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Original Article

Safety Evaluation of an Automated Remote Monitoring System for Heart Failure in an Urban, Indigent Population

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Abstract

Heart Failure (HF) is the most expensive preventable condition, regardless of patient ethnicity, race, socioeconomic status, sex, and insurance status. Remote telemonitoring with timely outpatient care can significantly reduce avoidable HF hospitalizations. Human outreach, the traditional method used for remote monitoring, is effective but costly. Automated systems can potentially provide positive clinical, fiscal, and satisfaction outcomes in chronic disease monitoring. The authors implemented a telephonic HF automated remote monitoring system that utilizes deterministic decision tree logic to identify patients who are at risk of clinical decompensation. This safety study evaluated the degree of clinical concordance between the automated system and traditional human monitoring. This study focused on a broad underserved population and demonstrated a safe, reliable, and inexpensive method of monitoring patients with HF.

Keywords: heart failure, safety net, automated remote monitoring, chronic illness, chronic conditions

Introduction

Heart Failure (HF) is the most expensive preventable condition, regardless of patient ethnicity, race, socioeconomic status, sex, and insurance status. As a chronic, progressive disease, HF is characterized by frequent hospital admissions and high mortality rates that result in medical costs of more than $30 billion annually.[1–5] It is the only cardiovascular disorder increasing in both incidence and prevalence. HF generates 3.5 million hospitalizations per year, with 6-month readmission rates between 15% and 50%.[6] Timely outpatient care and remote monitoring can significantly reduce avoidable HF hospital stays.[7,8] For patients with HF, both structured telephone support and telemonitoring effectively reduce all-cause mortality and HF-related hospitalizations.[9]

Traditional methods used for remote monitoring include scripted nurse-initiated telephone contact.[10,11] Although effective, it is costly.[8,12,13–15] Automated remote monitoring is a cost-effective, proven technique for improved clinical performance. Patients prefer automated speech recognition methods over waiting to speak to a human.[16] Engaged patients, regardless of education and technology experience, have demonstrated positive clinical, fiscal, and satisfaction outcomes.[12–15] Additionally, automated remote monitoring and communication tools reduce disparities and improve health outcomes regardless of race, ethnic, and social class.[12,17]

The Los Angeles County (LAC) Department of Health Services (DHS) is the second largest safety net system in the nation. LAC DHS has a long history of developing new and innovative strategies to address the needs of patients with a high burden of illness in a resource-constrained environment. LAC DHS has been successful with protocol-driven, nurse-executed disease management programs (DMPs) for patients with HF, the cornerstone of which is telephonic outreach for care management. The DMP has proven longitudinal effectiveness in reduction of inpatient admissions, readmissions, emergency department visits, and disease control. However, program costs, including nurse-administered remote monitoring, are high.[6]

LAC DHS recognized the need for low-cost remote monitoring. Together with a technology partner, the study team designed and implemented an automated system utilizing the most accessible technology in use today, the telephone. The Heart Failure Automated Remote Monitoring System

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(HF-ARMS) is a telephonic data collection tool that supports effective population health management using automated speech recognition.

The HF-ARMS is rooted in the theory that frequent, consistent monitoring for high-risk patients can reduce reactive rescue care. This monitoring (*a*) is personalized to the patient's condition and personal preferences, (*b*) enhances the patient-provider continuity relationship, and (*c*) facilitates early interventions that can reduce inappropriate use of reactive rescue-care resources in an efficient manner.

The HF-ARMS safety study evaluated the degree of clinical concordance between the automated system and traditional human monitoring.

Methods

Setting and sample

LAC DHS cares for more than 600,000 patients annually. At more than 4000 square miles, LAC is larger than Rhode Island and Delaware combined; more than 25% of all Californians reside there, and it is one of the most ethnically diverse counties in the United States.[18] Many of the patients who seek care in LAC DHS have multiple chronic conditions along with economic and social challenges including abject poverty, food insecurity, poor social/community support, and homelessness. More than 6600 continuity care patients in LAC DHS have HF.[19]

This prospective, single-arm study recruited 101 patients via a convenience sample and through referrals from the cardiology clinic at Olive View-UCLA Medical Center (OV-UCLA), a LAC DHS facility. Inclusion criteria included:

1. Adults (ages 18 years or older)
2. English speaking
3. HF diagnosis
4. Reliable access to a telephone
5. Cognitive integrity (ability to understand consent material)

Seventy-seven percent of participants were male, 43% were ages 55 years or older. Fifty-two percent were white, 22% Hispanic, 8% African American, 12% Asian, and 6% were Native American or Other.

Once consented, patients were given a simple digital scale and blood pressure cuff, and trained via return demonstration on how to interact with the HF-ARMS. Baseline measurements (weight in pounds, blood pressure, and pulse) and patient monitoring preferences (day of the week and time for a paired communication from both the HF-ARMS and a research assistant [RA]) were collected. These, as well as an initial estimate of dry weight, were reviewed and verified by a cardiologist familiar with the patient. Enrollment lasted approximately 15 to 20 minutes per patient. The Institutional Review Board at OV-UCLA approved this study.

Technology and data collection

HF-ARMS communication content is based on structured deterministic decision tree logic with clinical decision points (the ''call flow'') that guide each instance of the patient interview. The clinical algorithms used in the creation of the HF-ARMS are consistent with the American College of Cardiology and American Heart Association Guidelines for the Diagnosis and Management of Heart Failure.[20] The entirety of the call flow contains 29 clinical content areas with between 1 to 4 secondary questions per area; each call requires only a small subset of the questions as clinically appropriate.

HF-ARMS patient data collection was initiated via system-generated outbound calls made Monday through Friday, between 8 AM and 8 PM, following patient preference, on both a scheduled and triggered basis. Utilizing automated speech recognition with backup dual-tone multifrequency signaling (DTMF) to collect patient responses, the HF-ARMS made one or more call attempts with a decaying call cycle for a 24-hour period. If a patient was not reached, a new call was generated 30 minutes later, then an hour later, then 2 hours later, and so on. If a call attempt generated was outside of the call window parameters, it would roll over to the next available day and time. Patients could respond to the system via various modalities through a waterfall approach of:

1. Unstructured voice with automated speech recognition
2. Directed voice recognition with prompts
3. DTMF (''touch tone'')

HF-ARMS interactions collected objective and subjective physiologic and behavioral data (vital signs, symptomology, maximal activity level, dietary indiscretion, medication use, and rescue care resource utilization). The summary content of HF-ARMS communications and recognized response categories are presented in Table 1. The RA used a skip pattern survey that covered the same clinical content as the deterministic decision tree used by the HF-ARMS. Call results with details of the patient interaction and comparisons to previous responses were made available via a secure web interface in real time to care providers, which allowed them to retrieve patient responses.

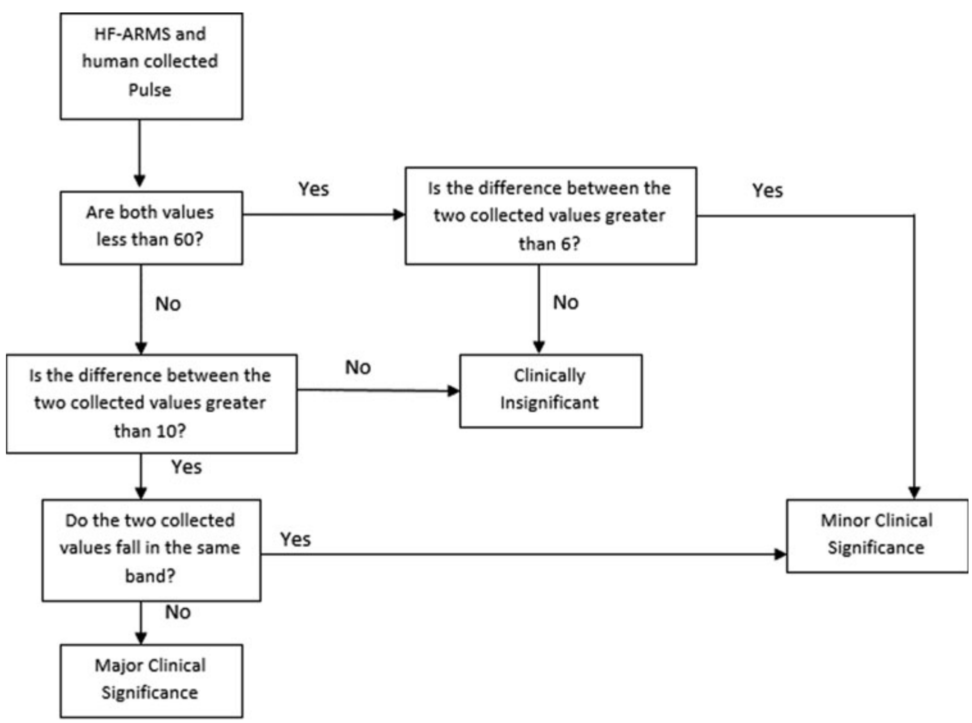
The call order, human or machine first, was randomized for each call pair. Calls scheduled on major US holidays were intentionally rescheduled to maximize reach rates. Patients were instructed to not rely on these calls to report a clinical problem but to contact their regular provider, or call 911 if they felt they were having an emergency.

A study database captured human- and system-collected patient data and highlighted discordant responses. All discrepant combinations were assigned a value of none, minor, moderate, or major clinical significance. Each question-answer pair was evaluated to determine the direction and magnitude that responses could have on triage decisions. Response mismatches and response-null combinations that resulted in potential HF-ARMS or human undertriage of patients were identified separately.

Undertriage was defined as data that led to an incorrect conclusion of clinical stability. Vital signs discrepancies were categorized by both the quantitative distance between values and the absolute value of each observation. A set of algorithms was developed to determine the impact of vital sign discrepancy on subsequent treatment choices and to identify the data collection method that was most frequently in error (Figs. 1–4). An attending physician reviewed all responses and, if there was discordance, determined if the RA, HF-ARMS, or neither correctly captured the patient intent. Table 2 delineates the response combinations that

Table 1. Data Collected by Heart Failure Automated Remote Monitoring Calls

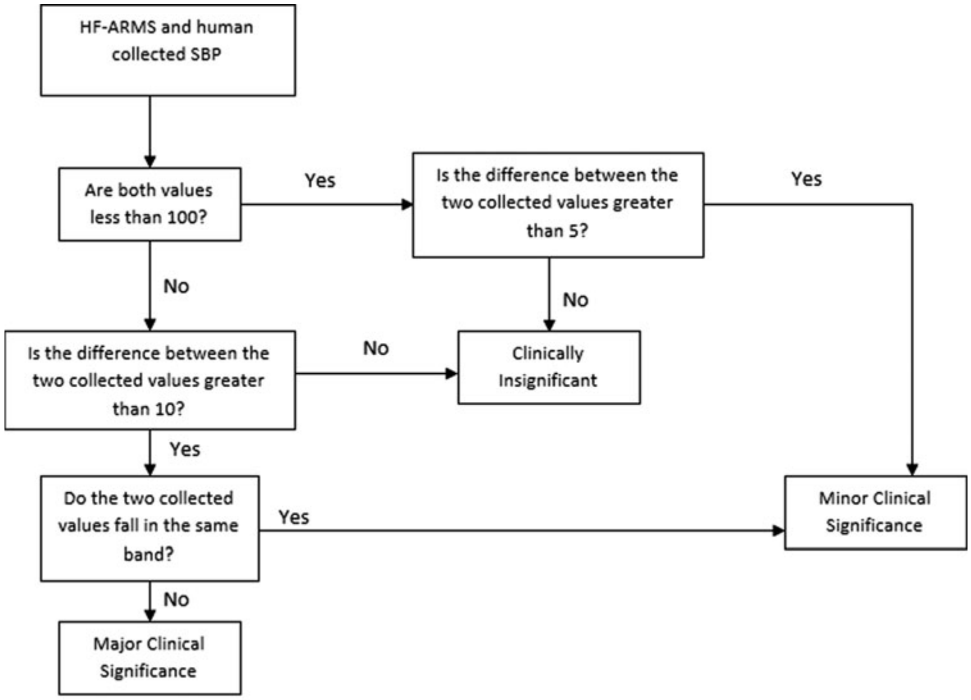
Variable	*Possible responses*			
Systolic blood pressure	Numeric			
Diastolic blood pressure	Numeric			
Pulse	Numeric			
Weight	Numeric			
Difficulty with low salt diet	No	Yes	Not sure	
Difficulty taking medication	No	Yes	Not sure	
Finger indentation on ankles	No	Yes	Not sure	
Finger indentation on shins	No	Yes	Not sure	
Increase in feeling bloated or full	No	Yes	Not sure	
Bend and reach as usual	No	Yes	Not sure	
Run out of medication	No	Yes	Not sure	
Seen recently for heart failure	No	Yes	Not sure	
Shortness of breath	No	Yes	Not sure	
Slept in chair	No	Yes	Not sure	
Slept with extra pillows	No	Yes	Not sure	
Swelling in legs/ankles	No	Yes	Not sure	
Once up in am, swelling gone	No	Yes	Not sure	
Visit emergency room or urgent care	No	Yes	Not sure	
Wake with shortness of breath	No	Yes	Not sure	
Past week activity level	Limited	Minimal	Moderate	Strenuous
Swelling more, less, same	Less	Same	More	Not sure
Symptoms of HF better, worse, or the same	Worse	Same	Better	Not sure
Number of pillows slept with	0–1	2	3	4 or more
Activity change over time	Less	Same	More	Not sure



Pulse Band Categorization

Pulse	BAND
0 - 59	1
60 - 100	2
101 -184	3

FIG. 1. Pulse significance algorithm. HF-ARMS, heart failure automated remote monitoring system.



Systolic Blood Pressure Band Categorization

Systolic BP Range (mmHG)	BAND
0-99	1
100-139	2
140-170	3
171-200	4
200+	5

FIG. 2. Systolic blood pressure significance algorithm. HF-ARMS, heart failure automated remote monitoring system; SBP, systolic blood pressure.

map the number of ''matches'' and ''discrepancies'' per call pair. In addition to discordant responses, study physicians made same-day follow-up calls to patients whose answers suggested that they were experiencing clinical decline.

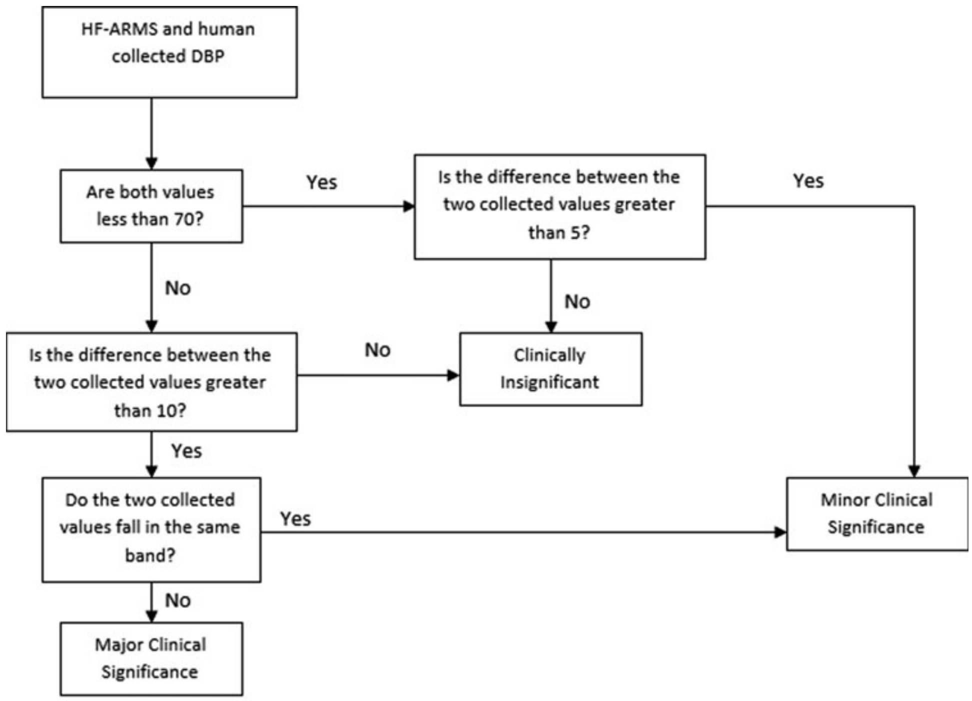
One content question was simplified mid-study based on discordant responses to clarify patient activity level equivalency. An additional technology enhancement was made concurrently to improve the system's ability to interpret compound responses by voice response (eg, the way numbers for systolic and diastolic blood pressure are typically reported: X over Y).

Study participants were recruited over a 6-month period. Evaluation of HF-ARMS utilization and performance used the first call as the baseline, with subsequent measures based on numeric call sequence. Each patient had a minimum 5-month call window during the 11-month intervention period. Analysis was normalized by weeks since index call, rather than by call date.

A satisfaction survey was administered over a 2-week period at the close of data collection. The study team examined match rate, operationally defined as the percentage of clinically equivalent information collected by the HF-ARMS as compared to data collected by an RA, in relationship to 3 variables: satisfaction with the HF-ARMS, education, and technology use. Satisfaction was captured using a 5-item Likert scale. Education was defined as the highest self-reported level of school completed by the patient. A patient self-reported active e-mail account was used as a proxy for technology. It was hypothesized that match rates would positively correlate with patient satisfaction, education, and technology use.

Resource utilization evaluation

To evaluate resource utilization, call information independent of clinical data was collected and analyzed for a patient subgroup. The number and length of each call placed by the HF-ARMS and a nurse practitioner (NP) in the OV-UCLA cardiology clinic were collected for a 50-day period. The NP placed calls to a comparable cohort of patients with HF who were unfamiliar with the HF-ARMS as part of her normal workflow. The NP logged outbound calls made to



Diastolic Blood Pressure Band Categorization

Diastolic BP Range (mmHG)	BAND
0 - 59	1
60 - 90	2
91 - 113	3

FIG. 3. Diastolic blood pressure significance. DBP, diastolic blood pressure; HF-ARMS, heart failure automated remote monitoring system.

patients, phone call duration, whether or not she connected with the patient, and post-call documentation time. The HF-ARMS maintained its usual callback cycle decay; the NP was required to make at least 3 attempts. A call was considered successful if the patient answered the call and provided information about his or her health status.

Sample size

The study team assumed moderate size of treatment effects in calculating statistical power. Power to evaluate program effects was determined with G*Power version 3.1 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). All power calculations were done at 2-tailed $\alpha = .05$. To estimate the ability to detect statistically significant outcomes, the team set power at .80 power and used Cohen's conventional standards for effect sizes with $f = 0.1$ for small effect size and $f = .25$ for medium effect size. Based on this analysis, the proposed sample size was sufficiently powerful to detect small effects.

Level of Clinical Discrepancies	Weight Delta (in lbs)
Clinical Match	0 – 1.0
Clinically Insignificant	1.1 - 2.0
Minor Clinical Significance	2.1 – 3.0
Moderate Clinical Significance	3.1 - 5.0
Major Clinical Significance	5.1 +

FIG. 4. Weight delta categorization.

Results

Study data points ($N = 33{,}524$) were evenly split between the HF-ARMS administered deterministic decision tree ($n = 16{,}762$) and human administered skip pattern survey ($n = 16{,}762$). In all, 578 matched call pairs from 77 patients met study inclusion criteria for analysis and were coded using the schema in Table 2.

In all, 92.5% of data collected by the HF-ARMS were clinically equivalent (Table 2, code 0, 1 or 2) to data collected by humans: 3.31% of call pair data had minor clinically significant discrepancies, 1.6% of call pair data had moderate clinically significant discrepancies and 2.59% of call pair data had major clinically significant discrepancies. The HF-ARMS

Table 2. Heart Failure Automated Remote Monitoring System/ Human Collected Data by Code Type and Time

Code	Meaning		*Prequestion change* (N = *6467*)	*Postquestion change* (N = *10,295*)	*Overall* (N = *16,762*)
Code 0	Response match: both human and HF-ARMS asked the question and obtained the same response		75.43%	89.45%	84.04%
Code 1	Null match: neither human nor HF-ARMS asked the question		0.96%	2.42%	1.86%
Code 2	Discrepant: both human and HF-ARMS asked the question but obtained different responses, clinically insignificant		11.29%	3.65%	6.60%
Code 3	Human undertriage	Discrepant, minor clinical significance	3.14%	0.84%	1.72%
Code 4	Human undertriage	Discrepant, moderate clinical significance	1.72%	0.49%	0.96%
Code 5	Human undertriage	Discrepant, major clinical significance	1.50%	0.71%	1.01%
Code 6	HF-ARMS undertriage	Discrepant, minor clinical significance	2.74%	0.86%	1.59%
Code 7	HF-ARMS undertriage	Discrepant, moderate clinical significance	0.54%	0.70%	0.64%
Code 8	HF-ARMS undertriage	Discrepant, major clinical significance	2.69%	0.88%	1.58%

HF-ARMS, heart failure automated remote monitoring system.

and human calls undertriaged patients at approximately the same rate (3.81% and 3.69%, respectively).

Depending on clinical stability, HF-ARMS calls lasted between 30 seconds and 5 minutes with an average duration of 2.5 minutes. Three percent of successful HF-ARMS calls required follow-up by a licensed health care provider. As patients gained experience with HF-ARMS, there was improved concordance between human and machine collected data. A significant decline in clinically significant discrepancy rates was observed for the sequence of calls 1 through 11 ($r = -.22$, $P < .001$). There was a significant (15.5%) increase in matched responses post mid-study system question modification and system engineering improvement (t (386.7) = 11.98, $P < .001$). The learning effect accounted for 4.9% of the improvement in discrepancy rate post question change. This represented about one fourth of the total improvement related to rewording questions and answers.

There was a 41% response rate to the satisfaction survey; 80% of respondents preferred the HF-ARMS calls to less frequent human monitoring; 72% percent of patients were satisfied or strongly satisfied. No statistically significant relationship was found between satisfaction and successful HF-ARMS performance ($P = .118$). The majority of respondents had either a high school education (41%) or some college (38%). Only one respondent had less than a high school education and 6 (19%) had a bachelor's degree or higher. Given the small number of respondents in each group, an analysis of variance was not appropriate. The existing education categories were collapsed into 2 categories, completed high school education or less ($N = 14$), and some college or more ($N = 18$). Correcting for unequal variances, the successful HF-ARMS rate was significantly higher among those with at least some college (Mean = 91.0%) than those with only a high school education or less (Mean = 83.4%), t (19.8) = −1.96), $P = .036$.

Twenty-two respondents (69%) reported having an active e-mail address, whereas 10 (31%) did not. Correcting for unequal variances, the successful HF-ARMS rate was significantly higher among those with e-mail (Mean = 91.0%) than those without (Mean = 80.5%), $P < .05$.

Patients reported positive halo effects of using the HF-ARMS. Many suggested that the weekly cognitive prompts reinforced their increased adherent health behaviors.

[The HF-ARMS] keeps me trying to be more serious about losing weight and my low-salt diet. It's a good system because it makes me think about not killing my heart.
- Male, age 47.

After a while practicing, practicing, practicing gets stuck in your head so [the HF-ARMS] is good for the reminder and I like to check myself weekly.
- Male, age 45.

Resource utilization analysis and associated call costs

On average, successful HF-ARMS calls in the 50-day period lasted 2.3 minutes vs. 8.3 minutes for successful NP calls, inclusive of call preparation time (identifying the patient's chart and contact information), time on the phone, and time spent for post-call documentation. For the patient subgroup reviewed for resource utilization, defined as effort needed to contact a patient successfully and collect data and the associated costs, the HF-ARMS placed 102 successful calls and the NP placed 19 successful calls with 12 unsuccessful attempts. HF-ARMS calls that did not result in a connection (ie, were not answered or reached a busy signal) were rescheduled by the system automatically. The NP spent an average of 2.20 minutes on unsuccessful calls.

Connected calls for HF-ARMS cost $0.25 per minute; those that did not result in a connection had no direct cost. The cost of successful HF-ARMS calls for the 50-day period was $0.85 per call. The marginal cost of successful NP calls for the same time period to a similar patient population was $17.89 per call.

Discussion

Telehealth expands access, allows for information exchange, and can deliver this information for use in care decision making. These technologies, including remote patient monitoring, extend care beyond face-to-face encounters, increasing the frequency of patient interactions and evaluation of health status.[21,22] Frequent monitoring of patients with chronic conditions delivers more data in a timely manner than could be obtained with traditional care delivery. With this information, providers can better tailor patient-specific treatment.[23] Computer systems can be more effective than providers at collecting information about patient symptoms;

patients who interacted with a computer were more honest and forthcoming in their responses, perhaps because of response bias and trying to please the provider.[24,25]

A recent comprehensive Agency for Healthcare Research and Quality systematic review of the literature on telehealth concluded that there was sufficient evidence to support its effectiveness for remote monitoring of patients with chronic conditions, including its use for patient communication and counseling.[23] However, employing it in disparate populations was not widely examined.

Cardiovascular morbidity and mortality disproportionately affects African Americans and Latinos as a direct result of underdiagnosis and undertreatment.[8,12] It is responsible for the largest racial disparity in life-years lost between whites and minorities in the United States.[8,13,14] Low-income, culturally diverse populations with chronic conditions such as HF are particularly vulnerable. Compared to heart disease patients in the non-safety-net population, adults with heart disease in the California safety net were much less likely to report that they had been given a heart disease plan by their medical providers and that they were confident in their ability to control the disease.[26]

Literature on structured telephonic support (automated or traditional) has little information on the evaluation of technologic interventions in safety net patients with chronic disease, though it has been suggested that remote monitoring might be a feasible option for those patients who are geographically or physically challenged.[12,27] In addition, there is a dearth of studies that evaluate value-based care and the cost-effectiveness of telemonitoring.[8,28]

Usual care for HF is dominated by episodic face-to-face encounters. Proposed alternative approaches include regularly scheduled structured telephone contact between patients and health care providers. Although less expensive than unscheduled rescue care provided in the emergency department or inpatient venues, a regularly scheduled visit generates significant cost to the system and patient.[17] Communication technologies that use real-time health information are increasingly relevant to clinicians.[29,30]

Telephonic automated remote patient monitoring confers a significant protective clinical effect in patients with chronic HF compared to usual care. The benefits include: increased access to health services, cost-effectiveness, enhanced educational opportunities, improved health outcomes, better quality of care, better quality of life, and enhanced social support.[28] The ability to recognize and mitigate clinical deterioration before the patient seeks help is a significant contributor to reducing avoidable hospital admissions.[27,31] Patients with HF frequently struggle with self-care knowledge, skills, and self-efficacy and need activation to promote the sense of control over their health outcomes.[32] Patients who participated in this study reported greater self-care awareness and confidence.

This study focuses on a broad underserved population and introduces a safe, reliable, and inexpensive method of monitoring patients with HF. The HF-ARMS is designed to facilitate patient engagement and optimize data collection for HF care management, improve health care outcomes, and reduce rescue care utilization costs, minimize physical and economic burden, and be responsive to patient care preferences.

Outbound calls from the care delivery system reduce the burden on patients of knowing when and how to report changes to the clinician. One goal of remote monitoring is to support crisis prevention and patient self-empowerment. By utilizing automated systems to collect routine data, and applying decision-support algorithms to identify those patients in need of attention, staff are freed up to engage in clinical activities more important than routine data collection.[33]

The HF-ARMS is easy to interact with. Several patients commented on their satisfaction with increased monitoring, noting they ''would be a fool to turn down the monitoring.''[19]

This study found the HF-ARMS use rate was significantly higher among those with e-mail (Mean = 91.0%) than those without (Mean = 80.5%), $P < .05$. These findings are counter to other research that suggests the ability to interact with automated remote monitoring systems is independent of education and technology use.[12,13,15] However, previous research conducted did not control for a ''digital divide'' nor did it report a great educational diversity. With ongoing expansion of technology, the study team expects increased penetration into the daily life of all population sectors.

One of the goals was to create a low-cost approach that would reliably gather objective and subjective clinical data. Internet-connected devices can be costly compared to simple and reliable scales and blood pressure cuffs that are frequently found in the home.[34,35]

The remote monitoring services cost analysis highlights the difference between technology and human efficiencies, allowing a care system to reserve human interaction for where necessary while leveraging the reach and low-cost of automated systems.

Limitations

This study was conducted at 1 LAC DHS facility with patients who spoke English as a primary or secondary language, and had relatively high levels of self-reported education and technology use. Given the small sample size and homogeneity of the population, generalizability may vary and further study on diverse populations across multiple safety net facilities and multiple languages, particularly Spanish, is anticipated. Greater longitudinal study may result in changes to patients' satisfaction and utilization. As e-mail and text have continued to spread, the study team believes the HF-ARMS should be made accessible across those modalities, too.

Conclusion

This study demonstrated that the HF-ARMS is safe and nearly clinically equivalent to traditional human remote monitoring in a low-income, underserved population at 95% lower cost. This patient-centric tool gives the care team access to electronic remote monitoring information in real time, improves communication between patients and providers, and empowers and encourages patients to actively manage their health.

Given the success of the HF-ARMS, the study team intends to expand the functionality and scope of the system to reach a greater number of patients. This will include adding Spanish language as well as making the HF-ARMS multimodal and accessible by patients or proxy via text message, web, and phone. To optimize health outcomes, we must identify how best to deliver generalizable interventions that improve overall population health in the private sector as well as to those who are socioeconomically disadvantaged.

Author Disclosure Statement

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