

Grant Final Report

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eHealth Blood Pressure Control Program (eHealth BP)

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Abstract

Purpose: Health Information Technology (HIT) can enable patient-centered care through the use of electronic interchange of health information from home to the medical office and back to home, with the aim of improving the quality of care.

Scope: Hypertension represents an ideal condition to test this model of patient centered eHealth BP enabled care since this condition is common, largely cared for by primary care physicians, and when uncontrolled is associated with significant morbidity and mortality.

Methods: The eHealth BP Control Program compared use of home blood pressure monitoring (HBPM) to HIT enabled eHealth BP system of care which integrated HBPM into a provider's EMR via a Web portal and use of a patient navigator.

Results: This eHealth BP program was feasible and acceptable to both patients and the provider team. Using a before and after quasi-experimental design, we found that, relative to HBPM alone (45% controlled BP at baseline), the eHealth BP control program improved BP control to 65% at the final visit. Both linkage of HBPM to an interactive Web portal and use of a patient navigator contributed to this improved outcome.

Key Words: None provided.

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Final Report

Purpose

Objectives of Study

Effective management of chronic illness, including hypertension, requires a close and ongoing partnership between the patient and all his or her healthcare providers. Health Information Technology (HIT) can enable patient-centered care through use of electronic interchange of health information from home to the medical office and back to home, with the aim of improving the quality of care. The use of an integrated Electronic Medical Record (EMR) and Personal Health Record (PHR) with device integration through a web portal connecting the patient virtually to their medical team provides the technological platform for this enhanced communication and the potential for improved care. However, research has shown chronic conditions require more than leveraging technological advances alone. Chronic conditions also require a “high touch”, team based approach to care, including patient education, collaborative self-management support, and care coordination.

We proposed to study the feasibility and acceptability of an eHealth BP enabled model of care for improved hypertension and elevated blood pressure control in a Primary Care Center environment. Hypertension and elevated blood pressure are a continuum and represent an ideal condition to test this model of patient centered eHealth BP enabled care since this condition is common, largely cared for by primary care physicians and is associated with significant morbidity and mortality from strokes, coronary heart disease, chronic renal failure and heart failure when unrecognized or poorly controlled. In addition, despite multiple national campaigns in the United States, best estimates suggest that 25% of hypertensive patients are unaware of their diagnosis and only 35% of hypertensive patients were adequately controlled. Thus, an eHealth BP enabled model of patient centered care, if effective, has the potential to improve blood pressure control and significantly reduce the subsequent morbidity and mortality associated with uncontrolled and unrecognized hypertension.

We proposed to study the feasibility and acceptability of a 4-component eHealth BP blood pressure control program which includes: 1) a personal health record (PHR); 2) home blood pressure monitoring (HBPM) device integrated into the PHR; 3) a blood pressure (BP) self management web portal and 4) use of a trained patient navigator (i.e., a community health worker). We hypothesized that, relative to HBPM alone, this 4-component program will increase patient activation, collaborative self-management care activities and medication adherence; reduce clinical inertia; and improve BP control.

The goal of this project was to obtain the necessary pilot data for a randomized practical clinical trial of the eHealth BP blood pressure control program.

This study was in two phases:

Phase I: Developmental Phase

During this phase, we developed and field tested the elements for the eHealth BP Control Program including: 1) the BP self-management web portal; 2) the training program and manual of procedures for the patient navigators; 3) the linkage of the HBPM device with a PHR and the web portal; 4) the academic detailing and practice toolbox for primary care providers; and 5) the office practice system changes necessary for primary care providers (PCP) to effectively use HBPM data for optimal clinical care and for the patient navigator to communicate effectively with the health care team regarding BP control. We also demonstrated the technological feasibility of seamless linking of the home blood pressure monitoring device to a personal health record and web-based patient centered self-management BP portal and an office-based provider portal.

Phase II: Open Trial Phase

Phase II was an Open Trial designed to field test the recruitment, assessment instruments, and adoption of the intervention, and to determine the effect sizes for the outcomes regarding patient activation, self-care activities, medication adherence, clinical inertia and BP control. This implementation gave us the needed experience and data in order to design an appropriately powered practical clinical trial to test the eHealth BP control program robustly in the future.

Scope

Background

Hypertension affects more than 65 million Americans and close to 1 billion people worldwide. When uncontrolled it is associated with an increased risk of total mortality, mortality due to cardiac disease, stroke, and chronic kidney disease and heart failure as well nonfatal cardiovascular disease (CVD) events. Population attributable risk fraction estimates suggest that high blood pressure accounts for 27% of all CVD events in women and 37% in men, 12.8% (7.1 million) of all deaths, and 4.4% (64.3 million) of all disability life-years lost in the US. Clinical trial evidence has clearly demonstrated that these risks can be significantly reduced with lifestyle change and use of blood pressure (BP) lowering medications. Evidence-based guidelines have been in place for nearly 30 years in an attempt to improve blood pressure control. Despite this 30 year effort, less than 35% of Americans with hypertension are optimally managed and 25% are unaware of their diagnosis. These risk identification and treatment gaps are greater for non-Hispanic blacks and Mexican Americans. If integrated into a team-based, patient-centered eHealth BP enabled care model, home blood pressure monitoring (HBPM) holds the promise to significantly reduce these risk identification and treatment gaps. HBPM overcomes many of the limitations of traditional office blood pressure measurement as it is cheaper, easier to perform than ambulatory BP monitoring, can differentiate true hypertension from white-coat hypertension, can identify masked hypertension in those with pre-hypertension, and shows a better correlation with target organ damage (retinopathy, kidney disease, left ventricular

hypertrophy) than office blood pressure. When combined with patient education and care management, HBPM holds promise to improve medication adherence and blood pressure control. A limited number of studies have aimed to test the efficacy of HBPM in improving blood pressure control with mixed results. A reviewed 11 trials and found that 6 of the 11 trials showed improved medication adherence if participants used HBPM compared to controls. A meta-analysis of 18 randomized trials comparing HBPM with usual care found that BP was better controlled in the HBPM group. Despite the modest BP lowering effects (2.2 mmHg systolic and 1.9 mmHg diastolic), the implications from a prognostic and population-based perspective are significant. Thus, the evidence to date does not support that HBPM by itself is sufficient to improve medication adherence and reduce blood pressure, but when combined with patient education, self-care support, regular communication with the care team, and care management, HBPM does hold substantial promise and is need of further study.

Context

Uncontrolled hypertension has been shown to be problematic with racial and ethnic minorities and the uninsured, who are typically serviced by community based, safety-net hospitals, which the Family Care Center (FCC) at Memorial Hospital of Rhode Island is one. The ‘high-tech’ solution alone in primary care practices with such a patient population/setting may be problematic. Our proposed high-tech/high-touch approach to our patients, using a Patient Navigator, showed it was possible to overcome the digital divide.

Settings

Third-year residents and attending physicians from the Family Care Center and Internal Medicine Departments at Memorial Hospital of Rhode Island were recruited as collaborating physicians. These participating physicians were consented and recruited their patients into the eHealth BP Control Program.

Participants

Using our electronic medical record (EMR), *Centricity*, we created a report of Family Care Center (FCC) and Internal Medicine patients with uncontrolled blood pressure (BP), which was defined as a patient having at least 50% of their BP uncontrolled during office visits over a two year period. Uncontrolled BP was defined as an office BP systolic blood pressure (SBP) >140mmHg or diastolic blood pressure (DBP) >90 mmHg for hypertension or SBP >130 mmHg or DBP >80mmHg for diabetes.

Inclusion criteria for participants include: 1) age 18 to 80; 2) diagnosed with hypertension or elevated blood pressure; 3) electronic health record data supporting poor BP control >140/90 for suspected hypertension (or >130/80 if patient is diabetic) within the past year; 4) have had at least two office visits in the past two years at FCC; and 5) can read and understand English. Participants may have co-morbid conditions of diabetes, depression, heart failure, coronary heart disease, stroke, COPD, mild to moderate renal insufficiency (est creat clearance >30 ml/min). Participants must have access to internet whether at home, community resource center or eHealth BP patient education room at the Family Care Center. Exclusion criteria: 1) unable to comply

with protocol; 2) pregnancy; 3) secondary hypertension (e.g.- renovascular); 4) participation in other hypertension clinical trials; 5) hospitalized in past six months for diabetes, renal failure, or heart failure; 6) severe renal insufficiency (est creat clearance \leq 30 ml/min); 7) patient already routinely using a home blood pressure monitoring device; and/or 8) patient not able to use HBPM device due to disability.

Table 1. Demographics for patients in the eHealth Blood Pressure Control Program (n=28)

Demographic	
Mean Age, yrs (SD)	58.5 (12.0)
Sex (%): Female	16 (57.1)
Sex (%): Male	12 (42.9)
Ethnicity (%): Non-Hispanic white	25 (89.3)
Ethnicity (%): Non-Hispanic black	2 (7.1)
Ethnicity (%): Non-Hispanic American Indian	1 (3.6)
Education (%): Less than high school	2 (7.1)
Education (%): High school graduate	9 (32.1)
Education (%): More than high school	17 (60.7)
Marital Status (%): Partnered	18 (64.3)
Marital Status (%): Not partnered	10 (35.7)
Employment (%): Employed	14 (50.0)
Employment (%): Retired or disabled	11 (39.3)
Employment (%): Not employed	3 (10.7)
Insurance Type (%): Private	14 (50.0)
Insurance Type (%): Medicare	10 (35.7)
Insurance Type (%): Medicaid	4 (14.3)

Table 2. Co-morbidities for patients in the eHealth Blood Pressure Control Program (n=28)

Co-morbidity	N	%
Hypertension	26	92.9%
Depression	9	32.1%
Diabetes without end organ damage	6	21.4%
Chronic pulmonary disease	5	17.9%
Connective tissue disease	3	10.7%
Leukemia	1	3.6%
Myocardial infarction	1	3.6%
Peripheral vascular disease	1	3.6%

Incidence

Incidence was not applicable to the eHealth Blood Pressure Control Program.

Prevalence

Prevalence was not applicable to the eHealth Blood Pressure Control Program.

Methods

Study Design

Recruitment of Patients and Providers. The Institutional Review Board (IRB) of Memorial Hospital of Rhode Island approved this study. Third-year residents and attending physicians from the Family care Center and Internal Medicine Department at Memorial Hospital were recruited as collaborating physicians. Patients aged between 18 and 80 with two uncontrolled office BP readings were occurring at any time in the preceding two years were recruited into the study from a disease registry within Centricity, the electronic medical record (EMR) of the practice. Recruitment occurred either by mail or during face-to-face encounters. Entry criteria included the ability for patients to read and understand the English language, access to the Internet, and an arm circumference of greater than 9 but less than 17 inches. Additionally, patients were enrolled based upon an elevated BP measured at the baseline visit. A HBPM target or goal BP level was set based upon guidelines from the American Heart Association HBPM and coronary heart disease prevention recommendations: the goal was less than 135/85 mmHg for individuals with average risk or less than 125/75 mmHg for patients with diabetes or coronary heart disease.

Deployment of eHealth BP-Enabled Support Tools. Patients gained access to either the high-tech only or high-tech/high-touch solution. The high-tech solution consisted of access to only the HBPM integrated PHR and the tailored web portal in order to monitor BP progress, while the high-tech/high-touch solution included support from the Patient Navigator (PN) in addition to the high-tech component. All participants received PN support during a final three-month stage of the overall nine-month study. Access to the HBPM integrated PHR and tailored web portal or eHealth BP enabled support tools allowed for an interactive interface to monitor BP trajectories. In addition to the high-tech solution, the high-touch component provided PN support to modify any technological barriers.

Nine-month eHealth BP Home Blood Pressure Monitoring Study Design. Twenty-eight patients with uncontrolled BP or hypertension were recruited, screened, and if they met eligibility criteria enrolled. All participants had a three month 'run in' period of only having a HBPM device. After 3 months, the participants were randomized to either the 3 component [HBPM + PHR + web portal] high-tech solution or the 4 component [HBPM + PHR + web portal + patient navigator] high-tech/high-touch solution with approximately half of the patients going to each group. After 3 additional months the remaining patients that only received [HBPM + PHR + web portal] at 3 months were assigned a patient navigator at 6 months as well. Thus we have measures of effect for the 1) participants on HBPM alone; 2) participants on the 3 component [HBPM + PHR + web portal] solution; 3) participants on the 4 component [HBPM + PHR + web portal + patient navigator] solution; and 4) the 20 patients who completed entire eHealth BP control program.

The above design allowed us to: 1) evaluate research procedures (consent process, randomization process, and assessment procedures) and establish their feasibility and acceptability to participants; 2) evaluate the barriers and facilitators to the intervention process (technical, procedural, etc); 3) estimate effect sizes of the 4 component program relative to

HBPM alone for improved BP control; and 4) estimate effect sizes of the 4 component program (high-tech/high-touch) relative to the 3 component program (high-tech).

Data Sources/Collection

Data sources / collection for the eHealth BP Control Program included:

1. The OMRON Home Blood Pressure Monitor (uploading recorded BPs to a computer application)
2. Patient Information and Questionnaires/Surveys collected at each of the 4 Research Visits (Baseline, 3 month, 6 month, and 9 month)
3. Google Analytics of patients' use and navigation of and uploads of BPs to the Good Health Gateway Web portal
4. Patient Navigator interaction / contact with enrolled patients (field notes) and the patients' PCP (communication with provider through the Centricity EMR)
5. Exit interviews with patients at the 9 month research visit
6. Chart audits of patients electronic medical record

OMRON Home Blood Pressure Monitor. At the baseline visit, patients were given an OMRON Home Blood Pressure Monitor (HBPM) and asked to use the monitor to become familiar with its functions and usability. Patients were asked to take a blood pressure reading once in the morning and once in the evening (twice daily) for a period of seven days. Patients were to report to the research staff any difficulties they had using the machine. At the 3 month Research Visits, blood pressure reading were uploaded from the patient's HBPM into an OMRON computer application for the purpose of determining each patient's average BP over a determined time period.

Patient Information and Questionnaires/Surveys. At each of the 4 patient Research Visits the following information was obtained/reviewed:

- Patient Contact and Demographic Information
- Patient Questionnaires (refer to Outcomes, Table 3, below)
- Review of Medications
- Adverse Events
- Exit Interview (RV4)

Google Analytics of Patients’ Use of the Good Health Gateway Web Portal. Through Google Analytics we were able to track 1) patients’ enrollment into the Good Health Gateway Web portal; 2) user sessions (time stamp of patients logging onto the portal); 3) how many times patients’ uploaded recorded BPs; and 4) how many times patients synched their BPs with their Personal Health Record ‘*HealthVault*[®]’

Patient Exit Interview. Patient exit interviews were administered by a research assistant at Research Visit 4. The purpose of the interview was to get patients opinions, thoughts and reactions to the eHealth Blood Pressure Control Program. Interview questions pertained to home monitoring, Technology–Good Health Gateway Web portal, Patient Navigator, Primary Care Provider appointments, and patients’ overall impression of the program and whether they would continue using their HBPM.

Interventions

Patient Navigator. One of the main interventions that was tested during the eHealth BP control program was the interaction and use of a Patient Navigator (PN) by patients. Under the guidance of a clinical psychologist, the PN in this study was trained to provide support to the patients for recording home BP, taking antihypertensive medication as prescribed, and attending visits with the PCP. In addition, the PNs were trained to provide some basic information about BP, interact with the patient care team, and use the electronic patient navigator tools (Patient Navigator Dashboard, EMR Patient Navigator Communication Form(s), see below). The PN did not provide health advice on other problems (e.g., diabetes), provide transportation to doctor’s appointments, fill out paperwork for the patient, provide language interpretation at doctor’s appointments, or assist the patient with goal setting for other health behaviors (e.g., diet, exercise). PNs were trained in motivational interviewing and goal-setting skills using a detailed manual.

Other interventions included:

OMRON Home Blood Pressure Monitor.

Figure 1. OMRON Home Blood Pressure Monitor



The OMRON Home Blood Pressure Monitor was used in this study because of the following features: 1) clinically proven accurate, 2) comfit cuff is pre-formed for a quick and proper fit for both medium and large sized arms (fits arms 9" to 17"), 3) automatically displayed the average of the last 3 readings taken within 10 minutes of each other, 4) simple, silent, 1-touch automatic operation with large display, 5) helped ensure accurate and comfortable readings, and 6) this model could be used with Microsoft HealthVault (which is a web-based platform from Microsoft to store and maintain health information) which in turn could take participant BP readings and be loaded onto the interactive Good Health Gateway web portal platform.

Interactive Good Health Gateway Web Portal used by patients to upload their home blood pressures.

Figure 2. Screenshot of Good Health Gateway Portal

A

Good Health Gateway® Managing your health has its own Rewards. Plus, we'll give you a few more!

MEMORIAL HOSPITAL OF RHODE ISLAND Log Out

WELCOME PATIENT Today's Date: September 24, 2010

Blood Pressure Management

My Home Page
Set-up and Instructions
My Monitoring Record
Rewards
Helpful Information
BP Wallet Card
Frequently Asked Questions
Message Inbox (50)

MONITORING REQUIREMENT: 14 RECORDINGS IN 30 DAYS (Recommend twice daily for 7 days) **IN PROGRESS**

Day 1	Session 1 (Morning)	Session 2 (Afternoon)
September 24, 2010		

PREVIOUS RESULTS (JULY 7, 2010 - JULY 20, 2010)

My BP: 131/85

How did we calculate this?

Congratulations!
Your blood pressure is considered controlled, putting you at a lower risk for heart attack and stroke. Feels great, doesn't it?

NEXT STEPS
In one month, repeat readings twice a day for 7 days. Please continue to accomplish your goals.
As of August 12, 2010, we are accepting additional blood pressure readings from HealthVault. You can also manually enter blood pressure readings in the "Add A Reading" box to the right.
The deadline for completing all the required readings is September 11, 2010. Since you have not submitted any blood pressure readings yet for this period, you must start to collect information by at least September 4, 2010 in order to submit the 14 reading sessions that are required in order to maintain compliance with this program.

ADD A READING

Date: 9/24/2010 Time: 11:08 AM

Blood Pressure: /
Systolic Diastolic

Pulse (optional): bpm

Save Recording

HealthVault
Data last updated: 24 seconds ago
Copy FROM HealthVault

TEXT REMINDERS
GoodHealthGateway can send you SMS text reminders when you miss readings or your reading window expires.
 Send SMS reminders.
Send text reminders to: change
Save Preference

MY GOAL BP:
135/85
What does it mean?

Patient Navigator Dashboard which allowed the PN to monitor patients' blood pressure in real time.

Figure 3. Screenshot of Patient Navigator Dashboard

B

Good Health Gateway® *Managing your health has its own Rewards. Plus, we'll give you a few more!*

MEMORIAL HOSPITAL OF RHODE ISLAND

Log Out
Today's Date: May 25, 2010

WELCOME PATIENT

Blood Pressure Management

Patient Navigator

Blood Pressure Admin

Message Inbox (1)

Patient Navigator

Program Participants (4)

Find by name: Show participants guided by:

Participant	Enrolled	Status	Current Reading
PATIENT 1	5/20/2010	COMPLIANT 5/25/2010 Phase #1	137/80
PATIENT 2	4/30/2010	COMPLIANT 5/18/2010 Phase #1	123/74
PATIENT 3	5/4/2010	BASELINE 5/4/2010 Awaiting Baseline	No complete sessions
PATIENT 4	5/6/2010	NO_RECORD Awaiting Baseline	No complete sessions

Centricity Patient Navigator Communication Form.

Figure 4. Screenshot of EBP Control Form

EBP Control Form:

EBP Control | Office Communication | Follow-up

EBP Control

Contact Date: [] [] Type of Contact: [] Comments: []

Light Color: [Red] Last Home BP Date: [04/18/2011]

Reason for Even driven contact: []

Avg BP Reading: [] / [] Systolic Range (High) [] Low [] Diastolic Range (High) [] Low []

Home BP Goal: [135] / [85] Risk Category: [Average] No. of Readings: [] Frequency: []

Patient's Understanding of BP: []

Why Control BP: []

Medication Reconciliation Review

ACCUPRIL TABS 10 MG (QUINAPRIL HCL) one po daily
ACCOLATE 20 MG TAB (ZAFIRLUKAST) one po twice daily
TRAMADOL HCL 50 MG TABS (TRAMADOL HCL) one po qid
VICODIN 5-500 MG TABS (HYDROCODONE-ACETAMINOPHEN) one po four times daily
METFORMIN HCL 500 MG TABS (METFORMIN HCL) one by mouth twice daily
FUROSEMIDE 20 MG TABS (FUROSEMIDE) 1 tab po qday
CYMBALTA 60 MG CPEP (DULOXETINE HCL) 1 qam
ACCUPRIL TABS 10 MG (QUINAPRIL HCL) one po daily

Medication Review Comments: []

BP Medication Adherence:

Excellent (>=6 days per wk) Fair (3 - 5 days per wk) Poor (<3 days per wk)

Comments: []

Home Blood Pressure Monitoring Comments: []

Patient's goals: [Wants to speak with PCP about a new medication and starting to eat a healthier diet.]

Prev Form (Ctrl+PgUp) | Next Form (Ctrl+PgDn) | Close

Measures

Outcome Assessments. Both process outcomes and primary and secondary outcomes of the open trial are described below Table 3.

Table 3. Primary and secondary outcomes

Table 3a. Primary outcomes

Measures	Baseline	3 months	6 months	9 months
Blood Pressure	RV1	RV2	RV3	RV4
Clinical Inertia (Chart Audits)	X			X
Morisky Scale of self-reported adherence	RV1	RV2	RV3	RV4
Patient Activation Measure	RV1	RV2	RV3	RV4
Niak Intention to Control HTN Index	RV1	RV2	RV3	RV4
Niak Collaborative Care	RV1	RV2	RV3	RV4
Niak Proactive communication	RV1	RV2	RV3	RV4

Table 3b. Secondary outcomes

Measures	Baseline	3 months	6 months	9 months
Health Status (SF-12)	RV1	RV2	RV3	RV4

Table 3c. Confounder/mediators

Measures	Baseline	3 months	6 months	9 months
Charlson co-morbidity index (Chart Audits)	X			X
Depression: CES-D	RV1	RV2	RV3	RV4

Table 3d. Process of care

Measures	Baseline	3 months	6 months	9 months
Pattern of utilization (Chart Audits, field notes)	X			X
Utilization of HBPM		X	X	X
Use of web-based self-management BP module			X	X
Utilization of PHR			X	X

Chart Audit. A pre/post patient chart abstraction occurred after the patient completed the 9 month eHealth Blood Pressure Control Program. The patients' medical record was reviewed from 9 months before enrollment into the eHealth BP Program up until they completed the study. Variables that were looked at include a) number of PN contacts/visits; b) overcoming clinical inertia by the medical staff; c) documentation of physician response to PN; d) nurse forms e) care manager forms; and e) interoffice communication between PN and health care team.

For all the Data Sources / Collection, Measures and Outcomes mentioned above, we have created access databases that are ready to be utilized for data entry and analysis with a large enough sample that would be found in a Randomized Practical Clinical Trial. The eHealth Blood Pressure Control Program final N=20.

Limitations

Limitations and challenges we found with the eHealth Blood Pressure Control Program are:

- Overcoming the digital divide
- Cuff size limitations leading to exclusion of higher risk patients
- Regression to the mean; ~40% controlled at baseline
- Greater need of technical support for synchronization of HBPM to Web portal and PHR than anticipated
- Extensive and timely PN training

The Lessons Learned of the eHealth BP Program included:

- PN needed to solve technological issues and provide support for participants
- Change inclusion criteria at enrollment and not use only EMR BP

Results

Principal Findings

Phase I.

1. Developed and refined a web-based patient centered decision support system for BP control using an iterative, user-centered design process so that it meets standards of feasibility and acceptability for patient navigators and participants.
2. Determined the appropriate and acceptable patient motivators (i.e., engaging content, social media, and incentives) leading to use of the eHealth BP control program (BP device, PHR, web portal, patient navigator).
 - a. Traffic light images used to reflect BP (green, yellow, red) were helpful to the PN, PCP and patients.
 - b. Blood pressure line graphs used on the Good Health Gateway Web portal were liked by patients - visual, easy to understand.
 - c. Educational materials and information was not utilized by patients.
 - d. Incentives for patients to take BP did not make a difference.

3. Developed and field-tested: a) a patient navigator training program; b) a manual of procedures for the patient navigators; and c) a measure of patient navigator adherence to the training manual.
4. Tested the functionality, security and fidelity of the secure data exchange between the HBPM device, PHR, web-based portal and EMR interface engine in both test and live (enterprise) environments. We found:
 - a. Due to the digital divide some patients had difficulty downloading required software to their computer which impeded their ability to upload BPs to the Web portal and be seen by the PN. This issue was overcome by use of the PN and research staff to assist patients in downloading needed software and could be accomplished by remote access to computers in future studies.
5. Developed and refined the academic detailing for primary care providers (PCPs) and the office system redesign procedures of communication, documentation and care so that they meet standards of acceptability for PCPs, office staff, and patient navigators.

Phase II.

1. Developed and refined recruitment methods for a future practical randomized controlled trial (RCT).
2. Refined research procedures for the informed consent, recruitment, screening, process assessment, database development, outcomes assessment and chart audits.
3. Field tested and refined a reliable measure of patient navigator adherence to the training manual and patient navigator supervision procedures.
4. Determined the degree of adoption by participants of the four intervention components (HBPM, PHR, web portal, patient navigator).
5. Determined the effect size estimates associated with changes in patient activation, self-care activities, medication adherence, reduced clinical inertia and improved BP control with implementation of the eHealth BP control program.
6. Evaluated the barriers and facilitators to the intervention process from the patient, provider and navigator perspectives using qualitative methods (i.e., interviews and field notes).
7. Determined the study design for a future RCT (two arms vs. three arms based upon the effect sizes and extent of adoption and barriers to the intervention components).

Outcomes

At the end of the study, the participant dropout rate was 28.6%. Overall, the percentage of controlled patients at the first research visit was 46.4% and increased to 65.0% at final research visit. After gaining the patient navigator, 75.0% of all of the recruited patients were controlled

Table 4. Percentage and change in percentage for the patients who were controlled

Percentages	All Recruited Patients (n=28)	Sample w/ Complete Data (n=20)
Rate controlled @ RV1	46.4	50.0
Rate controlled @ RV4	65.0	65.0
Rate controlled using PN	75.0	75.0
Change in % before and after PN	+8.3	+5.0
Rate Controlled using Web only (n=12)	66.7	72.7
Change in % before and after Web	+12.8	+18.2

Based upon these data, we performed a sample size calculation for $\alpha=.05$, $\beta=.80$, and determined we would need 96 individuals in each arm for a simple trial. Since we are proposing a cluster design trial, we need to account for clustering within practice. The intraclass correlation coefficient for blood pressure is 0.05, this calculates to a variance inflation factor of 2, thus we need 192 patients per arm to test our hypothesis. However, given 28.6% drop-out rate, we will need 270 per arm or 540 total patients. Assuming 30 patients per cluster, we need 28 providers or practices to participate in the proposed randomized trial.

Discussion

Integrating a home blood pressure monitoring program into the care of uncontrolled hypertensive patients in primary care was well received by patients, providers, and the health care team. Ninety percent of the enrolled patients were able to upload BP readings to the web portal. Approximately half of the patients required some technological support in order to use the eHealth BP system.

Findings from the eHealth BP Program suggest that a high-tech/high-touch approach laid the foundation for overcoming clinical inertia through optimizing medication dosage/titration with feedback regarding the patient's BP trajectory. Patients lauded the web portal for its ease at accessing the BP recording history that enabled the awareness of BP levels and determining the appropriateness of therapeutic strategy. Through the PN dashboard view, patients appreciated the PN or care team having access to their traffic light history and the BP measurements being integrated into their EMR. The patient-physician communication and information flow was enhanced by the PN using the web portal, following a patient's blood pressure readings, working with the patient, and talking to staff in the primary care / internal medicine offices. The web portal in conjunction with the EMR facilitated patient-PN and PN-medical care team contacts, which expedited patient-medical care team interactions.

Within a clinical practice, roughly two-fifths of the patients screened were eligible for the study. Reasons for the 3/5 potential participants ineligibility included: lack of internet access, HBPM cuffs not accommodating large and irregularly shaped arms (>17 inches in diameter) and regression to the mean. Nearly half of patients who were diagnosed in their charts as uncontrolled hypertensives showed blood pressure at or below goal during repeated measurements in the initial research visit. Although initially inclusion criteria were based only on elevated blood pressures as shown on charts, we needed to modify criteria to require that patients have elevated BP measurements at the initial research visit and not rely solely on the EMR BP measurements.

Human factors may have led to an increased need for technical assistance found in our pilot study. The sample was an older population (age mean=58.8, SD=12.1) even though educational level was relatively high (59.3% more than HS). Once enrolled in the trial, it became clear that many patients required greater technical support than originally anticipated in order to connect and upload their BP readings into the PHR. Once HealthVault[®] registration and connectivity was established and readings were synchronized with the patient tailored web portal, however, there were fewer technical issues. Lower education, ethnic and racial diversity, and older age have been documented as being associated with lower health literacy and decreased accessibility to the internet and/or a computer, as well as higher risk of high blood pressure. Patient navigators could be used as a resource to bridge the gap in understanding; these navigators may help to increase both health and technology literacy. Previous study protocols have stipulated patients demonstrate website proficiency or attend multiple HBPM training sessions before beginning the recording schedule. Additionally, a run-in period or a receipt of HBPM and website proficiency could be implemented in the protocol to circumvent utilization barriers. Further research is needed to determine the potential benefits of this e-health care model in a population with lower socioeconomic status that has subsequent elevated risk for uncontrolled BP and hypertension.

This feasibility study shows promising results of a high-tech/high-touch approach in advancing the meaningful use of technology in primary care.

Conclusions

- Integration of HBPM program primary care appears feasible, acceptable to patients, providers and the health care team.
- Barriers to recruitment, retention, issues related to the digital divide, technical issues of connectivity, workflow, and training of patient navigator, and education of providers on interpreting the HBPM values according to guidelines were assessed and appropriate strategies developed and tested to overcome these barriers in future trials.
- Based upon the findings of this R21 pilot study, a randomized cluster designed controlled trial of 540 uncontrolled hypertensive patients from 28 providers/practices comparing HBPM alone to the eHealth BP system should be able to demonstrate both the clinical effectiveness and cost effectiveness of the eHealth BP control system (linking HBPM to a interactive Web portal with patient navigator and enhance communication with the patient care team) in controlling hypertension.

- Limitations in current commercial e-health technology and the lack of technological skills of uncontrolled hypertensive patients in this family practice suggest that a patient navigator or other existing personnel resource (e.g., case manager, pharmacist) trained in use of patient-facing technology (connecting home BP monitor to computer and PHR, accessing secure portal of personal health information), as a viable solution for this technology to be used in most primary care practices.
- Training lay personnel to assume the role of PN required training and fairly close supervision in order for the PN to become competent. Using health care professionals and related clinical staff as patient navigators could have accelerated the training process, but these professionals require higher compensation.
- Next steps are to test the efficacy and cost effectiveness of this eHealth BP system of care in a variety of patient centered medical homes through a R18 mechanism.

Significance

- eHealth BP is feasible and acceptable.
- eHealth BP appears to be effective in controlling BP in patients previously uncontrolled at levels consistent with other studies of HBPM and case management but the small sample size and quasi-experimental design require a larger more rigorous study design to test effectiveness and cost effectiveness
- Elements of the digital divide are problematic but appear to have solutions using of a patient navigator and newer technologies (tablets, cell phones, kiosks).

Implications

Federal, state, commercial insurance and employer initiatives are supporting patient centered medical homes with increased use of electronic medical records and care management teams to improve the quality of medical care, insure patient safety, and reduce unnecessary costs. Within this context, demonstrating the power of utilizing collaborative health information technology using tested behaviorally science principles is a high priority. Use of home blood pressure monitoring is the now the standard of care for the diagnosis and management of hypertension in Great Britain and the American Heart Association and American College of Cardiology have recommended the same for the United States. Our pilot study suggested that using HBPM improved HTN control and a collaborative HIT could further increase HTN control. A larger well powered RCT is needed to test this hypothesis and its cost effectiveness.

List of Publications and Products

Bibliography of Outputs

Ahern DK, Stinson LJ, Uebelacker LA, et al. E-health blood pressure control program. *J Med Pract Manage* 2012; 28(2):91-100.