Trends in the Treatment of Hypertension within Managed Care Organizations: A National Survey of HMO Pharmacy Directors

Eric Bobal, Deborah L. O'Connor, John Keefe

OBJECTIVE:
To estimate the prevalence of changes to the initial treatment regimen of hypertensive patients in a managed care setting, and to identify the factors having the most impact on the cost of treatment. Utilization patterns specifically related to angiotensin-converting enzyme inhibitors (ACEIs) and calcium channel blockers (CCBs) were looked at because of their particular cost impact. Secondary goals were to assess the types of changes made to therapy and to estimate the ACEI/CCB concomitancy rates (the number of patients receiving both medications at the same time) among these hypertensive patients, and the cost impact of these.

SETTING:
In May 1995, a survey regarding the treatment of hypertension in managed care was faxed to a random sampling of pharmacy directors of 250 large (> 40,000 enrollees) managed care plans throughout the United States. A total of 29 pharmacy directors completed and returned the survey; all responses were included in the study analysis. The 29 plans represented various types of HMO—staff, group, independent-practice association, network, and mixed-model HMOs—which collectively accounted for 8.9 million enrollees, or approximately 16% of the total HMO universe. All plans had similar age and gender demographics composition.

PATIENT/PARTICIPANTS:
29 Pharmacy directors.

INTERVENTIONS:
Not applicable.

MAIN OUTCOME MEASURES:
PMPY and subjective evaluations.

RESULTS:
Most of the responding pharmacy directors (81%) indicated that the average hypertensive patient undergoes at least one, and often more than one, modification to the therapy regimen before achieving maintenance therapy levels (i.e., control of high blood pressure). When using either an ACEI or a CCB, the most common change made to initial therapy was to increase the medication dosage. This was estimated to occur 26.8% of the time with ACEIs and 22.5% with CCB therapy. Among patients who started therapy on ACEIs, switching to an antihypertensive in another class was the next most common step (18%), followed by adding a CCB or switching to another ACEI, both of which occurred about 11% of the time. Among patients who started therapy on CCBs, the next most common change after increasing the dosage was to add a diuretic (15%), followed by switching to another CCB (13%) or adding an ACEI (5%).

CONCLUSION:
Based on the qualitative responses of the pharmacy directors, it appears that changes to the initial antihypertensive treatment regimen are common. The survey data support the American Heart Association’s assumption that even among those taking antihypertensive medication, blood pressure remains uncontrolled (a systolic level ≥140 and/or a diastolic level ≥90) in an estimated 27% of patients. In addition, the need for modifications to therapy appears to have important cost implications. Overall, these findings suggest that more aggressive management of hypertension may effectively reduce both the number of subsequent physician visits and the need for complicated therapeutic regimens, which could improve patient compliance.

KEY WORDS:
Angiotensin-converting enzyme inhibitors (ACEIs), Calcium channel blockers (CCBs), Concomitancy rates, Hypertension

Hypertension, or high blood pressure (HBP), is a serious and costly illness affecting approximately 50 million Americans. HBP is associated with morbidity and mortality and increases the risk of several other illnesses, including cardiovascular disease (CVD) and renal disease, the incidence of which increases with age.

According to the American Heart Association (AHA), hypertensive disease cost an estimated $20.5 billion in 1996, $7.2 billion of which is attributed to medical services including diagnostic evaluations and ongoing changes to the drug regimen (e.g., routine or specialized laboratory tests, supplemental therapies, physician office visits). Hospital and nursing home services account for the next largest percentage of costs related to treating hypertension, contributing $6.1 billion per year. Together, drug costs and lost output contribute $7.2 billion to the

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cost of hypertension disease ($4.2 and $3.0 billion, respectively). These costs are all the more alarming in light of the fact that, according to AHA estimates, blood pressure was uncontrolled in 27% of patients taking antihypertensive medications between 1988 and 1991.2

According to the Fifth Report of The Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC-V), a systolic level ≥140 and/or a diastolic level ≥90 represents HBP. The aging of the American population likely will lead to increases in both the number of hypertensive patients and the percentage of patients with unmanaged blood pressure. The prevalence of uncontrolled HBP among patients taking antihypertensives raises important questions about the management of hypertensive disease in the United States, particularly in today’s health care climate in which outcomes and cost control continue to drive managed care.

What factors contribute to inadequately controlled blood pressure and to what degree do these factors affect the total cost of treating hypertension? Previous research by Jones et al. in the United Kingdom found that changes and discontinuation in initial antihypertensive therapy were common among populations of patients with hypertension.4 It seems plausible that multiple changes to the drug regimen are indicative of a larger issue, the need to more effectively manage blood pressure.

RESEARCH OBJECTIVES

This survey was conducted to assess whether multiple changes to antihypertensive drug therapy are present within diversified managed care settings and to gather qualitative information that would highlight a possible association between various treatment trends and uncontrolled blood pressure. The primary research objectives of this national survey of HMO pharmacy directors were to estimate the prevalence of changes among hypertensive patients who initiated treatment with an angiotensin-converting enzyme (ACE) inhibitors or calcium channel blockers (CCBs). Utilization patterns, specifically related to ACE inhibitors and CCBs, were examined because they have a higher ingredient cost than other antihypertensives. Therefore, secondary goals of this study were to determine comorbidty rates of combined treatment with ACE inhibitors and CCBs to assess the types of changes made to the treatment regimen and to identify the factors having the most impact on the cost of treatment. Finally, the survey was designed to gather the informed opinions of managed care pharmacy directors on specific issues related to antihypertensive drug use. The qualitative data focused on the respondents’ major concerns about the current management of hypertension, the degree to which hypertension receives economic scrutiny within their plans, and how the respondents think the treatment of hypertension could be improved in their plans.

### Table 1. Demographics of Managed Care Plans

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<thead>
<tr>
<th>HMO Model Type</th>
<th>Staff</th>
<th>Group</th>
<th>IPA</th>
<th>Network</th>
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<td>1,817,000</td>
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<tr>
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<td>Total Enrollment*</td>
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<td>3,360,975</td>
<td>2,803,175</td>
<td>1,880,275</td>
</tr>
</tbody>
</table>

* Total enrollment by plan is lower than total overall enrollment due to inaccurate reporting of percentages.

METHODS

Study Design

In May 1995, a survey regarding the treatment of hypertension in managed care was faxed to a random sampling of pharmacy directors of 250 large (>40,000 enrollees) managed care plans throughout the United States. A total of 29 pharmacy directors, representing 29 managed care plans with 8.9 million enrollees, responded regarding the management of hypertension within their respective HMO settings. The plans represented staff, group, independent-practice-association (IPA), network, and mixed-model HMOs from 17 states, plus the District of Columbia. Group models accounted for roughly 38% of enrollees, while IPA models represented about 29%. Network and staff models represented 16% and 15% of enrollees, respectively (Table 1).

The survey was composed of 39 questions covering various issues related to the treatment of hypertension. These questions assessed the prevalence of hypertension, current therapeutic treatment approaches, and the costs associated with treating hypertension in managed care settings. Respondents provided plan-specific demographic data on the characteristics of total enrollees, including the percentages of those having a drug benefit and the number of patients with hypertension, as well as estimates of the plan’s overall drug budget and the percentage of the budget accounted for antihypertensive products.

The survey also asked pharmacy directors to estimate the incidence of modifications to hypertension treatment regimens,
the impact of such changes on per member per month (PMPM) costs, and other factors that contribute to the cost of treating hypertension. Since the cost of ACE inhibitors and CCBs is significant, the pharmacy directors also were asked to provide information about the number of plan patients taking either ACE inhibitors or CCBs, the number taking both, the estimated total number of prescriptions, and the PMPM costs associated with each treatment. Two questions concerned the impacts of various factors on drug therapy failure: side effects, lack of efficacy, noncompliance, price, and patient misunderstanding. Therapy failure was defined as any change made to initially prescribed drug therapy. The second question asked them to rate the financial impact of switching, lab and hospital costs, increased physician visits, and greater drug utilization.

Plan Enrollee Demographics

Most enrollees (92%) had a drug benefit included in their health-care coverage. Overall enrollment by gender was similar—with 53.2% female and 46.8% male; 73.5% of enrollees were Caucasian and 15.1% were African American. The remainder were Asian American, Latino, or other. Approximately half of enrollees were age 21 to 60. Almost a quarter were 20 years of age or younger, and the remainder were age 61 years or older.

Hypertension was present in an average of 16% of total membership within these plans. This sample is similar to data from the National Health and Nutrition Examination Survey III (NHANES III), which estimated that 25% of adult Americans had HBP in 1995. There was no significant difference among the plans in the incidence of hypertension between female and male plan enrollees, at an average of 42% versus 58%, respectively. The number of hypertensive patients having concomitant diseases varied among plans. The average percentage of patients having both hypertension and angina was 7%; however, there was a very broad reporting range among the plans, between 0.5% and 24%. Similarly, the average percentage of patients suffering from both hypertension and congestive heart failure (CHF) was 8%, with responses ranging from 25% at one plan and 50% at another.

Plan Budgets

The survey assessed overall and average drug budgets for hypertension products among plans. A total of 27 plans reported budgetary data. The overall drug budget for all plans reporting data was $1.1 billion. Individual budgets ranged from $5.7 million to $225 million. The average budget allocation for hypertension products across HMOs was 15% of individual budgets ($147 million in this sample). Although this represents less than a fifth of overall expenses, budget allocations for hypertension products ranged from a low of 8% to a high of 26% of a plan's total pharmaceutical budget. The average percentage of the budget accounted for by ACE inhibitors

| Table 2. Prevalence of Concomitant Therapy in HMOs |
|--------------------------|-------------------|-------------------|----------------|-----------------|-----------------|
| Number of Patients | % of Patients | Number of Rxs | Rxs/Patient Average | PMPM Average |
| ACEI but No CCBs | 128,383 | 27% | 607,322 | 4.7 | $7.15 |
| | Range: 1-13 | Range: $0.36 to $33.00 |
| ACEI but No ACEI | 134,375 | 28% | 695,114 | 5.2 | $8.33 |
| | Range: 1-13 | Range: $0.32 to $43.40 |
| ACEI with CCBs | 15,158 | .03% | 74,611 | 4.9 | $17.25 |
| | Range: 1-24 | Range: $0.10 to $72.50 |

The aggregate enrollment of the 13 plans that reported this information is 4,777,160 (average enrollment of these plans is 341,226).

was 4%, with a range of 2% to 7%; for CCBs, this average was 7%, with a range of 3% to 13%.

RESULTS

Status of Hypertension

The management of hypertension and the costs associated with its treatment are of critical concern to managed care pharmacy directors. All survey respondents agreed that “the treatment of hypertension is an area under close economic scrutiny at managed care plans.” Furthermore, concern about the impact of treatment costs of treatment on plan budgets is not expected to abate in the near future. A majority (66%) indicated that they expect an increase in the number of newly diagnosed hypertensive patients among their members, which they believe will lead to higher overall expenditures for hypertensive disease. Membership growth was the primary reason cited for the expected increase, particularly because of an expected increase in the population eligible for Medicare. No respondent anticipated a decrease in the number of hypertensive patients.

Treatment Practices

Pharmacy directors were asked to estimate the number of dosage adjustments or product failures that the average hypertensive patient undergoes before achieving maintenance therapy levels (i.e., control of HBP). Of the 16 who responded to the question, most (81%) indicated that more than one modification to the therapy regimen was required. Increasing dosage was the most common action reported for patients taking either ACE inhibitors or CCBs as initial therapy. Among patients who started on ACE inhibitors, nearly 27% increased their dose within the first year of therapy. Among patients
who started on CCBs, approximately 23% increased their dose within the first year of therapy. Of the patients on initial ACE inhibitor therapy, the next most common modification was switching to an antihypertensive in another class, which reportedly occurred 18% of the time, and was followed by adding a CCB or switching to another ACE inhibitor—both of which occurred about 11% of the time. In contrast, among patients who started on CCBs, the next most common change following dosage escalation was the addition of a diuretic (15% of the time), followed by switching to another CCB (13%) or adding an ACE inhibitor (5%).

The ACE inhibitor and CCB concomitantly rates were difficult to determine. To assess utilization and costs associated with either ACE inhibitor or CCB therapy alone, as compared to combination therapy of ACE inhibitors and CCBs, respondents were asked to supply data on the number of patients, the total number of prescriptions, and the PMPM cost for each drug during one year. Not all respondents had access to this information, possibly because integrated data systems are not readily available at most plans. Approximately half of the pharmacy directors were able to provide the required data regarding the prevalence of concomitant therapy with ACE inhibitors and CCBs for the period of January through December 1994. The reported PMPM data for concomitant therapy contributed to a significant portion of the overall drug budget, ranging from $39.60 to $72.50. Table 2 summarizes the concomitancy data. PMPM costs for concomitant therapy varied most among IPA and network plans and were consistent among staff/group models.

Based on the reported concomitancy data, adding a CCB to existing ACEI therapy was more common than adding an ACEI to initial CCB therapy. For patients who started on an ACEI, a CCB was added in about 11% of cases, whereas patients who started on CCBs were concomitantly prescribed an ACE inhibitor in approximately 5% of cases.

Physician Visits

To track the number of physician visits related to the treatment of hypertension in these plans, pharmacy directors were asked to indicate any treatment that required a physician visit. A physician visit was required for the majority (76%) of cases in which a patient’s dosage of hypertension medication was increased, the patient was switched to a different class of product, or a product was added to or deleted from an existing therapy. New patients who were taking a nonformulary drug also were required to make an office visit. Other patients requiring an office visit included those having uncontrolled blood pressure, those using diuretics, and those having severe hypertension or other underlying diseases. Some pharmacy directors reported that physician visits were occasionally waived when adequate blood pressure monitoring was performed outside the physician’s office. In these cases, the pharmacy directors said physicians often permitted reliable, compliant patients to change their dosing with a telephone consultation.

PMPM Cost Factors

The impact that changing therapies had on hypertension PMPM costs was unclear. There was no consensus among respondents regarding the financial effect of switching hypertension medications on PMPM. Nearly one-third (30%) indicated that switching hypertension products significantly increased hypertension PMPM. An equal number claimed that switching products did not significantly increase the plan’s hypertension product PMPM. They said that the financial effects of switching hypertension medications depended on the following factors: the use of nonpreferred antihypertensive medications, patient noncompliance, wastage of medications, and rushed office visits.

When questioned as to the effect reducing incidence of dosage escalation would have on PMPM, the majority (60%) of respondents agreed with the statement, “reducing dosage escalation for hypertensive patients on CCBs would significantly reduce [the plan’s] PMPM.” The findings suggest that ACE inhibitor dosage adjustment has little if any effect on PMPM, largely because many ACE inhibitors are similarly priced, regardless of dosage level.

Treatment Protocols

Several questions addressed the degree to which plans were actively attempting to manage the treatment and costs of hypertension. To assess the degree to which managed care plans comply with treatment guidelines, the survey asked pharmacy directors whether their plans have protocols in place for the treatment of hypertension and, if so, to what degree they estimate that physicians comply with the plan’s protocols. Treatment protocols do not appear to be widespread among the plans surveyed; only about 25% of respondents using them and none of the pharmacy directors reported strict adherence to them. The release of the JNC-V treatment guidelines was cited as an incentive to develop and/or follow treatment protocols. Nevertheless, according to the pharmacy directors, most plans (76%) were not following set treatment guidelines at the time of the survey. One respondent indicated that his plan used its own internal guidelines, and two indicated that their plans were in the process of developing internal guidelines.

Despite the fact that physician office visits were believed to greatly affect the cost of treating hypertension, most of these plans do not attempt to regulate physician office visits through the use of incentives or restrictions. Only two pharmacy directors (7%) reported that their plan places incentives or restrictions on physicians relative to the number of visits for the treatment of hypertension. In both cases, physicians are reimbursed on a capitated basis, decreasing the incentive to see patients unnecessarily. Whenever patients are dispensed more than one prescription medication at a time, all plans require them to make a copayment for each.
Figure 1. Factors Impacting Drug Therapy Failure

Mean Responses of Factors Impacting Drug Therapy Failure

<table>
<thead>
<tr>
<th>Factor</th>
<th>Highest Impact</th>
<th>Second Highest Impact</th>
<th>Third Highest Impact</th>
<th>Fourth Highest Impact</th>
<th>Fifth Highest Impact</th>
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</tbody>
</table>

n= Total Responses

Drug Therapy Failure

The survey asked pharmacy directors to estimate the number of "product failures" that the average hypertensive patient would experience before his or her blood pressure was controlled adequately. A product failure was defined as any change in drug therapy (e.g., dosing, switching, adding) that occurred when a particular drug failed to produce the desired goals. The average estimated number of reported changes to a patient's drug regimen was 3.3, with responses ranging from one to 15 changes, or product failures.

Pharmacy directors also were asked to rate five factors, on a scale of 1 to 7, according to the degree to which they are perceived to impact drug therapy failure. For purposes of analysis, a rating of 1 to 2 was considered not very influential, 3 to 4 somewhat influential, and 5 to 7 highly influential. The factors reported as having the most impact on drug therapy failure were side effects and noncompliance, followed by lack of efficacy. Ninety-three percent of pharmacy directors rated side effects as moderately to highly influential in drug therapy failure. The majority of respondents also identified lack of efficacy (72%) and noncompliance (69%) as moderately to highly influential. Both price and patient misunderstanding were reported as having the least impact on drug therapy failure. Figure 1 shows the mean response rates regarding the impact of these five factors on drug failure.

Costs Related to Drug Failure

To gather information regarding the cost implications of drug therapy failures, pharmacy directors were asked to rate the impact of five factors, on a scale of 1 to 6, on the overall cost of treatment due to drug failure. For purposes of analysis a rating of 1 represented the most costly and a rating of 6 represented the least costly factor. These factors were switching costs, lab costs, hospital costs, increased physician visits, and increased drug utilization. Aggregate responses of the pharmacy directors revealed that drug utilization has the greatest impact on cost; 75.8% of respondents reported that this factor has a moderate-to-high impact on cost. More than half (68.9% and 55.2%, respectively) rated lab costs and switching costs as moderately to highly important in contributing to the cost of drug failure. Almost half (48.2%) the pharmacy directors said that physician visits have a moderate-to-high impact on costs. Only 24.1% rated hospital expenses as having an impact on the overall cost of treating hypertension.

Physician visits was not the only factor identified as contributing to the costs associated with increased dosing of medication or adding a product to existing therapy. Pharmacy directors listed these additional costs: wasted medication when a new drug was not tolerated, additional lab testing, side effects associated with a higher dose of medication, pharmacy time to change records, drug-dispensing fees, indirect costs to the patient, physician and patient education, and patient misunderstanding and noncompliance. When asked to rate the financial impact of "dosage creep" on PMPM, the pharmacy directors suggested that increasing CCB dosage has a slightly greater financial impact on overall treatment costs than increasing the dosage of ACE inhibitors.

Compliance Issues

Patient noncompliance is an important factor in the cost of treating hypertension. When asked what they considered to be the major causes of noncompliance among patients with hypertension, pharmacy directors cited forgetfulness, side effects, complicated dosing schedules, inconsistent monitoring, and perceived nonseriousness of hypertension. However, they believe that efforts such as patient education could help to increase compliance. A quarter of the respondents indicated that improved packaging would improve compliance, while others suggested that unique drug delivery methods could support patient compliance. Most (90%) thought that once-daily dosing or reducing the number of pharmaceuticals (83%) would help increase patient compliance.

DISCUSSION

Based on the survey findings, the majority of hypertensive patients had their initial treatment regimen changed. In fact, an average of 3.3 changes were made to the patient's drug regimen before adequate therapeutic response was achieved, suggesting that treating hypertension may be more complex than is commonly thought. These changes occurred equally across all managed care plan types, reflecting National Center for Health Statistics data estimating that 27% of medicated hypertensives have uncontrolled blood pressure. The most common
initial step following drug failure with either an ACE inhibitor or CCB was to increase the medication dosage. The addition of another drug in patients who initiated therapy on ACE inhibitors or CCBs was the next most common step.

Such modifications to initial drug therapy indicate a cautious, step-care approach to treating hypertension. The JNC-V advocates this approach and asserts that the goal is “to control blood pressure by the least intrusive means possible.” The high incidence of continued modifications to therapy, however, suggests that a more aggressive approach to treating hypertension may be warranted for patients who do not achieve adequate blood pressure control with initial drug therapy. Furthermore, choice of antihypertensive medication may prove critical in determining the need for future modifications to therapy.

In general, the majority of survey respondents claimed that any change to the drug therapy regimen would prompt a physician visit. This finding has important economic implications because increased physician visits was identified as the factor having the greatest overall impact on cost. Therapy failures and patient misunderstanding were reported to account for most of these visits. Clearly, the best medication choice should consider not only a patient’s special circumstances, such as concomitant diseases, age, and lifestyle, but also should reduce blood pressure without requiring additional modifications to the therapy regimen, modifications that would be associated with increased physician visits.

Patient compliance also was a major factor affecting outcomes in the treatment of hypertension. In fact, pharmacy directors cited patient noncompliance as the greatest obstacle to blood pressure control. They stressed the importance of ongoing patient education, including the need to improve patient understanding of both hypertension and the risks of undertreated and untreated hypertension. Respondents believed a once-daily, standardized dosing, free from side effects, would help improve patient compliance. They also identified counseling and the need to expand programs aimed at improving patients’ overall health as critical. Some suggested greater use of patient monitoring and treatment outcomes measures, as well as the need to create algorithms that would assist providers in the diagnosis and selection of appropriate treatment for hypertensive patients.

Study Limitations

Several limitations of this survey must be acknowledged. First, due to its qualitative nature, caution should be used when generalizing the findings to other HMO settings. The majority of the data collected constitute pharmacy directors’ opinions and best estimates of treatment practices within their respective plans. Quantitative research is needed either to support or refute these findings. Specifically, future investigations should determine the actual incidence of changes to the initial drug regimen, including the percentage of patients who experience one, two, and three or more changes to their drug regimen. Studies also are needed to explore and quantitify the effects of such changes on the management of and costs associated with the treatment of hypertension. For example, patients who experience several changes to their drug therapy may become less compliant, have a decreased quality of life, and/or require increased office visits and medications, all of which would result in higher treatment costs. An evaluation of drug use for the treatment of hypertension could address some of these issues.

A second possible limitation is the survey sample, which is not representative of the HMO universe. However, those plans surveyed do represent a sizable number of enrollees from all major types of HMOs (group, staff, IPA, network, and mixed models). Therefore, it is likely that the sample reflects typical practices in the largest HMOs.

Third, not all respondents were able to provide concomitancy data; therefore, additional research is needed to clarify actual concomitancy rates. Finally, while 29 pharmacy directors participated, some were unable to provide responses to every question.

CONCLUSION

Based on the findings of this survey, patients with hypertension frequently undergo several modifications to therapy before achieving adequate blood pressure control. These changes appear not only to negatively affect blood pressure control but also may lead to higher overall costs of treating hypertension, both of which results may contribute to less effective management of hypertension. Reducing the number of steps taken to achieve blood pressure control could improve the overall management of hypertension and possibly reduce treatment costs.

References