

## How Do Minor Changes in the Definition of Blood Pressure Control Affect the Reported Success of Hypertension Treatment?

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**Objective:** In 1999, the first reporting year of the Health Plan Employer Data and Information Set, our organization noted a significant difference in the proportion of patients with controlled blood pressure (BP) when the target was changed from  $< 140/90$  mm Hg to  $\leq 140/90$  mm Hg. We compared these data with a second larger dataset to determine if these findings were an isolated or common phenomenon and to determine what factors influenced this difference.

**Study Design and Methods:** Subjects were drug-treated hypertensive patients. Blood pressure measurements were taken from outpatient medical records.

**Results:** The percent of hypertensive patients with controlled BP levels was significantly greater ( $P < .001$ ) when the cutoff of  $\leq 140/90$  mm Hg was used rather than  $< 140/90$  mm Hg. When a single BP measurement was used to estimate control, the percent of patients with controlled hypertension increased 12.7% simply by changing the definition to include the level of systolic BP = 140 mm Hg or diastolic BP = 90. When multiple BP readings were used to estimate control, the difference was much less pronounced (2.7%).

**Conclusions:** When evaluating the success of hypertension treatment, defining BP control as a BP of  $\leq 140$  mm Hg systolic and  $\leq 90$  diastolic mm Hg will result in significantly more people having controlled BP than when  $< 140$  mm Hg systolic and  $< 90$  mm Hg diastolic are used. This difference is most likely the result of end-digit preference. The use of multiple measures reduces this effect. Policy makers and guideline authors should consider these aspects when setting BP goals.

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diastolic.<sup>1</sup> Between 1991 and 1994, only 27.9% of the US population with hypertension had a BP  $< 140/90$  mm Hg.<sup>2</sup>

Blood pressure measurement is difficult to obtain accurately.<sup>3</sup> Equipment and observer error is well known despite established standards for obtaining BP measurements.<sup>1</sup> End-digit preference or the observer's tendency to round measurements to the nearest zero is a well-recognized error that reduces measurement precision.<sup>3-5</sup>

The National Committee for Quality Assurance (NCQA) is a private, nonprofit entity that publishes measurements of quality known as the HEDIS score (Health Plan Employer Data and Information Set). HEDIS is a set of standardized performance measures designed to ensure that purchasers and consumers have the information they need to compare the performance of managed health care plans. In 1999, HEDIS included a measure for adequate control of treated hypertension that was identical to the JNC VI recommendation of a BP  $< 140/90$  mm Hg. This number is obtained by averaging the BP of patients on medications for hypertension using the last 1 to 3 clinic visits in the measuring year. If fewer than 3 BPs are available then the 1 BP measurement or 2 averaged are reported. In the year 2001, the HEDIS definition of hypertension control was changed to a BP  $\leq 140/90$  mm Hg ( $\leq 140$  mm Hg sys-

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Despite the established importance of recognizing and treating elevated blood pressure in reducing cardiovascular events and deaths, adequate control of blood pressure (BP) among the US population with hypertension remains elusive. In the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI), adequate control of hypertension was defined as a blood pressure of  $< 140$  mm Hg systolic and  $< 90$  mm Hg

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tolic and  $\leq 90$  mm Hg diastolic). They observed in the audited charts that many providers rounded off these numbers.

We wanted to determine the effects of including the level of 140/90 mm Hg as controlled. Specifically, how does this change affect managed care plans' quality assessments and what is the potential impact on health outcomes? We report here 2 datasets in which this bias may have significantly affected medical-record-based indices of antihypertensive treatment success.

## METHODS

Subjects were obtained from 2 datasets, both drawn from patients belonging to Group Health Cooperative of Puget Sound (GHC) a large, nonprofit health maintenance organization in the Pacific Northwest with a total enrollment of more than 500,000 patients. At GHC, wall-mounted aneroid sphygmomanometers are used.

The first reporting year of HEDIS in 1999, our organization noted a significant difference in the proportion of patients with controlled BP when the target was changed from  $<140/90$  mm Hg to  $\leq 140/90$  mm Hg. We compared these numbers with a second larger dataset to determine if this difference was an isolated or a common phenomenon and to determine factors that influenced this change.

The first sample of patients was obtained from charts audited for the first recording year (1999) of the HEDIS measurement for control of hypertension at GHC. The methods of patient selection and BP measurement used were according to the criteria set by the HEDIS tool for Medicare and non-Medicare populations. The denominator consisted of patients aged 46 to 85 years who had at least 1 outpatient visit with an ICD-9 diagnosis code of 401 during the first 6 months of the measurement year and had no history of previous myocardial infarction or end-stage renal disease. The diagnosis of hypertension was confirmed by chart review. Adequate control in this first set, defined as both a representative systolic BP  $<140$  mm Hg and a diastolic BP  $<90$  mm Hg, was determined by using the BP measurement recorded at the most recent outpatient visit during the measurement year, as long as the visit occurred after the diagnosis of hypertension was made. If no BP was recorded during the measurement year, the patient was defined as "not controlled." Blood pressure measurements taken

during diagnostic or surgical procedures (eg, stress test, sigmoidoscopy, or removal of a mole) or an emergency room visit were not included. Blood pressures that were self-reported by the patient were also not included. Patients with end-stage renal disease or a history of previous myocardial infarction were excluded.

The second dataset was a random sample of GHC enrollees during 1989 through 1994 who were being treated with medications for hypertension. These subjects were drawn from the control groups of ongoing case-control studies of cardiovascular disease at GHC's Cardiovascular Health Research Unit, and were frequency matched to incident cases of myocardial infarction by decade of age, sex, and year of enrollment. Subjects were eligible if they were between the ages of 30 and 79 years and if they had had at least 4 prior visits to a GHC provider. Those who had had a history of previous myocardial infarction were excluded. Each subject was assigned a randomly selected reference date. We defined the achieved BP as the mean of the last 3 BP readings recorded in the medical records during the year prior to the reference date. We did not include readings made prior to the initiation of antihypertensive treatment. We excluded control subjects whose medical records did not contain any achieved BP readings within the prior year. Three achieved BP readings were available for most subjects, although 362 (17%) patients had only 2 available BP readings and 291 (14%) patients had only 1 available BP reading.

We measured the difference in percent of patients with controlled hypertension when the cutoff for adequate control was defined as BP of  $<140$  mm Hg systolic and  $<90$  mm Hg ( $<140/90$  mm Hg) diastolic versus BP of  $\leq 140$  mm Hg systolic and  $\leq 90$  mm Hg diastolic ( $\leq 140/90$  mm Hg). Confidence intervals for proportions were constructed using exact binomial methods. McNemar's test was used to evaluate differences between alternate criteria for BP control. To look at the effect of using 1 versus 2 or 3 BP measurements on the definitions of control we used the most recent BP as the reference for 1 measurement, and the average of the 2 and 3 most recent BPs as "2 measurements" and "3 measurements."

## RESULTS

**Table 1** shows the characteristics of GHC enrollees treated with medications for hypertension from dataset 2 (complete information was not available for dataset 1, the HEDIS sample). The mean age

was 66 years, 72% were men, and 90% were Caucasian. For 69% of the dataset 2 populations the medical chart contained at least 1 BP recording prior to the initiation of medication, with a mean BP of 157/96 mm Hg before treatment. Most of the patients had combined systolic and diastolic hypertension (72%). Isolated systolic hypertension was uncommon under age 50 (5%) but occurred in 28% in those who were aged 60 to 69 years and in 44% at ages 70 to 79 years. An average of 2.8 BPs were recorded before treatment, showing that most of the time physicians were adhering to the JNC VI recommendation to measure BP 3 times before treating hypertension.

**Table 2** and **Figure 1** shows the results for control of hypertension for the 2 datasets. The criteria to determine average BP for the index year for each dataset were similar. For the HEDIS sample, the report separates Medicare patients from the commercial non-Medicare patients. In all 3 groups, the percent of individuals with controlled hypertension was significantly greater ( $P < .001$ ) when the cutoff of  $\leq 140/90$  mm Hg was used rather than  $< 140/90$

mm Hg. The percent of patients with controlled hypertension increased by 5% to 10% ( $P < .001$ ) just by changing the definition of controlled BP by 1 point.

**Figure 2** shows the relationship of age to controlled BP based on the target used for dataset 2. Blood pressure control tended to decrease with

**Table 1.** Characteristics of GHC Adult Enrollees With Treated Hypertension 1989–1994\*

Characteristic	Value
N	2136
Mean age, y	66 (range, 32-79)
Male	72%
White	90%
Mean number of treated BP readings in chart	2.6
Mean BP in treated hypertensives	145/85 mm Hg
Number (%) with BP recordings before treatment	1465 (69%)
Mean BP before treatment	157/96 mm Hg
Number (%) with both systolic and diastolic hypertension <sup>†</sup>	1055 (72%)
Number (%) with isolated diastolic hypertension <sup>†</sup>	132 (9%)
Number (%) with isolated systolic hypertension <sup>†</sup>	278 (19%)

Values taken from dataset 2.

\*Random sample of treated hypertensive GHC enrollees without prior myocardial infarction.

<sup>†</sup>Category of hypertension (in individuals with pretreatment BPs) defined as follows: systolic and diastolic hypertension (systolic BP  $\geq 140$  mm Hg and diastolic BP  $\geq 90$  mm Hg), isolated systolic hypertension (systolic BP  $\geq 140$  mm Hg and diastolic BP  $< 90$  mm Hg), and isolated diastolic hypertension (systolic BP  $< 140$  mm Hg and diastolic BP  $\geq 90$  mm Hg).

BP indicates blood pressure; GHC, Group Health Cooperative of Puget Sound.

**Table 2.** Percent of Patients With Controlled Hypertension Based on Set-Point Definition of Control

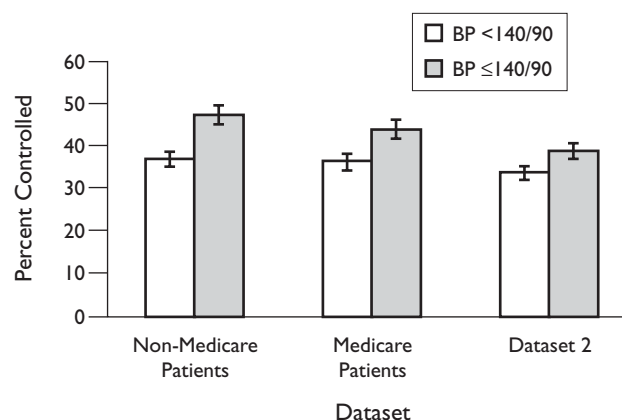
	BP < 140/90 mm Hg		BP $\leq$ 140/90 mm Hg	
	n/N (%)	95% Confidence Interval	n/N (%)	95% Confidence Interval
<b>Dataset 1</b>				
Non-Medicare patients	153/411 (37.2%)	32.4%-2.0%	195/411 (47.4%)*	42.5%-52.4%
Medicare patients	149/411 (36.3%)	31.5%-41.1%	180/411 (43.8%)*	38.9%-48.7%
<b>Dataset 2<sup>†</sup></b>	715/2136 (33.5%)	31.5%-35.5%	823/2136 (38.5%)*	36.5%-40.6%

\*These 2 definitions of controlled BP give statistically different proportions of control ( $P < .001$  by McNemar's test).

<sup>†</sup>Based on average of up to 3 BP readings.

BP indicates blood pressure.

**Figure 1.** Percent Controlled Blood Pressure Based on Whether Target Was <140/90 or ≤140/90 (with 95% Confidence Intervals)



increased age. When the target for BP control was changed from <140/90 to ≤140/90 mm Hg, the difference between patients with uncontrolled versus controlled BP trended upward; we found a 4% difference at age < 40 years and a 8% to 9% difference at age 60 and older. Based on patients with BP recorded prior to treatment in dataset 2, we observed that 69% of individuals with elevated systolic BP experienced reductions in systolic pressure by 20 mm Hg or more after treatment with medications. In terms of target systolic rates, however, only 41% were ≤140 mm Hg and only 33% were <140 mm Hg.

Subjects in dataset 2 had from 1 to 3 BP measurements in the recording year. **Table 3** stratifies the patients by the number of BP recordings. When only

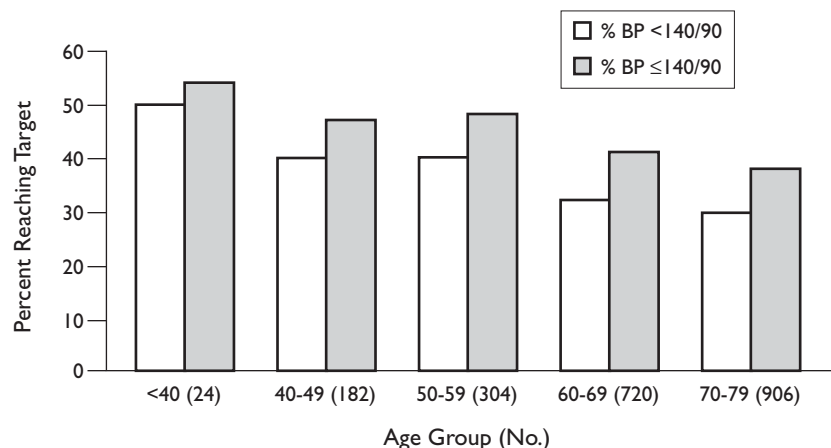
1 BP was used to determine BP for the reference year, 11% had a systolic BP of exactly 140 mm Hg, and 11.8% had a diastolic BP of exactly 90 mm Hg. Using only 1 BP reading, a total of 12.7% had (i) systolic blood pressure (SBP) <140 mm Hg and diastolic blood pressure (DBP) = 90 mm Hg, (ii) SBP = 140 mm Hg and DBP <90 mm Hg, or (iii) SBP = 140 mm Hg and DBP = 90 mm Hg. This percentage represents the group that would be defined as controlled according to the HEDIS 2001 cutoff, but not controlled according to the HEDIS 2000 and JNC VI cutoff. When 2 BP measurements were used to determine average BP, this group was substantially smaller (4.8%), and was further diminished when 3 BP measurements were used (2.7%).

DISCUSSION

We conclude that the use of HEDIS criteria defining normotension as ≤140 mm Hg systolic and ≤90 mm Hg diastolic will result in significantly more patients being considered as having controlled BP than when the JNC VI criteria of <140 mm Hg systolic and <90 mm Hg diastolic are used. This phenomenon is particularly pronounced when fewer than 3 measurements are used to determine BP level.

It is well established that control of hypertension decreases cardiovascular-related morbidity and mortality. Optimal systolic and diastolic BP goals for decreasing adverse cardiovascular events are still uncertain. The JNC VI and other agencies in the United States have chosen a BP of under 140 mm Hg systolic and 90 mm Hg diastolic as representing best control. Originally, the NCQA chose the same BP goal for its HEDIS measure. For the 2001 reporting year, the HEDIS measure of controlled BP was changed by the NCQA from < 140/90 to ≤ 140/90 mm Hg.<sup>6</sup> A policy analyst from NCQA reported that “the change to accepting a BP reading of less than or equal to 140/90, from less than 140/90, was made to accommodate practitioners [who] round their reading results” (Russell P. Evans, personal communication, February 3, 2003).<sup>11</sup> This rounding was found in the field during the first year of implementation. The change was to give practitioners the benefit of

**Figure 2.** Blood Pressure Control by Target and Age



**Table 3.** Achieved Blood Pressure Among Treated Hypertensive Patients, Measured by Average of 3, 2, or 1 Recent Measurements

	<b>SBP &lt; 140</b>	<b>SBP = 140</b>	<b>SBP &gt; 140</b>	<b>Total</b>
	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n</b>
3 SBP measurements	603 (40.7)	29 (2.0)	850 (57.4)	1482
2 SBP measurements	755 (41.0)	64 (3.5)	1024 (55.6)	1843
1 SBP measurement	830 (38.9)	235 (11.0)	1070 (50.1)	2135
	<b>DBP &lt; 90</b>	<b>DBP = 90</b>	<b>DBP &gt; 90</b>	<b>Total</b>
	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n</b>
3 DBP measurements	1106 (74.6)	46 (3.1)	330 (22.3)	1482
2 DBP measurements	1366 (74.1)	102 (5.5)	375 (20.3)	1843
1 DBP measurement	1460 (68.4)	252 (11.8)	423 (19.8)	2135
	<b>SBP = 140 and DBP &lt; 90 or SBP/DBP &lt; 140/90</b>			<b>Total</b>
	<b>SBP &lt; 140 and DBP = 90</b>	<b>SBP/DBP = 140/90</b>	<b>SBP/DBP &gt; 140/90</b>	<b>n</b>
	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n</b>
3 SBP/DBP measurements	518 (35.0)	40 (2.7)	0 (0.0)	924 (62.3)
2 SBP/DBP measurements	646 (35.1)	84 (4.6)	4 (0.2)	1109 (60.2)
1 SBP/DBP measurement	693 (32.5)	232 (10.9)	39 (1.8)	1171 (54.8)

DBP indicates diastolic blood pressure; SBP, systolic blood pressure.

the doubt, in relation to follow-up with members with hypertension.

Obtaining accurate BP measurements is difficult. Human and technical error frequently occurs. The American National Standards<sup>7,8</sup> for testing the accuracy of sphygmometers uses the standard that when BP machines are tested against a mercury manometer that 95% of the recordings should agree to within ± 10 mm Hg and 85% should agree to within 5 mm Hg; the mean difference between BP machines should be within 5 mm Hg with a standard deviation of 8. Machines thus vary, within an acceptable range. The variance between machines is likely to be random. Human error however, may include less random phenomena such as end-digit preference, with a preference to use zero or the desire to round numbers to the closest multiple of 2 or 5 (with preferences for 0, 5, and even digits).<sup>2-5</sup> This rounding could result in selective recording of BPs as 140 systolic and 90 diastolic as compared to 139 systolic and 89 diastolic. Our data derived from 3 groups of patients suggest that this phenomenon is

common and should be considered in measures of BP control, particularly if only 1 BP measurement is used to determine the success of treatment.

For some populations, such as for people with diabetes, BP targets lower than 139/89 mm Hg are recommended.<sup>9</sup> For other populations defined by age, sex, race, risk factors, and comorbidities, the ideal target for treated BP is controversial, particularly for systolic BP.<sup>10</sup> Choosing a single cutoff to define BP dichotomously as controlled or not controlled unfortunately ignores the overall distribution of what is a continuous variable. Observational studies show a direct continuous relationship between increasing BPs and cardiovascular events.<sup>11</sup> Lowering BP 1 mm Hg might result in a substantial reduction in cardiovascular events. It has been demonstrated, however, that the type of antihypertensive agents used may be more important than slightly tighter BP control.<sup>12,13</sup>

The Hypertension Optimal Treatment (HOT)<sup>14</sup> was designed to test whether lowering BP to less than 139/89 mm Hg would improve outcomes. Patients with uncontrolled hypertension were



randomly assigned to 1 of 3 diastolic BP targets:  $\leq 90$ ,  $\leq 85$ , or  $\leq 80$  mm Hg. For all subjects, no significant differences were noted in cardiovascular outcomes between the groups. On secondary analyses, subjects with diabetes benefited from tighter control, but patients without diabetes did not. When the investigators analyzed the trial data as an observational study, the risk of major cardiovascular events was lowest at a BP of 138/83 mm Hg. However, if diastolic or systolic BPs were evaluated separately, rates of cardiovascular events were similar for diastolic pressures between 80 and 90 mm Hg, and for systolic pressures from 130 to 150 mm Hg. When diastolic BP was lowered below 75 mm Hg, the cardiovascular benefits of treatment disappeared, suggesting a j-point phenomenon or that too much lowering of BP, if not harmful, is at least not helpful. The HOT trial failed to achieve major differences between BP groups, and some commentators have raised questions about the quality of this trial.<sup>15</sup> The HOT trial did not provide any definitive answers as to the benefits of tighter BP control.

Blood pressure readings vary over time,<sup>16</sup> by examiner skill, the measuring instrument used, and as we and others have reported, subject to end-digit reporting bias. When BP is very high, clinical decision-making is relatively straightforward. As BP comes closer to target, however, the variance of the readings obfuscates a precise definition of success. Automatic BP measuring devices have the potential to avoid many of these pitfalls as long as they are consistently accurate and used correctly. Moreover, automated machines have the capacity to download BPs into a database in which averaged BPs and trends could be monitored more precisely.

Performance measures should be accurate and reliable, improvable, and result in improved health outcomes. A good example of an ideal performance measure is influenza immunization rates, in which high rates are inversely proportional to influenza deaths. Most performance measures are, however, more complex. High rates for screening mammographies do not ensure that the films were well read, follow-up was done, treatment was optimal, or health outcomes were improved. Blood pressure is difficult to measure accurately and record reliably, and, similar to mammography, many other factors may contribute to health outcomes such as which medications are used, to what degree BP is reduced, and the presence and treatment of other cardiovascular risk factors. Defined targets for achieved BP have some utility in comparing managed care plans, but they do not translate easily into the more com-

plex care of hypertension. Innovations in BP measurement and giving credit for substantially decreasing BPs may improve the utility of performance measures for hypertension.

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