# Blood Pressure Goal Attainment According to JNC 7 Guidelines and Utilization of Antihypertensive Drug Therapy in MCO Patients With Type 1 or Type 2 Diabetes

VICKIE ANDROS, PharmD; ALLISON EGGER, MPH; and UMA DUA, PharmD

#### **ABSTRACT**

OBJECTIVE: Controlling hypertension (HTN) in patients with diabetes mellitus (DM) can reduce complications such as nephropathy, cerebrovascular disease, and cardiovascular disease. As part of a quality improvement project with a managed care organization (MCO), we evaluated blood pressure (BP) control relative to the type of drug therapy for patients with type 1 or type 2 DM who were identified from pharmacy claims for antihyperglycemic drug therapy.

METHODS: Pharmacy claims for antihyperglycemic drugs, including insulin, were used to identify a random sample of commercial members in an MCO comprising 30 health plans across the United States. Retrospective medical record review was conducted in October 2003 to collect data from 4,814 patient charts. BP goal attainment according to *The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7)* guidelines was determined for each patient from the most recent BP reading documented in the medical chart.

RESULTS: The distribution by type of DM was 21.0% (n = 1,011) for type 1, 75.7% (n = 3.644) for type 2, and 3.3% (n = 159) for cases not documented in the medical chart. Excluding 590 charts (12.3%) without BP values, there were 1,328 of 4,224 DM patients (31.4%) at JNC 7 BP goal (<130/80 mm Hg). Of the 1,328 patients at JNC 7 BP goal, 577 (43.4%) were at JNC 7 BP goal with no drug therapy. Excluding the 577 patients who did not require drug therapy to reach JNC 7 goal, 751 (20.6%) of the remaining 3,647 patients who required antihypertensive drug therapy were at JNC 7 BP goal, and 788 (21.6%) received no antihypertensive drug therapy. For the population of 4,224 DM patients with a BP value recorded in the chart, application of the lower BP goals in the JNC 7 guidelines reduced the proportion with controlled BP to 31.4% (1,328/4,224) from 42.6% (1,799/4,224) according to the former JNC 6 guidelines (P < 0.01). The proportion of DM patients with HTN was 59.6% (n = 2,870), and 28.4% (n = 814) of these patients were not taking either an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB). There were 704 patients with albuminuria or nephropathy (14.6%), of which 35.4% (n = 249) were not taking either an ACEI or an ARB, preferred therapy in these patients.

CONCLUSION: In this population of MCO members with DM for whom a BP value was recorded in the medical chart, 13.7% met JNC 7 BP goal with no antihypertensive drug therapy. For the patients with DM who received antihypertensive drug therapy and had a BP value recorded in the medical chart, only 26.3% were at JNC 7 BP goal. The application of JNC 7 guidelines significantly reduced the proportion of DM patients at target BP goal from 42.6%% to 31.4%

KEYWORDS: Hypertension, Managed care, Angiotensin-converting enzyme inhibitors, Angiotensin receptor blockers, Diabetes mellitus complications

J Manag Care Pharm. 2006;12(4):303-09

he JNC 7 Express: The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7), was initially published in the Journal of the American Medical Association in 2003 and redefined the stages of hypertension (HTN) established in the JNC 6 (Sixth Report, see Table 1). The complete JNC 7 report was published in August 2004 and is used as the standard for blood pressure (BP) control in this study despite the fact that the BP values were abstracted from medical charts in October 2003, the year prior to the release of the JNC 7 definition of appropriate BP control.

The treatment goal for individuals with HTN without other compelling conditions (i.e., diabetes mellitus [DM], heart failure, postmyocardial infarction (MI), chronic kidney disease, recurrent stroke prevention, or high coronary disease risk) is BP <140/90 mm Hg.1 JNC 7 guidelines set a goal of <140/90 mm Hg for the prevention and management of uncomplicated HTN to decrease morbidity and mortality by the least intrusive means possible.1 Although cardiovascular (CV) risk increases linearly with increases in systolic BP (SBP) >115 mm Hg, a more rapid increase in risk is noted when BP exceeds 140/90 mm Hg.2 In patients with HTN and DM or renal disease, the BP goal is <130/80 mm Hg. The American Diabetes Association (ADA) also recommends a BP goal <130/80 mm Hg for adults with DM.3 Epidemiological analyses indicate that the attainment of this BP goal is associated with a decrease in CV rates and mortality in persons with DM without compromising safety or increasing the cost of care.1

Also, the rate of decline in renal function among patients with diabetic nephropathy has been reported to be a continuous function of arterial pressure down to approximately 125-130 mm Hg SBP/70-75 mm Hg diastolic BP (DBP). The

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# TABLE 1 Blood Pressure Classification According to JNC 6 and JNC 7 Reports<sup>1,17</sup>

Blood Pressure Classification	JNC 6 (mm Hg)		
Optimal	<120 SBP and <80 DBP		
Normal	<130 SBP and <85 DBP		
High-normal	130-139 SBP and 85-89 DBP		
Stage 1 hypertension	140-159 SBP and 90-99 DBP		
Stage 2 hypertension	160-179 SBP and 100-109 DBP		
Stage 3 hypertension	180 SBP or 110 DBP		
Blood Pressure Classification	JNC 7 (mm Hg)		
Normal	<120 SBP and <80 DBP		
Prehypertension	120-139 SBP or 80-89 DBP		
Stage 1 hypertension	140-159 SBP or 90-99 DBP		

DBP = diastolic blood pressure; INC = Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (6=Sixth Report; 7 = Seventh Report); SBP = systolic blood pressure

# **TABLE 2** Criteria for Sample Population

Stage 2 hypertension

Criteria	No. (%)
Random selection of commercial members with pharmacy claims for antiyperglycemic agents	6,229 (100)
Exclusions: Patients deceased Patients no longer enrolled with MCO Access to chart denied by physician or medical group Charts not available for review Patients without diagnosis of diabetes in medical chart	24 (0.4) 122 (2.0) 623 (10.0) 497 (8.0) 149 (2.4)
Final sample	4,814 (77.3)

#### TABLE 3 Diabetes Patients at JNC 6 and JNC 7 Blood Pressure Goals for Adults<sup>1,17</sup>

JNC 6 BP Goal (SBP/DBP mm Hg)	Classification	JNC 7 BP Goal (SBP/DBP mm Hg)	
NA	Prehypertension and no compelling indications	<120/80	
<140/90	Hypertension and no compelling indications	<140/90	
<130/85	Hypertension and diabetes or renal disease	<130/80	
1,799/4,814 (37.4%)	All study patients at BP goal*	1,328/4,814 (27.6%)	
1,799/4,224 (42.6%)	All study patients with BP value at BP goal†	1,328/4,224 (31.4%)	

<sup>\*</sup> Entire study population of 4,814 (including those with missing BP value [n=590]). † 4,224 patients with BP value in medical chart (excluding those with missing

BP=blood pressure; DBP=diastolic blood pressure; JNC=Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (6=Sixth Report; 7=Seventh Report); NA=not available; SBP=systolic blood pressure.

Hypertension Optimal Treatment (HOT) trial along with other randomized clinical trials demonstrate the benefit of targeting a DBP of ≤80 mm Hg.<sup>4</sup> The updated JNC 7 guidelines emphasize SBP as the main focus of treatment since most patients with HTN (especially those older than 50 years) will reach their DBP goal once SBP is achieved. Along the same lines, the World Health Organization reports that suboptimal SBP (>115 mm Hg) is responsible for 62% of cerebrovascular disease and 49% of ischemic heart disease, with little variation by gender.1

Approximately 65 million Americans have high BP.5,6 A direct relationship exists between BP and risk of CV disease events; the higher the BP, the greater the chance of stroke, heart attack, heart failure, or kidney failure.1 In fact, HTN is second only to DM as the most common cause of end-stage renal disease (ESRD).<sup>1,7</sup> The risk of death from heart disease and stroke begins to increase at a BP of 115/75 mm Hg and doubles for every 20 mm Hg SBP/10 mm Hg DBP increase.1

Approximately 18 million Americans have DM, and 73% of patients with DM also have HTN.8 Studies have shown that patients with HTN and DM have approximately twice the risk of CV disease as patients with HTN but without DM. These patients are also at increased risk for diabetic nephropathy, retinopathy, and neuropathy. Controlling HTN in patients with DM has been shown to reduce the rate of progression of nephropathy and to reduce the complications of nephropathy, cerebrovascular disease, and CV disease. 4,9-11 The U.K. Prospective Diabetes Study (UKPDS) showed a 13% reduction in microvascular complications (retinopathy or nephropathy), a 12% risk reduction for any complication related to DM, a 15% decrease in deaths related to DM, and an 11% reduction in MI with each 10 mm Hg decrease in mean SBP.9 The HOT trial demonstrated improved outcomes, especially in preventing stroke, among patients in the lower target BP groups (i.e., DBP ≤80 mm Hg).4

The estimated total cost of high BP in the United States in 2005 was \$59.7 billion.6 Controlling high BP has the potential to prevent strokes and heart attacks and could result in potential savings of \$463 million in avoidable costs for hospital and other costs of therapy.<sup>12</sup> As noted previously, approximately three fourths of patients with DM also have HTN.8 The average cost per year for a patient with DM and HTN is \$13,446, with hospitalizations contributing to most of the cost.<sup>13</sup>

Among patients with HTN, more than 40% are not on drug therapy.<sup>1,5</sup> Many antihypertensive drugs are available to treat HTN. To achieve BP control, the majority of patients with DM will require 2 or more antihypertensive agents from different drug classes. 1,3 Angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), beta-blockers, diuretics, and calcium channel blockers have demonstrated a reduction in CV events in patients with DM. In addition to lowering BP, ACEIs and ARBs have been shown to slow the development and progression of diabetic nephropathy. Multiple

clinical trials demonstrate that use of ACEIs or ARBs in patients with DM have a renoprotective effect that provides both therapeutic and cost-effective outcomes. 14-16 Thus, the ADA recommends ACEIs and ARBs as first-line therapy for prevention and progression of macroalbuminuria and clinical nephropathy.

In this study, we quantified the BP goal attainment of this population according to both the JNC 6 (Sixth Report) and JNC 7 guideline (JNC 7 concurring with ADA) recommendations. We also evaluated the proportion of patients utilizing the preferred agents, ACEIs and ARBs.

#### **■■** Methods

We performed a retrospective analysis of data collected from a quality improvement (QI) initiative designed to evaluate comorbid diseases and outcomes in patients with DM. The patient population for this study was identified from a computerized, random selection of 6,229 commercial members with pharmacy claims for antihyperglycemic agents (Table 2). These members were enrolled in 30 health plans that were part of a managed care organization and located in sites in the Southeast, Southwest, mid-Atlantic, Midwest, Northeast, North central, and Western United States.

Nurses who were trained in the use of standardized data abstraction methods and who had prior data abstraction experience collected the data from the patients' medical records using a standardized data collection form. Approximately 50 nurses performed chart reviews at all sites during October 2003. The data abstracted from the patients' medical records included patient demographics, clinical history, comorbid diseases (coronary heart disease, HTN, nephropathy, obesity), drug therapies (HTN, DM, and dyslipidemic agents), and results of clinical examinations (BP readings) and laboratory tests (glycosylated hemoglobin [A1c], low-density lipoprotein cholesterol [LDL-C], microalbuminuria) pertinent to the management of DM

All analyses (univariate descriptive analyses and statistical tests) were carried out using SAS 8.2 software. Chi-square statistics were used to compare the difference in group proportions. A logistic regression analysis was performed to address geographic variation in the managed care population.

This research project compared data collected as part of a retrospective chart review from 4,814 patients with DM to guidelines set forth by JNC 7 and the ADA. The BP goals recommended by JNC 6 and JNC 7 reports based on BP classification and the existence of compelling indications are shown in Table 3.<sup>1,17</sup> Using the data collected, we determined BP goal attainment by comparing a patient's most recent BP reading documented in the chart (within the 2 years prior to chart review) with their BP goal according to both guidelines. Although the complete JNC 7 report was published in 2004, at the time these results were being analyzed, the JNC 7 Express guidelines had been published. And though it was expected that

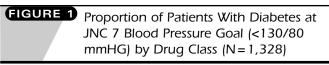
TABLE 4 Characteristics of All Study Patients
With Diabetes (N = 4,814\*)

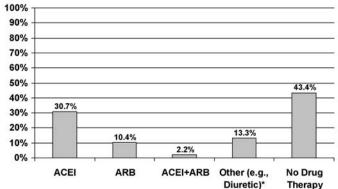
Variable		M	ean	
Average age Body mass index:	Females Males	33.9	52.2 years 33.9 kg/m <sup>2</sup> 32.3 kg/m <sup>2</sup>	
Variable		No.	(%)	
Gender:	Females Males	2,227 2,587	(46.3) (53.7)	
Diabetes type:	Type I ACEI ARB ACEI+ARB No ACEI or ARB Type 2 ACEI ARB ACEI+ARB No ACEI or ARB No ACEI or ARB	1,011 304 87 25 595 3,644 1,411 469 89 1,675 159 54 26	(21.0) (30.1) (8.6) (2.5) (58.9) (75.7) (38.7) (12.9) (2.4) (46.0) (3.3) (34.0) (16.4) (0)	
Hypertension†	No ACEI or ARB Yes ACEI ARB ACEI+ARB No ACEI or ARB	79 2,870 1,449 501 106 814 1,944	(49.7) (59.6) (50.5) (17.5) (3.7) (28.4) (40.4)	
Albuminuria/nephropathy	Yes ACEI ARB ACEI+ARB No ACEI or ARB	704 285 138 32 249 4,110	(14.6) (40.5) (19.6) (4.6) (35.4) (85.4)	
Race:	African American White Other Not documented	563 1,788 310 2,153	(11.7) (37.1) (6.4) (44.7)	

<sup>\* 590</sup> patient charts (12.3%) had missing BP value.

fewer patients would achieve BP control based on the more stringent JNC 7 BP guidelines than with JNC 6 BP guidelines, our intent in conducting the comparison was to quantify the impact of the JNC 7 standard. We also assessed the percentage of the entire population (patients with DM) and those with DM and albuminuria and/or nephropathy who were utilizing ACEIs and ARBs at the time of chart review.

<sup>†</sup> Hypertension was defined by a notation in the medical record indicating the diagnosis of hypertension (e.g., hypertension, elevated BP, high BP, ↑ BP). ACEI=angiotensin-converting enzyme inhibitor; ARB=angiotensin receptor blocker; BP=blood pressure.





\* Other drug therapy includes diuretics, beta-blockers, and calcium channel blockers. ACEI=angiotensin-converting enzyme inhibitor; ARB=angiotensin receptor blocker; JNC 7=Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.

#### ■■ Results

#### **Demographics**

Among the entire population, 21% (n = 1,011) were patients with type 1 DM and 75.7% (n = 3,644) were patients with type 2 diabetes, while 3.3% (n = 159) were identified as patients having diabetes but with no chart documentation of the type of diabetes (Table 4). The population consisted of 53.7% males and 46.3% females. More females had BP control (<130/80 mm Hg) than males in this population. There was racial diversity among the entire population, but the majority were white (n=1,788, 37.1%). As corroborated in previous research, more whites had BP control (<130/80 mm Hg) than African Americans and other races (whites 29.0%, African Americans 18.3%, other races 22.9%).

The mean age for the population was 52.2 years and the median age 54.0 years. Similar BP control was seen between the Medicare population  $\geq$ 65 years) and the other patients (<65 years). Height and weight were available in only 30% and 50% of the entire population, respectively. The average body mass index (BMI) for females was 33.9 kg/m2 and 32.3 kg/m2 for males. The most prevalent concomitant conditions were HTN, hyperlipidemia, and obesity. Among the most prevalent conditions, obesity was the only condition that was significantly higher among patients with DM and uncontrolled BP (>130/80 mm Hg) ( $\chi^2 = 22.9$  and P value <0.01). Notation indicating the diagnosis of HTN (e.g. HTN, elevated BP, high BP, ↑ BP) in the medical record existed in 59.6% of the entire population.

## **Blood Pressure Goal Attainment**

The average SBP was 130.3 mm Hg, and 75% of all patients'

SBP was ≤140 mm Hg. The average DBP was 77.9 mm Hg, and 75% of all patients' DBP was ≤84 mm Hg. Approximately 37% of the entire population met their JNC 6 BP goal, compared with 28% of the population using the JNC 7 BP goal (Table 3), resulting in a 9.8 absolute percentage difference. This correlates to a 26% relative percentage reduction in DM patients with controlled BP (P<0.01). Therefore, 1 out of 4 patients who were classified as having controlled BP according to JNC 6 guidelines are now classified as having uncontrolled BP according to JNC 7 guidelines. Approximately 12% of the entire population did not have a BP reading documented in the medical record to assess goal attainment.

A total of 4,224 patients had BP values documented in their medical charts. Among these patients, 1,328 (31.4%) were at JNC 7 BP goal (Figure 1, Table 5). Among the patients with a documented BP value (n=4,224), 68.6% (n=2,896) had uncontrolled BP (according to JNC 7 guidelines). The magnitude of BP reduction necessary to reach goal is shown in Figure 2. Only about 20% of patients with uncontrolled SBP and DBP (n=1,566) had a SBP and DBP less than 5 mm Hg from goal.

Among patients with DM and chart-documented HTN (defined by a notation in the medical record indicating the diagnosis of HTN, n = 2,870), only 21.1% of patients had BP controlled to <130/80 mm Hg. Approximately 10% of this subpopulation did not have a BP reading documented in their medical record to assess goal attainment.

# **Antihypertensive Drug Utilization**

Approximately 66% of the entire population was utilizing antihypertensive drug therapy. One third of all patients (n = 1,577) were on monotherapy treatment. A majority of these patients were on an ACEI, most commonly lisinopril. The average daily dose of lisinopril was 15.4 mg. Thirty-four percent of patients who discontinued ACEIs were being switched to other drugs in the same therapeutic class. Among those being treated with monotherapy, 24.9% were meeting the BP goal of <130/80 mm Hg. Two or more agents were utilized in 32.9% of all patients, and only 22.7% of these patients had controlled BP. Among the entire population, 36.8% were on ACEI, 12.1% on ARB, and 2.4% on an ACEI and ARB (Table 5).

Among those patients with chart-documented HTN (n=2,870), 90.4% were using antihypertensive agents. Approximately 48% were using 2 or more antihypertensive agents, and only 22% on monotherapy (n=1,218) had controlled BP. However, only 50.5% were on ACEI, 17.5% on ARB, and 3.7% on an ACEI and ARB. Among those patients not achieving BP control (n=1,975), 8% were not utilizing any antihypertensive agents, and 41% were using only 1 agent. Also, among those patients without BP control, 51.0% were on ACEI, 17.9% on ARB, and 3.9% on an ACEI and ARB.

Among the population with DM and uncontrolled BP  $(n=2,896; BP \ge 130/80 \text{ mm Hg})$ , 37.6% were using 2 or more

TABLE 5	Blood Pressure Goal Attainment by Antihypertensive Drug Type
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Antihypertensive Drug Type	At JNC 7 Goal (BP <130/80 mm Hg) No. (%)	Not at JNC 7 Goal (BP ≥130/80 mm Hg) No. (%)	Total Patients With BP Values in Chart	Missing BP Value in Chart No. (%)	All Study Patients No. (%)
ACEI	408 (25.5)	1,190 (74.5)	1,598	171 (9.7)	1,769 (36.7)
ARB	138 (25.8)	397 (74.2)	535	47 (8.1)	582 (12.1)
ACEI+ARB	29 (26.4)	81 (73.6)	110	4 (3.5)	114 (2.4)
Other (e.g., diuretic)*	176 (28.6)	440 (71.4)	616	78 (11.2)	694 (14.4)
No drug therapy	577 (42.3)	788 (57.7)	1,365	290 (17.5)	1,655 (34.4)
All study patients	1,328 (31.4)	2,896 (68.6)	4,224	590 (12.3)	4,814 (100.0)

<sup>\*</sup> Other drug therapy includes diuretics, beta-blockers, and calcium channel blockers.

ACEI= angiotensin-converting enzyme inhibitor; ARB= angiotensin receptor blocker; BP= blood pressure; JNC 7= Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.

antihypertensive drug agents. Twenty-seven percent of patients with DM and uncontrolled BP were not taking an antihypertensive agent, and 15.2% were taking antihypertensive agents not including an ACEI and/or ARB. The top 3 drug regimens for patients with DM and controlled BP as well as those with DM and uncontrolled BP included (1) ACEIs, (2) ACEI/diuretic combinations, and (3) ARBs.

Forty-eight percent of the entire population was not using an ACEI and/or an ARB (Table 5). More specifically, among those with type 1 DM (n=1,011), 30.1% were using an ACEI, 8.6% an ARB, and 2.5% an ACEI and an ARB. Among those with type 2 DM (n=3,644), 38.7% were using an ACEI, 12.9% an ARB, and 2.4% an ACEI and an ARB. Albuminuria (microalbuminuria or macroalbuminuria) and/or nephropathy was classified in 14.6% (n=704) of all patients. Within this subpopulation, 40.5% were utilizing ACEIs, 19.6% an ARB, and 4.6% an ACEI and an ARB (Table 4).

#### Discussion

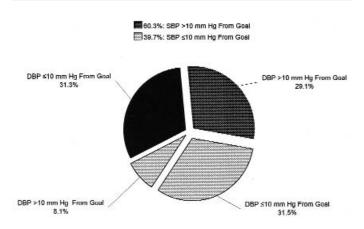
The present study evaluated attainment of JNC 6 and JNC 7 BP goals in patients with DM who were identified from pharmacy claims for antihyperglycemic drugs, including insulin, whether or not these patients had a diagnosis of HTN or had received antihypertensive drug therapy. In a prior study, Andros described the results of medical chart review in a population of patients with HTN (identified through medical claims for HTN) and chart-documented confirmation of both DM and HTN (n = 9,492). These data were presented as part an HTN research and QI initiative conducted among physician practices. Approximately 28% of the entire population with DM and HTN (including those with and without documented BP values) achieved BP control (<130/80 mm Hg), compared wih 27.6% of our study population of patients with DM. Among the patients in the present study with a documented BP value, 31.4% were achieving BP control (<130/80 mm Hg), 43.4% (n = 577) without drug therapy. By drug type, 55.4% were treated with an ACE inhibitor and 32.3% with an ARB in the prior study by Andros, versus 51.3% in our study. Among DM patients at JNC 7 goal who received antihypertensive drug therapy and those who were not at JNC 7 goal (n=3,647), 61.5% (n=2,243) were treated with an ACE inhibitor and/or an ARB.

Jackson et al. evaluated BP control and management of drug therapy for patients with concurrent heart failure and HTN in a managed care setting. Data included medical and pharmacy claims as well as results from medical chart review. The study found that, among the subpopulation with DM (n=113), 30.1% had their BP controlled (<130/85 mm Hg) and approximately 47% were receiving ACE inhibitors or ARBs, compared with our findings of 27.6% with BP controlled (to < 130/80 mm Hg) and 51.3% on ACE inhibitors or ARBs or both. In the present study population with documented BP values (n = 4,224), 31.4% achieved BP control (<130/80 mm Hg) and 53.1% were utilizing ACE inhibitors and/or ARBs.

Despite the fact that HTN is a common comorbidity of DM and that controlling HTN in patients with DM has been shown to reduce nephropathy, cerebrovascular disease, and CV disease, 12.3% (n = 590) of the population in this study did not have a BP reading documented in the chart. It is disappointing that BP is not being monitored more closely. On the other hand, 13.7% (577/4,224) of the patients with DM who had a BP reading documented in the chart were at BP goal without drug therapy.

The ADA guidelines for BP treatment goals (<130/80 mm Hg) have not changed recently, and the JNC 7 guidelines now concur with ADA recommendations for BP control of <130/80 mm Hg for patients with DM. Our findings suggest that 27.6% of the entire population met BP goals according to the JNC 7 report and that significantly fewer patients (9.8%, n=472) were meeting their BP goal as compared with JNC 6 recommendations. In examining the means and reduction in BP required to achieve BP control among this population with DM (Figure 2),

FIGURE 2 Patients With Uncontrolled Systolic and Diastolic Blood Pressure and Amount of Reduction Needed to Meet Goal (<130/80 mm Hg) (n=1,566)



DBP = diastolic blood pressure; SBP = systolic blood pressure.

approximately 20% of individuals who remain hypertensive require small decreases (<5 mm Hg) in BP to achieve goal. If the patients needing minimal reduction (<5 mm Hg) in SBP and DBP readings were at goal, nearly 50% of this entire population would be achieving BP goals instead of 27.6%.

Therefore, with greater utilization of appropriate antihypertensive agents, titration of doses, and use of combination therapy, it is possible that this patient population could lower their BP values to <130/80 mm Hg.

According to JNC 7 and the ADA, the majority of patients with DM will require 2 or more antihypertensive agents from different drug classes to achieve BP control. Almost half (48%, n=1,377) of the patients with DM and HTN (n=2,870) in this study were using 2 or more antihypertensive agents (data not reported). Combining agents with 2 different mechanisms of action can result in an additive BP-lowering effect and may permit for lower doses of each agent to be used, possibly decreasing the potential for dose-related side effects. Forty-nine percent of the patient population with DM, HTN, and uncontrolled BP could potentially have achieved BP control if they were first dose-titrated and secondarily placed on multiple antihypertensive agents, particularly an ACEI and/or ARB.

The JNC 7 report also suggests that all patients with DM and HTN should be treated with a regimen that includes either an ACEI or ARB. Furthermore, the National Kidney Foundation recommends that patients with chronic kidney disease (including albuminuria and/or nephropathy) should be treated with an ACEI and/or ARB in combination with a diuretic. Underutilization of antihypertensive agents was seen among the

entire population, among those with HTN, and among those with uncontrolled BP. Among the patients with DM and HTN (n=2,870), 71.7% (n=2,057) were being treated with an ACEI and/or ARB. Among those with documented albuminuria and/or nephropathy, 65% were being treated with an ACEI and/or an ARB. Considering the benefits of renal protection and control of secondary complications, ACEIs or ARBs are underutilized in this subpopulation.

For the end points of fatal coronary heart disease and non-fatal MI among patients with DM and HTN, the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) found no significant difference for patients who used ACEIs or calcium channel blockers versus a thiazide diuretic. <sup>20</sup> These findings suggest that thiazide diuretics should be considered first-line antihypertensive therapy in patients with DM, <sup>20</sup> but the ALLHAT findings did not include the intermediate outcomes of urinary microalbuminuria, A1c levels, and other physiological tests.

In the present study, a majority of patients were on lisinopril monotherapy at an average daily dose of 15.4 mg per day. One research study showed that lisinopril monotherapy at doses of 20 to 40 mg per day produced a mean reduction in both SBP and DBP of approximately 6 mm Hg.<sup>21</sup> Therefore, since our patients were receiving lower average doses, the predicted reduction in BP for these patients would most likely be something <6 mm Hg.

# Limitations

As part of the quality improvement initiative, trained nurses reviewed the medical records of eligible patients in the offices of the physicians identified as the prescribers for antihyperglycemic drug therapy. Since multiple physicians may follow individual patients, all the information of interest may not have been available in the physician's office where the chart was reviewed. Physician practices also vary in their documentation of BP and may only do so when the reading is high or low and of concern to the physician. Therefore, reliance on chart-documented information is a limitation of the present study.

Only BP readings taken by the physician or office staff and documented in the medical record were tabulated for the present study. Any BP readings reported by the patient (at home) were not included or evaluated. In excluding such readings, some patients may not have had an accurate evaluation of BP control due to phenomena such as "white coat" syndrome, which results in elevated office BP readings due to anxiety associated with the physician office visit. On the other hand, it is reasonable to expect that the patients in this study were accustomed to routine office visits as a result of their diagnosis of DM.

Another potential limitation of the study was the use of 1 BP reading to evaluate BP control. The decision to use 1 reading follows the methodology used in the Health Plan Employer Data and Information Set (HEDIS) Controlling High Blood

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Pressure measure. An average of up to 3 documented BP readings was also evaluated for each patient in the study. In assessing the average of up to 3 BP readings, approximately 30% of patients had controlled BP versus 27.6% when only 1 reading was evaluated.

Lastly, the use of retrospective chart review to identify medications is unreliable since this documentation is likely to be inconsistent, incomplete, and inaccurate. Patient compliance with antihypertensive therapy is also difficult to evaluate through this method of data collection.

#### **Conclusion**

More than two thirds of patients with DM in this study did not have controlled BP (<130/80 mm Hg) according to JNC 7 recommendations. Approximately 14% of the patients were normotensive without antidepressant drug therapy. Approximately 60% of the DM patients had HTN, and 28% of these patients were not taking either an ACEI or an ARB. About 15% of DM patients had albuminuria or nephropathy; of these patients, 35% were not taking either an ACEI or an ARB, preferred therapy in these patients.

#### DISCLOSURES

Funding for this research was provided by Sankyo Pharma Inc. and Forest Laboratories, Inc. and was obtained by Bharat Patel, PharmD, and H. Ed Perez, PharmD, cofounders of Total Therapeutic Management, Inc. Authors Allison Egger, Uma Dua, and Vickie Andros are employed by Total Therapeutic Management, Inc., which currently has research grants from Sankyo Pharma Inc., Forest Laboratories, Inc., and numerous other pharmaceutical and health care companies.

Andros served as principal author of the study. Study concept and design were contributed by Andros and Egger, with input from Dua. Data collection and interpretation was primarily the work of Egger, with input from Andros and Dua. Drafting of the manuscript and its revision were the work of Andros and Egger, with input from Dua.

### REFERENCES

- 1. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services; 2004. NIH Publication No. 04-5230.
- 2. Moser M. Guidelines and goals in the management of hypertension. *Medscape Cardiol.* 2003;7(1):1-3.
- 3. American Diabetes Association. Hypertension management in adults with diabetes. *Diabetes Care*. 2004;27(1)(suppl 1):S65-S67.
- 4. Hansson L, Zanchetti A, Carruthers SG, et al. Effects of intensive blood-pressure lowering and low-dose aspirin on patients with hypertension: principal results of the Hypertension Optimal Treatment (HOT) randomized trial: HOT Study Group. *Lancet*. 1998;351:1755-62.
- 5. Hajjar I, Kotchen TA. Trends in prevalence, awareness, treatment, and control of hypertension in the United States. Results from the National Health and Nutrition Examination Survey, 1988-2000. *JAMA*. 2003:290(2):199-206.
- 6. American Heart Association. *Heart Disease and Stroke Statistics*—2005 Update. Dallas, TX: American Heart Association; 2005.
- 7. Lim, HS, MacFadyen RJ, Lip GY. Diabetes mellitus, the renin-angiotensin-aldosterone system and the heart. *Arch Intern Med.* 2004;164:1737-48.

- 8. Centers for Disease Control and Prevention. *National Diabetes Fact Sheet: General Information and National Estimates on Diabetes in the United States*, 2002. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2003. Available at: http://www.diabetes.org/diabetes-statistics/national-diabetes-fact-sheet.jsp. Accessed May 20, 2005.
- 9. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. UK Prospective Diabetes Study Group. *BMJ*. 1998;317:703-13.
- 10. Heart Outcomes Prevention Evaluation Study Investigators. Effects of ramipril on cardiovascular and microvascular outcomes in people with diabetes mellitus: results of the HOPE study and MICRO-HOPE substudy. *Lancet.* 2000;355:253-59.
- 11. Furberg CD, Wright JT Jr, Davis BR, et al. Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium channel blocker vs. diuretic: the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). *JAMA*. 2002;288: 2981-97.
- 12. The State of Health Care Quality 2004. Washington, D.C.: National Committee for Quality Assurance; 2004. Available at: http://www.ncqa.org/communications/SOMC/SOHC2004.pdf. Accessed March, 2005.
- 13. Amin SP, Mullins CD, Duncan BS, Blandford L. Direct health care costs for treatment of diabetes mellitus and hypertension in an IPA-group-model HMO. *Am J Health Syst Pharm.* 1999;56(15):1515-20.
- 14. Rodby RA, Chiou C-F, Borenstein J, et. al., for the Collaborative Study Group. The cost-effectiveness of irbesartan in the treatment of hypertensive patients with type 2 diabetic nephropathy. *Clin Ther.* 2003;25:2102-19.
- 15. Rodby RA, Firth LM, Lewis EJ, for the Collaborative Study Group. An economic analysis of captopril in the treatment of diabetic nephropathy. *Diabetes Care*. 1996;19:1051-61.
- 16. Herman WH, Shahinfar S, Carides GW, et. al., for the RENAAL Investigators. Losartan reduces the costs associated with diabetic end-stage renal disease: the RENAAL study economic evaluation. *Diabetes Care.* 2003; 26:683-87.
- 17. The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services; 1997. NIH Publication No. 98-4080.
- 18. Andros V. Uncontrolled blood pressure in a treated, high-risk managed care population. *Am J Manag Care*. 2005;11(suppl 7):S215-S219.
- 19. Jackson JH, Frech F, Ronen R, Mullany L, et al. Assessment of drug therapy management and the prevalence of heart failure in a managed care population with hypertension. J Manag Care Pharm. 2004;10(6):513-20.
- 20. The ALLHAT Collaborative Research Group. Clinical outcomes in anti-hypertensive treatment of type 2 diabetes, impaired fasting glucose concentration, and normoglycemia. *Arch Intern Med.* 2005;165:1401-09.
- 21. Izzo JL, Weinberg MS, Hainer JW, Kerkering J, Tou CKP. Antihypertensive efficacy of candesartan-lisinopril in combination vs. up-titration of lisinopril: The AMAZE Trials. *J Clin Hypertens*. 2004;6(9):485-93.