HEALTH CARE REFORM

Monitoring Performance for Blood Pressure Management Among Patients With Diabetes Mellitus

Too Much of a Good Thing?

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Background: Performance measures that reward achieving blood pressure (BP) thresholds may contribute to overtreatment. We developed a tightly linked clinical action measure designed to encourage appropriate medical management and a marker of potential overtreatment, designed to monitor overly aggressive treatment of hypertension in the face of low diastolic BP.

Methods: We conducted a retrospective cohort study in 879 Department of Veterans Affairs (VA) medical centers and smaller community-based outpatient clinics. The clinical action measure for hypertension was met if the patient had a passing index BP at the visit or had an appropriate action. We examined the rate of passing the action measure and of potential overtreatment in the Veterans Health Administration during 2009-2010.

Results: There were 977,282 established VA patients, 18 years and older, with diabetes mellitus (DM). A total of 713,790 patients were eligible for the action measure; 94% passed the measure (82% because they had a BP <140/90 mm Hg at the visit and an additional 12% with a BP ≥140/90 mm Hg and appropriate clinical actions). Facility pass rates varied from 77% to 99% (P < .001). Among all patients with DM, 197,291 (20%) had a BP lower than 130/65 mm Hg; of these, 80,903 (8% of all patients with DM) had potential overtreatment. Facility rates of potential overtreatment varied from 3% to 20% (P < .001). Facilities with higher rates of meeting the current threshold measure (<140/90 mm Hg) had higher rates of potential overtreatment (P < .001).

Conclusions: While 94% of diabetic veterans met the action measure, rates of potential overtreatment are currently approaching the rate of undertreatment, and high rates of achieving current threshold measures are directly associated with overtreatment. Implementing a clinical action measure for hypertension management, as the Veterans Health Administration is planning to do, may result in more appropriate care and less overtreatment.


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Group Information: Members of the Diabetes QUERI Workgroup on Clinical Action Measures are listed at the end of this article.
threshold measures because they better capture the complexity of clinical decision making for hypertension. Specifically, clinical action measures focus not only on the risk factor level but also give credit when patients are receiving evidence-based treatment even when a risk factor threshold is not achieved. They also diminish the potential for overtreatment and unintended consequences by taking contraindications and variability of measurement into account. Finally, they examine care and risk factor control over time rather than only on 1 day.

In May 2006, more than 40 scientific and clinical experts in DM and quality measurement gathered at a federally sponsored multidisciplinary conference on DM quality measurement. Among the conclusions was the promotion of "tightly linked" clinical action measures to assess whether appropriate action was taken in response to substandard risk factor control, particularly for BP and lipid levels. Such clinical action measures have also been endorsed recently by other expert panels.

We collaborated with clinical and operations leaders in the Department of Veterans Affairs (VA) to specify a clinical action measure for BP management in DM. We further specified a marker of potential hypertension overtreatment to assess the proportion of patients who may be receiving overly aggressive and thus potentially risky treatment. We then examined performance on the measure and on the marker of potential overtreatment among almost 1 million patients with DM receiving primary care in the VA during 2009-2010 to assess what proportion of patients are meeting appropriate quality for hypertension, the degree of potential hypertension overtreatment, and the relationship between meeting current threshold measures and potential overtreatment.

### METHODS

#### MEASURE DEVELOPMENT

We specified the tightly linked clinical action measure for hypertension management in DM with assistance from experts in DM, hypertension, hyperlipidemia, and measurement construction. The measure was designed to acknowledge several tenets of evidence for BP management in DM. First, BP control clearly benefits patients with DM. However, current recommendations about stringent BP targets for DM (eg, BP <130/80 mm Hg) are based on observational analyses of clinical trials, and no experimental evidence currently supports a systolic BP (SBP) target of less than 140 mm Hg. Even in clinical trials that showed improved macrovascular outcomes with stringent (diastolic BP [DBP] <80 or 85 mm Hg) vs less stringent control, the achieved mean DBP was always higher than 80 mm Hg. Second, a recent randomized controlled trial found that randomizing patients with DM to stringent control (SBP <120 mm Hg) vs moderate control (SBP <140 mm Hg) achieved no clinical benefit and increased adverse drug events, while a follow-up of patients from another trial found that those who maintained tight BP control (SBP <130 mm Hg) did not have improved outcomes and may have had higher mortality than those who maintained average control (SBP, 130-140 mm Hg).

Third, clinical trials have rarely used more than 3 to 4 antihypertensive medications to achieve control. Fourth, several analyses have shown that low DBP levels (eg, <70 mm Hg) increase cardiovascular events among patients with DM or cardiovascular disease and that those with ischemic heart disease (IHD) may be at greatest risk due to coronary hypoperfusion. We therefore specified that appropriate quality for hypertension management among patients with DM could be met if the patient's BP was lower than 140/90 mm Hg or if the patient received appropriate care, as defined in the following subsection and in Figure 1. Similarly, with guidance from our workgroup, we specified a marker of potential hypertension overtreatment (Figure 1) that could signal which patients may be getting therapy that is not beneficial to them (and could be costly or even harmful) and therefore could benefit from medication de-escalation. Given that no experimental evidence supports an SBP lower than 140 mm Hg and that in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial, patients randomized to intensive SBP control (with a mean antihypertensive medication number of 3.4) had higher likelihood of serious adverse events, and that DBP levels lower than 70 mm Hg have been associated with harm, the marker of potential overtreatment focused on patients who had both low systolic (<130 mm Hg) and low diastolic (<85 mm Hg) values and were receiving 3 or more antihypertensive medications and/or were being actively intensified.

### COHORT AND MEASURE CONSTRUCTION

We used the VA National Central Data Warehouse to construct the cohort and measures (eAppendix; http://www.archintermmed.com). The cohort included established active primary care patients 18 years or older with a diagnosis of DM in the 24 months prior to the eligibility month. The eligibility month was the month during which the index BP (defined as the lowest DBP and lowest SBP measurements from the same day as the patient's last primary care visit during the measurement period) occurred. The measurement period was from July 1, 2009, to June 30, 2010. All VA clinics where primary care type services are delivered were included.

An eligible patient aged 18 to 75 years was determined to have appropriate care if the index SBP was lower than 140 mm Hg and the DBP was lower than 90 mm Hg; or if the index SBP was lower than 150 mm Hg and the DBP was lower than 65 mm Hg; or if the index SBP was lower than 150 mm Hg and the patient was receiving 3 or more moderate-dose antihypertensive medications (eTable); or if appropriate action occurred within 90 days (Figure 1). Similarly, a patient in the cohort was considered to have received possible overtreatment if their index SBP was lower than 130 mm Hg and DBP was lower than 65 mm Hg and they were receiving 3 or more BP medications and/or active medication intensification (Figure 1).

### STATISTICAL ANALYSIS

In our population, patients were cared for at 879 different sites of care, ranging from small community-based outpatient clinics to large medical centers, and thus our data are clustered hierarchically by site. We used a 2-level hierarchical multivariate logistic regression to estimate the rate of meeting the clinical action measure. The dependent variable was measured at the patient level, as were individual patient characteristics (sex and presence of IHD). An indicator representing each site of care was used to identify the second level in the regression, allowing us to estimate the variance of the constant term. This model accounts appropriately for the varying number of patients seen at any given site of care in generating site-specific rates and allows us to accurately estimate the variance in rates across sites. The predicted rates are empirical Bayes estimates, which account for the instability of the estimates for small sites. All models were estimated using the xtmelogit procedure in Stata 12.0 (StataCorp, 2010).
Figure 1. The tightly linked clinical action measure and the marker of potential overtreatment among patients with diabetes mellitus. A, Clinical action measure for patients aged 18 to 75 years; B, marker of potential overtreatment for patients 18 years and older. *Associated with a primary care visit. †With prescription refills of all 4 classes in the 120 days following the index BP. ‡With no dropping of a medication within 120 days following the index BP (existing medications had a fill in the 120 days following the index BP). BP indicates blood pressure; DBP, diastolic blood pressure; and SBP, systolic blood pressure.

Similarly, we calculated the proportion of all patients and those patients older than 75 years who received potential overtreatment and the reasons for overtreatment. We then examined associations between individual patient characteristics (age, sex, and IHD) and potential overtreatment. Using 2-level hierarchical logistic regression models, we examined the predicted rates of overtreatment across all sites of care. Finally, we constructed a 2-level hierarchical multivariate logistic regression model that simultaneously examined 2 risk factors for worse outcomes of overtreatment: age and IHD. We examined predicted rates of overtreatment of younger (aged 55 years) and older (aged 80 years) patients, with and without IHD, for sites at the median rate of overtreatment to demonstrate the range and variability in overtreatment by characteristics known to be associated with worse outcomes from diastolic hypotension.

We divided the 879 sites into quartiles based on meeting the current dichotomous threshold performance measure of BP lower than 140/90 mm Hg and examined the association between facility quartile and potential overtreatment using a multilevel logistic model. Finally, we examined what proportion of facilities in each quartile were also in the highest quartile of overtreatment.

We received institutional review board approval for the study from VA Ann Arbor Healthcare System’s Subcommittee on Human Studies.

**RESULTS**

**Table 1** describes the entire DM cohort as well as the cohort limited to ages 18 to 75 years, for whom the clinical action measure was applied.

**CLINICAL ACTION MEASURE**

Among patients with DM aged 18 to 75 years, 94% passed the measure (Figure 2A). Reasons for passing the measure are detailed in Table 2. Eighty-two percent had an index BP lower than 140/90 mm Hg. An additional 8% met the measure by having BP medication intensification. Although 21% of patients had a BP lower than 150/65 mm Hg, the majority of these patients met the measure on the basis of a BP lower than 140/90 mm Hg. Men were slightly more likely to meet the measure than women (94% vs 93%; P < .001), as were patients with IHD vs those without (95% vs 93%; P < .001). There was moderate variation across the 879 facilities in predicted probability of meeting the measure, ranging from 77% (95% CI, 69%-83%) to 99% (95% CI, 97%-99%) (P < .001).

**MARKER OF POTENTIAL OVERTREATMENT**

In the entire cohort (age ≥18 years), 197 291 (20%) had a BP lower than 130/65 mm Hg; of these, 80 903 mm Hg (more than 8% of the entire cohort) were potentially overtreated (Figure 2B). Among patients who were potentially overtreated, the mean SBP was 114.5 mm Hg and the mean DBP was 57.6 mm Hg. **Table 3** shows that patients with potential overtreatment are older, have lower mean index BP, and are more likely to be men and have IHD. Indeed, among the 263 492 patients 76 years and older, 30% had a BP lower than 130/65 mm Hg, and 40% of those with a BP lower than...
130/65 mm Hg were potentially overtreated (12% of all patients with DM 76 years and older). In multivariate analysis, the effect of age and presence of IHD continued to be independent predictors of overtreatment (data not shown).

Predicted probability of overtreatment for those 18 years and older varied by facility from 3% (95% CI, 2%-5%) to 20% (95% CI, 17%-22%). Predicted probabilities using a 2-level model showed that a 55-year-old patient without IHD had a predicted probability of overtreatment of 3.8% (95% CI, 3.7%-3.9%), while an 80-year-old patient with IHD had a predicted probability of overtreatment of 15.3% (95% CI, 14.9%-15.7%).

ASSOCIATION BETWEEN CURRENT PERFORMANCE MEASURES AND OVERTREATMENT

Table 4 shows a dose-response relationship between facility quartile of meeting the current dichotomous measure (BP <140/90 mm Hg) and potential overtreatment. Facilities in the lowest quartile of meeting the measure had a predicted overtreatment rate of 6.0% (95% CI, 5.7%-6.3%), while those in the highest quartile had a potential overtreatment rate of 8.6% (95% CI, 8.1%-9.0%). Furthermore, facilities in the highest quartile of meeting the lower-than-140/90-mm Hg measure were 3.7 times more likely to be ranked in the top quartile of potential overtreatment relative to facilities in the lowest quartile.

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COMMENT

Nearly 94% of patients with DM met the clinical action measure for BP measurement (82% had a BP <140/90 mm Hg and an additional 12% had a BP ≥140/90 but appropriate management). This represents a dramatic improvement in BP control over the past decade, during which there has also been an intense focus on perfor-
mance measures, guidelines, and quality improvement initiatives related to BP control.17 However, in the past, performance measures for BP control have been silent as to the manner of achieving control. The described clinical action measure captures not only the rate of control but also appropriate treatment and contraindications to further intensification. The measure acknowledges that some patients may never achieve target control despite appropriate treatment and gives credit for using evidence-based therapy. In addition, the measure states that patients with moderate systolic and low diastolic levels meet the measure without additional therapy. In this way, the clinical action measure promotes appropriate treatment without encouraging overtreatment. Finally, the clinical action measure at least partly takes into account variability in BP measurement by giving credit for a lower reading within 90 days.

For reasons stated previously, our measure focused on achieving a BP control level of lower than 140/90 mm Hg or appropriate management. While patients with high cardiovascular risk could possibly benefit from tighter control, those at lower cardiovascular risk could be harmed or incur additional cost and inconvenience of polypharmacy without substantial benefit.10,28 There has been considerable effort in the VA to have the majority of patients meet a dichotomous threshold measure of 140/90 mm Hg since 1999, and in 2010, more than 80% did so. Consequently, 31% of those with a BP lower than 140/90 mm Hg in our cohort had a DBP that is lower than 65 mm Hg, and 79% of those patients were receiving at least 1 antihypertensive medication. Indeed, our results suggest that more than 8% of all diabetic veterans may be overtreated. Older patients and those with IHD, who may be at highest risk from hypotension, impaired coronary perfusion, and polypharmacy, are also at greater risk for potential overtreatment.

Rates of potential overtreatment varied widely across facilities. Moreover, facilities that were successful in meeting current dichotomous threshold measures of a BP lower than 140/90 mm Hg were more likely to have higher levels of overtreatment. We posit that these findings are not unique for BP threshold measures and that similar or more stringent dichotomous threshold measures for glycated hemoglobin and low-density lipid levels may pose similar threats to many patients with DM.

Our results show that it is possible to construct a sophisticated, clinically meaningful performance measure using electronic data that includes diagnostic codes, vital signs, and prescription information. Automated data from the VA, including pharmacy and vital signs data, have been shown to be reliable compared with data abstracted from medical records.39,40 Not all health care systems have ready access to such reliable data elements, but our findings suggest that continuing to promote only dichotomous threshold measures for BP control is no longer optimal and may, in fact, encourage potentially harmful and wasteful overtreatment. The expansion of meaningful use criteria for electronic health records may rectify the lack of available data. Until then, national standard-setting groups must insist on better data availability that facilitates the use of more clinically meaningful measures.

While the action measure captured a robust set of criteria, it may still have underestimated the true rate of appropriate care. For example, we were not able to assess medications prescribed outside of the VA nor contraindications to treatment other than low diastolic levels. The new American College of Cardiology Foundation/American Heart Association performance measurement recommendations suggest a measure that can be met for those above threshold who are receiving 2 or more antihypertensive medications, rather than the 3 moderate-dose medications we specified.27 Had we incorporated these criteria, we would have found even higher rates of meeting clinical action.

Unlike the clinical action measure, the marker of potential overtreatment is not yet intended as a performance measure but rather as a signal that some patients with low BP may be receiving overly aggressive treatment. As such, it could be used in quality-improvement initiatives to give feedback to clinicians about patients who may benefit from de-escalation of their medications. Some patients identified as potentially overtreated may be receiving multiple medications to treat other conditions like heart failure, and their treatment may thus be appropriate. Furthermore, lack of benefit and possible harm of aggressive treatment for DBP and SBP has not been incorporated in national guidelines, and one would expect the number of potentially overtreated to decline if guidelines are modified. However, because this study found that there is substantial site-level variation in potential overtreatment and that sites with higher rates of meeting current measures are more likely to overtreat, there is no doubt that we need to further examine the aggressive use of medications among patients with low DBPs. Indeed, the measure we constructed likely underestimates the full extent of potentially hazardous, aggressive, and wasteful use of medications because we only considered low DBP as evidence of overtreatment if SBP was also low (<130 mm Hg) and further if there was in-

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**Table 2. Reasons for Passing the Clinical Action Measure for Hypertension Management Among 713,790 Patients With Diabetes Mellitus (Age 18-75 Years)**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Hierarchical, No. (%)a</th>
<th>Total, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index SBP &lt;140 mm Hg and DBP &lt;90 mm Hg</td>
<td>583,338 (82)</td>
<td>583,338 (82)</td>
</tr>
<tr>
<td>Index SBP &lt;150 mm Hg and DBP &lt;65 mm Hg</td>
<td>5946 (1)</td>
<td>149,497 (21)</td>
</tr>
<tr>
<td>Index SBP &lt;150 mm Hg and receiving ≥3 moderate-dose BP medications</td>
<td>13,725 (2)</td>
<td>105,813 (15)</td>
</tr>
<tr>
<td>Appropriate clinical action within 90 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase dose of existing BP medication</td>
<td>56,985 (8)</td>
<td>233,255 (33)</td>
</tr>
<tr>
<td>Start a new BP medication, or switch a BP medication class</td>
<td>8216 (1)</td>
<td>149,290 (21)</td>
</tr>
<tr>
<td>Repeated SBP measurement &lt;140 mm Hg and DBP &lt;90 mm Hg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meets the clinical action measure</td>
<td>668,210 (94)</td>
<td>668,210 (94)</td>
</tr>
<tr>
<td>Does not meet the measure</td>
<td>45,580 (6)</td>
<td>45,580 (6)</td>
</tr>
</tbody>
</table>

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure. aPatient can meet the measure based on only 1 reason, in the order listed in the table.
tensification and/or use of 3 or more BP-lowering agents. The patients so identified had mean achieved BP values lower than those in the intensive therapy arm of ACCORD and are thus subject to similar adverse consequences. If we relax the criteria for potential overtreatment just slightly, to BP lower than 133/85 mm Hg, the rate of overtreatment increases to nearly 10%. Although we did not examine the effect of overtreatment on adverse outcomes in this cross-sectional study, given the lack of evidence from stronger randomized trial designs that such aggressive BP lowering improves outcomes, some could view this conservative marker of overtreatment marker as just the tip of the iceberg.

We report our results in 1 high-performing health care system, albeit one with nearly 1 million patients with DM getting regular primary care across nearly 900 sites of care. This system has a longer history with performance monitoring than many other systems. The drive to improve BP control in the VA has been based primarily on motivation from the facility or regional directors to achieve nationally specified goals for meeting measures. Health systems and health care providers with direct financial incentives to meet measurement goals may have even more incentive to overtreat.

Despite calls by others to stamp out clinical inertia, we found little evidence that veterans are currently being undertreated. We note that other high-performing systems, like Kaiser Permanente, have achieved similar results in BP management. While recognizing this impressive achievement, it appears that in the VA, rates of potential overtreatment are currently approaching, and perhaps even exceeding, the rate of undertreatment and that high rates of achieving current performance measurement targets are directly associated with medication escalation that may increase risk for patients. While there is no doubt that appropriate management of hypertension among patients with DM is of critical importance, our data suggest that the VA and other high-performing health systems may have reached the point when threshold measures for BP control have the potential to do more harm than good. Accordingly, the VA has made the decision to implement clinical action measures for purposes of internal tracking and account-
istorative, technical, and material support: Lucaorto, Hogan, and Klamerus. Study supervision: Kerr.

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Financial Disclosure: None reported. Funding/Support: This study was funded by grant VA QUERI RRP 09-111 from the Department of Veterans Affairs. Additional support was provided by the VA Diabetes Quality Enhancement Research Initiative (grant DB 98-001) and the Measurement Core of the Michigan Diabetes Research & Training Center (National Institute of Diabetes and Digestive and Kidney Diseases of The National Institutes of Health [grants P60 DK-20572]).

Disclaimer: The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs or the University of Michigan.

Online-Only Material: The eAppendix and eTable are available at http://www.archinternmed.com.

Additional Contributions: Joseph Francis, MD, MPH, Stephan Fihn, MD, MPH, Rodney Hayward, MD, and Steven Bernstein, MD, MPH, provided valuable input.

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How Do Guidelines Impact Measures of Performance?

Can They Keep Up?

I mproving quality of health care delivery has been a major focus since the publication of the Institute of Medicine report “Crossing the Quality Chasm.”

While concerns about funding and access to quality health care have not been resolved, there is overwhelming agreement that the foundation of efforts to improve care is predicated on outcomes measurement. ²

Since the 1980s, 2 professional societies, the American College of Cardiology (ACC) and the American Heart Association (AHA), have collaborated on guidelines for cardiovascular disease (CVD). The methodology is a rigorous, systematic, peer-review process of scientific evidence to develop documents that guide practice. ³

Performance measures developed for CVD are the logical progression following implementation of guidelines as an indicator of quality of delivered care. Similar rigorous methodology for performance measures was developed by the ACC/AHA Task Force on Performance Measures in 2000. ²

Categorized as either “performance measures” or “quality measures,” performance measures are designated as appropriate for both quality improvement and external reporting and quality measures are those appropriate for quality improvement and not for external reporting until further validation and testing. Performance measures are complex and, in the case of cardiac risk factors such as hypertension and lipid levels, have to address whether patients are “treated” and whether they achieve “control.” All measures have limitations and pose challenges to ensure that they are accurate reflections of intended outcomes, ie, measurement of blood pressure (BP) control. Reporting of performance measures is crucial to ensure that care is appropriately evaluated, modified, and improved to ensure that patients receive the highest levels of quality care.

In this issue of the Archives, findings on performance of 879 Department of Veterans Affairs (VA) medical centers and outpatient clinics for hypertension management in diabetic patients are presented. In this analysis of 713 790 patients treated during 2009-2010, Kerr et al ⁴ have developed a performance measure for BP that is linked to clinical action measures (systolic BP [SBP] <140/diastolic BP [DBP] <90 mm Hg; or SBP <150 mm Hg/DBP <65 mm Hg; or SBP <150 mm Hg and receiving ≥3 or more moderate-dose BP medications; or an appropriate clinical action within 90 days). This methodology is important because it allows for acknowledgment of reaching a specific risk factor level, while it also attributes credit for working to achieve a goal over time rather than a single point in time. The authors also specified a marker of potential hypertension overtreatment (SBP <130 mm Hg/DBP <65 mm Hg and either receiving ≥3 BP medications, starting a new BP medication class within 90 days, or receiving an increase in BP medication dose within 90 days of the index BP) to define a group of patients who may have received aggressive, potentially risky treatment.

One important aspect of this Commentary is to acknowledge the VA for its systemwide approach, commitment to quality care, and forward thinking to implement an electronic medical record system that permits analysis of care across their very large system using both clinical and pharmacy data. In the report by Kerr et al, ⁴ 94% of diabetic patients met the clinical action measure for BP (82% had a BP <140/90 mm Hg and 12% had a BP ≥140/90 mm Hg but appropriate management). The attainment of such a large percentage of patients who achieved performance measures is an outstanding accomplishment.

That being said, there are concerns with the performance measure definitions used in this report. The issues noted herein illustrate concerns regarding the complexity of developing performance measures and their applications. While intended use is always a function of quality improvement, there may be unintended potential use as scorecards for health systems and individual practitioners in a more punitive way. The first concern is that the performance measure does not match available guideline recommendations at the time the index BPs were collected. The available hypertension and diabetes guidelines were the Seventh Report of the Joint National Committee (JNC7) hypertension guidelines published mid 2003 ⁵ and the 2009 American Diabetes Association (ADA) guidelines ⁶ Blood pressure goals for diabetic patients in JNC7 were SBP lower than 130 mm Hg/DBP lower than 80 mm Hg, and the ADA recommended the same. Neither guideline specified a lower threshold; however, the