Personal health records and hypertension control: a randomized trial

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ABSTRACT

Purpose To examine the impact of a personal health record (PHR) in patients with hypertension measured by changes in biological outcomes, patient empowerment, patient perception of quality of care, and use of medical services.

Methods A cluster-randomized effectiveness trial with PHR and no PHR groups was conducted in two ambulatory clinics. 453 of 1686 (26.4%) patients approached were included in the analyses. A PHR tethered to the patient’s electronic medical record (EMR) was the primary intervention and included security measures, patient control of access, limited transmission of EMR data, blood pressure (BP) tracking, and appointment assistance. BP was the main outcome measure. Patient empowerment was assessed using the Patient Activation Measure and Patient Empowerment Scale. Quality of care was assessed using the Clinician and Group Assessment Score (CAHPS) and the Patient Assessment of Chronic Illness Care. Frequency of use of medical services was self-reported.

Results No impact of the PHR was observed on BP, patient activation, patient perceived quality, or medical utilization in the intention-to-treat analysis. Sub-analysis of intervention patients self-identified as active PHR users (25.7% of those with available information) showed a 5.25-point reduction in diastolic BP. Younger age, self-reported computer skills, and more positive provider communication ratings were associated with frequency of PHR use.

Conclusions Few patients provided with a PHR actually used the PHR with any frequency. Thus simply providing a PHR may have limited impact on patient BP, empowerment, satisfaction with care, or use of health services without additional education or clinical intervention designed to increase PHR use.

Clinical trial registration number http://ClinicalTrials.gov Identifier: NCT01317537.

INTRODUCTION

The patient-centered medical home and accountable care movements emphasize patient involvement in managing their own health. A recent health information technology (HIT) action agenda posited ‘effective management of personal health information (PHI) empowers patients to actively partner with their healthcare providers in making important healthcare decisions, which can potentially lead to better healthcare and better health outcomes.’13 Despite patient and provider concerns (eg, about system interoperability, data security and privacy, health literacy, and patients’ special needs), information access and utility is a particular healthcare reform target, and personal health records (PHRs) are a widely espoused opportunity to effect this reform.2–6 Proposed stage 2 and 3 meaningful use criteria to be implemented in 2015 and 2015 include web-based portals, inclusion of electronic self-management tools, and the ability for patients to incorporate reports of their care experience and home-generated data.7

PHRs are systems for keeping track of one’s own health needs, healthcare utilization, additional care attributes, and personal health experiences. Defined as a ‘universally available, lifelong resource of health information needed by individuals to make health decisions,’ individuals own and manage the information in the PHR, which originates from healthcare systems, individual providers, and the patient. The PHR is maintained in a secure and private environment, with the patient determining rights of access. The PHR is separate from and does not replace the legal record of any provider.8 PHRs can be independent or ‘tethered’ to medical and/or insurance records from which ‘official’ health information is extracted. Various methods of populating the PHR with PHI exist, however the patient owns the PHR thereby providing patient access and control for life.

Currently 10% of the public report using a PHR, an increase from 5% in 2008.9 Although 79% believe that a PHR would provide significant healthcare management benefits, privacy issues and security concerns loom large.10 Another national survey indicates a 7% use rate, double that noted 2 years earlier.11 In a large health cooperative offering and encouraging PHR use for all members, 42% signed up but only about 16% have become active users.12

PHRs remain a hopeful antidote for patient inactivation and poor health outcomes. The conceptual framework of consumer engagement suggests that access to PHI typically contained in a PHR increases patient activation thus improving health behaviors. Although there is evidence for an association between patient activation and health behaviors,13 there is minimal evidence demonstrating that increased access to health information will increase patient activation or change health outcomes. With hypertension contributing to one out of seven deaths in the USA,14,15 even marginally activating patients may yield substantial outcome improvements. We examine PHR use and outcomes in a sample of ambulatory patients with hypertension. The critical questions are: (1) will patients utilize a PHR when provided? (2) if used, will patient activation increase? and (3) will improved health outcomes follow?
METHODS
Design
A prospective two-group cluster-randomized controlled trial was conducted in which 24 primary care physicians were ‘clusters’ with patients ‘nested’ within their practice. Physicians were randomized into two groups: intervention (PHR) or control (care as usual), with each physician only seeing intervention or control patients. We considered the patient—physician pair as the important level of intervention necessitating the clustered design. Repeated measures of study variables were obtained from patients at four visits (baseline, 3 months, 6 months, and 9 months—1 year). Data are hierarchical in nature with multiple levels of nesting (visit-patient-physician-clinic). The study was reviewed and approved by the Institutional Review Board at the academic center. Both patients and physicians completed informed consent documents in one-to-one sessions with one of five research associates.

Physician recruitment
Physicians were recruited from one Family Medicine and one Internal Medicine ambulatory clinic at a southern tertiary academic medical center during a lecture reviewing PHR functionality and study details including patient completed assessments of care and post-study chart audits conducted by research staff. Physicians from both clinics were randomly assigned to either the intervention (seeing only study patients given a PHR) or control group (seeing only study patients not given a PHR) using a random number generator. Initially, 10 physicians were recruited per clinic, providing five per group. After 3 months, we added four physicians from Family Medicine to increase patient enrollment, thus yielding 15 intervention physicians and 11 control physicians.

Patient recruitment and baseline assessment
Daily lists of study physicians’ scheduled patients were generated from the appointment registration system. Charts were independently reviewed by one of five researchers in conjunction with physicians to identify those with a documented hypertension diagnosis based on JNC 7 guidelines (pre-hypertension (systolic blood pressure (SBP) 120–139 mm Hg or diastolic blood pressure (DBP) 80–89 mm Hg), stage 1 (SBP 140–159 mm Hg or DBP 90–99 mm Hg), or stage 2 (SBP ≥160 mm Hg or DBP ≥100 mm Hg)). Patients with currently controlled and uncontrolled hypertension were included. Exclusion criteria included physician request, patient decline, or acute illness. Enrolled subjects were assigned to either the control or intervention group based on their physician’s previous randomization. Researchers solicited patient participation at a regularly scheduled appointment and asked patients to complete four visits 1.5 to 3 months apart. Consenting participants were compensated with gift cards totaling $100 ($20 visit 1, $15 visits 2 and 3, $50 visit 4).

Instrumentation
At baseline, in addition to demographic characteristics collected at the time of study enrollment, we measured adult literacy via the 66-item Rapid Estimate of Adult Literacy in Medicine (REALM) test, and ease of access to and familiarity with technology using the Internet Accessibility Questionnaire, developed for this study.

Outcome measures (collected at all four visits except where noted)

Biological measures
DBP and SBP
The primary outcome measure was blood pressure (BP). Two seated measurements were obtained at each study visit following JNC 7 recommendations using the auscultatory method with patients sitting quietly for 5 min before measurement. Other biological measures

Body mass index (BMI) was calculated from height and weight, and waist circumference measurements taken at each visit. Laboratory measures of fasting glucose, triglycerides, HDL and LDL cholesterol were obtained from medical records as close in time to each visit as available. Metabolic syndrome was established if three or more of the following were present: fasting glucose ≥110 mg/dl; triglycerides ≥150 mg/dl; LDL <40 mg/dl in men or <50 mg/dl in women; abdominal obesity; and BP of at least 150/85.

Patient empowerment measures
Patient Activation Measure (PAM)
The 13-item PAM measures patient knowledge, skill, and confidence in health self-management. The PAM predicts self-directed behavior change, patient participation in the medical encounter, use of healthy behaviors, and use of quality data.

Patient Empowerment Scale
The Patient Empowerment Scale assesses patient’s perceived risks and benefits of access to their own health information.

Perception of practice quality measures
Patient Assessment of Chronic Illness Care (PACIC)
The 20-item PACIC assesses patient perceptions of the degree to which chronic care model components are incorporated into their care.

Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group Survey
Developed and validated by the Agency for Healthcare Research and Quality (AHRQ), the CAHPS Clinician and Group Survey includes three subscales (Access to Care, Provider Communication, Clerks and Receptionist at Provider’s Office) and a global rating. Twenty-seven experimental health technology questions were administered at baseline and at the end of the study.

Utilization measures
Patients’ self-reported number of hospital days, emergency room visits, and outpatient visits were collected at enrollment and at study end. Intervention patients reported PHR use frequency at study end.

PHR intervention

PHR description
This study employed the Cerner Corporation proprietary PHR system (IQHealth) deployed under the brand name My HealthLink. My HealthLink provides a secure, comprehensive, electronic record that enables consumers to store PHI. This PHR is ‘tethered’ allowing data from the electronic medical record (EMR) to ‘load’ for view only into the PHR. During this study only problem lists and information on medications, allergies, and immunizations were available for patients to review in ‘view only’ mode.

Core functions include: (1) secure messaging; (2) access to educational materials; (5) medication interaction checking; (4) recording and monitoring of health measures, for example, BP; (4) viewing of some EMR data (see above); and (5) some goal setting and health diaries. All messages were sent to a study nurse who triaged the messages, arranged appointments, and interfaced with physicians and nursing staff as needed. Prior to the study, PHR modifications were made based on
The design effect was calculated as $S^2_{\text{Residual}}$ is the number of clusters. Harmonic mean of the number of participants per cluster and $k$ line variable, the adjusted level 2 ICC was calculated as

$$\text{adjusted } 2\text{-ICC} = \frac{S^2_{\text{Residual}}}{\frac{S^2_{\text{Residual}} + S^2_{\text{Clinic}}}{n} - k}$$

where $m_0$ is the harmonic mean of the number of participants per cluster and $k$ is the number of clusters. The design effect was calculated according to Armitage and Berry as $\text{VEF}=1+(m_0-1)\text{ICC}/[m_0(m_0-1)k]$, where $m_0 = \lfloor n - (\Sigma X^2/n)/k \rfloor$, $k$ is the total number of clusters, $m_0$ is the number of participants in the $i^{th}$ cluster with $i$ ranging from 1 to k, and $n$ is the total number of participants in the study.

We additionally considered hierarchical random effects and repeated measures over time for PAM, PACIC, CAHPS, and the biological markers. Our major focus in modeling and hypothesis testing was to compare PHR versus care as usual differences in ‘improvement’ over time using generalized linear mixed models (GLMMs) for each outcome measure separately.

SAS PROC GLIMMIX was used to conduct a three-level GLMM analysis of covariance (ANCOVA) to model the visit 4 measures with the corresponding visit 1 baseline measure (Base) as a covariate. The models for the visit 4 outcome variables contained the following fixed factors, covariates, and interaction terms: Group, Clinic, Gender, Race, Education, Base, Age, Age×Group, Group×Clinic, Group×Base, Group×Gender, Group×Race, and Group×Education. Age was mean centered by Physician prior to analysis. We modeled the random component of Physician (nested within Clinic) using both random intercepts and random slopes. The Clinic random component was modeled using random intercepts.

We were unable to successfully model a four-level model using visit data as another level due to missing data on visits 2 and 3 and convergence problems. We therefore conducted the ANCOVA analyses detailed above.

All hypothesis testing and modeling controlled the type I error rate at the 0.05 significance level and all tests were two-tailed. Since hypotheses were planned a priori, no adjustments for multiple comparisons to the $\alpha$ level were made for the main outcome analyses.

**Blood pressure monitors**

Approximately half of the control and intervention patients, randomly selected, were given portable BP monitors (Model HEM-790IT; Omron, Kyoto, Japan) that loaded data via a USB port to the PHR.

**Statistical methods**

Analyses were undertaken using SAS/STAT software V.9.2 and IBM SPSS Statistics V 18.0 and V 19.0.

**Descriptive statistics**

Group means for quantitative variables were compared using independent sample $t$ tests; group proportions for categorical variables were compared using $\chi^2$ tests.

**Main trial analyses**

Adjusted intra-class correlation coefficients (ICC) and design effects were calculated for selected variables using baseline data. A cluster-randomization design (with physicians as clusters and subjects nested within physician) was used to reduce the possibility of cross-arm contamination. SAS PROC MIXED was used to estimate variance components for a three-level model for the selected baseline variables adjusting for Group, Gender, Race, Education, and REALM Score. The level 1 variance component is denoted as $S^2_{\text{Residual}}$, the level 2 variance component as $S^2_{\text{Clinic}}$, and the level 3 variance component as $S^2_{\text{Clinic}}$. The subscript for the level 2 variance component denotes that Primary Care Physician is nested within Clinic. For each baseline variable, the adjusted level 2 ICC was calculated as $[S^2_{\text{Clinic}} + S^2_{\text{Clinic}}]/[S^2_{\text{Residual}} + S^2_{\text{Clinic}} + S^2_{\text{Clinic}}]$. Standard errors (square root of variances) for the ICC estimates were calculated according to Donner and Koval: variance (ICC)=$2(1-\text{ICC})/[1+(m_0-1)\text{ICC}]/[m_0(m_0-1)k]$, where $m_0$ is the harmonic mean of the number of participants per cluster and $k$ is the number of clusters.

We examined frequency of PHR use and change using ANCOVA modeling visit 4 measures against the four-level frequency of use variable: no use (during training), low use (1–2 times after training), medium use (3–5 times after training, every other month, or monthly), and high use ($\geq$2 times per month). This variable was dichotomized as no versus any use for ease of interpretation in logistic regression analyses of biological characteristics, patient empowerment, patient perception of quality of care, and use of medical services as well as demographic patient and visit characteristics at enrollment as predictors for PHR use, and reported as crude ORs and 95% CIs. Education and race were dichotomized due to small cell sizes. We used multivariable logistic regression with backwards elimination of significant univariable predictors and reported adjusted ORs and 95% CIs.

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All hypothesis testing and modeling controlled the type I error rate at the 0.05 significance level and all tests were two-tailed. Since hypotheses were planned a priori, no adjustments for multiple comparisons to the $\alpha$ level were made for the main outcome analyses.

**Sub-analysis of PHR users**

Because of low PHR use rates among the intervention group, we performed exploratory subgroup analyses using a four-level frequency of use variable: no use (during training), low use (1–2 times after training), medium use (3–5 times after training, every other month, or monthly), and high use ($\geq$2 times per month). This variable was dichotomized as no versus any use for ease of interpretation in logistic regression analyses of biological characteristics, patient empowerment, patient perception of quality of care, and use of medical services as well as demographic patient and visit characteristics at enrollment as predictors for PHR use, and reported as crude ORs and 95% CIs. Education and race were dichotomized due to small cell sizes. We used multivariable logistic regression with backwards elimination of significant univariable predictors and reported adjusted ORs and 95% CIs.

We examined frequency of PHR use and change using ANCOVA modeling visit 4 measures against the four-level frequency of use variable and controlling for visit 1 measures. Significant $F$ tests were followed with $t$ tests between all combinations of the four-level frequency of use variable, employing the Bonferroni method of $p$ value adjustment.

**RESULTS**

**Enrollment**

Of 1686 approached patients, 443 (26%) were consented, enrolled and verified as hypertensive. Patient disinterest was the most common reason for exclusion ($n=546$, 44%), followed by computer concerns ($n=207$, 17%) (figure 1).

**Patient characteristics**

Mean age was 55 years. Differences were observed in gender (75% of the intervention group and 68% of the control group were female; $p=0.03$) and in health literacy measured by the REALM (higher in the intervention than the control group; $p=0.03$). No
Intra-class correlations
There were 24 primary care physicians (clusters). Average cluster size was 18.4, ranging from three to 37. The ICC ranged from 0.001 to 0.167, while the design effect ranged from 1.02 to 3.74. Weight and BMI had the smallest ICCs (0.001 and 0.002, respectively) and design effects (1.02 and 1.04, respectively), suggesting that patients within each primary care physician cluster are no more similar in weight and BMI than patients within other physician clusters. Variables with ICCs in the range of 0.02–0.04, with corresponding design effects in the range of about 1.4–1.6, suggest that patients within each physician cluster are more similar to each other than patients within other physician clusters. The largest ICC (0.167) and design effect (3.74) was found for the CAHPS HIT access-to-care scale. All ICCs and design effects are available in the online supplementary tables.

Main trial results
The primary comparison of interest for each outcome variable is the comparison of group main effect (ie, PHR versus care as usual) in the adjusted means. Although there were statistically significant group differences for some of the outcomes, none of the raw effect sizes were of sufficient magnitude to imply clinically meaningful differences between groups (table 2).

Predictors of frequency of PHR use at enrollment
Significant baseline predictors of any PHR use versus no use can be seen in table 3. Patients from Family Medicine were more likely to use the PHR than those from Internal Medicine. As age increased by 4 years, PHR use decreased by 4%. Higher self-rated computer skills, greater number of self-reported internet-use items, higher average DBP, and higher provider communication scores on the CAHPS instrument were associated with greater PHR use. The number of self-reported days in hospital approached significance, with a greater number of inpatient days associated with lower PHR use. Similarly, multivariable analyses indicated that patients from Family Medicine (OR 4.20; 95% CI 1.65 to 10.70), those with a greater number of self-reported internet-use items (OR 1.30; 95% CI 1.08 to 1.57), fewer hospital inpatient days (OR 0.72; 95% CI 0.57 to 0.92), and higher provider communication scores (OR 6.42; 95% CI 1.77 to 23.24) had significantly more frequent PHR use (see online supplementary tables).

Associations of PHR use with change from visit 1 to visit 4
In univariable ANCOVA analysis of visit 4 measures (table 4), frequency of PHR use was a significant factor for the CAHPS HIT helpfulness (p=0.02) and provider communication (p=0.03) subscales, with higher PHR use associated with higher HIT helpfulness scores and lower provider communication scores.
PHR use was not a significant factor for BP (p=0.10), although a five-point reduction in diastolic BP occurred in the highest use group. PHR use was also associated with fasting glucose (p=0.003), a finding modified by fasting glucose at baseline (see online supplementary tables for complete results).

**DISCUSSION**

Two main findings were observed. Among those patients provided the PHR, utilization of the PHR was quite low with only 26% using it frequently. Additionally, we found minimal differences between patients provided with PHR access and those without PHR access in this effectiveness trial conducted in two busy primary care clinics. Contrary to optimism about PHR impact, PHR access alone failed to activate patients, improve outcomes, increase satisfaction with care, or change the frequency with which patients use medical services. Simply providing patients with a method to access their healthcare information will not ensure changes in patient outcomes. This
PHR utilization was infrequent, with 54% of our sample using it about twice monthly. Additionally, only 26% of patients used it weekly or more. Furthermore, only 10% used the PHR to document or track BP, thus perceptually limiting immediate health practice, while for others, readiness may re

Table 2 Generalized linear mixed models analysis of covariance estimated least squares means

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>p Value (two-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological measures</td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>Average SBP</td>
<td>129.7</td>
<td>129.3</td>
</tr>
<tr>
<td>Average DBP</td>
<td>77.3</td>
<td>75.6</td>
</tr>
<tr>
<td>Weight in pounds</td>
<td>213.0</td>
<td>209.3</td>
</tr>
<tr>
<td>BMI</td>
<td>34.3</td>
<td>33.8</td>
</tr>
<tr>
<td>Waist circumference</td>
<td>108.0</td>
<td>107.0</td>
</tr>
<tr>
<td>HDL level</td>
<td>49.8</td>
<td>49.2</td>
</tr>
<tr>
<td>LDL level</td>
<td>108.4</td>
<td>101.0</td>
</tr>
<tr>
<td>Triglyceride level</td>
<td>139.2</td>
<td>138.3</td>
</tr>
<tr>
<td>Fasting glucose level</td>
<td>126.3</td>
<td>116.4</td>
</tr>
<tr>
<td>Patient empowerment measures</td>
<td>PAM total activation score</td>
<td>71.4</td>
</tr>
<tr>
<td>PES total empowerment score</td>
<td>41.2</td>
<td>40.1</td>
</tr>
<tr>
<td>PES empowerment subscale</td>
<td>23.9</td>
<td>22.6</td>
</tr>
<tr>
<td>Patient perceptions of quality measures</td>
<td>PACIC total score</td>
<td>70.7</td>
</tr>
<tr>
<td>CAHPS global doctor rating</td>
<td>9.39</td>
<td>9.43</td>
</tr>
<tr>
<td>CAHPS access to care composite</td>
<td>4.8</td>
<td>4.9</td>
</tr>
<tr>
<td>CAHPS provider communication composite</td>
<td>5.68</td>
<td>5.77</td>
</tr>
<tr>
<td>CAHPS office staff composite</td>
<td>5.4</td>
<td>5.6</td>
</tr>
<tr>
<td>CAHPS HIT helpfulness scale</td>
<td>3.72</td>
<td>3.68</td>
</tr>
<tr>
<td>CAHPS HIT access-to-care scale</td>
<td>4.69</td>
<td>4.83</td>
</tr>
</tbody>
</table>

*p<0.05.

BMI, body mass index=(weight (lbs)/height (in)^2)×703; CAHPS, Consumer Assessment of Healthcare Providers and Systems; DBP, diastolic blood pressure; HDL, high-density lipoprotein; HIT, health information technology; LDL, low-density lipoprotein; PACIC, Patient Assessment of Chronic Illness Care; PAM, Patient Activation Measure; PES, Patient Empowerment Scale; SBP, systolic blood pressure.

underscores the necessity to consider the immediate health outcome potential of subsequent stage 2 implementation plans for meaningful use criteria which require that patients are provided with information access after inpatient and clinical encounters with expectations that 20% will use a portal at least once. Our results suggest stage 2 implementation may not produce changes in patient health outcomes. Whether this is due to limited likelihood of patient use or limited impact when used is not yet understood.

The observed infrequent use of PHRs is similar to the findings of others.9 11 12 27 28 PHR utilization was infrequent, with 54% using it less than twice in 9–12 months, 20% using it 3–5 times, and 26% using it about twice monthly. Only about 10% used the PHR weekly or more. Additionally, only 26% of patients approached to participate in the study actually volunteered, so PHR utilization by the general population of patients similar to our sample may actually be much less than we observed. Future research may clarify the meaningful ‘dose’ of PHR utilization associated with favorable outcomes.

Although patients acknowledged the practical utility of our PHR, many expectations were not met. PHRs operate at increasingly useful levels.29 Our PHR stored information, provided some linkages, and allowed limited tracking and appointment scheduling. Previous inquiry to refine this PHR yielded informative patient recommendations, only some of which were implemented.22 Of note, we did not find that ease of entry of BP data via a USB port produced any additional effect on PHR use or outcomes.

Some optimism about PHRs remains. Patients who were the most frequent PHR users evidenced a reduction of 5.25 points in DBP and 3.97 points in SBP. Although it is not clear that this reduction can be attributed to PHR use, greater motivation to change in general, or other unexamined constructs, considering factors related to frequency of use may clarify practical directions for future research that can produce changed health outcomes.

Access and technology skills were important. Considering PHR use as a ‘health practice,’ self-efficacy theory suggests that patients need to view themselves as capable of successfully using the PHR.3 Self-rated computer skills, number of ways the internet is used, and baseline perceptions of the utility of HIT predicted PHR use, all indicative of higher computer self-efficacy. Overall, 83% of infrequent users possessed a home computer compared to 91% of frequent users. Mobile technology may reduce technology disparities and could expand potential PHR access.30

Salient clinical need evidenced in our frequent users as high initial BPs may encourage use. Self-management support trials and studies of increased access to one’s health information find similar results.18 31–36 The 70% of our patients demonstrating controlled hypertension may not have perceived a need to document or track BP, thus perceptually limiting immediate need for a PHR. Patients perceiving pronounced need, such as those receiving a new critical diagnosis or those challenged to manage conditions such as abnormal BP, may maximize PHR use.

Patients with the lowest PHR use had the lowest baseline activation scores and patients with the highest PHR use had the highest scores suggesting that activation may be a PHR use mediator. However, our high user group demonstrated reduced activation by visit 4. Our study team is challenged to explain the degradation. For some patients, readiness to engage with the healthcare system may involve ‘surrendering’ decision-making involvement, while for others, readiness may reflect active decision-making preferences. Patients ‘taking care of (their) health problems’ may influence PHR use in contrasting ways.37
Thus before we can expect PHRs to change clinical outcomes, we need to understand how both patient and provider engage the PHR and use the information contained within the PHR in the context of collaborative care. In our study, conversations initiated by both patients and physicians about the PHR and the health data contained therein varied greatly.

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Potential predictors at enrollment of frequency of PHR use (intervention group)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Variables</strong></td>
<td><strong>Categories</strong></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of use</td>
<td>Total*</td>
</tr>
<tr>
<td>Patient characteristics</td>
<td></td>
</tr>
<tr>
<td>Age at enrollment (years)</td>
<td>58.70±10.65</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>Female</td>
</tr>
<tr>
<td>Race</td>
<td>White</td>
</tr>
<tr>
<td></td>
<td>Black/other</td>
</tr>
<tr>
<td>Education</td>
<td>HS diploma or less</td>
</tr>
<tr>
<td></td>
<td>Some college</td>
</tr>
<tr>
<td>HTN at enrollment</td>
<td>Uncontrolled</td>
</tr>
<tr>
<td></td>
<td>Controlled</td>
</tr>
<tr>
<td>Clinic patient attended</td>
<td>Internal Medicine</td>
</tr>
<tr>
<td></td>
<td>Family Medicine</td>
</tr>
<tr>
<td>IAO at home</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>IAO self-rated computer skills</td>
<td>5.15±2.92</td>
</tr>
<tr>
<td>IAO number of internet-use items</td>
<td>3.58±2.38</td>
</tr>
<tr>
<td>Biological measures</td>
<td>Average SBP</td>
</tr>
<tr>
<td></td>
<td>Average DBP</td>
</tr>
<tr>
<td>Patient perceptions of quality measures</td>
<td>CAHPS provider communication composite</td>
</tr>
<tr>
<td>Health care utilization</td>
<td>Self-reported hospital days</td>
</tr>
</tbody>
</table>

*Categories of frequency of use: no use indicates PHR use only during training; any use indicates PHR used outside of training. Data missing on 53 patients from the intervention group.
†For categorical variables, frequency (%) is reported. For continuous variables, mean±SD is reported.
‡Includes patient, provider, and methods.
§Includes some college, 2-year degree, 4-year degree, or >4-year degree.
CAHPS, Consumer Assessment of Health Plans Survey; DBP, diastolic blood pressure; HS, high school; HTN, hypertension; IAO, Internet Accessibility Questionnaire; PHR, personal health record; SBP, systolic blood pressure.

Considering the context of the patient-physician relationship, we found that higher scores on the CAHPS provider communication subscale were associated with greater use of the PHR. Others have found that use of PHRs is most likely when the invitation and interaction of the provider encourages such use.50–40 Thus before we can expect PHRs to change clinical outcomes, we need to understand how both patient and provider engage the PHR and use the information contained within the PHR in the context of collaborative care. In our study, conversations initiated by both patients and physicians about the PHR and the health data contained therein varied greatly.

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Analysis of covariance of visit 4 measures by frequency of PHR use among the intervention group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency of use of PHR</strong></td>
<td><strong>No use</strong></td>
</tr>
<tr>
<td><strong>V1 mean</strong></td>
<td><strong>V4 mean</strong></td>
</tr>
<tr>
<td>Biological measures</td>
<td>Waist circ (cm)</td>
</tr>
<tr>
<td></td>
<td>Average SBP</td>
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<td></td>
<td>Average DBP</td>
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<tr>
<td>Patient perceptions of quality measures</td>
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<tr>
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<td>CAHPS provider communication composite</td>
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<tr>
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<td>CAHPS HIT helpfulness</td>
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*Categories of frequency of use: no use indicates PHR use only during training; low use indicates PHR used one to two times after training; medium use indicates PHR used three to five times after training, every other month, or monthly; and high use indicates PHR used at least two times per month. Data missing on 53 patients from the intervention group.
†Differences detected between no use versus high use (p<0.03), and medium use versus high use (p<0.01).
‡Differences detected between no use versus medium use (p<0.03), and medium use versus high use (p<0.04).
§Significant interaction between frequency of use and baseline categorical variable.
**Differences detected between low use versus high use (p<0.01), and medium use versus high use (p<0.02).
††Differences detected between no use versus low use (p<0.01), and no use versus high use (p<0.04).
ANOVA, analysis of covariance; CAHPS, Consumer Assessment of Health Plans Survey; circ, circumference; DBP, diastolic blood pressure; HIT, Health Information Technology; PHR, personal health record; SBP, systolic blood pressure; V1, visit 1; V2, visit 2; V3, visit 3; V4, visit 4.
Perhaps the PHR serves as a ‘cue to action’ as suggested by the health belief model.41 42 We found that patients with the highest BP’s and the highest provider communication ratings exposed themselves to the ‘cue’ most often. Future research should examine how to reinforce use in the clinical context and may improve PHRs’ outcome potential.

Examining system level variables, the Family Medicine clinic reported greater PHR use. Discussions with clinic stakeholders suggest patient continuity is highly embedded in their care process, and Family Medicine care teams have used an EMR for 13 years. Both provider and patient comfort with technology and established long-term relationships between patients and providers appear to have stimulated adoption and use of the additional technology of a PHR.

Limitations
Several limitations were present making the reason for failure to find differences unclear. We tested only one PHR with limited EMR/PHR interoperability. Significant numbers of patients declined to participate in the study, limiting the sample representativeness. Some possible cross-arm contamination may have occurred as intervention patients and control patients received care in the same clinics, and although physicians saw either study patients who had the PHR or study patients who did not, nursing staff saw all patients. PHR use frequency may have been greater if enrollment had been limited to patients with uncontrolled hypertension, maximizing the potential for greater BP change. Finally, we were unable to calculate individual use via PHR data extraction and relied on patient self-report to determine PHR frequency of use.

Conclusions
Health informatics trials are complex interventions, used with great variability by the patient and provider and uniquely implemented within each healthcare system.43 We found infrequent use of a PHR, no increase in patient activation with PHR access or use, and little change in outcomes except in limited areas among those using the PHR frequently. While clinical outcomes such as BF are typically considered the prime objective, process adaptation and intermediary measures are arguably critical to understand PHR use. Expectations of the outcomes produced by patient access to a PHR may need to be tempered until we understand which patients choose to use PHRs and how they use them. It is critical to understand how providers and systems can best incorporate PHRs into the practice settings and individual clinical encounters where the physician and patient join together to use the increased health information. Meaningful use criteria will support the provision of and access to web portals and PHRs. However, additional steps will be necessary before we can conclude that such access will improve patient health outcomes.

Acknowledgments
Cerner Corporation worked substantially with us as we implemented this project. Local team members included Hal Scott, Director of Health Informatics, Bruce LeClair, MD and Shila Brown, MD, who were physician liaisons in study clinics. In addition, we would like to acknowledge the work of the following research staff in recruiting and working with our study patients: Christine Abbott (also a Patient Advisor), Greg Ford, Gillian House, Anna Nelson, and Debra Rose, RN. Thanks also to the Institute for Patient- and Family-Centered Care for helping us focus on patient-centered interests and needs in PHR design.

Funding
This work was supported by grant number R18 HS017234 from the Agency for Healthcare Research and Quality originally awarded to Pat Sodomka who unfortunately passed away prior to completion. Dr Peggy Wagner assumed the role of Principal Investigator to complete the work in project year 03. We are pleased that we can offer this work as a tribute to Ms Sodomka’s continued and extensive presence in the area of patient- and family-centered care. The findings and conclusions in this document are those of the authors, who are responsible for its content, and do not necessarily represent the views of AHRQ. No statement in this report should be construed as an official position of AHRQ or of the US Department of Health and Human Services.

Competing interests None.

Ethics approval Ethics approval was provided by Georgia Health Sciences University Institutional Review Board.

Provenance and peer review Not commissioned; externally peer reviewed.

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