
A Randomized Trial of Telemonitoring Heart Failure Patients

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EXECUTIVE SUMMARY

The purpose of this study was to measure the ability of telemonitoring to reduce hospital days and total costs for Medicare managed care enrollees diagnosed with heart failure. Patients were recruited and randomly assigned for six months to either telemonitoring or standard care. Telemonitoring transmitted vital signs and clinical alerts daily to a central nursing station. Utilization of covered services was analyzed for the six-month telemonitoring period to test for hypothesized reductions in hospital days and changes in utilization of the emergency department (ED), urgent care, and primary care. Negative binomial regressions adjusted for gender, age, co-occurring diabetes, co-occurring chronic obstructive pulmonary disease, and residence neighborhood were used to analyze units of service, and two-part (hurdle) multivariable models were used for expenditures. The main finding was a tendency for lower total number of hospital days for patients assigned to telemonitoring. Results for other covered services were generally consistent with hypothesized direction and magnitude; however, statistical power was reduced because of lower-than-expected recruitment rates into the study. Within a managed-care environment, telemonitoring appears to facilitate better ambulatory management of heart failure patients, including fewer ED visits, which were offset by more frequent primary care and urgent care visits.

For more information about the concepts in this article, contact Dr. Orwat at jorwat@luc.edu.

INTRODUCTION

Heart failure (HF) is a serious health problem with high morbidity and mortality as well as high cost. The prevalence of HF in the United States is approximately 5.8 million people, and at age 40 the lifetime risk of developing the disease is one in five (American Heart Association 2010). Hospital discharges for HF totaled 1,106,000 in 2006, up from 877,000 in 1996 (American Heart Association 2010). The estimated direct and indirect cost in the United States is \$39.2 billion in 2010 (American Heart Association 2010). For those over 65, HF is a common reason for admission to the hospital (Rich et al. 1995; Halderman et al. 1999). High utilization of emergency and inpatient hospital services has led many health plans to adopt various disease management techniques in order to identify and intervene earlier on behalf of patients at risk for disease progression and acute exacerbations. In addition, many insurers and healthcare delivery systems have implemented various forms of telemedicine to monitor patients more closely than would otherwise be convenient or affordable.

Telemedicine is the application of communications technology to healthcare information to provide and support healthcare interventions over geographic distances (Committee on Evaluating Clinical Applications of Telemedicine 1996). Examples include the use of technology by physicians for diagnostic consultation with distant specialists, coordination of patient care, and patient monitoring. Remote monitoring for people living with HF, or telemonitoring, is the use of technology that facili-

tates a clinician's remote monitoring of physiological and behavioral factors that are measured by patients at home (Cleland et al. 2005). Such close supervision could reduce the rate of emergencies and hospital admissions, lessen the severity and length of stay for patients who are admitted, and improve HF patients' quality of life (Rich et al. 1995; Louis et al. 2003; Cleland et al. 2005). However, little peer-reviewed literature is available on outcomes associated with telemonitoring, specifically as an incremental intervention associated with disease management in a community-dwelling population.

A meta-analysis by Louis and colleagues (2003) reported findings for 18 observational studies and 6 randomized controlled trials (RCTs) involving telemonitoring and heart failure. Studies suggest that telemonitoring, used either alone or as part of a multidisciplinary care program, was accompanied by high patient acceptance, and compliance with telemonitoring facilitated early detection of deterioration, reduced readmission rates, and reduced lengths of hospital stays in patients with heart failure (Louis et al. 2003). One observational study also showed a reduction in costs (billed charges) associated with readmissions (Louis et al. 2003). A large RCT study showed a significant reduction in mortality at six months by monitoring weight and symptoms in patients with heart failure, although no difference was observed in readmission rates (Louis et al. 2003); another randomized study showed no difference in outcomes between the telemonitored group and the standard-care group (Louis et al. 2003).

Cleland and colleagues (2005) conducted a study that found similar admission and mortality rates among patients randomly assigned to nurse telephone support or telemonitoring, but the mean duration of admissions was lower for the telemonitoring group (Cleland et al. 2005). Jerant, Azari, and Nesbitt (2001) performed a small, randomized trial ($N = 37$), which found that HF-related readmission charges were lower in the telemonitoring group than in the usual care group (not significant), although telemonitoring had favorable utilization-related outcomes, such as significantly fewer HF-related emergency department (ED) visits and charges ($p < 0.05$). In a multi-site study of 280 HF patients who were randomized to either a heart failure program or the heart failure program plus a telemonitoring system, no statistically significant differences in hospitalization rates were found, but a 56 percent reduction in mortality occurred ($p < .003$) for patients randomized to utilize telemonitoring during the six-month observation period (Goldberg et al. 2003).

This article presents the results of an experiment testing the extent to which telemonitoring (compared to standard care) reduces the need for hospital services in a managed care population with a diagnosis of heart failure and changes utilization patterns for other covered services—ED, urgent care, office visits, and prescription drugs.

METHODS

Study Sample

Patients with heart failure were recruited from the CIGNA HealthCare for Seniors

insurance plan, in which care is provided and coordinated by the CIGNA Medical Group (CMG). CMG is a large medical group practice owned and operated by CIGNA Healthcare of Arizona, which bears first-dollar risk for inpatient and outpatient care. Potential subjects were identified with one or more diagnoses of heart failure using International Classification of Diseases, 9th Revision diagnostic codes in CIGNA's claims data and then verified in medical records. Other inclusion criteria included (a) age 65 or older and (b) enrollment in the CIGNA Seniors plan for at least six months prior to the study. Exclusion criteria included (a) severe dementia; (b) end-stage kidney disease; (c) late-stage cancer; (d) enrollment in a hospice program; (e) inability to speak English; (f) inability or unwillingness to complete the informed consent form; and (g) intention to leave the health plan, move out of the area, or travel extensively in the next six months.

Each potential research participant was sent a letter from a CMG physician describing the study and requesting participation, with follow-up communication. For those expressing interest, CMG conducted enrollment sessions that included a description of the study, informed consent and authorization to release health records for the study, demographic forms, and questionnaires to assess baseline patient characteristics that were hypothesized to influence a patient's attitudes toward technology management of chronic illness. These baseline characteristics included symptoms of depression, self-efficacy (confident in one's ability to succeed with a task), health locus of control

(whether guidance is found in oneself or in external forces), and health status. Baseline assessments were used to identify differences between the intervention and control groups. Depression was assessed using the self-reported, nine-item Patient Health Questionnaire—Quick Depression Assessment (PHQ-9) (Kroenke and Spitzer 2002; Kroenke, Spitzer, and Williams 2001; Martin, Rief, and Klaiberg 2006). The six-item Self-Efficacy for Managing Chronic Disease Scale was used to measure a person's confidence in managing several domains commonly affected by health status, such as role function and symptom control (Lorig et al. 2001). The Health Locus of Control Survey was used to assess the individual's beliefs about the control they have over their health outcomes, scoring the extent to which their locus of control is internal, chance, placed in powerful others, placed in their doctors, or placed in other people (Wallston 2005; Wallston 2004). Finally, health status was assessed using the SF-12® Health Survey, with quality of life assessed using the question "In general, would you say your health is: Excellent, Very good, Good, Fair, Poor?" (Ware, Kosinski, and Keller 1996).

Subjects were assigned a unique identifier and randomized to the telemonitoring or control group using an adaptive randomization method to ensure equivalent groups by balancing co-occurring diabetes mellitus (DM), co-occurring chronic obstructive pulmonary disease (COPD), pre-enrollment healthcare utilization, and geographic area relative to the center of Phoenix, Arizona, the health plan's primary service area. Geography was a factor

because of varying patient characteristics in each of the four areas comprising Phoenix: Central, Sun City, West, and East. For example, Sun City is a community built specifically for residents older than 55 years of age, who tend to have higher socioeconomic status, are somewhat sicker and older, and have greater informal support structures within the community than the Central, West, and East geographic groups.

Monitoring devices were then installed by an authorized vendor in the homes of subjects assigned to the telemonitoring condition. The monitors remained in the home for up to six months, the fixed observation period for both telemonitoring and control subjects. Data collection commenced in April 2007 and ended in November 2007.

The Intervention

The intervention consisted of telemonitors in subjects' homes for six months. The Honeywell HomMed Sentry and Genesis monitors and proprietary Central Station software are hospital-grade U.S. Food and Drug Administration Class II medical devices. During the study period, the monitors were programmed to guide subjects through a daily process of vital-sign collection (weight, blood pressure, heart rate, and blood oxygen levels), weekly prompts to answer a predetermined set of questions, and, if appropriate, engaged with other peripheral devices (e.g., glucose meter for patients with diabetes). Subjects received instruction and training in the use of the equipment from the installation vendor, including equipment limitations. In particular, patients

and their families were advised that the monitors sent information routinely each morning and were not an "emergency alert system," even though subjects could use the monitors to record information any time of the day if they wished to supplement the daily (early-morning) readings.

Software running on the central nursing station automatically color coded and sorted the patients' results each day for review and action by a CMG healthcare registered nurse. In this review, the nurse would be shown "red alerts," representing readings outside of programmed parameters; "yellow alerts," signifying incomplete data; and "green" results, representing completed readings within parameters. The healthcare professional then decided whether and how to respond to each alert, such as calling the patient for further information or recommending healthcare services.

ANALYSIS

The main rationale for the study was to test the premise that telemonitoring would facilitate early ambulatory management of patients who might otherwise experience acute exacerbations sufficient to trigger ED visits or inpatient hospitalizations. Also of interest was the possible substitution of emergency services with less expensive services. The main dependent variable was inpatient hospital utilization—that is, hospital days. Secondary dependent variables included the number of ED visits, urgent care visits, and admissions to acute care hospitals; average acute days per hospital admission; and the number of primary care visits. To identify differ-

ences in the intervention and control groups, negative binomial regression was employed, adjusting for sex, age, co-occurring diabetes, co-occurring COPD, and geographic area within greater Phoenix. Negative binomial regression is preferred over Poisson regression for modeling count data, when the data are "overdispersed," defined as when the mean and variance are not equal.

In addition to these utilization measures, we analyzed expenditures in order to better understand the financial implications of telemonitoring. We used the log transformation of each patient's total expenditures for all covered services as the dependent variable in an ordinary least squares regression (OLS), adjusting for the covariates of gender, age, co-occurring diabetes, co-occurring COPD, and CMG geographic region. Total expenditures were log transformed to improve the linear relationships between variables, which otherwise are affected greatly by skewed distributions. Other expenditures (visits to an ED or urgent care facility and inpatient hospital stays) were analyzed using two-part models, sometimes referred to as hurdle models, which separate the expenditure outcomes into two distinct parts: the dichotomous outcome of whether or not the type of service had expenditures above zero (the first part of the model), and the conditional extent or volume of expenditures for such services if they were above zero. More specifically, the first hurdle used a logistic model to estimate the relative odds ratios of having any expenditures for a type of service, while the second part used OLS models to estimate variation in positive expenditures for that type of

service. Both analyses adjusted for sex, age, co-occurring diabetes, co-occurring COPD, and geographic area within greater Phoenix. All of the hypotheses regarding the effectiveness and efficiency of telemonitoring were tested against a one-sided alternative (i.e., null hypotheses of no difference between telemonitoring and control groups were tested against the one-sided alternative that the telemonitoring group had lower utilization and expenditures). All analyses were run in SAS 9.1.3.

RESULTS

Study subjects ($N = 390$) were followed for an average of 175.5 days, with control subjects averaging slightly longer follow-up compared with intervention subjects—178.1 days versus 172.9. These averages were less than the full 180 days described by protocol because of the occurrence of mortality, hospice, and a few instances of withdrawal from the study.

This study realized a lower-than-expected recruitment. The statistical power analysis determined that to have 80 percent likelihood of discerning a statistically significant 25 percent reduction in utilization (assuming a normal distribution), we needed a sample size of 350 subjects in each of the intervention and control groups, far more than the total number of subjects (390) recruited for the study. Although the specific reasons for the lower recruitment number are unknown, it may have happened because of study-exclusion criteria (e.g., study participants were required to remain in the Phoenix area for the entire observation period, which eliminated those who may leave during

the summer); because prospective candidates and their physicians did not believe they met the clinical definition for heart failure; or because of a lack of comfort with technology, and thus a reluctance to enroll.

No statistical differences between the intervention and control group were identified with regard to demographics (Table 1). Just over 40 percent of the entire sample was female, the average age was 76.1 (*s.d.* 8.1), and 90.4 percent were white. Almost two-thirds (65.8 percent) of the sample was married, and 86 percent of subjects had a household income between \$10,000 and \$70,000.

Both the intervention and control groups were similar with regard to baseline self-efficacy, perception of health locus of control, depression, or health status (Table 2). These domains were measured at baseline because the effects of telemonitoring may differ for subjects who are more ill, less able to comply due to depression, or less able to rely on external supports. The mean self-efficacy score was 7.1, where a higher score indicates a higher level of self-efficacy on a scale from 0 to 10. Just over 16 percent of the sample had responses to the PHQ-9 that suggest a depressive disorder. Over half (53.7 percent) indicated their health was fair or poor.

Effects on Utilization and Expenditures

In direction, the study results conformed squarely to the hypothesized pattern of effects that telemonitoring would have on various types of services (Table 3). The intervention was related to lower hospital admissions (incidence rate ratio = 0.87), hospital days (incidence rate ratio = 0.73), and ED visits

TABLE 1**Subjects' Characteristics at Baseline (N = 390)**

Characteristic ^a	Total Sample (n = 390)	Intervention (n = 193)	Control (n = 197)
Age (<i>s.d.</i>)	76.1 (8.1)	76.7 (8.2)	75.7 (7.7)
Sex (female)	40.4%	42.0%	38.6%
Race			
White	90.4%	89.6%	90.7%
African American	3.8%	4.4%	2.6%
Marital status			
Married	65.8%	65.8%	66.8%
Divorced	7.3%	6.6%	9.3%
Never married	3.3%	11.0%	4.7%
Widowed	23.0%	26.5%	19.2%
Household income			
\$10,000 or less	6.3%	3.9%	7.5%
\$10,001–\$30,000	52.5%	55.6%	49.5%
\$30,001–\$70,000	36.2%	37.1%	36.2%
Greater than \$70,000	5.0%	3.4%	6.9%
Level of education			
Less than high school graduate	10.6%	10.9%	10.1%
High school graduate	57.8%	60.6%	55.6%
College graduate/graduate school	31.6%	29.0%	34.4%
Geographic area			
Central	23.1%	23.8%	22.3%
East	32.3%	32.1%	32.5%
Sun City	23.9%	24.9%	22.8%
West	20.8%	19.2%	22.3%
Comorbid diabetes	51.8%	52.8%	50.8%
Comorbid COPD	26.6%	28.0%	25.4%

^aCharacteristics are self reported on demographic form during enrollment.

NOTE: COPD = chronic obstructive pulmonary disease.

(incidence rate ratio = 0.94); these were offset by more physician ambulatory visits (incidence rate ratio = 1.06) and urgent care visits (incidence rate ratio = 1.60). As part of the intervention, nurses

coached patients to see their physicians or, in the interest of haste, directed patients from the ED to one of CIGNA's urgent care centers. Despite consistently moving in the hypothesized direction,

TABLE 2
Baseline Health Characteristics of 390 Subjects Recruited for Study

Characteristic ^a	Total Sample (n = 390)	Intervention (n = 193)	Control (n = 197)
Self-efficacy, mean score (s.d.) ^b	7.1 (2.0)	7.0 (2.1)	7.1 (1.9)
Health locus of control, mean score (s.d.) ^c			
Internal locus of control	23.6 (6.5)	23.8 (6.4)	23.4 (6.6)
Chance locus of control	15.9 (6.7)	15.9 (6.9)	15.8 (6.5)
Powerful others locus of control	20.2 (4.6)	20.0 (5.0)	20.4 (4.3)
Doctors locus of control	10.1 (2.0)	9.9 (2.2)	10.4 (1.8)
Other people locus of control	10.0 (3.7)	10.1 (3.8)	10.0 (3.6)
Depression—PHQ-9 ^d			
% suggest depressive disorder	16.20%	15.8%	16.8%
Depression score	5.9 (5.4)	5.8 (5.3)	6.0 (5.5)
Quality of life—SF-12 ^e			
Health is excellent or very good	11.2%	12.1%	10.3%
Health is good	35.0%	35.4%	34.9%
Health is fair or poor	53.7%	52.3%	54.9%

^aCharacteristics are self-reported at time of enrollment.

^bSelf-Efficacy Survey (Lorig et al. 2001) completed upon enrollment. Scored by taking the mean of the six items, range 1–10.

^cHealth Locus of Control Survey (Wallston 2005, 2004) completed upon enrollment. Eighteen items scored into 5 subscales noted above. Survey question 14 was not included in the survey of subjects for this study.

^dNine-item Patient Health Questionnaire (PHQ-9)—Quick Depression Assessment (Kroenke and Spitzer 2002; Kroenke, Spitzer, and Williams 2001; Martin, Rief, and Klaiberg 2006) completed upon enrollment. Percent suggest depressive disorder: percentage of sample whose responses to the PHQ-9 suggest a depressive disorder; depression score: total of 9 items is an indicator of severity. Average total.

^eSF-12® Health Survey (Ware, Kosinski, and Keller 1996). First question of SF-12 used to define quality of life: "In general, would you say your health is: Excellent, Very good, Good, Fair, Poor?"

the intervention only achieved statistical significance for two utilization measures: The higher rate of urgent care visits among the telemonitored group was found to be highly significant ($p < 0.01$), and the lower average of hospital days for the telemonitored group was found to be marginally significant ($p < 0.1$). Expenditures showed a similar pattern by type of service (data not shown).

Table 3 also shows patterns for cohorts defined by other variables

included in the analysis. Generally, higher utilization rates for all types of services were observed for patients with comorbid diabetes or COPD, as well as higher age. Females had more urgent care and physician ambulatory visits. In addition, significant differences were seen in almost all types of services by neighborhood and clinic setting. Expenditures for prescription drugs were nominally higher for the telemonitored group; they were significantly higher for

TABLE 3
Utilization, Intervention, and Control

	Incidence Rate Ratio					
	ED Visits	Urgent Care Visits	Hospital Admissions	Hospital Days	Hospital ALOS	Primary Care Visits
Intervention	0.94	1.60**	0.87	0.73*	0.85	1.06
Gender (female)	1.06	1.37**	1.01	0.89	0.92	1.16**
Age	1.02**	0.99	1.02*	1.04**	1.02*	1.00
Co-occurring DM	1.18	1.17	1.01	1.03	0.89	1.13*
Co-occurring COPD	1.70**	1.41**	1.58**	1.54*	1.37	1.04
Geography						
Central	—	—	—	—	—	—
Sun City	0.90	0.50**	0.51**	0.37**	0.46**	1.79**
West	0.76	1.19	0.73	0.69	0.80	1.00
East	1.16	0.97	0.91	0.79	0.63*	1.19*

*One-tailed significance < 0.1.

**One-tailed significance < 0.05.

NOTE: ALOS = average length of stay; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; ED = emergency department.

females, those with co-occurring diabetes, and those with co-occurring COPD, and they were lower for higher ages ($p < 0.05$) (data not shown).

Although the sample size was not large enough to detect statistically significant differences, total cost was 12 percent lower in the intervention group compared to the control group ($p = 0.14$), controlling for sex, age, co-occurring DM and COPD, and geographic region. Co-occurring diabetes and co-occurring COPD were associated with higher costs ($p < 0.05$).

DISCUSSION

Telemonitoring holds promise to improve ambulatory management of complex patients, and possibly to

reduce costs for the treatment of heart failure or other chronic and complex diseases. Studies to examine the potential benefits of telemonitoring are challenging due to the need for a strong research design (e.g., RCT) and a sufficiently large sample size. This study had strong design features but failed to recruit subjects in sufficient numbers to make conclusive statistical inferences about the observed differences. Although we were unable to identify statistically significant differences, arguably due to a smaller-than-expected sample size, the quality of the study and the results' conformity to expectations for a complex set of hypotheses lend credibility to the efficacy of telemonitoring. These results must be taken within the

context of a well-managed population. Although not statistically significant, total all-cause expenses were lower for the intervention group over the control group.

Because telemonitoring collects clinical information that is transmitted to nursing staff in order to interpret and respond as needed, the process may lead to reduced costs as a result of earlier identification of potential problems. More diversion from more expensive ED visits to ambulatory and urgent care settings may have taken place, for example, and some inpatient admissions may have been avoided. Acute hospital admissions and days seemed to be lower in the intervention group. No study to our knowledge has identified a significant difference in all-cause acute admissions. Expenditures for inpatient expenses were 16 percent lower with telemonitoring.

Subjects in this study volunteered from a well-managed Medicare population. For example, both the intervention and control groups received intensive care management that included continuous monitoring of utilization and intervention (e.g., care management after any ED visit). Also, according to CIGNA's standard protocols, both intervention and control patients received intensive case management while in the hospital that included immediate discharge planning. As a result of the high level of care management and the potential increased motivation from volunteerism, these findings may be somewhat conservative. If telemonitoring were studied in a population not managed as well, we may expect to find greater effects of telemonitoring.

A formal evaluation of the financial return on investment would benefit from a larger study with correspondingly more definitive results. Further, because findings from this study showed significant differences across settings in practice patterns and local policies, such an analysis would benefit from examining health plans and associated medical centers. Future studies may approach actual implementation costs of telemonitoring by considering variations per patient and per month as well as local delivery systems. All of these parameters would help to refine the implementation and, together with negotiated lease fees and staffing costs, would determine costs by setting.

Remote patient monitoring continues to be of interest in the management of patients with complex medical conditions such as heart failure. Economic studies that attempt to estimate the cost-effectiveness of these interventions are often hampered by variability in the interventions and by heterogeneity of delivery systems. This study contributes to the knowledge base by *suggesting* that telemonitoring has an influence on treatment patterns and should be considered within the context of other studies. Future studies may examine cost savings in high-cost (e.g., more severe) populations. Further, identification and calculation of the direct and indirect cost savings by those living with congestive heart failure may strengthen the case for telemonitoring from the patient's perspective.

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PRACTITIONER APPLICATION

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This study presents compelling information about the effect telemonitoring of heart failure patients has on their healthcare utilization. The introduction provides pertinent data on the negative effect heart failure has on the healthcare system

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