FOCUS MOBILE HEALTH

30 Days to Make a Difference

Evaluating the 30-Day Effects of a Comprehensive Remote Patient Monitoring, Shortened Provider Feedback Interval, and Patient Engagement and Education Program on Hypertensive Patients

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ABSTRACT

Facilitated by a combination of remote patient monitoring using mobile and wireless devices, and patient engagement, coaching and education, the average systolic blood pressures for 34 patients dropped by 20 points in week four, continuing to a 30 point drop in week five. Physicians' use of remote patient monitoring coupled with a Telemonitoring Service Center extended their care into the home, creating a near-real-time feedback loop that facilitated shortened provider feedback intervals, and more precise medication therapy. Due to weekly educational sessions performed by the Telemonitoring Service Center, patients felt they better understood the hypertension and its associated risks and management principles that would help them to better self-manage their condition on an ongoing basis.

KEYWORDS

Quality improvement, self-management, remote patient monitoring, Triple Aim, hypertension, patient education, medication, mobile, telemedicine, home care.

BLUETOOTH-ENABLED BLOOD pressure devices communicated vitals to gateways, which then transmitted these measurements to monitoring software in real-time via the mobile network. Medical staff in the Telemonitoring Service Center not only monitored daily measurements, but facilitated a telephone-based, weekly patient questionnaire and patient education session, and kept providers apprised of the patients' status. Providers could then respond as necessary to make changes in treatment, including medications, to more quickly bring the hypertension under control.

By extending the point of care to the patient's home or other location via mobile health (mHealth) networks and devices, engaging and educating the patient regarding the management of her condition telephonically, and facilitating near real-time changes in treatment, it is believed programs such as this are applicable to a variety of conditions, and will lead to increased healthcare

FACILITATED BY A COMBINATION of remote patient monitoring using mobile and wireless devices, and patient engagement the average systolic blood pressures for 34 patients dropped by 20 points in week four,continuing to a 30-point drop in week five.

quality, reduced costs, and an improved patient experience—the Triple Aim.

Background

Whether an approach that incorporates mobile remote monitoring of blood pressure, shortened provider feedback intervals, and use of a monitoring and engagement center to provide live telephonic engagement and education can improve outcomes and increase patient satisfaction for hypertensive patients within 30 days is unclear.

Objective

To assess the efficacy of a 30-day approach combining mobile remote patient monitoring, shortened provider feedback intervals, and patient engagement and education on the treatment of hypertensive patients.

Goals

Primary: To improve subjects' average blood pressures by 10% (systolic or diastolic blood pressure).

Secondary: To assess patient satisfaction and feelings of empowerment to self-manage at the end of the study period.

Methods

Thirty-four hypertensive patients were enrolled by their cardiologist to measure blood pressure at home twice a day, having it immediately transmitted to the monitoring and engagement center. The data were monitored by a nurse and, when determined by preset protocols, provided to the physician office where a nurse practitioner determined whether an adjustment to a patient's medications or other treatment change was necessary. This follows the remote patient monitoring (RPM) process of "collect, transmit, evaluate, notify and intervene" promoted by the Center for Technology and Aging.[1] Patients also participated in weekly assessment and education calls. We evaluated outcomes based on the effects on systolic and diastolic blood pressures, and responses to a patient satisfaction survey performed at the close of the study.

Results

The improvement of average blood pressure including a decrease in the systolic from baseline 155.9 +/- 18.0 to 133.2 +/- 6.8 in week four, and a decrease in diastolic from 88.7 +/- 9.7 to 76.2 +/- 2.6 over the same time period ($P<0.001$). Patient satisfaction scores were also extremely positive, especially regarding the patients' perceived value of the educational sessions on their self-management of hypertension. Feedback of filtered monitoring data to physician offices enabled medication changes as deemed necessary by a nurse practitioner, saving both physician time and office visit time and costs. Though it is difficult to identify the specific impact of individual interventions on the entire patient population, the effectiveness and positive impact of the comprehensive program are obvious.

Conclusion

A 30-day program combining daily mobile remote patient monitoring, near-real time provider feedback and associated medication changes, and patient engagement and education was shown to produce significant reductions in high blood pressure, and improvement in patient feelings of empowerment for self-management of their condition, with a likely reduction in office visit costs (Funded by Vitaphone USA Corporation).

INTRODUCTION

Chronic hypertension affects an estimated 30.4 percent of the U.S. adult population, but only 46.5 percent of those have their high blood pressure under control.[2] The societal cost of hypertension in the US is estimated at $131 billion annually.[2] Controlling hypertension depends primarily on both the use of appropriate medications and patients' self-management of their conditions. A faster, yet non-intrusive, and efficacious approach to both of these is needed if comprehensive therapies are expected to scale nationally and internationally. It is not known whether a 30-day approach which combines mobile

remote patient monitoring, shorter provider feedback intervals, and patient education will significantly decrease systolic and diastolic blood pressures, while also resulting in patients' feelings of empowerment and ability to self-manage their hypertension.

Previous and ongoing successful remote patient monitoring (RPM) programs have shown RPM successful in "reducing hospitalizations and health care costs; improving patient knowledge, satisfaction, and clinical outcomes; and activating patients to better manage their own health and care."[3] Yet, RPM use for hypertensive patients is not yet widespread. With half of all patients who are under antihypertensive drug therapy not meeting treatment goals, there is an opportunity to apply RPM and patient engagement to improve the outcomes and treatment of hypertensive patients.[4] What has not been shown is whether such improved outcomes can be expected within a 30-day program.

To investigate whether a combination of RPM, shortened provider feedback intervals, and patient engagement/education results in improved systolic and diastolic blood pressures, and increased patient feelings of empowerment for self-management of their condition (self-efficacy), we enrolled 34 patients with baseline systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg for a minimum of 30 days.

METHODS

Study Design

In this single arm, self-control study, a comparator arm was not used due to the small sample size and the likely heterogeneous nature of study population characteristics. Inclusion criteria were patients with chronic hypertension and baseline office blood pressure found to be >140/90 mmHg. Systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg was acceptable.

Private physicians enrolled 34 patients with an average baseline systolic blood pressure of 155.9 +/- 18.0 and average diastolic blood pressure of 88.7 +/- 9.7. Enrolled patients received a blood pressure cuff that transmits values via the Bluetooth wireless standard to a gateway device, which in turn transmits values via a mobile cellular network to the monitoring and engagement center's data servers. Patients were also provided with hard copies of educational materials to be referenced during weekly telephonic engagement and education sessions over the course of the study. During an initial courtesy call, a registered nurse trained the patients regarding the setup of the equipment, informed them as to how to take their blood pressure, and provided an introduction to the educational materials.

TABLE 1: Alerts and Protocols.

Parameter	Condition	Task to be done by Monitoring/Engagement Center
Systolic increased	> than 180 mmHg	*Call patient, verify value, inquire regarding symptoms. If systolic BP is over 180 will call patient's provider and only if he is not available advise to go to ER if necessary
	> 150 mm HG x 3 readings in rolling 7 day period	Nurse to evaluate and contact provider.
Systolic decreased	>=20% reduction from patients baseline with accompanying symptoms	* Contact patient, evaluate for symptoms. Contact the provider. If unable to reach provider advise patient to go to the ER.
Diastolic	> than 110 mmHg	*If diastolic BP is over 110, call provider. If unable to reach provider advise patient to go to ER.
	> > 95 mm Hg x 3 readings in a rolling 7 day period	Nurse to evaluate and contact the provider.
Heart rate	> 110 or < 45 with symptoms	Call patient to determine if symptomatic or asymptomatic. If symptomatic call provider.
Table 1.	Alerts and Protocols	*Verify value by obtaining second measurement

Weekly calls began with a patient questionnaire (e.g., "How are you feeling today?"; "Any changes to your medications?"), and then proceeded with that week's educational session. At the end of the fourth week, a post-survey (regarding the educational content) was administered. When each patient completed their study period, they also completed a patient satisfaction survey.

As patients were enrolled on a "rolling basis," the entire study period consisted of approximately 60 days. All patients were residents in the Los Angeles area, and were patients of private physician practices.

Alerts and protocols as described in **Table 1** were established:

A weekly summary report was sent to the physician office, including a trend graph, table including blood pressure / heart rate measurements, date and time of measurements, a summary of the weekly follow up questionnaire responses, medication reconciliation, any medication alert messages, educational topics covered and symptoms if applicable.

Blood-pressure readings were taken twice daily: between 8 a.m. to 9 a.m. and 5 p.m. to 6 p.m. Bilateral measurements (from both arms) were taken on Monday mornings.

Study Oversight

The pilot was sponsored by Vitaphone USA, whose representatives performed the monitoring and engagement activity from the Las Vegas-based Vitaphone Telemedicine Service Center (TSC). The TSC is nurse-managed and physician supervised. A single registered nurse, with nurse manager backup, monitored and engaged the patients, scheduled and performed the courtesy calls, weekly questionnaires and educational sessions, and produced summary and alert reports for the physician offices. Two cardiologists committed to the study, enrolling qualified patients. Vitaphone staff were in contact as needed with the physician offices during

FIGURE 1: Sample Size and Standard Deviation.

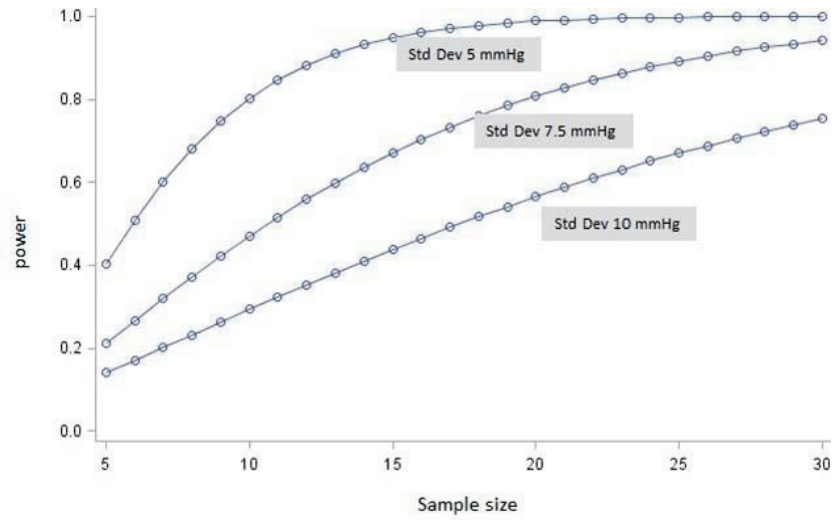


TABLE 2: Study Participant Baseline Characteristics and Medication Changes.

Polled number of patients		N=34
Male, n(%)		15 (44.1)
Age (year)		72.3±8.9
Monitoring Times (days)		37.0±7.7
Number of patients taking medication	0 meds	2
	1 meds	4
	2 meds	6
	3 meds	22
Number of antihypertensive medication or dosage changes during study		18
Baseline Systolic BP (mmHg)		155.9±18.0
Baseline Diastolic BP (mmHg)		88.7±9.7
Baseline Heart Rate		74±10

Table 2. Study Participant Baseline Characteristics, and Medication Changes During Study

the study, and a nurse practitioner in the physician offices made medication adjustments as necessary. One author—both a biostatistician and physician—established the study methods, worked with the cardiologists and the nurse manager to design the study, and established alert levels and associated protocols. The registered nurse executed the post-survey and patient satisfaction survey, which were analyzed by the nurse manager.

Statistical Analysis

In this pilot study, the single arm self-control (each observation acts as a control) study design was applied. The study compared those who used the program for 30 days (and up to an average of 37 days) to their own baseline blood pressure. The additional variable measured included patient feedback regarding satisfaction, feelings of empowerment to manage their condition, willingness to recommend the program to others, etc.

Analyzing the change from baseline, a simple one sample paired t-test was used to analyze statistical significance. The results were to be reported with a p value which will indicate the likelihood that variations are due to chance rather than the intervention.

Data for this project were analyzed using the statistical software, SAS, version 9.3 (SAS Institute Inc., Cary, NC). For blood pressure deduction analysis, the null hypothesis (Ho) was that there was no difference between program user and non-user. The paired t-test was used to determine if there was a statistically significant change in blood pressure (after-before). It was expected that 30 subjects would afford 80.5 percent statistical power to detect a 7.4 mmHg average of the differences after 30 days, with a standard deviation of 10 mmHg. Bivariate comparisons were made using chi-square tests for patient satisfaction analysis. The reduction in time to the clinical decision was compared using analyses of covariance. Two-sided p values were used for all other comparisons. The a priori level of significance was 0.05 (See **Figure 1**).

RESULTS

Study Population

Between October 2012 and January 2013, 34 patients were enrolled in the study group. Demographic and risk-factor characteristics were similar across the group.

All enrolled patients met the eligibility criteria. The majority of the patients were on three or more medications. **Table 2** shows the baseline characteristics of the patients.

Primary Outcome

Figure 2 indicates the clinical outcomes for the study population after 37 days. The P-values of <0.001 for the decreases in systolic and =0.0053 for diastolic blood pressures indicate that the results are due to the intervention. Monitoring was continued past 30 days (approximately 5 weeks). Over 4 weeks, the patients' average systolic blood pressure (SBP) decreased from 155.9 +/- 18.0

to 133.2 +/- 16.8 mmHg, while average diastolic blood pressure (DBP) decreased from 88.7 +/- 9.7 to 76.2 +/- 12.6. In the fifth week (at 37 days), overall blood pressures continued to decrease to averages of SBP 125.8 +/- 14.4 and DBP 79.8 +/- 6.5.

Secondary Outcomes

At the end of the patient's study period, each was asked to complete a patient satisfaction survey. Twenty-nine surveys were returned. **Table 3** shows the results of the patient satisfaction survey:

The results of the patient satisfaction survey indicate a high degree of satisfaction, improved education of the patients regarding their knowledge of their hypertension and how to manage it (self-efficacy), and interest to recommend the program to others. It also indicates a low willingness of the patients to pay out-of-pocket for such monitoring services.

An additional outcome is the recognition that the remote patient monitoring and feedback to the physician office enabled a nurse practitioner to make adjustments to medications (change of medication type or of doses of existing medication) without having the patient come into the physician office. This saved office visit costs, as well as saving patient time away from home or work, and related expenses (e.g., gas, parking). Having the nurse practitioner make the medication adjustments also saved physician time, theoretically enabling the physician to see more patients. An economic analysis was not completed on this study, so no formal economic conclusion can be made, though one might deduce that additional cost savings may have occurred through avoidance of potential acute events (e.g., myocardial Infarction), due to the reduced time taken to get the patients' blood pressures under control, especially if the program were scaled to include more patients.

DISCUSSION

The study, which was initiated to determine whether a combination of remote patient monitoring, shortened provider feedback intervals, and patient engagement and education would both improve outcomes and increase patients' abilities to self-manage

FIGURE 2: Blood Pressure Change During Study.

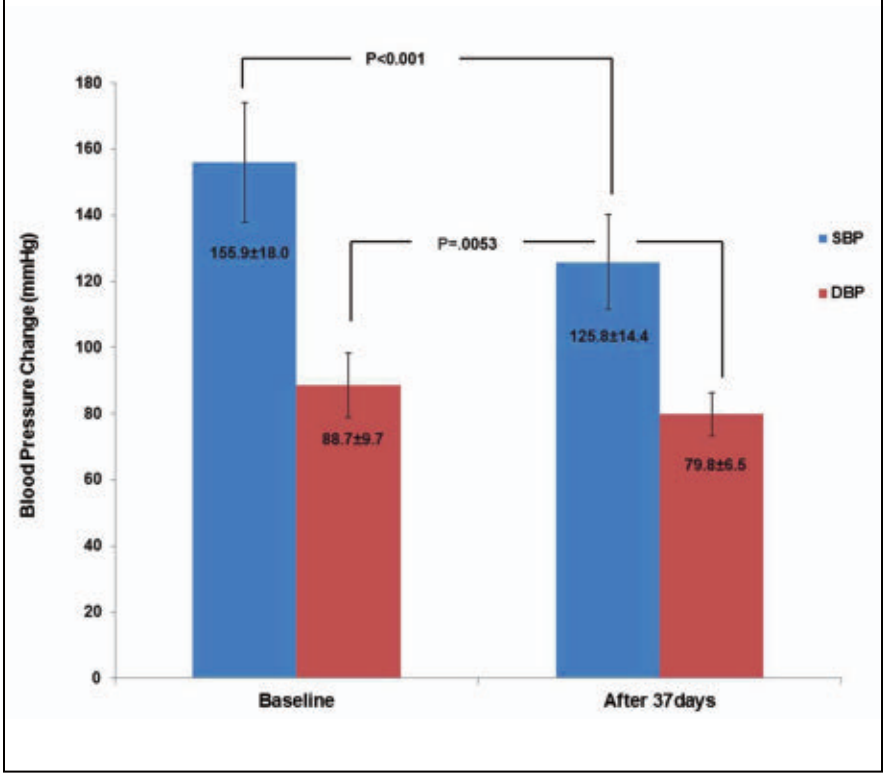


TABLE 3: Patient Experience Survey Questions.

Patient Satisfaction Survey Questions	Avg. Rating
1. The courtesy call was helpful in understanding the program.	4.62
2. The welcome package included all of the materials needed for the program	4.41
3. The equipment was easy to use.	4.45
4. The weekly follow up calls and education were helpful.	4.62
5. I learned new information that will be helpful in managing my Hypertension.	4.41
6. I better understand hypertension, risk and key management principles that will help me to better manage my condition	4.45
7. The staff was friendly and courteous.	4.69
8. It would be helpful to me if I could continue this program.	3.66
9. I would recommend this program to others.	4.34
10. I would be willing to pay for continued participation in this program if my insurance does not cover this expense.	2.07
Rating Scale	
5=strongly agree	
4=agree	
3=neither agree/disagree	
2=disagree	
1=strongly disagree	

THE RESULTS OF THE patient satisfaction survey indicate a high degree of satisfaction, improved education of the patients regarding their knowledge of their hypertension and how to manage it, and interest to recommend the program to others.

their condition, is deemed a success. A primary goal had been to improve blood pressure (either systolic or diastolic blood pressures) by 10 percent in 30 days: systolic was improved by 14.6 percent and diastolic by 14.1 percent at four weeks, bringing them not only to the <140/<90 range, which is associated with significant reduction of cardiovascular disease (CVD) complications, but also into the <130/<80 range, which is the target for hypertension patients that also have renal disease or diabetes. The patient satisfaction survey showed that the patients "Strongly Agree" regarding both their experience with the program, and the positive impact the program had on their knowledge of and ability to self-manage their hypertension.

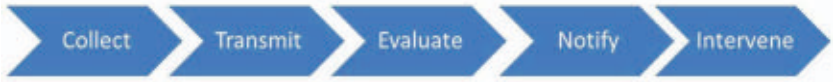
The process and program for this study followed closely the RPM process identified by Center for Technology and Aging, which is shown in **Figure 3**.[1]

The above-described process has been recognized as a best practice by the Center for Technology and Aging, and should continue as the foundation for effective scaling of this program.

In this study, the RPM process was followed as described here:

- Data was collected via the wireless (Bluetooth) blood pressure cuff.
- Data was transmitted from the blood pressure cuff to the cellular-enabled gateway, which in turn transmitted the data to the Telemedicine Service Center's data servers.
- Telemedicine Service Center Staff evaluated the data, with the assistance of specialized software, containing algorithms which compare incoming data with established thresholds.
- Weekly, and as needed, physician offices were notified of patient status and potential problems.
- Providers intervened as needed, in some cases with nurse practitioners making adjustments to medications.

FIGURE 3: Center for Technology and Aging Remote Patient Monitoring Process.



The addition of patient educational modules, which included discussions of risks and complications, medications, and diet and exercise had the complementary impact of increasing the patients' feelings and knowledge of self-management. This increased confidence in the ability to manage their condition is known as "self-efficacy," and is thought to be critical to adherence to behaviors that will control chronic disease.[5-7]

As noted earlier, 30.4 percent of the US population have hypertension, yet only 46.5 percent have their hypertension under control.[2] Globally, suboptimal blood pressure ranks first in the list of risks of death, affecting an estimated 1 billion individuals.[8] Additionally, the prevalence and hospitalization rates of congestive heart failure (CHF) patients continue to increase, with readmission of CHF patients a national priority, and the majority of CHF patients have hypertension before developing CHF.[9] Any improvement that can be made in the management of hypertension, especially if lifestyle management is also positively affected, should reduce the prevalence and severity of CHF. Thus, management of hypertension, and increased patient self-efficacy should be a national and international health priority, not just for the impact on hypertension, but for its cause-effect relationship of hypertension with other chronic disease and their health and economic impacts.

The patient satisfaction survey indicates that patients would not pay for this service if it is not covered by their insurance. Unfortunately, at this time, RPM is not reimbursable by Medicare, nor by most

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private insurers, though at least eleven states have some form of coverage under their Medicaid programs.[10,11] Model policy language proposed by the American Telemedicine Association for consideration by states includes RPM in its definition of telemedicine services to be covered.[11] In spite of its inclusion in the model language, states that are passing telehealth parity laws, which mandate private insurance coverage of some telemedicine services, often establish coverage for a narrow selection of services delivered to rural areas.[12] To cover the services such as provided in this study, then, an organization must view it is an investment for which a return, such as reduced healthcare costs under a capitated or shared savings plan, reduced readmission penalties for hospitals, or prevention of more costly conditions and acute events can be recognized. Further study of the economic benefits of this program should be considered, in order to increase the likelihood of reimbursement under current fee-for-service programs, though fee-for-value or free-for-quality programs may readily embrace such a program, following the lead of organizations such as the Veterans Administration and Kaiser Permanente.[13]

Our results yield several important conclusions. First, it is possible to significantly reduce blood pressure on a population by implementing a 30-day program that uses RPM to extend the reach of the patient's provider into the home (or wherever the patient is), for the purpose of monitoring, evaluating the effectiveness of existing treatments and true blood pressure, and making adjustments to identify the appropriate medications and dosages for the patient. This can be done in a manner with which patients are satisfied, and providers are appropriately, but not overly, involved.

Second, it is possible in a 30-day program to also implement a consistent patient education program, including tests, that yields increased patient self-efficacy, or the confidence and knowledge to implement behaviors that will improve outcomes, from medication adherence to diet management and exercise.

By combining these two efforts into one program, patients are able to see firsthand the impact of appropriate medication therapy on their condition, while also learning about the various types of antihypertensive medications in their educational program, which should increase the recognition of the important value of medication adherence to the medication most appropriate to their condition. Similarly, having a single clinical contact, the TSC, providing both the telephone-based interaction regarding the RPM, and the education—as an extension of the provider's office—should increase the trust in and felt importance of the educational content and sessions.[14]

Further work is needed to evaluate the specific financial and economic impacts of this 30-day program, but the reduction in physician office visits and associated provider and patient costs, and reduction in provider intervention times to change medication therapy, coupled with a relatively low-cost monitoring solution should have a positive economic impact. If so, this program could be seen as positively impacting all three of the Triple Aim elements:

- Improving the patient experience of care (including quality and satisfaction).
- Improving the health of populations.
- Reducing the per capita cost of healthcare.[15]

The success with this program provides confidence that not only is this program scalable across many patients, both nationally and globally, but that the basic elements – combining the three aspects of mobile remote patient monitoring, shortened provider feedback intervals, and patient engagement/education – should be considered when addressing other conditions, such as congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and diabetes. **JHIM**

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