

# The Effect of Physiologic Home Monitoring and Telemanagement on Chronic Heart Failure Outcomes

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## Abstract

The purpose of this study was to determine the effect of physiologic home monitoring and telemanagement on chronic heart failure outcomes. Outcomes included: hospital readmissions, length of stay, charges and quality of life. Sixty 60 patients ( $61 \pm 13$  years, 62 % African American, 67% female) measured their weight, blood pressure, heart rate, and oxygen saturation daily. These data were transmitted telephonically via the monitor's modem and patients were telemanaged accordingly. Readmissions, length of stay, and hospital charges, were all significantly ( $p < 0.001$ ). decreased compared to pre-study values and quality of life was significantly ( $p 0.002$ ) improved from baseline.

## INTRODUCTION

Heart failure (HF) is a clinical syndrome affecting nearly five million people in the United States (US), with over 400,000 new cases are diagnosed annually.<sup>1</sup> Heart Failure is listed as the principal cause of death for approximately 42,000 persons in the US each year, and this number increases to 250,000 persons annually when principal and contributing causes of death are collectively considered.<sup>1, 2, 3</sup>

Available data indicate that HF may cost the U.S. health care system as much as \$36 billion annually, with estimates of 75% of annual costs expended on hospitalizations, 20% on long-term care and only 5% for all other care areas.<sup>4-6</sup> Each year, over one million hospitalizations are related to HF.<sup>1-3</sup> Additionally, a considerable proportion of these hospitalizations are attributed to older persons. In patients over 65 years of age, HF is the most frequent indication for hospitalization and the most frequent discharge diagnosis submitted for Medicare reimbursement.<sup>7,8</sup> Moreover, as the US population ages, the incidence and prevalence of HF is expected to increase.

As HF rates continue to grow and further impact patients, families and health care systems, increased significance is placed on demonstrating positive outcomes related to this devastating health problem. At the University of Illinois at

Chicago (UIC), research was conducted to test a novel management strategy called telemanagement with transtelephonic monitoring (TM); developed specifically to decrease hospitalizations for patients with costly chronic illnesses, including HF. This strategy is operationalized in the absence of face-to-face contact and consists of a physiologic monitoring period, wherein medications are optimized and patient education is begun, and a maintenance phase of periodic follow-up phone calls.

Telemanagement is a form of telemedicine, and refers to medical/nursing management interventions made over the telephone; transtelephonic monitoring refers to the transmission of physiologic variables over existing telephone lines to a network server to be displayed on a conventional personal computer (PC). The transmitted physiologic variables provide objective data, which may indicate the need for medical/nursing interventions that are subsequently made over the telephone. Telephone interventions are not new; however, clinical interventions in most previously reported programs<sup>9, 10, 11, 12, 13, 14</sup> were based solely upon subjective information solicited from the patient and/or family. The availability of objective physiologic data, trans-telephonically transmitted in near real time, which can be coupled with a patient's subjective input, makes the TM method unique. The technology also adds to the cost-effectiveness and efficiency of the method.

While others have recently reported a study validating telemedicine equipment,<sup>15</sup> we believe our study is the first of its kind reporting clinical, humanistic, and economic outcomes from telemedical interventions.<sup>16,17</sup> We hypothesized that our method of TM would be feasible to implement and effective in producing positive outcomes. We further hypothesized that feasibility and effectiveness would be demonstrated in a safe as well as efficient manner.

This study was approved by the UIC Institutional Review Board (IRB) and supported by a grant from the National Institutes of Health (NIH). The reader is asked to keep in mind that this study was the initial clinical testing of this form of telemedicine implementing interventions for chronic HF patients in the absence of face-to-face contact. As such, a randomized two-group design was not used in this initial study and we readily recognize the limitations of the study because of the design used. Based on the feasibility and effectiveness demonstrated in this study, however, a randomized trial was planned and is currently in progress.

The purpose of this study was to determine the feasibility and effectiveness of TM on outcomes related to the management of chronic HF. The primary outcomes included: 1) HF-related hospital readmissions, 2) length of stay (LOS) for any HF readmissions, and 3) hospital charges for any HF-related readmissions. Secondary outcomes included 1) changes in quality of life from baseline, 2) blood pressure reduction in hypertensive participants, 3) health care provider time, 4) costs of the TM method, 5) patient safety, and 6) patient satisfaction with the telemanagement method.

## **METHODS**

### **MATERIALS**

The materials needed for the TM model included a home monitor attached to an integral scale stand, a data-receiving computer, and a network server connection. Other than the UIC network server, all hardware and software were developed by and purchased from AvidCare, formerly Advanced Medical Devices (Milwaukee, WI). All devices used were extensively validated prior to this study and subsequently approved for use by the Federal Drug Administration (FDA) in 1996.

### **HOME MONITOR AND SCALE**

The home monitor (HM) is a small, lightweight device (64mm x 152mm x 89mm, 680 grams), that automatically notifies patients to obtain their vital signs. The display on the device has a readability equivalent to the 5th grade reading

level. The device shares patients' existing telephone lines and does not cause interruption of existing phone service, except during data transmissions. The HM was programmed for this study to measure blood pressure (BP), heart rate (HR), arterial oxygen saturation (O<sub>2</sub> sat) and weight. Each of these variables is measured by a clinically proven, FDA-approved monitoring module incorporated into the HM. The rationale for selecting the variables that were monitored is presented following the remaining description of the required materials.

### **DATA-RECEIVING COMPUTER**

The data-receiving computer is a dedicated IBM-compatible (Dell) personal computer (PC) running proprietary software developed by AvidCare. Aside from storing each patient's electronic health file, the computer automatically receives and displays patient transmissions as well as audible/visual alarms if any data exceed preset alarm parameters. The receiving computer is positioned on the cardiac surveillance (telemetry) unit of the UIC Medical Center, directly adjacent to the telemetry technician's station. At the UIC, a telemetry technician is on duty 24 hours per day, seven days per week as part of the existing inpatient telemetry service. All telemetry technicians (and telemetry nursing staff) were given special training with the data-receiving computer, preparing them to effectively operate the computer and follow triage algorithms for any alarms received.

Alarm parameters were established according to each patient's baseline condition, as deemed appropriate by the medical director and an advanced practice nurse (APN) who collaboratively coordinated the study. Maximum and minimum deviations from baseline were programmed into the monitoring station software such that when a patient's physiologic data exceeded these limits, an alarm would sound, prompting the attention of the telemetry technicians. The telemetry technicians subsequently followed a triage algorithm that guided the resolution of all alarms. The telemetry technician also paged the APN with all alarm data and actions taken. The utilization of existing telemetry personnel was intended to augment the efficiency of the method.

### **NETWORK SERVER**

The UIC has an extensive network server system. Therefore, aside from receiving alphanumeric pages from the telemetry staff regarding aberrant data, the study coordinator and/or the study medical director could also access a patient's file via a server connection. This allowed for data to be accessed

from any remote location, with a computer/laptop modem by dialing into the UIC network.

### **MONITORED VARIABLES: BLOOD PRESSURE AND HEART RATE**

Nearly 50 million Americans have hypertension,<sup>18,19</sup> and after coronary heart disease, it is the most common antecedent of HF.<sup>1</sup> Clearly, control of hypertension is critically important to the management of HF, yet national data suggest that overall BP control (< 140/90 mmHg) was achieved by only 27% of diagnosed hypertensive adults from 1991-1994.<sup>19</sup> Alarming, this percentage is less than the 29% achieved from 1988-1991.<sup>18,19</sup> Moreover, BP was chosen as a clinical outcome for this study because hypertension is particularly pervasive among African Americans,<sup>18,19</sup> who comprise a racial majority of the UIC patient population. See Table 1 for patient demographics and other characteristics.

The non-invasive blood pressure (NIBP) module within the HM is consistent with the American National Standard for Electronic or Automated Sphygmomanometers, ANSI/AAMI SP10-1992. The module is fully automatic, not requiring manual inflation, and is rated for automatic self-monitoring. The NIBP module is incorporated within the HM control unit and communicates to the HM's microprocessor. Blood pressure measurements determined with this device are considered equivalent, within the limits prescribed by the standard, to those obtained by intra-arterial measurement. The NIBP device also determines heart rate, although this was not a clinical outcome of this study. Heart rate is an essential physiologic variable to be monitored, and can be especially useful for the management of medications with chronotropic properties.

### **MONITORED VARIABLES: ARTERIAL OXYGEN SATURATION**

Oxygen saturation (O<sub>2</sub>Sat), measured by pulse oximetry, was not a specific or direct clinical outcome in this study. However, guidelines from the Agency for Health Care Policy and Research (AHCPR) recommend that O<sub>2</sub>Sats below 90 percent, not due to pulmonary disease, are indicative of a need for hospitalization.<sup>20</sup> Therefore, oximetry has the potential to provide useful information in the absence of face-to-face contact, which is inherent to telemanagement. Furthermore, since pulse oximetry is evaluated from arterial pulsations, HR data is also made available.

### **MONITORED VARIABLES: WEIGHT**

Hyper- and hypovolemia, best measured by a scale, are particularly challenging problems in the management of chronic HF. Daily weights are recommended by most HF experts<sup>20-22</sup> for early detection of fluid accumulation or depletion. While fluid weight gain/loss was not a clinical outcome, it indirectly affects multiple other HF outcomes; therefore, objective daily weights are essential data for chronic HF management. Patients in this study were instructed to weigh themselves daily in the morning after voiding, before eating/drinking, and in the same amount of clothing each time. The integral scale stand (to which the home monitor was attached) was capable of weights up to 700 pounds.

### **SAMPLE**

All patients admitted to the UIC Medical Center between September 1995 and April 1997 with a diagnosis of HF and meeting inclusion/exclusion criteria were asked to participate. All qualifying participants were required to sign an IRB-approved informed consent.

Inclusion criteria included at least one of the following: 1) documented diagnosis of HF as determined by radiographic evidence of pulmonary congestion; 2) documented New York Heart Association (NYHA) functional classification III or IV; 3) conventional clinical HF symptoms of dyspnea and edema that responded to diuresis; 4) echocardiographic evidence of heart failure (either systolic or diastolic dysfunction).

Exclusion criteria included: 1) unstable angina; 2) renal failure; 3) severe dementia or other debilitating psychiatric disorder; 4) end-stage heart failure requiring regular inotropic infusions; 5) anticipated survival of less than six months; 6) planned discharge to a long-term care facility; 7) current illicit drug use; 8) participation in another HF research protocol within the last six months; 9) scheduled HF-specific home health nursing; and/or 10) lack of an operating home telephone line.

One hundred thirty hospitalized patients were identified during the above time frame with a diagnosis of HF. Seventy patients were excluded from participation for the following reasons: twenty patients had participated in other HF-related research within the last six months; eight patients required dialysis and another four patients were being considered for dialysis; ten patients were scheduled to have HF-specific home nursing services upon discharge; six patients had

recent myocardial infarctions resulting in unstable angina; six patients were discharged to long-term care facilities; five patients died before discharge; nine patients did not have operating telephone lines; and two patients were suspected of current drug abuse other than alcohol. No eligible patients refused participation.

Sixty patients (n = 60) met the inclusion/exclusion criteria described above and comprised the study sample. Mean age of participants was 61 ± 13 years and mean NYHA class was 3.2 ± 0.5. The sample was 62% African American, 31% Caucasian, 6% Hispanic, and 1% American Indian. Sixty-seven percent of the sample was female.

This sample is representative of the ethnic and gender composition of the general population of patients who receive health care services at the UIC Medical Center (52% African American). During the study time period, UIC census information further indicates that 54% of the patients hospitalized for HF were female. See Table 1 for other patient demographics and characteristics.

**Figure 1**

Table 1: Patient demographics and characteristics

Age	61 ± 13 years
Gender	67% Female
NYHA	3.2 ± 0.5
LVEF	33% ± 12.82
Race	62% African American  31% Caucasian  06% Hispanic  01% American Indian
Etiology	45% HTN  25% HTN/CAD  08% CAD  08% IDCM  13% Other
Co-morbidity	55% CVA HX  18% Type 2 DM (requiring insulin)  3% Type 2 DM (oral medication)  15% COPD
Education	06% Elementary school  62% Some HS/degree  24% Some college/degree  08% Did not respond
Employment Status	11% Working  24% Retired  65% Not working
Payer Mix	49% Public Aid/Medicaid  46% Private/Medicare  05% No coverage

NYHA = New York Heart Association; LVEF = left ventricular ejection fraction; HTN = hypertension; CAD = coronary artery disease; IDCM = idiopathic dilated cardiomyopathy; CVA = cerebral vascular attack; HX = history of; DM = diabetes mellitus; COPD = chronic obstructive pulmonary diseases; HS = high school. (values are presented as mean ± SD or rounded percent of total sample)

**PROCEDURE**

After discharge from a heart failure hospitalization, patients used the HM for two to three months (mean 76.3 ± 20.4 days) and transmitted data 1-2 times daily (mean 2.0 ± 0.78

times/day). Patients were asked to transmit more frequently to assess responses when medications (especially ACE-inhibitors and beta-blockers) were being actively titrated. Patients/families received HM operating instructions from a trained bio-technician who installed the device in each patient's home. Installation/instruction time was approximately 30 minutes.

During the monitoring period, telephone interventions were prompted by the alarms received, and telemanagement interventions were based on the existing, evidence-based clinical recommendations/guidelines for HF,<sup>20, 21, 22, 23, 24, 25, 26, 27</sup> and hypertension.<sup>18,19</sup> Initial calls were made by the telemetry technician who, following triage algorithms, separated emergency from non-emergency alarms. The telemetry technician then communicated all alarm information to the APN (via phone or pager), who subsequently contacted the patient regarding the aberrant data, if necessary. The majority of medication interventions and patient education calls were made directly by the APN following clinical guidelines, but the study medical director was available by pager at all times for consultation and/or questions from the APN. Monitoring was discontinued when a patient demonstrated a continuous two-week period with no significant alarms. Following discontinuation from the physiologic monitoring phase of the TM method, regardless of the monitoring period duration, each patient received monthly assessment calls until one year post study enrollment. No patients resumed use of the HM as a result of the monthly assessment calls, however, several patients (16) were instructed to make outpatient clinic appointments with their respective physicians.

The primary outcomes were analyzed at three, six and twelve months following study enrollment. These data were compared to each participant's previous history of HF admissions, length of stay, and hospitalization charges from three, six and twelve months prior to enrollment.

The secondary outcome of quality of life was measured using the Minnesota Living with Heart Failure Questionnaire (MLHF), a 21-item questionnaire developed by Rector, Kubo, & Cohn.<sup>28, 29, 30, 31</sup> The MLHF provides an overall total score as well as physical and emotional sub-scale scores relating how persons with HF perceive how their condition has affected the quality of their lives in the past month. Only the overall score data only is presented here. The response scale of each item ranges from 0 (none) to 5 (very much). The total score is the sum of the responses to

the 21 items, with the sub-scale scores equal to the sum of each of the respective sub-scale items. Total scores can range from 0 to 105, with higher scores indicative of a less favorable quality of life. Baseline quality of life scores were assessed at the beginning of the physiologic monitoring period and compared to scores obtained at three, six and twelve-month time periods thereafter; the post-discharge assessments were each compared to the respective patient's baseline score.

### **STATISTICAL ANALYSIS**

Data for all variables were tested for normal distribution using the Kolmogorov-Smirnov Goodness-of-Fit test. Paired t-tests for within-group pre-post comparisons were used for normally distributed, continuous variables (with Bonferoni correction whenever appropriate); the chi-square test for any discrete variables; and the Wilcoxon rank-sum test for non-normally distributed categorical and continuous variables. Descriptive statistics and frequencies were used for demographics and patient characteristics. An analysis of covariance (ANCOVA) was used to test for confounding variables that might have affected the statistical significance of the results. The SPSS 8.0+ for Windows statistical software was used for these analyses. An alpha level of < 0.05, determined a priori, indicated the level of statistical significance.

### **RESULTS**

#### **PRIMARY OUTCOMES**

Positive outcomes at three, six and twelve months after enrollment in the study, demonstrated the clinical and cost effectiveness of the TM method (Table 2). At three months post study enrollment, data for the 58/60 surviving patients indicate an 81% change in HF admissions ( $p < 0.001$ ), 90% change in LOS for these admissions ( $p < 0.001$ ), and a 91% decrease in associated hospital charges ( $p < 0.001$ ) compared to their respective data for the three months preceding study enrollment. The above percentages represent three-month pre/post decreases in HF admissions from 62 to 12, inpatient days from 326 to 35, and hospital charges from \$699,880 to \$65,613.

At six months post study enrollment, a 77% change in HF admissions ( $p < 0.001$ ), 86% change in LOS for these admissions ( $p < 0.001$ ), and an 88% decrease in associated hospital charges ( $p < 0.001$ ) was demonstrated by the 56/58 surviving patients. These represent decreases in HF admissions from 70 to 16, inpatient days from 395 to 56, and hospital charges from \$890,159 to \$110,797.

At 12 months post study enrollment, data for the 48 surviving patients indicate a 70% change in HF admissions ( $p < 0.001$ ), 73 % decrease in LOS ( $p < 0.001$ ), and a 76 % ( $p < 0.001$ ) change in hospital charges compared to the 12-month period prior to study enrollment. These percentages represent decreases in HF hospital admissions from 74 to 22, LOS from 388 to 105 and hospital charges from \$880,695 to \$214,603. See Table 2 below for primary outcome summary.

**Figure 2**

Table 2: Primary outcome summary

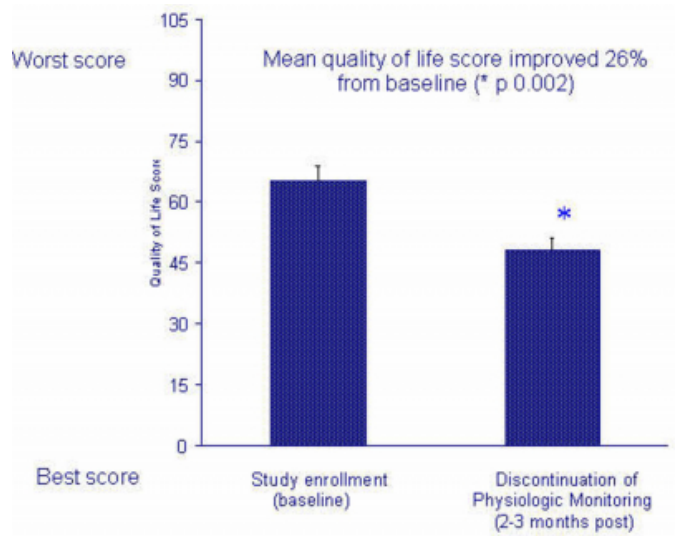
Primary Outcomes	Endpoint Month (surviving n)	Pre-Intervention (retrospective data)	Post-Intervention (prospective data)	Percent Change*	Significance (p value)
Number of HF re-admissions	3 (58)	62	12	81	$\leq 0.001$
	6 (56)	70	16	77	$\leq 0.001$
	12 (48)	74	22	70	$\leq 0.001$
Length of stay of HF re-admissions	3 (58)	326	35	90	$\leq 0.001$
	6 (56)	395	56	86	$\leq 0.001$
	12 (48)	388	105	67	$\leq 0.001$
HF re-admissions charges	3 (58)	\$699,880.	\$65,613.	91	$\leq 0.001$
	6 (56)	\$890,159.	\$110,797.	88	$\leq 0.001$
	12 (48)	\$880,695.	\$214,603.	69	$\leq 0.001$

Primary outcomes: heart failure (HF) readmissions, length of stay of HF readmissions, cost of HF readmissions and quality of life at 3, 6 and 12 months. The data at each interval is cumulative. Therefore, as each time point for data comparison increases in duration, so do the number of hospital admissions within each interval. \*Percent change was determined by difference between pre intervention and post intervention, at the interval indicated by the “Endpoint” column, relative to values pre intervention.

**SECONDARY OUTCOMES**

Significant improvement in quality of life was demonstrated by a 26% change ( $p < 0.002$ ) from baseline (figure 1). At six and twelve months post enrollment, quality of life continued to remain significantly improved 26% ( $p < 0.002$ ) and 23% ( $p < 0.003$ ) from baseline, respectively.

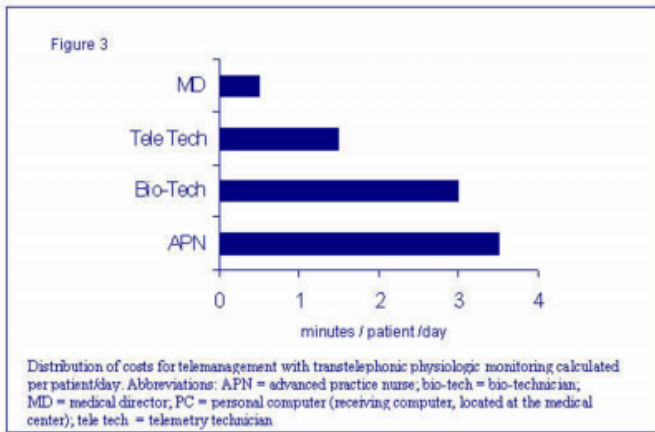
**Figure 4**



Quality of life was measured with the Minnesota Living with Heart Failure Questionnaire (permission granted by the Department of Research, University of Minnesota). Higher scores indicate less favorable quality of life as perceived by the patient; 105 is the highest possible score. Quality of Life was assessed at baseline (beginning of home monitoring phase), at discontinuation of the physiologic monitoring (2-3 months post), and every month thereafter to 12 months from study enrollment. Significant change from baseline to discontinuation from monitoring phase depicted in above figure.

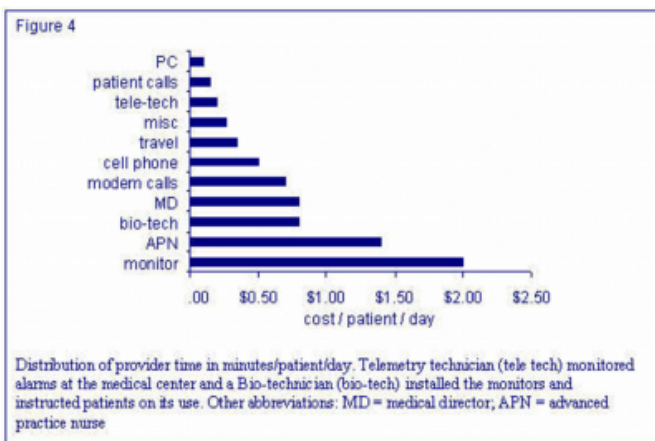
Mean arterial pressure (MAP) was assessed for patients who required blood pressure reduction at baseline. Because of the need for afterload reduction in most HF patients, criteria for BP reduction were baseline systolic (SBP) and diastolic (DBP) blood pressures greater than 120 and/or 80 mmHg, respectively. Baseline mean arterial pressures (MAP) were calculated from the SBPs and DBPs transmitted over the first 5 days of the monitoring period. Baseline MAPs were then compared to end MAPs (calculated from the last 5 days of a monitoring period). Patients requiring blood pressure reduction at study onset demonstrated a significant reduction in MAP; baseline MAP among these patients was 99.8 mmHg and end MAP was 93.5 mmHg ( $p < 0.001$ ), providing further evidence of clinical effectiveness. See figure below for change in mean arterial pressure (MAP) from baseline (beginning of home monitoring) to discharge from monitoring system. Data is only for the patients who required blood pressure lowering.

Figure 5



With the exception of the APN who focused on patient education, provider time was most related to responding to alarming data. In response to aberrant data for any parameter, telemetry technicians telephoned patients 1,183 times; the APN was consulted 1,601 times, and telephoned patients 1,390 times to assess any changes in status and reinforce dietary and medication compliance; cardiology fellows were consulted 527 times and telephoned patients on 152 occasions; attending cardiologists were consulted on 298 alarms and telephoned patients regarding 42 alarms. Medications were adjusted in response to 186 alarms, a clinic visit was scheduled following 31 alarms, and patients were directed to an emergency room in twelve instances, which were followed by nine hospitalizations for HF decompensation. Efficiency was demonstrated by the relatively minimal amount of time and cost involved, compared to the outcomes achieved. Provider time (minutes/patient/day) and total method costs (cost/patient/day) are represented in figures 3 and 4 below.

Figure 6



{image:6}

Safety was evaluated by adverse events in relation to an unanswered alarm. No adverse events were reported in any patient’s electronic record or are known to have occurred as a result of an unanswered alarm or technical malfunction. The latter was assessed by verifying patient/family phone calls and auditing traditional medical records.

Patient satisfaction was evaluated at the end of each monitoring period with a satisfaction questionnaire, scoring items on a 1-5 Likert scale, with 5 rating the highest level of satisfaction. Satisfaction questions asked patients to rate their perceived satisfaction with: the overall quality of the TM method, the convenience of the service, the professional manner of the TM staff in general, and particularly the telemetry and installation technicians, and also their satisfaction with having care provided over the phone by the APN. Two overall questions were also included regarding any perceived interference in daily activities do to the operation of the device or calls received from health care providers. These were scored with 1 representing very interfering and 5 indicative of no interference. A mean satisfaction score of > 4.75 was recorded for 95% of the sample.

**DISCUSSION**

The sequelae of chronic HF is well known, with frequent decompensation of the chronic state resulting in recurrent hospitalizations. Yet most HF experts agree that many of these costly incidences of decompensation can be avoided, or at least lessened in severity, and require less in-patient time when hospitalization is unavoidable. Therefore, the importance of maintaining HF patients in an optimally compensated state is critical. Reports suggest that inadequate physician follow-up, insufficient titration of medications, patient non-compliance, and failure to promptly seek medical attention when symptoms reoccur are among the contributing, yet preventable, factors leading to re-admissions for chronic HF decompensation.<sup>9, 32, 33, 34</sup> Clinical management strategies and patient compliance, aimed at maintaining an optimally compensated state may decrease the need for HF re-admissions, shorten hospital stays when re-admissions are unavoidable, reduce hospital charges, and perhaps improve humanistic or quality of life outcomes.

Several heart failure programs/clinics, following a multidisciplinary but traditional clinical model, have addressed these contributing factors and have been successful at preventing hospital admissions.<sup>35</sup> Moreover,

these programs have done so without the need for sophisticated technology and have still demonstrated cost effectiveness. Just calling patients on the telephone for example, which HF nurses have been doing for decades, has shown to be a very effective management strategy.

Therefore, the question is raised, as to why our method/system is necessary. What does it have to offer patients, clinicians and/or health care payers above and beyond what other programs have already reported? To these concerns, we suggest that our telemanagement method provides a major advantage as either a 'stand-alone' program or as an adjunctive strategy for existing programs.

We believe the major advantage provided by our method is efficiency, which as described, translates into more cost savings. We estimate that in a theoretical TM model, a knowledgeable nurse may be capable of monitoring up to 300 multi-morbid, chronically ill patients. In this model, half of the day would be allocated to responding to alarms with subsequent patient phone calls for assessment and patient education; the remainder of an eight hour day could be spent on paperwork/charting and system issues (calling pharmacies, physicians, referrals etc). If the population was composed of patients with a lesser acuity rating, more patients could be added to one nurse's case-load. Furthermore, costly office space and multiple indirect costs would not be required because the nurse could work totally from his/her home.

Our method may also be adventitious in a managed care model, wherein efficiency and outcomes, beyond what might be termed cost effective for another program, is essential. That is, if a program saves on costs, but the costs are still more than allocated per patient, the cost effectiveness becomes relative.<sup>35,36</sup> Therefore in the managed care setting, specialized heart failure programs/clinics may not be an option because of their expense, even though cost effectiveness (which becomes relative) has been demonstrated.<sup>35-37</sup> In this scenario, perhaps more efficient, yet research supported strategies, may be needed for the management of chronic HF

We believe our telemanagement method is appropriate for large or small practice groups in urban or rural communities and for varying payer-plans. While it was specifically developed to improve care and contain cost for labile and very non-compliant patient types, it also serves as a teaching tool or prophylactic treatment modality for moderately-complaint patients or those with limited disease-knowledge being discharged from the hospital earlier than required to

assure adequate patient education. Patients that are very compliant and knowledgeable, without lives complicated by the social/economic issues that can often 'de-rail' otherwise compliant patients, most likely would not derive the same cost/benefit ratio.

In summary, we believe the data from this initial study suggests our method to be feasible and effective, as manifested by the ease of implementation and the positive outcomes achieved. Generalization of results, however, is not possible at this time and the results presented here can only be applied to the sample studied. It should be noted that this study examined the feasibility and effectiveness of a management method that included both transtelephonic monitoring and telemanagement. Therefore, we suggest that for this study's sample, the efficiently-achieved positive outcomes resulted from a combination of the initial availability of objective data with rapid and vigilant attention to aberrancy (physiologic monitoring period immediately after hospital discharge), as well as clinical management directed by evidence-based guidelines and continued periodic disease-specific patient education provided throughout the study. This study was not powered as a mortality study, therefore making it impossible to draw any mortality conclusions as such.<sup>38</sup>

The major limitations of this study include the research design and sample size. However, when considering the positive outcomes that were achieved with this sample, as well as the limited amounts of time and cost involved with implementation, we believe our method has potential significance for the management of chronic conditions in the context of a cost-conscious healthcare environment. Additionally, considering the 24 hr/day, seven day/week monitoring coverage, and the alarm system, which demonstrated a lack of adverse events resulting from alarms not being addressed or mechanical alarm malfunction, our telemanagement method appears feasible and safe. Clearly, further research is needed to explore and validate the system and method's full potential.

### **ACKNOWLEDGMENTS**

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