Effect of a Standardized Nurse Case-Management Telephone Intervention on Resource Use in Patients With Chronic Heart Failure

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Background: Case management is believed to promote continuity of care and decrease hospitalization rates, although few controlled trials have tested this approach.

Objective: To assess the effectiveness of a standardized telephonic case-management intervention in decreasing resource use in patients with chronic heart failure.

Methods: A randomized controlled clinical trial was used to assess the effect of telephonic case management on resource use. Patients were identified at hospitalization and assigned to receive 6 months of intervention (n = 130) or usual care (n=228) based on the group to which their physician was randomized. Hospitalization rates, readmission rates, hospital days, days to first rehospitalization, multiple readmissions, emergency department visits, inpatient costs, outpatient resource use, and patient satisfaction were measured at 3 and 6 months.

Results: The heart failure hospitalization rate was 45.7% lower in the intervention group at 3 months (P=.03) and 47.8% lower at 6 months (P=.01). Heart failure hospital days (P=.03) and multiple readmissions (P=.03) were significantly lower in the intervention group at 6 months. Inpatient heart failure costs were 45.5% lower at 6 months (P=.04). A cost saving was realized even after intervention costs were deducted. There was no evidence of cost shifting to the outpatient setting. Patient satisfaction with care was higher in the intervention group.

Conclusions: The reduction in hospitalizations, costs, and other resource use achieved using standardized telephonic case management in the early months after a heart failure admission is greater than that usually achieved with pharmaceutical therapy and comparable with other disease management approaches.

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EART FAILURE (HF) is an extremely common disorder and one that is associated with significant morbidity, mortality, and cost.1-3 Because of this burden, investigators are actively exploring ways to improve the outcomes associated with HF. Pharmaceutical therapy reduces hospitalization from 12%4 to 35%,5 depending on the agent. Higher rates are found when a combined end point of mortality and rehospitalization is used.^{6,7} In comparison, in randomized trials of comprehensive disease management, hospital admission rates were reduced from 27%8 to 73%,9 with most interventions demonstrating reductions in the 40% to 50% range. 10 Disease management approaches shown to be effective include multidisciplinary disease management, 11 heart failure clinics, 12 and community outreach programs. 13 Telephonic case management is another approach believed to promote continuity of care and decrease hospitalization rates in

persons with HF. However, few clinical trials have tested the effectiveness of this approach, 14-16 and only 1 study was conducted among patients with HF. 14

Case management has been differentiated into community outreach and telephonic approaches.17 Community outreach programs typically involve home visits by a registered nurse, physician, and/or pharmacist. 13,18 The face-to-face visit in the patient's own home is used to evaluate the living situation, physically assess the patient, and continue patient education. In contrast, telephonic methods of case management often involve a nurse calling patients after discharge from a hospital to ensure that the treatment plan is being followed: questions are answered, early symptoms are addressed, and teaching is continued.19 Telephonic case management may be particularly challenging because of the lack of visual cues and the inability to physically examine the patient. Therefore, much of the effectiveness of telephonic case management de-

PATIENTS AND METHODS

STUDY SAMPLE

Although it was the physicians who were randomized, patients were the unit of analysis for this study. It was not feasible to randomize patients in the same physician practice to different groups because of the possibility that the physicians would modify care in the control group to mimic aspects of the intervention. Physicians known to admit patients with HF were matched by specialty (eg, cardiology or internal medicine), practice size (number of physicians within a single provider site), and number of HF admissions in the prior year. After matching, physicians were randomly assigned to the intervention or usual-care control group. All physicians within a single provider site were assigned to the same group. A total of 281 physicians were randomized. Physicians were not informed of the group to which they were assigned.

A 40% decrease in the HF hospitalization rate was anticipated based on prior studies. ¹⁰ Assuming a power of 0.80, a 2-tailed α of .05, and a small to moderate effect size (Cohen d=.33), we required 290 patients (145 per group) to detect a difference of 40% in HF hospitalization rates. A larger sample size would have been needed to detect differences in outpatient resource use, ^{15,16} but this outcome was not the focus of the analysis.

After institutional review board approval was obtained, bilingual nurse research associates screened patients hospitalized at 2 Southern California hospitals to determine eligibility. Included were patients with a confirmed clinical diagnosis of HF as the primary reason for their hospital visit and those who spoke either English or Spanish. Excluded were patients with cognitive impairment or psychiatric illness, severe renal failure requiring dialysis, terminal disease (eg, cancer and/or acquired immunodeficiency syndrome), discharge to a long-term care facility, or previous enrollment in an HF disease management program. Approximately 1145 patients were screened and 573 (50%) of these met eligibility criteria. Of these eligible subjects, 358 (62%) were included in this study. The rest declined participation (n=148), were under the care of a physician who refused the intervention (n=29), withdrew during the course of the study (n=28), or were dropped for reasons such as having moved out of the country (n=10).

INTERVENTION

After obtaining informed consent, telephonic case management by a registered nurse was provided using a decision-support software program developed by Pfizer Inc.²¹ The software program was designed to emphasize those factors-previously-shown-to-predict-hospitalization-in-persons with HF (ie, poor adherence to medication regimens and diet recommendations and lack of knowledge of the signs

and symptoms of worsening illness).²² The software program uses automated tools for setting priorities for patient education, data collection, and documentation. Important clinical information is organized within the program to facilitate patient care by the case managers (Figure). Best practices—derived from published guidelines, prior research, and input from experts—are supported by the program.^{23,24} The software was refined after exploring the needs of patients with HF, their caregivers, and case managers. An advisory board of cardiologists, primary care physicians, and case managers provided critical feedback throughout the process of software development.

In this study, the intervention group (n=130) was telephoned within 5 days after hospital discharge and thereafter at a frequency guided by the software and case manager judgment based on patient symptoms, knowledge, and needs. For example, a patient reporting sudden weight gain would receive a follow-up telephone call the following day to evaluate the response to suggested interventions and to closely monitor the signs and symptoms of fluid retention. Patients exhibiting shortness of breath often received an additional telephone call on the same day to ensure that physician contact had been made and that his or her instructions were understood by the patient. When access to prescribed medications was identified as a problem, frequent telephone calls were often necessary to arrange for a supply of medications.

Patients received an average of 17 phone calls at decreasing levels of intensity, length, and frequency over the 6-month follow-up period (median, 14 phone calls; interquartile range, 11-22 phone calls). Each patient was estimated to have received 16 hours of a case manager's time overall. Time not spent directly with patients was used in speaking with family members, consulting with community agencies and other professionals (eg, physicians, dietitians, social workers, and physical therapists), preparing reports for physicians, and researching drugs, diets, and information requested by patients. Printed educational material was mailed to patients monthly. Physicians were sent automated reports produced by the software that updated them on patient progress and were telephoned by the case managers as needed. Guidelines for the treatment of systolic HF²³ were distributed to physicians with their first notification of patient progress. Care for patients in the usualcare control group (n=228) was not standardized, and no formal telephonic case-management program was in existence at these institutions. These patients presumably received some education regarding HF management prior to hospital discharge.

OUTCOME MEASUREMENT

Demographic (eg, age, sex, primary language, marital status) and clinical data (eg, HF type) were collected from the

pends on the unique abilities and experience of the provider. A recent editorial on HF home care noted that "intermediaries [are] step[ping] up to the role of a heart failure expert, and frankly, some do it well while others do it not so well . . . there remains too much variability."²⁰ In the present study, care was standardized using a decision-support software program from Pfizer Inc called At Home With Heart Failure.²¹

The primary aim of our study was to assess the effectiveness of a standardized telephonic nurse casemanagement intervention in decreasing resource use in patients with chronic HF. A randomized controlled clinical trial was conducted to test the primary hypothesis that HF hospitalization rates would be lower in the intervention group than in the "usual-care" control group. Secondary hypotheses were that the following would be

medical record at the time of index hospitalization. Functional status was measured using the New York Heart Association (NYHA) classification system. Few patients had physician documentation of NYHA class, so a single master's-prepared nurse practitioner rated NYHA class on every patient based on information available in the hospital record. Functional status was also assessed using the Specific Activity Scale. Comorbidity was measured using the interview format of the Charlson Index. Severity of illness during the index hospitalization was assessed using the refined diagnostic-related grouping technique from 3M (St Paul, Minn). Baseline drug therapy was obtained from the index hospitalization medical record. Subsequent drug therapy was obtained by self-report at 3- and 6-month intervals.

Data on acute care resource use (ie, hospitalization rates, readmission rates, hospital days, days to first rehospitalization, total number of readmissions, and HF costs) were gathered from automated financial records at 3 and 6 months following discharge from the hospital for the index admission. Any out-of-system inpatient resource use was identified by patient self-report at 3 and 6 months. Acute care costs were measured using a combination of direct and indirect costs, which were obtained from the hospital's automated financial records using Eclipsys (formerly Transition Systems Inc), Atlanta, Ga. Direct costs reflect the cost of providing care, while indirect costs reflect overhead.

Six months after the index admission, nurse research associates visited physicians' offices to abstract records to obtain information on outpatient resource use measured as the number of physician office visits, emergency department and urgent care visits, and outpatient cardiac tests. A survey measuring satisfaction with care was administered to patients by telephone at 6 months. The survey contained 5 questions addressing, respectively, (1) current treatment, (2) convenience of health care, (3) patient education, (4) medication schedule, and (5) the care from the physician.

The cost of the intervention was calculated using estimates of the time required for case manager training and patient care. The nurses received 10 days of intense training and continuing mentoring in case management thereafter (ie, 15 one-hour sessions); a total of 95 hours of training was provided each case manager. Each patient was estimated to require approximately 16 hours of a case manager's time over the 6-month period. An hourly rate of \$22.66 plus 17% of that figure for employee benefits was used in the calculations based on mid-range salary rates during the study period.

STATISTICAL ANALYSIS

The intervention and usual-care control groups were assessed for balance on demographic and clinical characteristics at baseline. The effectiveness of the intervention was assessed by comparing outcomes between the interven-

tion and usual-care control groups at 3 and 6 months following discharge from the index hospitalization. Analyses were performed using SPSS statistical software, version 7.5 (SPSS Inc, Chicago, Ill). A P value less than .05 was predetermined as indicating a statistically significant difference between the groups. Covariates were used in the analyses if group differences were evident at baseline and there was a plausible association with the outcome variables. Cost analyses were conducted using logarithmically transformed data because of the severe positive skewness caused by multiple zeros. Descriptive statistics for the untransformed cost data are reported.

Investigators routinely report both hospitalization rates and readmission rates in the literature. Thus, both are included here. Unadjusted hospitalization rates represent the mean number of hospitalizations per patient and are calculated as the number of hospitalizations for the sample within 3 and 6 months of index hospital discharge divided by the full sample size, regardless of whether a readmission occurred. ^{11-13,27,28} Unadjusted readmission rates reflect the proportion of the sample admitted at least once during the study period. ²² Unadjusted readmission rates were calculated as the percentage of patients readmitted to the hospital after the index admission.

To test the primary hypothesis of group differences in HF hospitalization rates, the number of hospitalizations per patient within 3 or 6 months of index discharge was analyzed by analysis of covariance. Readmission rates were analyzed using multiple logistic regression. The log odds of the probability of being readmitted at least once within 3 or 6 months of index discharge was modeled as a linear function of the intervention group after adjusting for the covariates. Multiple linear regression models were used to analyze the average number of accumulated hospital days (for HF and all causes) and inpatient HF costs during the 3- and 6-month follow-up. The mean number of days between index hospital discharge and the first rehospitalization was compared using analysis of covariance. The rate of multiple readmission during the 6-month study period was calculated as the percentage of patients admitted more than once and tested for group differences using logistic regression. Group differences in the rate of emergency department and physician office visits during the 6-month study period were tested using logistic regression. Patient satisfaction was analyzed using multiple linear regression.

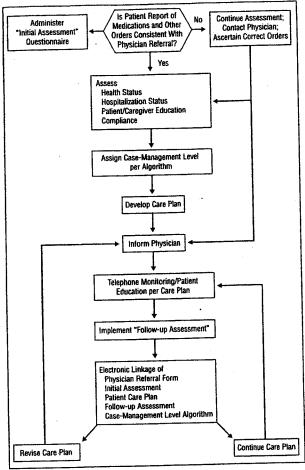
All analyses were conducted using 2 covariates on which the groups différed at baseline in spite of randomization: β-blocker use and chronic lung disease. In no analysis was either covariate significant. Correlations between the covariates and the outcomes were typically in the .02 to .04 range; none was higher than .09. Therefore, all reported results reflect group differences without adjustment for covariates, although results with covariates are shown in **Table 1**.

decreased: all-cause hospitalization, readmission rates (for HF and all causes), average number of hospital days (for HF and all causes), and inpatient HF costs at 3 and 6 months. Days to first rehospitalization, multiple readmissions (ie, >1) for any cause, and outpatient resource use (ie, emergency department and urgent care visits for any cause and/or physician office visits) were evaluated at 6 months. Outpatient resource use was as-

sessed to determine if shifting of costs from inpatient to outpatient care occurred. Patient satisfaction was assessed at 6 months.

RESULTS

After randomization, physician agreement to participate was sought, but not all physicians were willing to



Telephonic case management was standardized using a computer software program²¹ developed by Pfizer Inc, New York, NY, in which patients were comprehensively assessed and managed. The frequency of subsequent phone calls was determined by the case-management level assigned by the nurse. Calls emphasized monitoring and patient education. Physicians were kept informed through written reports and by telephone if necessary.

allow their patients to be approached. A final sample of 358 patients (130 intervention and 228 control) was used for the analysis of acute care resource use. However, data on outpatient resource use and satisfaction were only available on a subsample of 242 patients who were divided between the intervention (n=130) and control (n=112)groups. The only significant difference between the subsample of 242 and the 116 on whom outpatient resource data use were not available was primary language; more patients whose primary language was Spanish were in the sample of 116 than in the 242 on whom outpatient resource use data were available. All 358 patients were drawn from the a priori randomization of physicians to the intervention or control group.

PATIENT CHARACTERISTICS

The overall sample was elderly (mean ± SD age, 72 ± 12 years), almost equally divided by sex (51% female), predominantly unmarried (56% widowed, single, or divorced) (Table 2), and functionally compromised (97% were NYHA class III or IV) (Table 3). The only significant differences between the groups on demographic or clinical descriptors were a higher use of \beta-blockers and a lower incidence of chronic lung disease in the intervention group.

PRIMARY ANALYSIS

Heart failure hospitalization rates were 45.7% lower in the intervention group than in the usual-care control group at 3 months (P=.03). At 6 months, HF hospitalization rates were 47.8% lower in the intervention group than in the control group (P=.01) (Table 1).

SECONDARY ANALYSES

Acute care resource use was consistently lower in the intervention group than in the usual-care control group at 3 and 6 months. All-cause hospitalization rates dropped 25.6% at 3 months and stayed 28.2% lower in the intervention group at 6 months (P=.03). Heart failure readmission rates (ie, the percentage of patients admitted at least once during the study period) were 36% lower in the intervention group at 3 and 6 months, but reached statistical significance only at 6 months. Allcause readmission rates were not significantly different at either 3 or 6 months. The average number of days spent in the hospital for HF was 46% lower at both 3 and 6 months, although only the 6-month difference reached statistical significance. The number of all-cause days in the hospital was 27% lower at 3 months and 28% lower at 6 months in the intervention group, but not significantly different between the groups. Inpatient costs for HF admissions were 35% lower at 3 months and 45.5% lower at 6 months, but the difference between groups only reached statistical significance at 6 months.

The mean time from index hospital discharge to rehospitalization was longer in the intervention group but not significantly different between the groups (Table 1). The percentage of patients experiencing multiple readmissions (2 or more during the 6-month period) was 43% lower in the intervention group and significantly different between the groups. There were no significant differences between the groups in the number of outpatient resources used (ie, physician office visits and/or emergency department visits) during the 6-month period.

Patient satisfaction information was available from only 184 of the 242 patients we attempted to survey. The others were traveling, in the hospital, living in an extended care facility, or dead. There were no significant demographic or clinical differences between the patients who responded to the survey and those who were unavailable. Patient satisfaction was significantly higher among persons assigned to the intervention group than among those in the usual-care control group.

The intervention was calculated to cost \$443 per patient, if the cost of training is included. If each case manager carries 130 patients per year (2080 working hours in the year/16 hours per patient = 130 patients per year), the cost of a 16-hour intervention provided over 6 months is \$424 per patient. When training costs were divided among 130 patients, an estimated \$19 of training costs was added to each patient to produce the \$443 per patient estimate.

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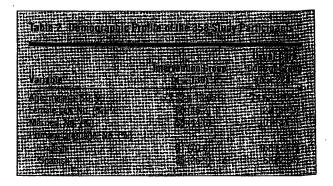
^{*}Data are given as mean ± SD or percentage.

COMMENT

Patients with HF who regularly received standardized telephone calls from a registered nurse case manager required significantly fewer resources over the 6 months of study than patients receiving usual care. Experts argue that the key to a successful HF program is access to and continuity of care. ^{10,24,29} The results of this trial support that theory.

Significant cost savings were demonstrated with this intervention. The cost of acute care for each patient in the usual-care group was \$2186, on average, but the average cost per patient in the intervention group was only \$1192. This difference computes to about \$1000 less per patient over the 6 months of the study compared with those in the usual-care control group. This savings is more than double the estimated \$443 cost per patient for the 6-month case-management intervention.

Although pharmaceutical therapy is the mainstay of HF care, its ability to limit acute care resource use and decrease costs is rarely as potent as that of disease management. For example, the angiotensin-converting enzyme inhibitor ramipril decreased HF hospitalizations only 12%. Captopril reduced HF admissions by 22% in the SAVE trial. Hospitalization for worsening HF was 23% lower in patients treated with digoxin than in those given placebo in the DIG trial. Bisoprolol decreased the HF hospitalization rate by 32% in the CIBIS II study.

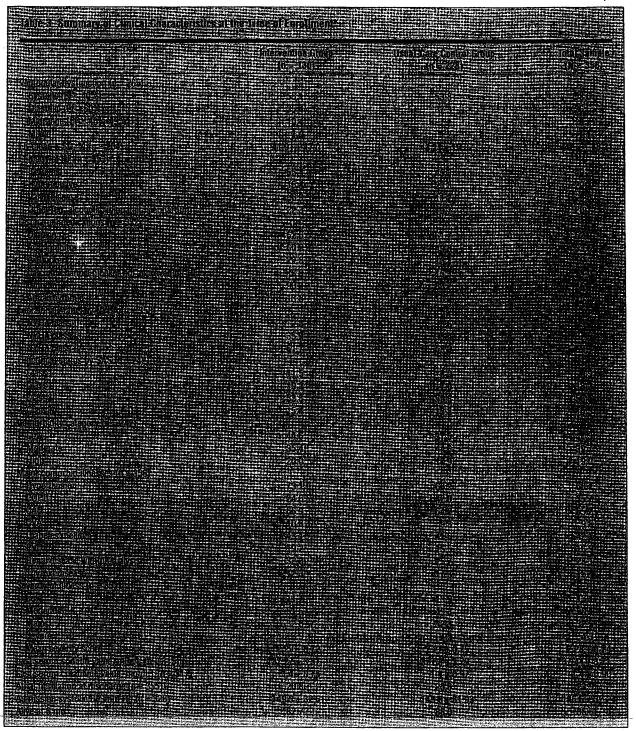


the RALES trial, treatment with spironolactone decreased the frequency of HF hospitalization 35% in comparison with placebo.⁵ Disease management may have superior outcomes because the disease management providers typically emphasize the importance of medication compliance, help patients design dosing systems and ways to remember their scheduled medications, and "problem-solve" medication adverse effects. In this way, disease management augments the effectiveness of pharmaceutical therapy.

Surprisingly, few other investigators have scientifically tested an intervention of this style with a chronically ill patient population, although telephonic case management is used widely in disease management programs across the country. 33 We identified 3 controlled clinical

[†]Analyses were conducted with and without 2 covariates (β-blocker use and chronic lung disease).

[‡]Patient satisfaction was measured as points.



*Data are given as mean ± SD or percentage. EF indicates ejection fraction; HF, heart failure; ACE, angiotensin-converting enzyme; NYHA, New York Heart Association; SAS, Specific Activity Scale; COPD, chronic obstructive pulmonary disease; CAD, coronary artery disease; CVA, cerebrovascular accident; PVD, peripheral vascular disease; and BP, blood pressure.

†P<.05.

trials in which the intervention was delivered almost entirely by telephone, but only 1 of these was conducted with HF patients. 14-16 Wasson and colleagues 15 demonstrated a significant 19% reduction in scheduled and unscheduled clinic visits, 28% fewer days in the hospital, and 28% lower cost among chronically ill patients called

an average of 8 times over a 2-year period. Patient satisfaction increased significantly. Infante-Rivard and colleagues¹⁶ lowered outpatient physician office visits 15% in an elderly group who were provided as many as six 30-minute phone calls over a 48-week period, although the difference between the intervention and control groups

[‡]To convert creatinine to micromoles per liter, multiply by 88.4.

was not statistically significant. West and colleagues¹⁴ provided a primarily telephonic intervention (a mean of 13.2 calls over a 6-month period) to a group of patients with HF and significantly reduced physician office visits (cardiology, 31% lower; general medical, 23% lower), emergency department visits (HF, 67% lower; all-cause visits, 53% lower), and hospitalization rates (HF, 87% lower; all-cause rates, 74% lower).

Together, these studies suggest that telephonic case management can significantly decrease physician office visits, hospital days, emergency department visits, and rehospitalization rates. The results of this study support this conclusion, although in this study, emergency department visits increased—perhaps because patients in the intervention group sought care early enough to avoid rehospitalization. The published range of decreases in resource use seen in the various trials suggests that some telephonic case-management interventions are more effective than others. At this point it is unclear whether intensity of the intervention, standardization of the approach, patient characteristics such as severity of illness, or some combination of these factors influences the effectiveness of the approach. Further research is needed to identify the best way to implement a telephonic casemanagement intervention.

A review of studies in which telephone access was included as only 1 component of a multifactorial intervention program suggests that treatment intensity is partially responsible for the effectiveness of this telephonic intervention. Two of 4 HF disease management programs that included telephone access as a component of therapy demonstrated a beneficial effect on acute care resource use. 27,34 The other 2, which demonstrated no benefit, seem to have offered weak telephone interventions.35,36 For example, in 1 of these latter studies, an average of 7.5 follow-up telephone calls were provided, but each call was an average of only 5.7 minutes long.35,36 True case management emphasizing the essential factors that predict rehospitalization would be difficult to accomplish in that time. In the other study that found no beneficial effect, a median of 4 telephone calls were made over the entire 5-month follow-up period.35 In contrast, weekly calls were made in the 2 trials in which benefit was found. 27,34 In the present trial, the case managers expended 16 hours over 6 months, most of which was spent counseling the patients over the telephone. This observation suggests that the intensity of the intervention is related to its effectiveness.

Standardization of the intervention is another potentialexplanationoftreatment effectiveness. In the present trial, a computer software program was used to standardize care and documentation. West and colleagues¹⁴ also used a method of standardization and also demonstrated significant reductions in resource use. However, others who apparently did not standardize the intervention also found a decrease in resource use.¹⁵ The fact that the reductions found with an unstandardized approach were not as great as those found in the present study and in the study by West et al¹⁴ suggests that standardization of the content may augment the power of a telephonic intervention by assuring that essential content is addressed.

Severity of illness may be another factor influencing the outcomes achieved with a telephone intervention. In the present study, the vast majority (97%) of the patients were in NYHA class III or class IV at the time of enrollment, but most (60%) of those studied by West and colleagues14 were less symptomatic (ie, classes I and II). In the study of the intervention that provided only brief telephone calls (5.7 minutes) and increased resource use rather than decreased it, many (49%) of the patients were in class III or class IV.36 This disparity of findings suggests that there may be an interaction between treatment intensity and illness severity. Previous research testing a multidisciplinary disease management approach for patients with HF supports this observation. 28 In that study, a moderately intense intervention increased acute care resource use in patients with asymptomatic disease (NYHA class I) but decreased acute care resource use in those in the early symptomatic (NYHA class II) stages. Further research is needed to identify the patient population expected to benefit most from particular styles and intensities of disease management approaches.

Limitations of this study may stem from randomization of physicians rather than patients, which might have introduced a sample selection bias. However, the randomization strategy yielded 2 groups that were equivalent in most of the measured variables. Those variables on which the groups differed were evaluated as potential covariates and not found to be associated with study outcomes. Another limitation is that the sample size was not adequate to detect differences in outpatient resource use. However, our concern was the potential for an increase in outpatient resource use, and no such trend was observed. Physician blinding may not have been sufficient to prevent bias: those randomized to the intervention group probably deduced it based on receipt of reports and intermittent case manager calls. It is possible that these physicians delivered less care or postponed hospitalization in these patients because of the support from the case managers. This effect was not unanticipated or undesired clinically, but it could bias the study results in favor of case management. Future studies would be enhanced by careful logging and reporting of actual hours spent per case manager with each patient rather than applying an estimated average per patient. .

In summary, this clinical trial is one of the few testing a commonly used intervention—telephonic case management. The results of this study demonstrate that standardized nurse case management provided to an ill HF patient population by telephone during the early months after an HF admission can achieve significant cost savings, reductions in resource use, and increases in patient satisfaction. The reduction in resource use seen in this study is comparable to that observed with other disease management approaches and greater than that seen with most pharmaceutical therapy. The effectiveness of the approach may be a function of the intensity and focus of the intervention, standardization, patient characteristics such as illness severity, or an interaction among these factors. Further research is needed to identify which of these components is essential and if a briefer, less intense intervention will be as effective in an HF patient population.

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