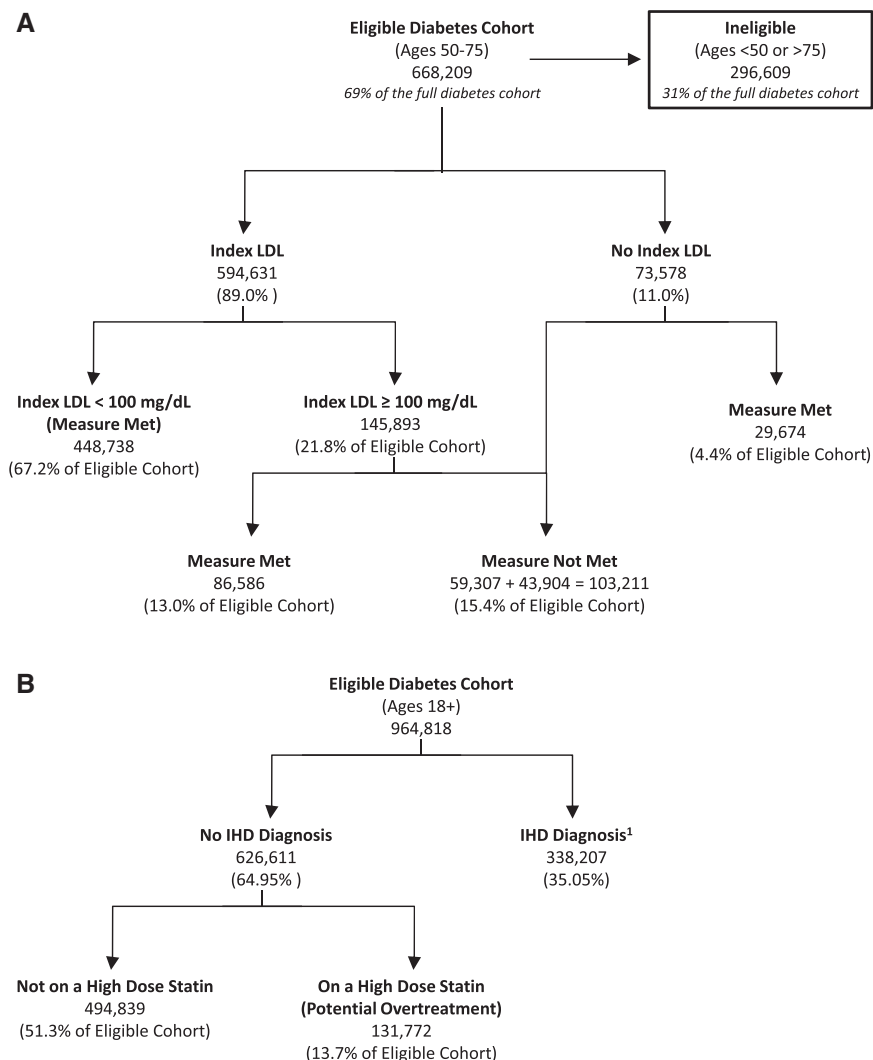


Figure 2. A, Quality of care by the linked action measure is met in 84.6% of patients. **B**, A total of 13.7% of patients with diabetes mellitus have potential overtreatment. LDL indicates low-density lipoprotein; IHD, ischemic heart disease; ICD, *International Classification of Diseases*; CABG, coronary artery bypass graft; and PCI, percutaneous coronary intervention.

¹IHD defined as the presence of ICD-9 codes 410, 411, 412, 413, or 414 (or presence of procedure codes for CABG or PCI) in the year prior to or during the study.

the proportion meeting the overtreatment measure was 0.33 ($P < 0.0001$). Table 3 describes the relationship between facility quartile of meeting the current official VA treat-to-target threshold measure (LDL < 100 mg/dL) and potential overtreatment. Facilities in the lowest quartile of meeting the VA quality measure had a predicted probability of overtreatment of 10.7% (CI, 10.2–11.1), whereas those in the highest quartile of meeting the threshold measure had a predicted probability of overtreatment of 14.3% (CI, 13.8–14.8).

Discussion

We developed and examined a clinical action performance measure for lipid management among patients of age 50 to 75 years in the VA. We found that 85% of patients met this performance measure compared with 67% using the traditional metric of achieving an LDL < 100 mg/dL. Even the finding of 67% of patients meeting the intermediate outcome measure of LDL < 100 mg/dL is higher than previously published estimates of LDL attainment outside the VA, but it is certainly consistent with trends over time toward lower

LDL levels, increasing use of statins (including potential overtreatment with high dose statins), as well as treatment guidelines and performance measures stressing achievement of LDL thresholds in the VA.^{19,21,23,26}

The clinical action measure that we developed and that is now implemented in the VA recognizes not just LDL levels but also the most definitive evidence-based treatment (moderate-dose statins) and appropriate responses to LDL levels (starting or increasing statins). This has several effects. First, it represents a broader consensus because there is ongoing debate about the appropriateness of LDL targets given that nearly all clinical trial evidence (particularly in primary prevention) is based on fixed, low to moderate doses of statin. Second, it limits the potential for overtreatment with higher doses of statins in those without IHD who do not achieve LDL targets. Third, it avoids providing incentives for combination therapy of statins with other lipid-lowering agents that have been shown to be ineffective or to have no clear evidence supporting their use.

For consistency with current threshold measures, meeting the LDL goal is presented first in the hierarchy (Table 2). However, in the future, we may wish to present being on a

Table 2. Reasons for Passing the Clinical Action Performance Measure for Lipid Management Among Diabetic Patients 50 to 75 Years of Age (n=668 209)

Reason	Hierarchical*		Total†	
	n	%	n	%
Index LDL <100 mg/dL	448 738	67.2	448 738	67.2
On at least a moderate-dose statin at the time of the index LDL‡	50 032	7.5	317 736	47.6
Appropriate clinical action within 90 days after the index LDL (includes index LDL date)				
On at least a moderate-dose statin	29 571	4.4	70 627	10.6
Increase of statin dose (at a dose lower than moderate)	481	0.1	4953	0.7
Start or change statin (at a dose lower than moderate)	5727	0.9	86 355	12.9
Repeat LDL value <100 mg/dL	775	0.1	19 099	2.9
No index LDL but received a fill for a moderate-dose statin or higher during or at end of measurement period§	29 674	4.4	29 674	4.4
Meets the clinical action measure	564 998	84.6	564 998	84.6
Does not meet the measure	103 211	15.4	103 211	15.4

LDL indicates low-density lipoprotein.

*Patient can meet the measure based on only 1 reason in the order listed.

†Patient can meet the measure based on all reasons for which the patient qualifies.

‡Patients were considered to already be on a statin if they had a medication fill within 100 days before the index LDL.

§During the last 120 days of the measurement period.

moderate-dose statin first to motivate clearly appropriate care. If we reversed the order of credit to focus first on moderate-dose statin use, regardless of the presence of an LDL measurement, ≈62.6% would currently meet the measure because they were on at least a moderate-dose statin, 21.0% because of an LDL <100 mg/dL, and 1.1% because of appropriate clinical actions.

New performance measures for the management of coronary artery disease and hypertension suggested by the American College of Cardiology Foundation, American Heart Association, and others have also promoted giving credit for threshold assessment of LDL at 100 mg/dL or if statins are prescribed.³⁷ These measures have not yet been specified, so it is unclear whether they would provide credit for clinical

actions such as statin prescription within 90 days and for statin use even when an LDL level is not obtained. Our results show that when these criteria are included, an additional 10% of patients are receiving appropriate care. We have shown similar results for hypertension care using clinical action measures.⁵²

We found that 13.7% of patients were being potentially overtreated with high-dose statins despite not having IHD. This rate of potential overtreatment is likely conservative because the evidence supporting use of high-dose statins is mixed, particularly in those with stable IHD.^{27,53,54} Furthermore, in our analysis, there was no evidence that the use of high-dose statins among those without IHD correlated with cardiovascular risk. A 40-year-old patient without hypertension (an SBP of 130 mm Hg) was more likely to be prescribed high-dose statins (17.6% [CI, 17.3–18.0]) than a 60-year-old patient with an SBP of 150 mm Hg (14.0% [CI, 13.7–14.3]).^{44,55} This suggests that the use of high-dose statins with the attendant risks may be more reflexive than based on calculated cardiovascular risk such as can be obtained from the UK Prospective Diabetes Study Risk Engine.⁴⁴

Our examination of use of high-dose statins in patients without IHD is not intended as an assessment of performance but rather as a marker of possible overtreatment among patients who may benefit from therapy deintensification. Up to 1% of patients on high-dose statins may experience complications like myopathy and rhabdomyolysis.^{27–31} Physicians and health systems have an obligation to prescribe medications at the doses likely to maximize benefit and minimize risk. To do otherwise promotes inefficient and potentially harmful care. Furthermore, rates of potential overtreatment in patients without IHD varied widely among facilities, and we found that facilities with high proportions of patients meeting the threshold measure of LDL <100 mg/dL had greater proportions of use of high-dose statins. Taken in combination with other findings, this suggests that facilities with high rates of meeting a treat-to-target measure of LDL control are more likely to

Table 3. Relationship Between the Proportion of Patients per Facility Meeting the Current LDL <100 mg/dL Threshold Performance Measure and Potential Overtreatment*

Proportion of Patients per Facility Meeting the LDL <100 Threshold Performance Measure by Quartile, %	Independent Effect of Current Performance on Predicted Probability (CI) of Potential Overtreatment, %†
Lowest (8.4–60.3)	10.7 (10.2–11.1)
Second (60.3–66.5)	12.4 (11.9–12.8)
Third (66.5–71.0)	13.7 (13.2–14.2)
Highest (71.0–84.0)	14.3 (13.8–14.8)

LDL indicates low-density lipoprotein; CI, confidence interval.

*Potential overtreatment defined as the following: among all diabetic patients, the proportion of patients without ischemic heart disease who are prescribed high-dose statins.

†Predicted probability of potential overtreatment per quartile of meeting the current threshold measures based on multilevel logistic regression for facilities at the median rate of overtreatment ($P < 0.001$). These estimates isolate the hypothetical effect of a facility being in different quartiles of current performance if the propensity to overtreat at a sample of facilities was otherwise the same. Given that current performance and potential overtreatment are correlated, the observed probabilities would differ by much more.

use high-dose statins, thus potentially putting patients at risk for harm from overtreatment. Such unintended consequences of performance measurement provide more impetus for implementing measures that focus on appropriate treatment rather than arbitrary threshold targets and that may prompt consideration of deintensification when appropriate. Future longitudinal studies should explicitly explore the link between statin overtreatment and adverse events in real-world practice to determine the frequency and importance of these events.

Clinical action performance measures motivate appropriate treatment (and decrease potential overtreatment) by rewarding care processes beyond achievement of a target LDL value. The results of our study demonstrate the feasibility of clinical action performance measures using administrative data derived from electronic medical record data. Although not all care systems or insurers have access to comprehensive electronic data that include laboratory values and prescribing history, our findings suggest that continued use of threshold measures of performance for lipid management, particularly in high-performing systems, may promote overtreatment.^{5,7,56} Use of the clinical action measure in this study was not without limitations, however. We were not able to account for medications prescribed outside the VA. We were also unable to assess patient contraindications to statins (such as prior adverse reactions), although we did exclude those with end-stage liver and kidney disease. It is possible, therefore, that even more patients were receiving appropriate care than we were able to capture. Further refinements of the clinical action measure would examine receipt of medications from other sources and definite contraindications to statins.

Additionally, we limited the measure to patients 50 to 75 years of age because there is the greatest evidence of benefit in this age group and because all patients with diabetes mellitus in this age are at relatively high cardiovascular risk.⁴⁴ In the meta-analysis of 18 686 diabetic patients in 14 trials of moderate-dose statin therapy that showed reduced myocardial infarctions, inclusion ages for individual trials placed most patients in the 50- to 75-year age range.² The purpose of a performance measure on lipid management is to highlight care that should definitely be provided on the basis of Level 1A evidence from multiple randomized, controlled trials or meta-analyses.⁵⁷ Although guidelines might correctly urge providers to consider use of statins in otherwise high-risk younger or older patients with diabetes mellitus, performance measures are not intended to guide but rather to mandate care. In the future, an optimally designed performance measure for lipid treatment should define eligibility not only also by diagnosis and age, but also by a measure of cardiovascular risk such as that derived from a risk equation like the Framingham Heart Study or the UK Prospective Diabetes Study.^{44,55,58,59}

In summary, we demonstrated the design and use of a clinical action performance measure for lipid management among nearly 700 000 patients with diabetes mellitus seen in nearly 900 VA facilities. High rates of passing the action measure are reflective of both the comprehensive structure of the clinical action measure and the high-performing healthcare system. However, the pattern of use of high-dose statins among patients without IHD indicates that providers may be overusing high-dose statins to achieve the current threshold LDL

targets. Use of the clinical action measure has the potential to enhance more appropriate treatment over time by de-emphasizing the attainment of an LDL target and motivating moderate-dose statin use. The VA has committed to implementation and evaluation of the lipid management clinical action measure in 2012.

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Supplemental Methods

Supplemental Methods 1 – Medication related definitions

Table 1. Daily doses for low, moderate, and high dose statins

Statin	Low Dose (mg/day)	Moderate Dose (mg/day)	High Dose (mg/day)
atorvastatin	<10	≥10 to <40	≥40
fluvastatin	<80	≥80	-
lovastatin	<40	≥40	-
pravastatin	<40	≥40	-
rosuvastatin	<5	≥ 5 to <10	≥10
simvastatin	<20	≥20 to ≤40	>40

Moderate dose statin

These were based on statin daily doses capable of producing a 30-40% reduction in LDL.¹⁻⁴ Table 1 above contains the specific medications, and the daily doses associated with each category.

On a statin at the time of the index LDL

We examined all statin medication fills during the 100 days prior to the index LDL, not including the date of the index LDL (which are captured below). Most fills in the VA system are for 90 days. We allowed a 100-day look back period prior to the index LDL to allow for refills that were not requested within an exact 90-day interval.

1. To identify whether a patient passed the clinical action measure, we used any instance of a moderate daily dose statin fill in the 100 days prior to the index LDL, even if it was not the last fill. For purposes of a performance measure, we wanted a patient with a moderate dose (or higher dose) fill followed by a low dose fill in the 100 days prior to the index LDL to pass in the same way that a patient with a single fill of moderate dose (or higher dose) would pass.
2. To identify the medication the patient was on at the time of the index LDL we selected the most recent statin fill prior to the index LDL date. If there was more than one fill on that date, we used the highest potency statin and dose combination (e.g., if there was a fill for 10 mg daily of rosuvastatin and a fill for 20 mg daily of simvastatin we used the 10 mg rosuvastatin).

On a statin within 90 days following the index LDL

We examined all statin medication fills 90 days after the index LDL. This did include the date of the index LDL. Together, the 100 day look back period (above) and 90 day look forward period allowed maximal certainty that a patient with a fill around the time of the index LDL was captured within our algorithm.

1. To identify whether a patient passed the clinical action measure, we used any instance of at least a moderate daily dose statin fill in the 90 days after the index LDL.
2. When examining overtreatment, if there was more than one statin medication filled during this time period we used the highest potency statin and dose combination.

Increase statin dose

An increase in the daily dose of the same statin medication from the time of the index LDL to 90 days following the index LDL, using the medication the patient was on at the time of the LDL and any fill after the index LDL indicating a higher daily dose of the same medication (e.g., a patient was on 20 mg of fluvastatin daily before the index LDL date and received any fill for 40 mg fluvastatin daily within 90 days after the index LDL).

Start a statin

The initiation of a statin during the 90 days following the index LDL. The patient had no prescription for a statin in the 100 days prior to the index LDL.

Change a statin

A change in statin medication (e.g., change from fluvastatin to simvastatin) during the 90 days following the index LDL.

For those without an index LDL only: On a statin

We examined all statin medication fills during the last 120 days of the measurement period. Because the most-common fill period is for 90 days, a 120-day look back period allowed us to capture most fills, even if the patient had made a somewhat off-cycle fill. If there was more than one statin medication filled during this time period we used the highest potency statin and dose combination.

High dose statins

These were based on statin daily doses capable of producing greater than 40% reduction in LDL. Table 1 above contains the specific medications and the doses included.

¹D Preiss, SRK Seshasai, Welsh P, et al. **Risk of Incident Diabetes with Intensive-Dose Compared With Moderate-Dose Statin Therapy: A Meta-analysis.** *JAMA.* 2011; 305(24):2556-2564.

²VA Pharmacy Benefits Management (2011). "Statin Criteria for Use (Pravastatin, Rosuvastatin, Atorvastatin, Fluvastatin, Fluvastatin XL); VHA Pharmacy Benefits Management (PBM) Services, Medical Advisory Panel (MAP) and VISN Pharmacist Executives (VPEs)." Assessed October 3, 2011, at <http://www.pbm.va.gov>.

³Cannon CP, Braunwald E, McCabe CH, et al. Intensive versus moderate lipid lowering with statins after acute coronary syndromes. *NEJM.* 2004;350(15):1495-504.

⁴Cannon CP, Steinberg BA, Murphy SA, et al. Meta-Analysis of Cardiovascular Outcomes Trial Comparing Intensive Versus Moderate Statin Therapy. *J Am Coll Cardiol.* 2006;48:438-45.

Supplemental Methods 2 – Definitions for study cohort construction and relevant variables

Study Cohort

Data source: VA National Corporate Data Warehouse (CDW), which contains information on outpatient encounters; ICD-9 diagnoses; prescription medication fills, doses, quantities and days supply; vital signs; and laboratory values.

Active VA primary care patients aged 18 and over with established diagnoses of diabetes mellitus were identified for the 12-month study period of July 1, 2010 to June 30, 2011. Patients were assigned to a facility based upon the site with the preponderance of primary care visits during the measurement period or, in the case of a tie, the last site where they received primary care during the measurement period. (A facility could not be assigned for 0.05% of patients who had equal visits at multiple sites and were last seen at two locations on the same day during the measurement period; these patients were dropped from the cohort.)

Definition list

Active VA patients: Those patients having at least two primary care clinic visits in the 24 months prior to the study period (i.e., July 1, 2008 to June 30, 2010). At least one of the primary care clinic visits had to occur during July 1, 2009 to June 30, 2010.

Primary care visits: We used VA clinic codes for outpatient visits where primary care type services are delivered (e.g., general medicine, hypertension, endocrinology).

Established diabetes: Those patients having at least 2 outpatient visits coded with ICD-9 codes for diabetes or having a total of at least 31 days of prescription diabetes medications filled (see definitions for these below) in the 24 months prior to the study period (i.e., July 1, 2008 to June 30, 2010). Metformin alone did not identify a patient as having diabetes. One of the visits or a medication fill had to occur during July 1, 2009 to June 30, 2010 to assure that this was an established diabetes case.

Diabetes medications: Insulin, Acarbose, Acetohexamide, Chlorpropamide, Exenatide, Glimepiride, Glipizide, Glyburide, Miglitol, Nateglinide, Pioglitazone, Pramlintide, Repaglinide, Rosiglitazone, Sitagliptin, Tolazamide, Tolbutamide

ICD-9 codes for diabetes: 250.xx-diabetes mellitus, 357.2-neuropathy in diabetes, 366.41-diabetic cataract, 362.0-diabetic retinopathy, 962.3-insulin poisoning, E932.3 adverse effect of insulin

Ischemic Heart Disease (IHD): The presence of ICD-9 codes 410, 411, 412, 413, or 414 (or presence of procedure codes for CABG or PCI) in the year prior to or during the measurement period

Exclusions

Patients with no PCP visits during the study period.

Patients with a date of death on or before June 30, 2011 in the patient file

Patients with life expectancy less than 6 months recorded in a structured format within the medical record (Health Factors Data) on or before June 30, 2011

Patients were excluded if they had any of the following in the 12-months prior to or during the study period:

Dialysis:

ICD-9 codes: V56, 458.21, V45.1

Procedure (CPT) codes: 90935, 90937, 90945, 90947, 90999

Other VA clinic codes identifying dialysis services: 602, 603, 604, 606, 607, 610, 611

Pregnancy:

ICD-9 codes: 630-679, V22-V24

Liver cancer:

ICD-9 code: 155

Esophageal cancer:

ICD-9 code: 150

Pancreatic cancer:

ICD-9 code: 157