

Managing congestive heart failure



Providers are overcoming the underuse of ACE inhibitors for congestive heart failure with the use of guidelines, more PCP education, & integrated home care.

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BY JAN WEAVER

It's a disheartening paradox that even with recent advances in cardiovascular medicine, more people are dying from congestive heart failure (CHF) than ever before. These advances have prolonged survival for patients at risk, pumping up the numbers who may go on to develop CHF.

According to the American Heart Association (AHA), approximately 4.7 million Americans suffer from CHF. Aging baby boomers are expected to swell this number, doubling CHF rates over the next 25 years.

At AHA's annual conference last November, Michael Alderman, MD, warned, "[CHF] is likely to be an increasing public health problem. Current data suggest that, as people live longer...they face more CHF," said Alderman, who is chairman of epidemiology and social medicine at Albert Einstein College of Medicine, Bronx, NY. He presented results of a

long-term study of hypertensive individuals in whom CHF rates increased tenfold, despite well-controlled blood pressure and stable rates of stroke and heart attack.

CHF's growing prevalence should alarm the cost-conscious health care marketplace. CHF is resource-intensive, bleeding 10 billion health care dollars annually. Hospitalization accounts for \$7 billion, a cost tied to CHF's episodic treatment. More than one third of patients hospitalized for acute episodes are readmitted within 6 months, according to AHA figures.

Emerging CHF programs aim to put a stop in this revolving door of acute treatment and hospital readmissions. These programs place special emphasis on patient education, home health follow-up, and clinical guidelines that encourage appropriate pharmacotherapy.

AGING DRUG THERAPY

Drug-use protocols aim to remedy the historical underuse of angiotensin-converting enzyme (ACE) inhibitors in CHF pharmacotherapy.

National guidelines (and others) recommend that ACE inhibitors along with diuretics and digitalis be the mainstay of drug therapy for symptomatic CHF.

ACE inhibitors are the only drugs proven to delay the onset of CHF in high-risk patients and to improve survival in patients with advanced disease. According to Marc Thames, MD, chief of the division of cardiology at University Hospitals of Cleveland (OH), ACE inhibitor therapy saves 50 lives and prevents 200 hospitalizations per 1,000 patients treated. Thames addressed the National Managed Health Care Congress last year, as reported in the June 1996 issue of *PharmaCare Economics*. He said ACE inhibition is more economical than most interventions, costing \$15,000 per year of life saved.

Despite their clear benefit, ACE inhibitors are used in only about 30% of appropriate CHF patients. Harvard researcher Randall S. Stafford, MD, PhD, and colleagues reviewed records of patient office visits between 1989 and 1994. They found that ACE inhibitors were given to less than one-third of CHF patients treated. To make matters worse, ACE inhibitor use did not increase over five years. Stafford, an instructor of medicine at Harvard Medical School and Massachusetts General Hospital, presented these results at last year's AHA conference. "These data suggest a need to move beyond clinical trials of ACE inhibitors and focus attention on modifying physician practices," he said.

DO CARDIOLOGISTS DO IT BETTER?

According to Barry Massie, MD, better use of drug therapy in CHF could have "enormous clinical and economic impact." More than \$100 million could be saved annually if physicians prescribed cardiac medications appropriately, he told attendees of the American College of

CONGESTIVE HEART FAILURE'S GRIM STATISTICS

- 4.7 million Americans are afflicted with congestive heart failure
- 400,000 new CHF cases are diagnosed each year
- CHF contributes to 250,000 deaths annually
- CHF is the leading cause of hospitalization for persons 65 years and older
- CHF rates are higher in people who survive myocardial infarction
- Sudden death occurs 6 to 8 times more frequently in CHF patients than in the general population
- Total per-patient expenditures for CHF are estimated at \$10,000 annually
- CHF hospitalization costs per patient annually are around \$7,000
- CHF-related deaths increased 82.5% from 1979 to 1992
- Hospital discharges for CHF rose from 377,000 in 1979 to 875,000 in 1993

Cardiology's 45th annual scientific session last March.

He presented results of a survey of CHF patient management practices of more than 1,800 general practitioners, internal medicine specialists, and cardiologists. Massie, who participated in development of the Agency for Health Care Policy and Research's (AHCPR) 1994 clinical guidelines for heart failure, found that cardiologists used ACE inhibitors as first-line therapy in 85% of patients with mild to moderate CHF and in 95% of patients with severe CHF. These figures were much lower for family practitioners (62% and 83%, respectively) and for internists (74% and 83%, respectively).

"Cardiologists use ACE inhibitors in a higher proportion of patients and use doses more equivalent to those used in clinical trials," Massie tells *PharmaCare Economics*. "They also use them in patients with lower blood pressures and more impaired renal function, but at levels that are still recommended."

LOW BLOOD PRESSURE?

Primary care physicians may be scared off by ACE inhibitors' tendency to lower blood pressure in CHF patients, who are already hypotensive. They may also worry about small increases in serum creatinine, even though these changes are reversible if the drugs are discontinued.

Thames says MCOs that use primary care physicians as CHF gatekeepers to save money may actually end up spending more. When correctly administered, CHF drugs help keep patients out of the hospital, where the most costly care occurs. And since most studies show primary care physicians are less likely to prescribe CHF drugs properly, they may unwittingly increase the chances of hospitalization.

But Massie offered this codicil: "Our survey found that the more recently trained primary care physician practices more like a cardiologist. We found the demarcation [at] five years from when they received their training. And that really coincides with many of the recent advances in the treatment of heart failure."

Massie says CHF management by cardiologists is most appropriate in the more severe cases (New York Heart Association Classes 3 and 4). These are patients who are "high resource utilizers" for whom the high cost of cardiologist usage and follow-up is low compared to that of hospitalization.

He cautions that randomized, prospective

studies are needed to determine whether prescribing behavior really does make a difference. "We don't have studies that demonstrate this will result in different outcomes; it's just inferred from the major trials," he says.

"[Cardiologists] can't do it alone," says Massie. "When you go to a cardiologist, you



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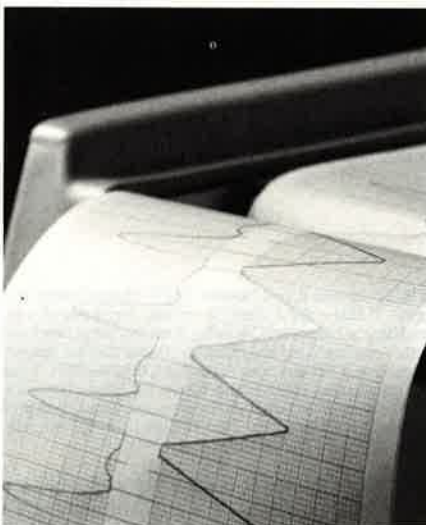


lose the overall primary-care grasp of the entire patient. And most of these patients are, indeed, multiple system-disease patients."

SOME POPS KNOW BETTER

But 1994 data showed that generalists at Columbia San José Medical Center, California, had the better track record for discharging CHF patients on ACE inhibitors, according to Monica Miyaji, RN, BSN. Miyaji is the center's quality improvement coordinator and served on the team that conducted a CHF clinical outcomes study at San José.

The multidisciplinary team, which included family practitioners, internists, and cardiologists, evaluated treatment variations in CHF and devised a clinical guideline based on their study.



"The incidence of use was slightly lower in our cardiology group," Miyaji told *PharmaCare Economics*. Thanks to physician education initiatives, ACE inhibitor use has increased at San José from 25% to 80% since early 1995.

San José's guidelines for CHF pharmacotherapy advocate ACE inhibitor use, but only after diuretics when treating acute episodes. "If the patient had not been treated with ACE inhibitors prior to admission, we don't recommend starting them on one until after their initial diuresis. This decreases the chance of a hypotensive episode. And if they're already on them, we cut the dosage in half until after their initial diuresis is complete," says Miyaji.

PATIENT EMPOWERMENT

While appropriate pharmacotherapy is key to improving outcomes, so is patient compliance, said Miyaji. The single element of San José's CHF study that has demonstrably improved outcomes is patient education. "If the patient doesn't take the drug because they don't understand why, you can prescribe from here to eternity and it won't make a difference."

A significant portion of patients—almost two-thirds—don't comply with medication regimens, making this a key reason for hospital readmissions. Miyaji noted there was a 45% drop in CHF readmissions in the group of patients who received education about their disease and its treatment. San José expects this decrease to generate cost savings of \$186,000 (based on \$6,000 per readmission) over six months, she said.

In the San José study, patients were divided into control and interventional groups, the latter receiving print and video educational materials at an estimated cost of \$50 per patient. "Patient education and, in fact, disease management programs, don't have to be high-tech or expensive to positively affect outcomes," Miyaji notes.

Miyaji adds, "There are three kinds of patients—those who know what to do and do it; those who would do it if they knew, and those who aren't going to do it anyway. All the education in the world isn't going to make them compliant." San José's efforts concentrate on the middle group of patients, who are the majority.

The flip side of the issue is the all-too-common perception of health care practitioners that patients can't be taught to manage their disease, says Miyaji. At San José, physicians support the efforts of nurse practitioners, who drive the educational component of their program.

HIGH-TECH AND HUMANITY

The Buffalo Grove, IL-based disease management firm, Cardiac Solutions, offers a CHF management program they describe as “physician directed, nurse mediated and patient managed.” Known as Multifit, its blend of high-tech and human interaction has reduced CHF readmission rates 70% since the program was initiated in March 1996 in 10 Humana markets. Cardiac Solutions, a division of Ralin Medical, has contracted with several other MCOs—Oxford Health Plans, U.S. Healthcare, United Healthcare, Blue Cross and Blue Shield of Massachusetts—to implement Multifit. These MCOs will pay Cardiac Solutions on a global fee or a shared savings basis.

Cardiac Solutions’ model is based on a methodology developed at Stanford University called Multifit. Multifit is a clinical management system that incorporates a database for outcome analysis, treatment guidelines for physicians, and educational materials for patients. “Multifit helps define the caregiving process—what the [doctor-patient] relationship should be,” says Judy Lenane RN, MHA, vice president of new business development for the company.

Multifit’s developer Robert DeBusk, MD, explained that the program provides an “infrastructure” for putting clinical guidelines into practice. “Guidelines keep getting developed and developed and developed. They wind up someplace, I don’t know where,” he told the National Managed Health Care Congress last June. Multifit “linked the guidelines to a delivery system...in which [they] can be implement-

ed.” DeBusk is cardiac rehabilitation program director at Stanford University.

While the Multifit operating system is the brains of Cardiac Solutions’ CHF program, “care management” nurses are its hands. The company supplies its own cardiac nurses, recruited, trained, and credentialed by Cardiac Solutions. These nurses play a key role, acting as liaison between patient, family, and physician, as



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well as between the physician and the protocol itself. They monitor adherence to Multifit’s treatment model, comparing its guidelines to the patient’s treatment plan and pointing out any deviations to the patient’s physician.

Like other CHF management programs, a primary goal of Multifit is to improve patient compliance through education. Its method is based on the premise that, if patients understand the consequences of noncompliance, they will be motivated to stick with the treatment plan.

“Patients are told what the outcome will be if

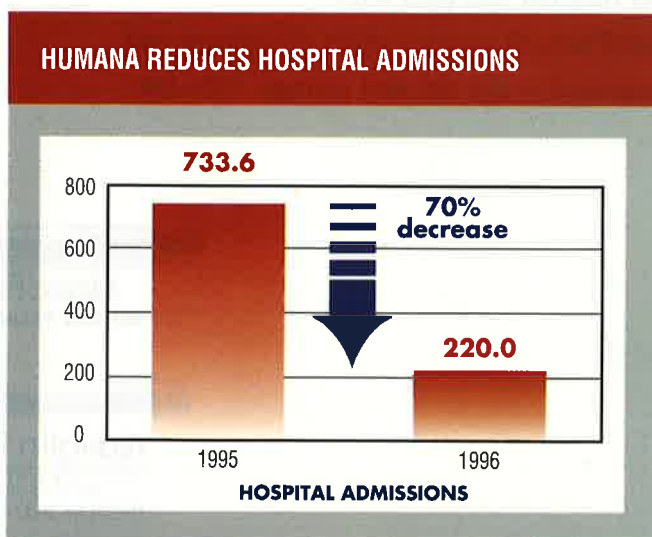
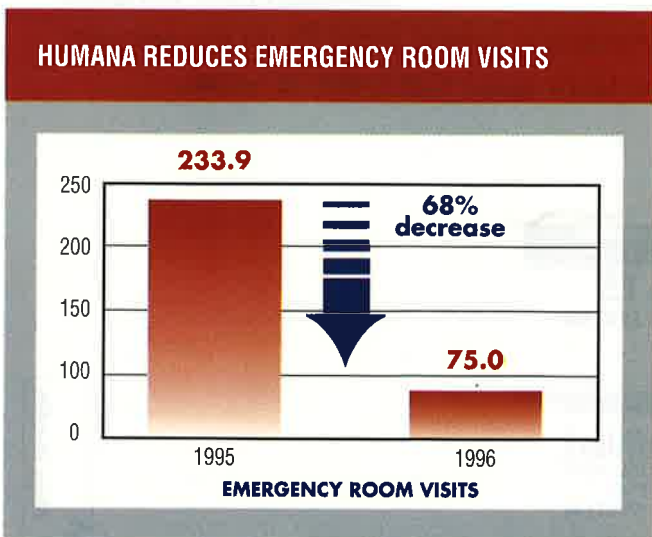
a certain course is followed and then are given feedback as to how well they are doing in pursuing those long-term goals,” DeBusk explained.

Nurses work with patients to help them set achievable self-management goals. Based on patients’ own estimation of their ability to comply with healthful regimens, nurses devise appropriate interventions. They then follow up with aggressive telemonitoring of the patients’ compliance to low-salt diets, medication regimens, and daily weighing schedules.

Since Multifit has been in place, Humana has seen a significant drop in hospital readmissions based on their 1995 readmission rate. Of the 902 patients enrolled in the program, the HMO operator could have expected 733.6 readmissions rather than the 220 that actually occurred. Using 1995 historical data, emergency room visits also dropped, from 233.9 to 75.

Cardiac Solutions also credits Multifit with shortened hospital stays (by 12%)—despite the fact that their program is not involved in inpatient care. Because outpatients are enrolled in a support system, says Lenane, their condition is not allowed to deteriorate.

The success of the support system is reflected in a significant rise in drug utilization costs, says Cornelia Tilney, vice president of marketing for Cardiac Solutions’ parent, Ralin Medical. “Drug costs in one market increased 161% (annualized) over the prior year on a per patient basis,” she says. “That’s exactly what we want to see. It indicates higher drug compliance, and pharmaceuticals are far more cost-effective than hospitalizations and ER visits.”



Based on 902 patients for 3028 member months from March-September 30, 1996. Data for 1995 reflects 3028 member months for CHF patients
Source: Cardiac Solutions

Cardiac Solutions claims Humana's decline in hospital days would be steeper if only those factors directly related to CHF were considered. Humana is encouraged by early results of Multifit and is enrolling Class 3 and 4 CHF patients in its other markets.

HOSPITAL AT HOME

Meanwhile, a group of cost-conscious Wheaton, IL, physicians has taken CHF management into their own hands. Internist Scott Kolbaba, MD, and his colleagues formed Affiliated Physicians Health Management, an IPA that has developed its own disease management protocols. Their protocols—35 to date—are designed to minimize hospital costs by beefing up the role of home care. Working with ServiceMaster Home Health Care, Downers Grove, IL, Kolbaba and colleagues custom-designed their own home care entity, called "Hospital at Home."

Affiliated Physicians' home-care efforts are in response to insurer-driven early discharges. Kolbaba said a CHF patient typically goes from an intensive care setting to a home setting with no care, thus risking complications and a poor outcome. Hospital at Home allows for early discharge while providing an intermediate physician-supervised plan to bridge this gulf.

Kolbaba tells *PharmaCare Economics* that CHF care is generally administered in the cardiac unit, which is expensive. But once patients are out of danger, little reason exists to keep them there. "We think that if a patient is in this condition, they can probably go home—but they still need some monitoring," he says.

Home care for CHF is not unique. San José's program and the one offered by Cardiac Solutions incorporate home-care protocols. So is Affiliated Physicians' program any different? "Ours has a component of physician care," said Kolbaba. Hospital at Home extends the physician's care via daily nursing visits and a faxing system that makes real-time nurse-physician interaction possible. Physicians are able to monitor their patients uninterrupted from a distance and are able to respond to timely data.

Kolbaba sees Affiliated Physicians' protocols as having an important part in bolstering its managed care business. But what happens if the MCO with whom they're contracting has its own protocols? "Protocols are revised every few weeks," notes Kolbaba. "We're willing to use whatever works and makes sense. And we have enough computer power to track different protocols for the same diagnosis. Then we can ana-

lyze which works better." Nevertheless, Kolbaba is confident their methods will be persuasive. "We have more than just protocols. We have statistics to back them up, a way to track outcomes, and a method of delivery care that works," he says. Affiliated Physicians has retained Stanford economist Alan Garber, MD, PhD, to its perform outcomes analyses.

Affiliated Physicians' CHF protocol has been in existence three months and has been used "successfully" on a half dozen patients,

says Kolbaba. Over the next year, the IPA plans to implement it in two medical centers.

While the results aren't all in, early results of budding CHF programs indicate they will generate substantial cost savings. Their developers realize that good medicine is cost-effective medicine, and if patients' interests are kept first and foremost, economic benefits will follow. ■

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Beta blocker therapy prolongs survival

So-called "third-generation" beta blockers may lining up behind ACE inhibitors as the next "hot" drug class in the treatment of congestive heart failure (CHF).

Beta blockers have been generally contraindicated in CHF treatment. It was assumed that these agents, by blocking beta receptors, would make a weak heart even weaker. But research over the past decade indicates beta blockers may, in fact, strengthen a failing heart. Except in patients with pulmonary complications, insulin-dependent diabetes, or acute heart failure, newer beta blockers such as carvedilol could have the net effect of prolonging survival when added to standard CHF therapy.

The MOCHA (Multicenter Oral Carvedilol Heart Failure Assessment) trial is one of four recent studies that examined the role of carvedilol (SmithKline Beecham's Coreg) in treating CHF. Published last year in *Circulation*, the study showed a 73% drop in death rate among carvedilol-treated patients over six months compared with those receiving placebo. Michael Bristow, MD, PhD, chief of cardiology at the University of Colorado School of Medicine, Denver, conducted the study.

Carvedilol works by inhibiting the adrenergic system, overstimulated in a CHF patient because the body perceives the heart's failing performance as an emergency and responds by telling it to secrete norepinephrine. This results in a continual flood of adrenergic hormone, damaging to heart muscle cells.

Third-generation beta blockers such as carvedilol and bucindolol offer a "more comprehensive anti-adrenergic profile" than older beta blockers, said Bristow. Bucindolol is currently in phase III trials, and carvedilol is approved for treatment of hypertension.

In one of the *Circulation* trials, Bristow and colleagues compared carvedilol and a "second-generation" compound called metoprolol. He

and his colleagues were able to demonstrate that carvedilol lowered norepinephrine levels in the heart while metoprolol had "no apparent effect."

"Data support the hypothesis that you get a more comprehensive blockade of adrenergic drive with carvedilol, which may explain the apparently superior clinical results," Bristow tells *PharmaCare Economics*. He cautioned that a large-scale, placebo-controlled, multicenter mortality trial is needed to make these findings conclusive.

Bristow's MOCHA trial showed that "carvedilol produced dose-related improvements in [heart] function and dose-related reductions in mortality and hospitalization rate." Among patients receiving the highest doses of carvedilol, the death rate was 1.1% compared with 15.5% in patients getting placebo.

Beyond MOCHA

In the U.S. Carvedilol Heart Failure Program trial, Bristow and colleagues showed that, when added to standard CHF therapy—ACE inhibitors, diuretics, and digitalis—carvedilol slows the progression of heart failure in patients with mild symptoms.

But don't ACE inhibitors do all these good things? "ACE inhibitors' reduction in mortality is modest at best," said Bristow. "This is probably not the reason to use those drugs. The main advantage of an ACE inhibitor is that it delays progression of heart failure. If one looks at the data across [these] trials, the reduction in mortality appears to be two to three times greater with carvedilol than with ACE inhibitors."

A fourth trial, PRECISE (Prospective Randomized Evaluation of Carvedilol on Symptoms and Exercise) published in *Circulation* found that carvedilol produces important clinical benefits in patients with moderate to severe heart failure when added to standard therapy. ■