# New Diabetes HEDIS Blood Pressure Quality Measure: Potential for Overtreatment

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**Objective:** To examine reasons for failing to meet the new Healthcare Effectiveness Data and Information Set (HEDIS) blood pressure (BP) measure for diabetes patients (BP <130/80 mm Hg), which may not accurately identify poor-quality care and could promote overtreatment through its performance incentives.

**Study Design:** Retrospective chart review.

**Methods:** We formed 2 cohorts of diabetes patients in 9 general medicine clinics in an academic healthcare system. Cohort A (n = 124) failed the new HEDIS measure but passed the old measure (systolic blood pressure [SBP] 130-139 and diastolic blood pressure [DBP] <90 mm Hg; or SBP <140 and DBP 80-89 mm Hg). Cohort B (n = 125) failed the old measure (SBP ≥140 and/or DBP ≥90). We reviewed medical records to ascertain clinician response to elevated BP.

**Results:** Physicians documented treatment changes in only 4% and 28% of cohort A and B patients, respectively. Refractory systolic hypertension was common in those aged ≥65 years; 60% of those in cohort B and 58% in cohort A took 3 or more antihypertensive medications and/or had a diastolic BP below 70 mm Hg.

**Conclusions:** We identified a substantial cohort of elderly diabetes patients with DBP <70 mm Hg who were on 3 medications at adequate doses, but who did not meet the current performance measurement criteria (140/90 or 130/80 mm Hg). We suggest that such patients be excluded from performance measures, or if included, be noted for special attention by clinicians to balance intensification with risk.

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Aggressive management of hypertension in patients with diabetes mellitus is one of the most beneficial treatments in medicine. The UKPDS (United Kingdom Prospective Diabetes Study) and HOT (Hypertension Optimal Treatment) trials demonstrated that for patients with diabetes and marked hypertension, taking up to 3 to 4 blood pressure (BP) medicines substantially decreases both macrovascular and microvascular diabetic complications, including stroke, heart attack, and visual impairment.[1,2] These trials usually targeted lowering diastolic blood pressure (DBP), so recommendations for systolic blood pressure (SBP) targets come from cohort analyses of these trials, which have consistently found a continuous log-linear relationship between lower SBP and lower cardiovascular (CV) risk at least down to an SBP of 130 mm Hg.[2,3] However, cohort studies also have consistently found that once a patient's SBP is considered, elevated DBP is no longer an independent CV risk factor and that a DBP <70 mm Hg is associated with an exponential increase in CV mortality in older patients.[2-4] To encourage aggressive treatment of hypertension, the National Committee for Quality Assurance recently adopted a new Healthcare Effectiveness Data and Information Set (HEDIS) BP performance measure of <130/80 mm Hg for patients with diabetes (the clinical goal in the American Diabetes Association and Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure [JNC 7] guidelines),[5,6] in addition to the established HEDIS BP performance measure of ≤140/90 mm Hg.[7]

Although there is near-universal agreement on the benefits of aggressive BP treatment for those with diabetes, the new HEDIS BP performance measure of <130/80 mm Hg for diabetes has generated considerable controversy. For example, this measure was adopted despite the objections of the Technical Expert Panel of the National Diabetes Quality Improvement Alliance.[4] One concern about this quality measure was that unadjusted BPs may be an unreliable measure of quality, especially because the severity of patients' hypertension and their age are known to greatly influence whether an SBP of <130 mm Hg is achievable.[1-3] Although substantial research suggests that well-constructed process measures often show better quality in sicker patients,[8] this is not always true of unadjusted outcome measures. Therefore, an unadjusted BP performance measure of <130/80 mm Hg would be expected to systematically penalize those caring for

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**Take-Away Points**

There are concerns that the new Healthcare Effectiveness Data and Information Set (HEDIS) diabetes blood pressure measure may not accurately identify poor-quality care and could promote overtreatment through its performance incentives.

- The new HEDIS blood pressure measure commonly mislabeled patients as being inadequately treated, especially elderly patients.
- New blood pressure measures should be developed to encourage aggressive treatment of hypertension without unduly promoting overtreatment.

sicker and older patients. A second concern was that this measure could create performance incentives for overtreating refractory systolic hypertension, leading to potential patient harm from polypharmacy and pushing DBP substantially below 70 mm Hg.[2,4,9]

Because of the above concerns, the National Diabetes Quality Improvement Alliance's Technical Expert Panel recommended that the new HEDIS BP performance measure of <130/80 mm Hg should exclude those patients requiring more than standard doses of 3 to 4 BP medications, as well as those patients whose DBPs are <70 mm Hg. However, not knowing which medications were permissible and having no dosing information made the medication exception infeasible.

We could find little evidence in the medical literature regarding how often the circumstances that are of concern with the new HEDIS criteria actually occur in a primary care diabetes population. Therefore, we examined BP levels and medication treatment intensity in patients with diabetes receiving primary care in a large academic healthcare system. We were interested in the circumstances surrounding those patients with diabetes who failed to meet the new HEDIS BP performance measure of <130/80 mm Hg (with special attention to those whose BP was <140/90 but not <130/80 mm Hg) and examined the proportion of patients (1) who already were on moderate doses of 3 or more BP medications (the maximum therapy examined in most clinical trials) and (2) who already had a DBP of <70 mm Hg (the flexion point in cohort studies at which CV mortality starts to substantially increase).[2,9] In addition, we examined whether there were differences in the above factors between patients age 65 years and older compared with those younger than age 65 years, as older individuals are more prone to refractory systolic hypertension.

## METHODS

### Study Design and Patient Population

This is a retrospective, descriptive study of patients cared for in 9 general medicine outpatient clinics of a large academic healthcare system. The majority of clinics are located in community settings in which patients are cared for by full-time clinicians. Adult patients were identified from a validated diabetes registry developed by our healthcare system, which includes more than 11,000 patients. Although the Diabetes Alliance Technical Expert Panel recommended that the BP measure only be applied to those with hypertension, the new HEDIS measure was applied to all patients with diabetes, mainly because of the difficulty in obtaining accurate information on which patients were previously diagnosed with hypertension. In addition, our population differed slightly from HEDIS specifications because HEDIS was developed for defined managed care populations and our registry includes all patients with diabetes regardless of insurance (eg, fee-for-service, managed care, Medicaid, Medicare). Therefore, we used an adaptation of the HEDIS denominator population specifications in our study. The registry includes all outpatient BP readings documented either in the vital signs component (which includes BP) of the health system electronic medical record's vital signs, or from outpatient physician progress notes. We selected 2 patient cohorts for this study. Cohort A included patients with diabetes whose most recent BP did not meet the new HEDIS quality indicator of BP <130/80 mm Hg, but who would have been considered in compliance with the established HEDIS BP criterion of BP <140/90 mm Hg. These patients had either an SBP of 130 to 139 and a DBP of <90 mm Hg or an SBP of <140 and a DBP of 80 to 89 mm Hg. Cohort B included patients whose SBP was ≥140 and/or whose DBP was ≥90 mm Hg and thus did not meet the established HEDIS criterion for patients with diabetes.

We reviewed the electronic medical records of a randomly selected sample of 398 patients from the Diabetes Registry who met the inclusion criteria, 195 in cohort A and 203 in cohort B. Patients were excluded from the study (37 and 43 patients from cohorts A and B, respectively) if their most recent visit with an elevated BP was with a provider who does not routinely address hypertension (eg, an ophthalmologist, a podiatrist). Patients also were excluded (8 and 10 patients from cohorts A and B, respectively) if on full chart review the lowest BP reading recorded at the visit was <130/80 mm Hg or if the patient did not have diabetes. Consistent with HEDIS measurement criteria, patients over age 75 years were excluded (26 and 25 patients from cohorts A and B, respectively), leaving 124 patients in cohort A and 125 patients in cohort B. The study period was from June 2005 through November 2007. The study was approved by our institutional review board.

The review confirmed the diagnosis of diabetes and, beginning with the patient's most recent clinic visit as the in-

**Table 1.** Clinical Characteristics of the Patients With Diabetes, by Blood Pressure Group

| Characteristic | All Patients (n = 249) | Cohort A (n = 124)[a] | Cohort B (n = 125)[b] |
|---|---|---|---|
| Age, mean (SD), y | 57.6 (11.0) | 57.0 (11.6) | 58.2 (10.3) |
| Age, median (range), y | 57 (26-75) | 56 (26-75) | 60 (30-75) |
| Male, % | 50.6 | 50.8 | 50.4 |
| Hemoglobin A1C <9%, % | 89.1 | 90.3 | 87.9 |
| Hemoglobin A1C <7%, % | 51.4 | 53.7 | 49.2 |
| LDL-C <130 mg/dL, % | 81.9 | 80.7 | 83.2 |
| LDL-C <100 mg/dL, % | 60.2 | 59.7 | 60.8 |

A1C indicates glycosylated hemoglobin; LDL-C, low-density lipoprotein cholesterol.
[a]Cohort A had either systolic blood pressure of 130-139 and diastolic blood pressure of <90 mm Hg *or* systolic blood pressure of <140 and diastolic blood pressure of 80-89 mm Hg.
[b]Cohort B had systolic blood pressure of >140 and/or diastolic blood pressure of >90 mm Hg.

dex visit, collected the following data from the chart review or the registry: age, sex, most recent BP measurement, glycosylated hemoglobin, low-density lipoprotein cholesterol, class and doses of antihypertensive medications, and physician response to the elevated BP (no change in BP medications, increase dose of BP medications, or start a new BP medication) as well as the reasoning behind the treatment decision.

### Data Analysis

Descriptive analysis is presented by using means and standard deviations. Frequency data are presented by using count and percentage. To compare patients by age group, a *t* test (continuous data) or a $\chi^2$ test (categorical data) was used. All analyses were performed with Stata, version 8.1 (StataCorp, College Station, TX).

## RESULTS

Among patients in the diabetes registry, 44% met the new HEDIS BP criteria of <130/80 mm Hg and were excluded from this study. The clinical characteristics of the patients with diabetes who did not meet the established and new HEDIS BP performance measures are summarized in Table 1. The patients' mean age was 58 years, and 51% were male. More than half the patients seen in these clinics met the HEDIS performance measure for glycosylated hemoglobin (<7%), and three-fifths met the HEDIS performance measure for low-density lipoprotein (<100 mg/dL). Overall, the age distribution and HEDIS measures were similar to those of other high-performing health systems reported in the literature.[10]

Blood pressures and medications for those not at recommended BP goals are summarized in Table 2. Among cohort A patients (those meeting the established HEDIS criteria but not the new tight control criteria), 72% were on an antihypertensive medication. Among cohort B patients, who had an elevated BP defined as an SBP of ≥140 and/or a DBP of ≥90 mm Hg, 84% were on at least 1 antihypertensive medication and 31% were on 3 or more antihypertensive medications. Across both cohorts, the most commonly prescribed initial medication was an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB). Among patients on at least 2 antihypertensive medications, more than 90% were on an ACEI or ARB and three-quarters were on a thiazide diuretic, and low and subtherapeutic doses were extremely rare in those not at goal.

For patients with elevated BPs, physicians made and documented treatment changes in 4% and 28% of the patients in cohorts A and B, respectively. During routine follow-up patient visits at which no therapeutic changes were made or documented, the most common reason noted in the medical record was that the physician was satisfied with the BP control (17%), but in a large number of records the clinician did not address the high BP at the visit (46%).

There were significant differences between those patients age 65 years and older and those younger than age 65 (Table 3). Patients age 65 or older were 4 to 6 times more likely than younger patients to have a DBP <70 mm Hg ($P$ <.001). Among older patients in cohort A, 47% were found to have a DBP of <70 mm Hg and 29% were on 3 or more antihypertensive medications at moderate or higher doses. Furthermore, most older patients in both cohorts were found to have a DBP of <70 mm Hg and/or to be on 3 or more antihypertensive medications (58% in cohort A and 60% in cohort B, compared with 20% and 37% in younger patients).

## DISCUSSION

Despite the near-universal agreement on the benefits of using 3 to 4 antihypertensive medications in pursuit of optimal BP control, some critics have questioned the merit of using BP goals and other surrogate outcome measures as performance standards.[4,11] Therefore, we examined the circumstances sur-

**Table 2.** Blood Pressures and Medications for Patients Not at Recommended BP Goals

| Medical Record Data | Cohort A[a] | Cohort B[b] |
|---|---|---|
| **BP level, mm Hg** | | |
| SBP, mean (SD) | 128.3 (6.8) | 148.0 (11.4) |
| SBP <130, % | 37 | 2 |
| DBP, mean (SD) | 76.4 (8.4) | 79.0 (11.1) |
| DBP <80, % | 39.5 | 47.2 |
| DBP <70, % | 19 | 18 |
| **Number of antihypertensive agents, %** | | |
| None | 28 | 16 |
| 1 | 24 | 32 |
| 2 | 28 | 21 |
| 3 or more | 20 | 31 |
| **DBP <70 mm Hg or patient on ≥3 antihypertensive agents, %** | 31 | 43 |
| **Antihypertensive medication class for patients on only 1 medication, %** | | |
| ACEI or ARB | 65 | 60 |
| Thiazide diuretic | 21 | 18 |
| Beta-blocker | 14 | 18 |
| Calcium channel blocker | 0 | 5 |
| **Antihypertensive medication class for patients on 2 or more medications, %** | | |
| ACEI or ARB | 92 | 91 |
| Thiazide diuretic | 75 | 75 |
| Beta-blocker | 50 | 57 |
| Calcium channel blocker | 32 | 54 |
| **Clinician response to elevated BP, %** | | |
| No change in BP medications | 96 | 72 |
| Increase dose of BP medication(s) | 2 | 14 |
| Start a new BP medication | 2 | 14 |

ACEI indicates angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.
[a]Cohort A had either SBP of 130-139 and DBP of <90 mm Hg *or* SBP of <140 and DBP of 80-89 mm Hg.
[b]Cohort B had SBP of >140 and/or DBP of >90 mm Hg.

rounding those patients who failed to meet the HEDIS diabetes BP performance measures (with special attention to those with a BP of ≥130/80 and <140/90). We found that clinicians often did not act on BPs within this range, but whether this inaction reflects clinical inertia or patient-specific clinical concerns (ie, medication nonadherence) remains unknown.[12] The clinicians may not have taken action based on clinical judgment, as HEDIS measurement does not apply to every patient. In our study, three-fifths of those patients age 65 years or older who failed to meet the new HEDIS criteria would have met the Diabetes Alliance Technical Expert Panel recommendations for appropriate management (ie, being on 3 or more antihypertensive medications at standard doses and/or having a DBP of <70 mm Hg); this combination of circumstances also was common among those not meeting the established measure (<140/90 mm Hg). Undertreatment was more common in younger patients who did not meet the HEDIS criteria, but about 1 in 5 patients in cohort A and 1 in 3 patients in cohort B had a DBP of <70 mm Hg and/or were on 3 or more medications.

The number of patients with poor BP control on fewer than 3 medications who did not have their elevated BP addressed or medications increased confirms persistent problems with treating hypertension in patients with diabetes. However, our results suggest that patients not meeting the new HEDIS measure frequently fall into categories in which there is considerable controversy about the effectiveness and safety of further intensification, and that these situations occur much more commonly in the elderly. To date, no study has examined the safety or benefit of using more than 3 to 4 BP medications in pursuit of BP less than 130/80 mm Hg. A recent study showed combining an ACEI and an ARB in high-risk diabetes patients resulted in a reduction of SBP of 2 to 3 mm Hg compared with a single agent, but no benefit in primary outcomes was seen and combination therapy resulted in more adverse events.[13] Because the benefit of lower SBPs has clear diminishing returns, especially after an SBP <140 mm Hg is achieved,[2,14] any increase in harm that may occur due to multidrug treatment of mild refractory systolic hypertension could negate the small expected benefits of adding more antihypertensive medications. Of note, none of the studies used by advocates to support the SBP goal of <130 mm Hg achieved this goal in even half of the "tight control" study patients. The mean SBP achieved in the intensive BP treatment group was 135 mm Hg in the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), 140 mm Hg in the HOT trial, and 144 mm Hg in the UKPDS.[1,2,15] Finally, the same cohort studies that suggest a small benefit from reducing SBP from 140 to 130 mm Hg also found a large increase in CV mortality in patients with DBP below 70 mm Hg, especially

**Table 3.** Diastolic Blood Pressure and Antihypertensive Medications by Age

| Characteristic | Cohort A[a] | | Cohort B[b] | |
|---|---|---|---|---|
| | <65 y | ≥65 y | <65 y | ≥65 y |
| **Number of patients** | 86 | 38 | 90 | 35 |
| **DBP <70 mm Hg, %** | 7 | 47[c] | 10 | 40[c] |
| **Number of antihypertensive agents, %** | | | | |
| None | 30 | 24 | 19 | 9 |
| 1 | 29 | 11 | 30 | 37 |
| 2 | 25 | 37 | 21 | 20 |
| 3 | 16 | 29 | 30 | 34 |
| **DBP <70 mm Hg and/or patient was on ≥3 antihypertensive agents, %** | 20 | 58[c] | 37 | 60[d] |

DBP indicates diastolic blood pressure; SBP, systolic blood pressure.
[a]Cohort A had either SBP of 130-139 and DBP of <90 mm Hg *or* SBP of <140 and DBP of 80-89 mm Hg.
[b]Cohort B had SBP of >140 and/or DBP of >90 mm Hg.
[c]$P < .001$.
[d]$P < .05$.

in those with refractory systolic hypertension for whom pulse pressures became high. Although many argue that this association is not causal, this finding has been found consistently in the best available epidemiologic evidence. A plausible biologic mechanism exists—the heart is unique in getting most of its circulation during diastole. If this finding is causal, then overaggressive treatment of refractory systolic hypertension could substantially increase risk of CV mortality.[2,4,9,16]

These findings do not suggest that further efforts to improve BP control in these patients are necessarily inappropriate, only that the treatment is controversial and goes beyond the current evidence. It seems likely that those patients on 3 to 4 medications but not at the BP goal are a heterogeneous group, including (1) those who are refractory to treatment, (2) those who are optimally treated but had an isolated elevated measure at their last visit, (3) those who are nonadherent to treatment, and (4) those for whom a different combination of medications might work better. Providers and healthcare systems should be encouraged to work with patients by using a shared decision-making process to address nonadherence and optimize antihypertensive treatment. Some might argue that concerns about overtreatment are unfounded, because providers should not worry about a measure when further treatment is not in the patient's best interest and that these measures are meant to be used at the population level, not for guiding individual decisions. This point of view can be quite valid when exceptions to the rule are infrequent or when the costs and risks of further intervention are small, but we personally believe this argument is not valid when a large proportion of those not meeting the measure are receiving care that is appropriate, or even preferable, to costly and potentially harmful care that is encouraged and rewarded by the measure.[4,17,18]

Therefore, our results suggest that the conditions that concerned the Diabetes Technical Expert Panel and the American College of Physicians' Guideline Committee are common, warranting a re-examination of the new, and perhaps even the established, HEDIS BP measures. A commentary written by Pawlson states that the National Committee for Quality Assurance is in full agreement that more refined measures are needed.[19] However, he notes that lack of funding and difficulties in obtaining clinically detailed data are barriers to advancing ambulatory care quality measures. One simple refinement that would not require the collection of additional data would be to count the BP measure as being met when either (1) DBP is <80 and SBP is <130 mm Hg or (2) DBP is <70, thus no longer requiring further intensification once a patient's DBP drops below 70 mm Hg. This would not completely address the concern about promoting polypharmacy, especially in younger patients with marked hypertension, but would address concerns about potential dangers in pushing DBP to low levels in those with refractory systolic hypertension. This change in the performance measure also could potentially decrease inequities in the measure's accuracy related to case mix, especially the age and hypertension severity of a clinician or healthcare system's patient population. Although a new performance measure perhaps is not currently feasible in most healthcare systems because of limitations in data availability, some might argue that a more optimal measure also would give credit if the patient is on adequate doses of at least 3 BP medications and the medical record documents that the primary care physician or the healthcare team/system has addressed medication adherence, used shared decision making, and offered case management for further treatment intensification when desired by the patient.

### Limitations

This study reflects care of patients managed at 1 academic medical center, and the results may not generalize to other settings. However, these patients were cared for primarily by full-time clinicians and represent more than 4700 patients with diabetes. In addition, this study reports on patients seen between 2005 and 2007, and may not reflect current care. Finally, the information on a clinician's reason for not intensifying treatment was limited to medication interventions and what was recorded in the medical record.

## CONCLUSION

We identified a substantial cohort of elderly patients with diabetes and a DBP <70 mm Hg who were on 3 antihypertensive medications at standard doses but who did not meet the current performance measurement thresholds for treatment of hypertension (<140/90 or <130/80 mm Hg). We suggest that such patients be either excluded from performance measures or be noted for special attention by clinicians to balance intensification with risk if they are included.

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