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The Effectiveness of Heart Failure Disease Management: Initial Findings from a Comprehensive Program

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ABSTRACT

A prevalent, chronic condition among members of the mushrooming elderly population in the United States, heart failure (HF) is a logical focus for population-based disease management. Evidence supporting the premise that multidisciplinary interventions can significantly improve clinical outcomes while decreasing the cost of medical care for people with HF is steadily mounting. A growing number of controlled and observational studies focus on the effects of HF disease management on re-admission rates, length of stay, and improvement in appropriate diagnostic testing and prescribing. This paper describes a large-scale, comprehensive HF program and reports on clinical quality, utilization, and financial outcomes observed after 1 year. The preliminary findings strengthen the case for comprehensive HF disease management as an effective means for improving clinical outcomes and reducing total medical costs for large patient populations.

INTRODUCTION

A DEVASTATING DISEASE in terms of its prevalence, morbidity and mortality, and financial costs, heart failure (HF) ranks high on the list of chronic conditions burdening the U.S. health care system today. Recent statistics show that HF affects an estimated 5 million Americans, with approximately 400,000 new cases diagnosed each year.[1] Jolting as these statistics are, they are likely an underestimation of the actual incidence of HF. In one retrospective review of 225 randomly selected patients, investigators concluded that many patients admitted with shortness of breath and low left ventricular ejection fraction had HF but are not diagnosed.[2]

A patient's prospects for survival following a diagnosis of HF are bleaker than those for most forms of cancer. HF carries an overall mortality rate of 50% within 5 years of diagnosis. Croft et al.[3] reported a 6-year mortality rate secondary to HF of 84% in men and 77% in women. Despite continued advances in medical treatment for the disease, the mortality and morbidity attributed to HF have continued to rise. Between 1979 and 1997, HF deaths increased by 145% and HF hospitalizations rose by 155.2%.[4]

When viewed in the context of an aging U.S. population, the implications of the preceding take on added dimension. As 75 million "baby-boomers" age, the number of Americans over the age of 65 is expected to double over the next 30 years.[5] The incidence of HF increases with age: In people over the age of 65 it approaches 1%, and in the 70–79 age group it increases to 4%. By the year 2007, the prevalence of HF is

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expected to reach 10 million cases in the United States alone.[6]

According to Medicare program (HCFA/CMS) data, expenditures for HF in 1991 were higher than the combined expenditures for the five most common diagnosis-related groups for cancer, and higher than those for myocardial infarction.[7] In dollars, HF management, including hospitalization costs (inpatient and pharmacy) and outpatient visits, approached $38 billion. By 1996, HF accounted for 2.8% of all hospital discharges and 22% of all discharges for cardiovascular disease in the United States. "Based on an increase in the number of patients with heart failure since 1991, the total cost for HF management for 1999 is estimated to approach $56 billion."[6] Data suggest that half of the 15–30% HF related readmissions (within 90 days) are preventable.

Barriers to effective outpatient management

Medical management after the onset of HF is challenging for both physicians and patients. For the primary care physician (PCP), each new clinical trial and each new or revised guideline increases the complexity of the care and treatment of the patient with HF, particularly the patient with a co-existing chronic condition. A majority of patients with HF have one or more comorbid conditions. Diabetes, a complex disease in its own right, is a common co-existing condition, as are hypertension, hypercholesterolemia, and depression.

National guidelines for the medical management of patients with HF, published by the Agency for Healthcare Research and Quality (AHRQ) and the American College of Cardiology (ACC)/American Heart Association (AHA), are readily available from a variety of sources, including medical professional organizations, government agencies, managed care organizations, and other health care insurers. However, the administrative data [for example, Health Plan Employer Data and Information Set (HEDIS®; National Committee for Quality Assurance) data] reported by health plans show persistent and disturbing variances between recommended treatment and standard practice. Physician adherence to the established guidelines for the use of angiotensin converting enzyme (ACE) inhibitors has been the focus of numerous studies. While there is plentiful evidence that ACE inhibitors reduce disability, improve functional capacity, and prolong life in patients with HF, studies show that physicians continue to underutilize these drugs. In one study, only 73% of the patients most likely to benefit from and tolerate such therapy were prescribed ACE inhibitors at discharge from the hospital.[8]

Barriers to effective treatment of HF are not limited to physician issues. Cardiovascular disease often arises from unhealthy lifestyle patterns such as smoking, poor diet, or inactivity. Patients with HF often find it difficult to make necessary changes in behavior and lifestyle. Chin and Goldman[9] found that some admissions for HF could be attributed to patient inability to adhere to dietary (salt) restrictions or medication regimens. Psychosocial factors such as depression, hostility, and the social isolation often associated with age and infirmity have all been shown to contribute independently to mortality and morbidity in patients with cardiovascular disease—and anger and hostility are strongly associated with the development of HF.

Of particular interest are findings suggesting that as many as 15% of hospital readmissions for HF are related to underutilization of prescribed medication.[10] In his discussion of the economic burden of HF, O'Connell[6] estimates that "if pharmacologic and behavioral approaches were combined, the five-year mortality rate could be reduced by as much as 50 percent."

Disease management approaches to HF

Successful outpatient management models have been described in the literature, each employing a systematic approach to HF care and each resulting in improved quality as measured by decreased utilization of health care resources or by increased utilization of appropriate medications. Multiple approaches including outpatient HF clinics, predischarge team planning, off-site case management with home visits, and Internet-based interventions have been developed and researched. Positive findings consistently include reduction in adverse clinical outcomes (e.g., readmissions) and

costs with corresponding improvement in medication use and quality-of-life (QOL) indicators.[11–15] In a critical review of the evidence for HF disease management programs prior to 1999, Rich[16] catalogued 10 observational studies that suggested an association between multidisciplinary approaches and reduced inpatient admissions and length of stay (LOS), improved QOL, and lower overall cost of care. He also reviewed six randomized studies that effectively reduced inpatient utilization, improved functional capacity, and enhanced patient knowledge and compliance with treatment regimens. The long-term impact and cost-effectiveness of these models have yet to be determined.

Evidence of value of programs focused on developing self-management skills continues to mount. A recent AHRQ study of self-management programs at several university-based centers concluded that such programs improve health and reduce use of health care resources by people with chronic diseases.[17] In evaluating HF disease management programs, brief interventions (requiring 80–120 min of physician and other health care provider time) have been shown to be effective for patients who are highly motivated, have less comorbidity, are better educated, and have more social support. For patients who need more motivation, support, or skills training than a brief intervention can provide, intensive interventions have been shown to produce a greater effect than brief interventions.[18]

PROGRAM DESCRIPTION

American Healthways Corporation (AMHC) provides the Cardiac Healthways[SM] HF Program described herein to members of a large (over 800,000 members) midwestern U.S. commercial health plan. Holistic in approach, the program is designed to coordinate all health care needs of participants, not just those related to the managed disease. Stated program goals include promoting the physician–patient relationship; supporting the physician with patient management through regular health assessments, symptom monitoring, and ongoing patient education; improving the health status of the population; and, as a result, reducing the cost of medical care. The program is grounded in nationally recognized, evidence-based guidelines for medical management and treatment of heart failure, including the ACC/AHA Guidelines for the Evaluation and Management of Heart Failure; the National Cholesterol Education Program Guidelines (ATP III); the Joint National Committee for Treatment of High Blood Pressure (JNC VI); and the ACC/AHA Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 Update.

Education and support for PCPs

Cooperation and communication with the PCP are essential to the success of a disease management program developed around a pri-

Table 1. Focused Interventions for PCPs

Physician intervention	*Frequency*
Introductory letter	Initially
Cardiac care guidelines	Annually, as updated
Sample participant "welcome kit"	Initially
Provider service manager visit	Minimum once
Single topic sheet: beta-blocker indications and dosing	
Single topic sheet: ACE inhibitor indications and dosing	
Participant medication list	Semiannually
Computer-generated alerts/reminders	Semiannually
Patients not on ACE inhibitors or beta-blockers	
Home-monitoring alerts re weight, blood pressure, pulse	Daily, as needed
Cardiac-specific newsletter	Quarterly
Toll-free hotline	Ongoing
Flow sheet for documenting compliance with guidelines	Initial and annually
Satisfaction survey	Minimum annually

mary care "gatekeeper." The PCP is brought into the loop at the time of a patient's enrollment, and frequent contact is made throughout the patient's participation in the program (Table 1). Program staff sends an introductory letter along with a synopsis of the most recent ACC/AHA cardiac care guidelines to the PCP. Medication list updates, including both pharmaceutical claims data and patient self-reported information, are sent periodically to the PCP for all her/his participating patients. Software-generated reports are sent to alert physicians of HF patients who may be appropriate for certain treatments, such as ACE inhibitors or beta-blockers, and whose pharmacy records indicate that these medications are not prescribed.

A group of specially trained registered nurses, assigned to physician territories, visit offices to orient PCPs and their office staffs to the HF program. They provide education, offer encouragement and tools to assist the PCP in adhering to standards of care (e.g., indications for prescribing ACE inhibitors), and establish collaborative relationships to facilitate follow-up visits.

Focused interventions for program participants

Program participant interventions and associated frequencies are listed in Table 2. The key participant intervention is the "Care Call." Care Calls, regularly scheduled telephone contacts initiated by the program's nursing staff, serve as a basis for conducting health assessments as well as providing disease-specific education, advocacy, and provider treatment plan support on an ongoing basis. Participant responses to the assessments direct the nurses to educational points for discussion with the participant. At each follow-up phone call, nurses use a "follow-up assessment" script designed to quickly identify any decompensating symptoms. In the event of urgent symptoms, the nurses reinforce self-management by assuring that patients make contact with their PCPs. All HF participants meet criteria for the highest level (Level 4) in the program's proprietary population stratification model, and, accordingly, they are referred to nurses with the highest level of training for Care Calls. On the initial call, the nurse conducts a thorough HF assessment to further stratify the patient, which, in turn, drives the scheduled Care Call frequency. Care Calls range from weekly to every 6 weeks for HF members.

The nurse conducts a thorough medication review on the initial call, cataloguing all medications the participant is taking along with dosages and frequencies, compliance, medication knowledge, and attitude toward taking medications. From this discussion, the nurse is directed to education points on medications and suggested questions for the participant to ask his/her physician (i.e., "Would a beta-blocker be a good medication for me to be on?" "Should I be taking an ACE inhibitor?"). During follow-up calls, the nurse asks about any changes in medications.

Table 2. Focused Interventions for HF Program Participants

Participant interventions	*Frequency*
Letter of introduction and welcome kit	On identification
Standards of care mailings	Quarterly
Health education mailings	As requested by member or PCP
Cardiac-specific newsletters	Quarterly
Care Calls	
Initial welcome call	Once
Assessments (e.g., HF, medication, health status, depression risk screen, QOL)	Annually
Scheduled follow-up calls and re-assessment	According to protocol
In-home telemonitoring (weight, blood pressure, pulse)	According to protocol
Self-Care Goal Agreement	Ongoing
CHF toll-free hotline	Ongoing
CHF website	Ongoing
Satisfaction survey	Minimum annually

Whenever the nurse perceives a participant knowledge deficit, he/she supplements the discussion with a mailed single topic information sheet. Examples include information specific to medications such as ACE inhibitors, beta-blockers, aspirin, or statins; nutrition (low sodium diet); or congestive HF (CHF) (e.g., "What is CHF?"). All information from calls is entered in the HF participant's electronic medical record.

Another important element in the Care Call is the Self-Care Goal Agreement. A product of the nurse–participant telephone discussions, the agreement documents the participant's identified self-care goals. The goals are directed toward behavior modification that supports both the physician's treatment plan and the participant's objectives.

By means of these regular interactions with program participants, nurses are able to identify those patients most likely to benefit from in-home monitoring. After consultation with a patient's PCP, the nurse may arrange for electronic monitoring of the patient's weight, heart rate, and blood pressure. Patient selection and the duration of the in-home monitoring are determined by protocol.

SUBJECTS AND METHODS

The program is provided on an engagement basis to health plan members (i.e., all Commercial and Medicare + Choice members identified as having HF are automatically included in the program unless they exercise their right to "opt-out" by choosing not to participate). Identification is made on the basis of a minimum of one HF inpatient claim/encounter or two HF outpatient claims/encounters within a 12-month period with matching primary or secondary ICD-9 diagnosis codes listed in Table 3. Types of claims include professional, facility, and ancillary (inpatient, outpatient, home health, pharmacy, durable medical equipment, and any other ancillary) charges. Once identified, members and their PCPs are welcomed to the program via introductory letters, welcome kits, and Standards of Care notices. An electronic database equipped with proprietary software enables program staff to track participants' medical claims, drug prescriptions, nature and frequency of laboratory tests, and, in most cases, laboratory test results.

INITIAL RESULTS

Table 4 provides summary demographic data for program participants. Participant characteristics were well balanced with respect to age and gender for the baseline and report periods. Change in male–female ratio over the report period was marginally significant ($p < 0.05$). More than one-third of participants had

Table 3. Identification Scheme for HF Program

ICD-9 code	*Description*
398.91	Other rheumatic heart disease, rheumatic HF (congestive)
402.01	Hypertensive heart disease, malignant, with CHF
402.11	Hypertensive heart disease, benign, with CHF
402.91	Hypertensive heart disease, unspecified, with CHF
404.01	Hypertensive heart and renal disease, malignant, with CHF
404.02	Hypertensive heart and renal disease, malignant, with CHF and renal failure
404.11	Hypertensive heart and renal disease, benign, with CHF
404.12	Hypertensive heart and renal disease, benign, with CHF and renal failure
404.91	Hypertensive heart and renal disease, unspecified, with CHF
404.93	Hypertensive heart and renal disease, unspecified, with CHF and renal failure
425.0	Cardiomyopathy
428.0	HF, CHF
428.1	HF, left HF
428.9	HF, unspecified

Health plan members were identified for inclusion in the program based on at least one inpatient claim/encounter or two outpatient claims/encounters within a 12-month period with matching ICD-9 diagnostic codes listed.

Table 4. HF Program Data Summary

	Baseline	*Year 1*
Total participants	1,637 (100%)	1,973 (100%)
Age groupings		
19–34	17 (1.0%)	22 (1.1%)
35–50	118 (7.2%)	102 (5.2%)
51–65	326 (19.9%)	425 (21.5%)
66–80	643 (39.2%)	694 (35.2%)
81+	533 (32.6%)	730 (37.0%)
Gender		
Female	914 (55.8%)	1,032 (52.3%)
Male	723 (44.2%)	941 (47.7%)
Comorbidities		
CHF only	1,070 (65.4%)	1,251 (63.4%)
CHF with diabetes	567 (34.6%)	722 (36.6%)
Continuously enrolled	1,218 (74.4%)	1,456 (73.8%)

diabetes as a comorbid condition. Of health plan members identified with HF and enrolled in the program, 641 opted out. There were no apparent characteristics that distinguished this group from the participant group on analysis. Approximately 75% of participants were continuously enrolled in the program. One hundred twenty deaths (approximately 6%) were identified among program participants during the first year (June 1, 2000–May 31, 2001), an appreciably lower rate than expected in the general population (i.e., overall death rate from HF in the United States in 1999 was 18.8%).

Outcome variables for the first year of the program (June 1, 2000–May 31, 2001 with 6-month run-out) were compared with participant historical data in the year prior to engagement in the program (Baseline; January 1, 1999–December 31, 1999 with 6-month run-out).

CLINICAL PROCESS OUTCOMES

Three clinical processes were examined for indications of program effectiveness. The data included patients with systolic as well as diastolic dysfunction.

Appropriate use of ACE inhibitors

For the baseline and report period, the number and percentage of all program participants on an ACE inhibitor were calculated. Those taking an angiotensin receptor blocker or a combination of hydralazine and nitrates were included in the numerator.

Appropriate use of beta-blockers

For the baseline and report period, the number and percentage of program participants on a beta-blocker following diagnosis of myocardial infarction were calculated.

Appropriate low-density lipoprotein cholesterol (LDL-C) screening

For the baseline and report periods, the number and percentage of all program participants with administrative evidence of having a lipid profile screening were calculated. LDL-C profiles are presumed to be due 12 months following a preceding screening. Table 5 shows statistically significant ($p < 0.001$) improvement in appropriate utilization of ACE inhibitors and LDL-C testing for program participants during the first year of enrollment. While a 16.4% improvement was observed in beta-blocker utilization following myocardial in-

Table 5. Changes in Clinical Quality Process Measures for Members Enrolled in the HF Program

	Baseline (1,647 members)			*Year 1 (1,973 members)*			
Clinical measure	*N*	*D*	*%*	*N*	*D*	*%*	χ^2 (p)
LDL	320	1,637	19.5%	741	1,973	37.6%	139.82 (<0.001)[1]
ACE[2]	702	1,389	50.5%	1,092	1,707	64.0%	59.95 (<0.001)[1]
Post-myocardial infarction	30	70	42.9%	32	54	59.3%	3.28 (n.s.)

The percentages with each clinical measure were calculated from the given numerator (N) and denominator (D). n.s., not significant.

[1]Critical value at $p = 0.001$: 10.827.

[2]Excludes members with history of renal failure and members with medication allergy to ACE inhibitors who are not taking an angiotensin receptor blocker or a combination of hydralazine and nitrates.

Table 6. Change in Hospital Utilization with HF Program

	Baseline (1,637 members)	*Year 1 (1,973 members)*	*% change*
Admissions per 1,000	1,409.5 (total = 2,008)	1,149.2 (total = 1,949)	−18.5%
Days per 1,000	9,416.2	7,324.9	−22.2%
Average LOS	6.7 days	6.4 days	−4.4%
ER admissions per 1,000	1,239.6 (total = 1,766)	935.1 (total = 1,586)	−24.6%

farction, significance was borderline at the $p < 0.05$ level. In all likelihood, the small numbers account for this.

OTHER OUTCOMES

A comparison of hospital utilization patterns for the two periods yielded additional positive findings. Total admissions decreased, and, as shown in Table 6, reductions were realized in the number of inpatient admissions per thousand (18.5%), days per thousand (22.2%), and average LOS (4.4%). Visits to the emergency room (ER), costly in both human and financial terms, also decreased in the first year. ER admissions per thousand dropped by 24.6%. A preliminary examination of readmission rates showed a decline in the number of readmissions within 30 (18.8%) and 60 (19.2%) days of discharge with a primary diagnosis of CHF (ICD-9 code 428.0). Adjusting for the difference in member months, the percentage reductions are even greater (−31.7% and −32.2%, respectively).

A cost adjustment was necessary in order to make valid financial comparisons between the two periods. An "inflation factor," reflecting the increase in total medical costs over the period, was calculated using medical claims for the "nondisease" population. The nondisease population, defined as all health plan members without any indication of either HF or diabetes, experienced an 18.2579% increase in medical costs. This estimate of the overall increase in costs was used as a multiplier in adjusting baseline figures for financial comparisons. A comparison of inflation-adjusted financial data from the year prior to implementing the program and the first year of the program showed total medical dollars per member per month (PM/PM) decreasing by 28%, with the expected increase in pharmacy costs being offset by the sharper reduction in medical spending for urgent and inpatient care (Table 7).

Finally, summary data from a satisfaction survey of a random sample of 103 (approximately 6%) program participants yielded findings consistent with the preceding positive outcomes. Of the respondents, 89.4% rated their

Table 7. Change in Medical Expenditures for Members Enrolled in the HF Disease Management Program

	Baseline (1/1/99–12/31/99) (1,637 members)		*Year 1 (6/1/00–5/31/01) (1,973 members)*	
Member months	17,096		20,352	
		Adjusted base[1]		*% change*
Medical dollars PM/PM	1,060	1,253.74	870	−30.6%
Pharmacy dollars PM/PM	66	77.71	89	+14.5%
Total dollars PM/PM	1,126	1,331.45	959	−28.0%
Total medical expenditures	$19,248,198	$22,762,514	$19,519,448	

[1]Cost-adjusted for inflation in medical costs: baseline multiplier 18.2579%.

overall satisfaction with the program from "good" to "excellent."

DISCUSSION

The observed increases in pharmacy and ACE inhibitor utilization are indications that targeted program interventions had the desired effect on the behavior of both patients and their physicians. Summary statistics for in-office education with provider offices for the first year revealed the intensity of program communication efforts: 317 office/clinic visits, 258 physician interactions, and 325 clinical staff interactions. One question to be addressed in the future is why, with the program's emphasis on proper use of and dosing with ACE inhibitors, the utilization of ACE inhibitors in this population is less than the utilization reported in studies of smaller populations.[11,12]

The phenomenon of "regression to the mean" is understood to be a factor in explaining decreases in medical costs for HF populations, particularly those identified on the basis of a hospitalization in the baseline year. To minimize the effect of this potential bias, the program population was identified via outpatient as well as inpatient data, and the analyses include members with and without hospitalizations for both the baseline and the report period. Medical expenses for health plan members without evidence of HF or diabetes rose by 18.25% during the report period, supporting the premise that the positive financial outcomes observed were due to the intervention rather than regression to the mean.

Using cost-adjusted medical expenditures for the baseline, estimated total cost savings for program participants in the first year is $6,359,712. The average first year savings for a HF program are 10% beyond the cost of the program. While the costs of providing this program are not available for publication, the financial outcomes suggest that the program was cost-effective.

CONCLUSION

HF is aptly described as an "emerging epidemic" in the Medicare population. Prospects for survival for older adults with HF in the United States are dismal. Growing numbers of adults are at increased risk for developing HF due to hypertension, diabetes, and/or myocardial infarction. Evidence of the effectiveness of HF disease management has been reported in a number of small population studies. This observational study extends our understanding of the role of HF disease management in controlling or retarding the progression of HF, improving participants' health status, and decreasing overall medical costs in a large population. While it is recognized that it may take several years to fully determine its effectiveness, the initial outcomes of this HF disease management program are uniformly positive. Analyses of clinical processes and a spectrum of other variables, including medical utilization, financial data, and participant satisfaction, suggest that the program's multiple physician- and patient-focused interventions are associated with significant improvement in outpatient medical management, reduced inpatient utilization, and decreased medical costs for participants.

The evidence for HF disease management is growing, but, if the staggering clinical and economic effects of the disease are to be contained, the health care industry must continue to develop and refine strategies for controlling the progression of HF in diagnosed patients and for preventing the onset of HF. Proactive steps must be taken to control the condition prior to the onset or early in the course of progressive left ventricular dysfunction. Predictive models to identify patients likely to develop HF and early interventions to head off adverse clinical events are already being studied. Incorporation of primary prevention strategies, such as treatment of hypertension and hyperlipidemia and intensive education for physicians and patients alike, holds promise for improving or reversing myocardial dysfunction. A multifaceted program such as the one described could become even more effective by broadening its scope to include prevention.

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