

Risk Stratification: A Key to Managing Hypertension in the Managed Care Setting

An interview with Joseph L. Izzo, Jr., MD, Professor of Medicine and Pharmacology, Chief, Director of Clinical Pharmacology, State University of New York at Buffalo, Buffalo, New York

A physician and clinical pharmacologist with considerable experience in hypertension, Dr. Joseph L. Izzo, Jr., firmly believes that stratification of risk is the key to successful management of hypertension, not only in private medical practices, but also in managed care settings.

In addition to his positions at SUNY Buffalo, he is Director of the Food and Drug Administration's Clinical Pharmacology Training Program and former Chairman of the Department of Medicine at the Millard Fillmore Health System in Buffalo, New York. He received his training in experimental therapeutics, primarily in hypertension, at the National Heart, Lung, and Blood Institute, and is also a board-certified nephrologist.

Dr. Izzo has written numerous articles on hypertension that have been published in major peer-reviewed journals and is senior

editor of *The Hypertension Primer*, a publication of the American Heart Association.

Impact on Managed Care

AJMC: *What is the impact of hypertension and its treatment on managed care?*

Dr. Izzo: The impact of hypertension on managed care is complex. First, we need to address the impact on consumers of managed care and their impact on providers.

Regarding the impact on consumers, managed care has rarely provided directed leadership or effective care for people with high blood pressure. In fact, evidence suggests that, in isolated circumstances, decisions have been made not to treat high blood pressure because its consequences (and costs) fall due long after patients have moved to a different plan. In these cases, cost shifting has occurred.

In stable managed care plans, where there is not much population turnover, that philosophy is going to be doubly problematic: subscribers who are not getting the care they deserve today will suffer the consequences of inadequately treated hypertension 20 years from now, when the bills that fall due will be even higher.

There are a few isolated examples of true leadership in some health

maintenance organizations (HMOs). The first characteristic necessary for success is that there be engaged physician leadership to ensure that appropriate quality measures are applied to the population in an evenhanded way.

I was fortunate that the first graduate of our clinical pharmacology program, Dr. Brian Snyder, has become the clinical pharmacologist at Health Care Plan, a medium-sized HMO in Buffalo. He has been effective, not only in controlling formulary costs, but also in providing state-of-the-art practice guidelines for the plan's subscribers.

Recently, I had the opportunity to review his performance over the past several years and I was gratified to find that the drug usage pattern at Health Care Plan was remarkably closer to the JNC-VI [Joint National Committee] guidelines than the usual practice in our community.

Specifically, there was a marked reduction in the tendency to use calcium channel blockers as first-line therapy and a marked increase in the initial use of β -blockers and diuretics. Not only was the drug profile less expensive, but the hypertension control rates were over 50%, almost twice as good as those published as national averages.

It appears that having physician leadership, particularly from a clinical pharmacologist who understands drugs and drug therapy, is very effective in the managed care setting.

A second point that is important for managed care to understand is that there must be an adequate data management system. Without tracking modalities, we cannot really understand who is adequately controlled and who is not. Information hardware is critical, as are staff members who know how to ask the proper questions and how to validate and analyze the data appropriately.

Too many managed care systems feel that the computer itself will do all the work, and that couldn't be further from the truth.

AJMC: How was hypertension treated in the past in a managed care environment and how is it being treated today?

Dr. Izzo: The managed care environment is not much different from general practice in that hypertension treatment in both settings depends primarily on the attitudes of the physicians. In the past, we thought that the patients were the primary

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problem because they failed to adhere to medical regimens. However, an increasing number of studies have focused on physicians' attitudes as a barrier to practice. We now find that many physicians do not feel that mild or stage I hypertension is sufficiently problematic to warrant treatment and that patients then follow their physicians' lead.

In addition to these attitudes, there are other major barriers to appropriate care for patients with hypertension, especially in the managed care setting. For example, the short amounts of time available for physicians to spend with patients are huge impediments to adequate patient education and appropriate follow up. Efforts must therefore be made to ensure that enough time is spent with patients to support appropriate outcomes.

AJMC: What has your experience been in treating hypertension in a

managed care setting? Your experience with Blue Cross/Blue Shield?

Dr. Izzo: My experience is indirect and in a consultative capacity. I would, however, like to comment on a novel experiment being done by Drs. Reese Davis and Joel Overbach at Blue Cross/Blue Shield of Rochester, where there is strong IPA [International Pharmaceutical Association] involvement and very strong physician leadership.

The insurer recognized the importance of physician leadership and physician education and took steps to have Dr. Davis, the Director of Medical Education, assist those developing practice guidelines and monitoring physician performance. Dr. Overbach, a clinical pharmacist who is an expert in data systems and data interpretation, works very closely with the medical education director.

In this environment, the Board of Directors of the IPA adopted a strategy to identify 4 to 6 major therapeutic areas in which cost saving can occur along with improved clinical care. One of the areas is hypertension.

At this point, we have early results of their intervention trials, and they look very positive. The nature of the intervention begins with an educational program for all participating physicians. The program, which is held in the evening, consists of a scientific lecture, a lecture by the clinical pharmacist on practical issues related to medication dispensing and dosing, and a charge to the physician practitioners to improve certain areas of medical practice.

It is understood from the beginning that physician buy-in is the most important commodity. To achieve this, Blue Cross/Blue Shield divided the drug withhold into 2 parts. The first part was used as a stipend, amounting to about 20% of the total, that was paid to the practitioner to attend the medical education conferences. The second part of the drug

withhold will be returned to the physicians based on the performance of the group collectively, not as individuals. Thus, the return to the physician will be proportional to how effectively the whole group embraces more cost-effective management of hypertension.

Although the data are still preliminary, physician acceptance of the program is extremely high.

JNC-VI Guidelines

AJMC: What impact will the JNC-VI guidelines have on the treatment of hypertension in managed care settings?

Dr. Izzo: The JNC-VI guidelines are important, but we need a little historical perspective. JNC-I through JNC-V have not been well embraced by the medical community because the guidelines did not deal with "real world" issues such as the fact that each patient is typically complex and has problems other than essential hypertension that affect clinical management decisions. JNC-VI attempts to recognize the importance of these other conditions in a therapeutic decision-making algorithm that is relevant to hypertension.

JNC-VI may appeal somewhat more to managers of care and insurance companies than practitioners because it happens to use very inexpensive drugs as its fundamental set of recommendations. The importance for managed care, however, is to understand that Risk group A, for whom diuretics and β -blockers are recommended by JNC-VI, has a prevalence in the population of < 10%. The vast majority of the hypertensive population has a more complicated form of hypertension that requires a higher order of decision making and the use of more expensive drugs right from the beginning.

The critical element in the new JNC-VI approach is appropriate risk

stratification. That has not been done in a systematic way to this day. I also believe that risk stratification is one of the true advances of JNC-VI and the issue most likely to bring appropriate management to individual patients.

Risk stratification is essential because all patients are not the same, nor is it true that one drug fits all patients. Therefore, a spectrum of agents must be used in a responsible fashion to achieve the best outcomes. There's also a big misconception that the patients at the highest risk won't benefit from therapy. The truth is exactly the opposite—the highest-risk patients benefit the most from therapy.

These high-risk patients would require combinations of expensive drugs, but the overall cost of care decreases because the drug acquisition cost is a tiny fraction of the whole spectrum when one considers hospitalization, rehabilitation, and management of complications stemming from untreated or poorly treated hypertension such as heart failure, myocardial infarction, stroke, and chronic renal failure.

The insurer must make an early investment in better blood pressure control and more expensive medications to achieve the downstream benefits. Unfortunately, this is where the cost shifting comes in. If a subscriber stays in a plan for more than 2.8 years, management won't pay for many complications. But if a plan is responsible for an individual for 15 or 20 years, that plan had better invest up front in the appropriate therapy or it will pay much more later.

The HEDIS 2000 Initiative

AJMC: What are the clinical and practical ramifications of the HEDIS [Health Plan Employer Data and Information Set] 2000 Initiative, which includes hypertension management as a quality assurance measure?

Dr. Izzo: HEDIS should be extremely important to the population's health in general, probably much more so than is currently recognized. It has been a struggle to find a good way to define good care of hypertension. The new HEDIS guidelines measure the control rate of hypertension, that is the percentage of hypertensive patients with pressures below 140/90 mm Hg on their last visit. It's much more difficult to ascertain reliable, representative blood pressures than simple variables such as blood cholesterol or glycosylated hemoglobin.

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Although highly imperfect, the blood pressure control rate reflects overall quality of care. I think HEDIS always wanted to have blood pressure near the top of the list of quality indicators; it just turns out that it's difficult to manage. Because there is now a HEDIS standard, we can be more aggressive in advancing the agendas related to hypertension and antihypertensive medications, especially in the managed care setting.

I believe consumers will gravitate to blood pressure as a quality indicator very quickly. I think the public understands the importance of high blood pressure and the consequences of failure to treat adequately. My guess is that when the dashboard of HEDIS indicators is published for HMOs, and consumers can see how

their HMO performed in terms of quality, one of the first things they will look at is blood pressure control. That will keep us where we need to be—focused on blood pressure care.

In that respect, HEDIS cannot be underestimated. HMOs will now be held directly accountable by their subscribers. HEDIS will, in effect, hold managed care's feet to the fire, making sure that quality remains one of the critical assessment variables and that we don't degenerate to cost-based healthcare alone.

Vascular Compliance

AJMC: *Why is vascular compliance an important issue/component in the evaluation of hypertension?*

Dr. Izzo: Vascular compliance is the new kid on the block for risk stratification and may rapidly become one of the crucial elements in the assessment of patients with hypertension. We know that the presence of diabetes, cardiac disease, and kidney disease confers marked increase in risk. We also know that systolic hypertension is a major risk factor—and that systolic blood pressure is far better than the diastolic blood pressure as a disease marker and a therapeutic endpoint.

As it happens, people with high systolic blood pressure have increased vascular stiffness, which is also known as decreased vascular compliance. Systolic blood pressure increases as blood vessels get stiffer. The problem with using systolic blood pressure alone, however, is that it is not a very precise measure of vascular stiffness and risk. It is highly likely that we can inexpensively measure vascular compliance using new office devices and thereby improve our risk stratification in a given patient.

Very clearly, the people with increased stiffness or low compliance of the blood vessels are the most likely to benefit from therapy, as we

have learned from the Framingham and MRFIT [Multiple Risk Factor Intervention Trial] studies and the SHEP [Systolic Hypertension in the Elderly Program] trial. The good news here is that thiazide diuretics, which are extremely inexpensive, are effective in treating people with potential problems stemming from arterial stiffness. A measurement of arterial stiffness would identify people with stiff arteries earlier, perhaps before blood pressure elevations are sustained. This high-risk group could then be treated earlier and more effectively.

Another reason to measure arterial stiffness is that some people with a mild elevation in systolic pressure have a high cardiac output syndrome rather than increased vascular stiffness. These people would do well on a β -blocker or an angiotensin-converting enzyme (ACE) inhibitor.

Using these new and inexpensive techniques, we should be able to differentiate appropriate therapy early on and prevent long-term consequences of hypertension. Decreased arterial compliance is therefore an early marker of disease and, I think, a guideline to appropriate therapy. It is even possible that some drugs may allow reversal of arteriosclerosis or, to use the laymen's term, hardening of the arteries. By measuring serial changes in compliance, we should be able to test this possibility in individual cases, changing therapy as needed. It is also possible that certain classes of drugs are better than others at treating vascular disease.

Comorbid Conditions

AJMC: *Patients with hypertension often have other diseases or conditions, such as diabetes, obesity, and lipid abnormalities. What are the costs to the healthcare system of treating hypertension alone? Of treating hypertension and its associated comorbidities?*

Dr. Isszo: The key is to go back to the importance of risk stratification. The high-risk people are high-cost people in terms of the number of drugs, the number of visits, and so forth. However, the failure to treat high-risk individuals effectively costs even more—severalfold more—than spending a little bit more on medications and preventive management.

Once again, it comes back to the need for managed care organizations to identify their high-risk subscribers. I believe that there should be a risk stratification system that is linked to different levels of care to manage high-risk patients.

As a group, hypertensive patients with diabetes are at especially high risk. Every effort should be made to control not only the blood glucose as tightly as possible, but also the blood pressure and blood cholesterol. Recent studies such as the United Kingdom Prospective Diabetes Study [UKPDS] clearly point out that blood pressure management is more important than blood glucose management in controlling microvascular complications such as heart attacks and heart failure. Good glucose control is important in controlling microvascular complications such as retinopathy and nephropathy. Substudies of lipid-lowering trials indicate that good cholesterol control is also useful, although not quite as important as control of blood pressure and blood sugar.

The patient with hypertension and diabetes therefore must have tight glycemic control, blood pressure con-

trol, and cholesterol control. Otherwise, we all pay the price down the road.

Formulary Issues

AJMC: *Do you have any comments regarding formulary issues in the management of hypertension?*

Dr. Isszo: There has been a tendency among hospitals and HMOs to equate care costs in hypertension with drug acquisition costs. Much of the analysis of formulary budgets is done along those lines. This is a tremendous error that is propagated day after day in hospitals, HMOs, and insurance plans. We need to have a better assessment of the true cost of care and then look at the fraction of the total cost of care that composes the drug budget. Otherwise, we will be penny wise and pound foolish.

Again, this is why you have to stratify risk. If you try to treat high-risk patients with low-cost drugs and you don't achieve the endpoint reductions that are necessary, the ultimate cost to the plan will be very high. The diabetics stand out, renal failure patients stand out, the cardiac and heart failure patients stand out as individuals who should receive ACE inhibitor therapy, which currently costs more per pill than diuretics or β -blockers. Yet the return on the investment in ACE inhibitors will understandably yield a net savings. I cannot overstate that responsible managed care plans must understand that disease management programs must analyze total cost of care and not drug acquisition costs alone.