A MIXED-METHODS EVALUATION OF STANDALONE PERSONAL HEALTH RECORD USE BY PATIENTS WITH TYPE 2 DIABETES

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Abstract

Background: Self-management of diabetes is key for achieving positive clinical outcomes, with personal health records (PHRs) proposed as a patient-centered technology for facilitating self-care. However, few studies have described patient engagement with a PHR, including facilitators and barriers to use from the perspective of actual users.

Objectives: To compare use of a standalone PHR by patients with Type 2 diabetes to usual care through assessment of self-care behaviors, and short-term impact on social cognitive outcomes and hemoglobin A1c (HbA1c).

Methods: A mixed-methods design combining a comparative effectiveness pilot with qualitative interviews was used. Qualitative interviews explored the primary outcome of changes in self-care behaviors, while quantitative data obtained from health records and a survey focused on social cognitive and clinical outcomes.

Results: A total of 117 participants completed the study (intervention group = 56, control group = 61). Only 23 individuals used the PHR at least once after baseline. Five themes emerged from the qualitative analysis describing participants’ experiences with the PHR and identifying reasons for lack of engagement. Quantitative findings supported qualitative results with no significant changes in HbA1c and only a significant increase in diabetes knowledge in the intervention group.

Conclusions: Study findings revealed low PHR uptake and minimal impact on study outcomes, including lack of communication and information-sharing between patients and providers. Future research should explore the fit of PHRs within the context of other self-management tools, integration with provider workflow, and the need for enhanced functionalities beyond an information repository to optimally support patient self-care.

Keywords: health information technology, mixed methods, patient engagement, patient portal, personal health record, type 2 diabetes

Introduction and Background

Currently 26.9 million people are diagnosed with diabetes in the United States. An individual with diabetes experiences excess yearly medical costs on average of $9,601 directly attributable to their condition. This problem can be addressed by patients becoming more engaged in their diabetes self-care. Personal health records (PHRs) prominently emerged in the early 2000s, highlighted by a seminal paper in 2003 by Tang, which defined it as a patient-centered technology designed to empower patients and facilitate an active role in self-care. The PHR was unique in that it was a patient-controlled technology to facilitate self-tracking and management of health information and
subsequent sharing and exchanging of this information with health care providers.\textsuperscript{3,4} There were two primary types of PHRs: standalone, which were often offered by non-health care entities (e.g., Google, Microsoft, WebMD) and required the patient to enter and maintain all data in the PHR on their own; and tethered, which were connected to the provider-based electronic health record (EHR) and allowed the patient to import some of their health data into the PHR.\textsuperscript{5} Within the context of diabetes care, PHR use was hypothesized to lead to improvements in self-care behaviors and, subsequently, positively impact clinical outcomes.\textsuperscript{6-8}

Despite these proposed benefits, the PHR was never widely adopted, with estimates as low as 10 percent of US consumers in 2012.\textsuperscript{9} Identified barriers to PHR use included, costs, security and privacy concerns, inconvenience, design shortcomings, and lack of interoperability across health care systems and organizations.\textsuperscript{10-12} Additionally, the limited research examining the impact of PHR use on clinical outcomes of diabetes demonstrated inconsistent findings.\textsuperscript{13-19}

As PHRs transitioned out of use, patient portals rose to take their place, supported by federal initiatives such as meaningful use and subsequent programs.\textsuperscript{20} Patient portals bear resemblance to tethered PHRs with their connection to the provider-based record and typically allow patients to make medical appointments, refill medications, and securely message their providers.\textsuperscript{21} However, most are not patient-controlled. Patient portals have demonstrated variable adoption levels, with a systematic review and meta-analysis finding a mean adoption rate of 52 percent.\textsuperscript{22} Similar to PHR-based studies, a literature review of patient portal use in patients with diabetes found variable impact on clinical outcomes.\textsuperscript{23}

Given the lack of universal adoption of patient portals and inconsistent findings regarding impact on clinical outcomes from both the patient-controlled PHR and the provider-controlled patient portal, there is an ongoing need to understand how and why patients are engaging with these technologies to better support efforts for adoption and sustained use.\textsuperscript{24-28} Additionally, learning about standalone PHRs is still important, as it is estimated that 13 percent of office-based physicians still do not have EHRs, meaning that only the few remaining standalone PHRs are available to patients receiving care from these physicians.\textsuperscript{29}

The objective of this study was to describe how patients with Type 2 diabetes engaged with a standalone PHR to manage their diabetes-related health information. Primary outcomes were social cognitive measures of diabetes knowledge, modifying factors, and self-efficacy, with a secondary outcome of short-term impact on HbA1c.

\textbf{Methods}
This study used a mixed-methods design combining a quantitative comparative effectiveness pilot with qualitative in-depth interviews. Given the primary outcomes of the study, emphasis was placed on interview findings and quantitative social cognitive responses. The clinical outcome was of secondary focus, as the short study period for each participant (three to six months) was likely insufficient to demonstrate measurable HbA1c change resulting from PHR use. Still, it was important to measure clinical outcomes to help set a realistic context for the potential short-term impact of a PHR or other patient-centered health technologies on diabetes outcomes. This study was approved by the authors’ university institutional review board (IRB #09-15470).

Study Setting and Time Frame

The study was conducted in three ambulatory care clinics (two internal medicine practices and one endocrinology practice) with a total of 13 providers (11 internal medicine physicians, one endocrinologist, and one nurse practitioner). This study was conducted from June 2011 through August 2012.

Participant Recruitment and Randomization

Medical record review was used to identify patients meeting the inclusion criteria: Type 2 diabetes diagnosis with an HbA1c value of ≥7.0 percent; no diagnosis of impaired cognitive function (e.g., dementia); English-speaking; and self-reported access to and comfort with using a computer. Participants were randomized to either the control group, which received usual care, or the intervention group, which was provided in-person training for using the PHR to manage their diabetes-related health information. Based on the clinics’ patient population, it was determined that a convenience sample of 140 participants was achievable. Participants were enrolled using unequal randomization (73 in the intervention group and 67 in the control group) to ensure similar numbers in each group, assuming more drop-outs from the intervention group.

Study Intervention

For the purpose of this study, the PHR was operationalized as online, patient-controlled, and not offered by a specific health care provider. Selection of the study PHR (Microsoft HealthVault) followed a previously published evaluation focusing on PHRs that were free and met a majority of patient-desired PHR features identified through an in-depth literature review.

Participants in the intervention group received hands-on PHR training, guided by a step-by-step instruction manual with screenshots and written directions, which was provided to them for personal use. Participants were required to demonstrate the ability to enter the following information: birthdate, height, weight, medical condition(s), medication(s), blood glucose, blood pressure, HbA1c, low-density lipoprotein (LDL) cholesterol, and dates of their last eye and foot exams. Participants were directed to use the PHR in any way needed to help manage their diabetes-related health
Conceptual Framework

This study utilized a conceptual framework built on social cognitive theory (SCT), which states that self-efficacy is a primary determinant of a person's decision to establish and maintain effective self-management behaviors. This study hypothesized that PHR use would directly enhance self-efficacy and self-care, while simultaneously indirectly enhancing self-efficacy through modifying factors and diabetes knowledge.

Modifying factors include perceived barriers, diabetes education, and social support. Providing diabetes education and having appropriate social support will assist patients in understanding the actions needed to manage their diabetes care. Understanding the perceived barriers that interfere with self-care will help patients to identify facilitators of self-care, generate workable strategies for overcoming those barriers, set realistic outcome expectations, and improve self-efficacy.

Diabetes knowledge is necessary for understanding the clinical improvements that will result from self-care behaviors such as maintaining appropriate diet and exercise and being adherent to prescribed medication therapies. Providing patients with a tool to systematically track their health information over time will allow patients to see changes in diabetes-related outcomes based on behaviors taken, leading to improvements in self-efficacy.

Diabetes Care Survey

The Diabetes Care Survey (DCS) was constructed as a 127-item hybrid instrument by: 1) extracting items from previously validated instruments; 2) using an unpublished instrument measuring knowledge of medical conditions and prescription medications; and 3) developing new items. Items for the three social cognitive concepts (modifying factors = 18 items; diabetes knowledge = 16 items; and self-efficacy = 41 items) were constructed using a 5-point Likert scale (1=Strongly Disagree to 5=Strongly Agree). Responses were summed and averaged to calculate a score for each concept. The remaining 52 items addressed diabetes self-care behaviors, access to various aspects of diabetes care, and demographics.

Qualitative Interview Protocol

An interview protocol was developed to explore the central guiding question: “How have you used the PHR to manage your diabetes-related health information?” Interview questions are displayed in Table 1.

Clinical Data Collection – Baseline

All participants completed the DCS and had the following data abstracted from the EHR at baseline: age; year of diabetes diagnosis; body mass index; the most recent values for HbA1c, blood pressure,
blood glucose, LDL cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides, and serum creatinine; presence of diabetes-related complications; current medical conditions and medications; presence of diagnosed depression; date of last eye and foot examinations; date of last influenza and pneumococcal vaccinations; smoking status; and alcohol consumption. Current medical conditions were used to calculate a Charlson Co-Morbidity Index score, which is a tool to predict one-year mortality or hospitalization for patients with various chronic conditions. It was used in this study as a proxy to measure extent of additional chronic diseases in each patient beyond Type 2 diabetes. Participants in the intervention group also received the study intervention training.

Clinical Data Collection – Follow-up

Follow-up visits were conducted three to six months after the baseline visit, corresponding to typical intervals for diabetes care visits. At follow-up, participants completed the DCS and had data abstracted from the EHR. All intervention group participants also completed interviews, guided by the interview protocol. This purposeful sampling procedure was used to ensure that data saturation would be achieved. Interviews typically took 15-20 minutes to complete and were conducted in person at the follow-up visit, or by telephone. Interviews were audio-recorded and transcribed.

Qualitative Data Analysis

Qualitative transcripts were analyzed iteratively, using a process of reading through each transcript multiple times to immerse the researcher in the participants’ perspectives. This data immersion allowed for a reflexive process of understanding the impact of the researchers’ biases on the data analysis and interpretations drawn. Each transcript was individually analyzed using memoing and in vivo coding (which uses the participants’ own words and phrases as codes) to most accurately capture participants’ experiences with the PHR. After all transcripts were coded, categories were identified that grouped together codes with similar meaning. Cross-category analysis through comparing and contrasting represented ideas led to the emergence of themes that reflected patients’ use of the PHR to manage their diabetes-related health information.

Quantitative Data Analysis

Demographic data, diabetes self-care behaviors, and access to various aspects of diabetes care were compared at baseline between the control and intervention groups to ensure that the randomization process was effective. Independent samples t-tests were used to analyze continuous variables, and chi-square tests were used to analyze categorical variables, with a significance level set at p≤0.05.

To compare changes within the control and intervention groups from baseline to follow-up for social cognitive outcomes, paired samples t-tests were used with a significance level set at p≤0.05. The
same analysis was used to compare changes within the control and intervention groups from baseline to follow-up for the clinical outcome of HbA1c. Additionally, independent samples t-tests were used to compare control and intervention groups at follow-up. In the sub-analysis, PHR use logs were examined, and any participant using the PHR at least once after baseline was classified as a PHR user. Clinical outcomes for users and non-users were compared using the same process for the intervention and control groups.

Mixed Data Analysis

Mixing in this study occurred during data interpretation. Qualitative themes from participants about their PHR use and self-reported behaviors were interpreted within the context of the quantitative findings (social cognitive outcomes, and secondarily, change in HbA1c).45

Results

A total of 117 participants completed the study: 61 members of the control group and 56 members of the intervention group. The 23 participants who did not complete the study either asked to be removed from the study or did not return for a visit within the study time frame. Within the intervention group, few participants were PHR users (n=23).

Demographics

Table 2 displays the demographic characteristics for the overall sample. Participants were on average 59 years old, and the majority were female (54.7 percent), white (76.1 percent), married (59.0 percent), unemployed (53.0 percent), had less than a college education (62.4 percent), and had a yearly income less than $70,000 (68.5 percent). There were no statistically significant differences for any of the demographic variables between the control and intervention groups at baseline.

Qualitative Findings

Five themes emerged from the qualitative analysis. Each theme is described along with a representative participant quote.

Theme 1: Few people use the PHR more than once or twice.

Most intervention group participants did not use the PHR more than once, and only one participant indicated that they enjoyed using it. Reasons for lack of use fell into two major groups: 1) technical problems with hardware, internet access and speed, or computer comfort of the user; and 2) not identifying a clear value for use. One participant stated that, “My A1c has been steady. So I didn’t feel like I really needed to use it as often ... that wasn’t particularly useful for me.”

Theme 2: PHR users are individuals who are already tracking information.

PHR users reported that PHR use did not change their self-care behaviors, as many were already using other strategies for tracking information (e.g., paper records, glucometers, or Excel
spreadsheets). One user shared, “Being able to average and get my blood sugars in Excel is what I am used to.”

Theme 3: PHR users find value in self-management.

PHR users reported engaging with the PHR to support their diabetes self-management and described PHR use in ways that reflected self-motivation. A PHR user shared that, “I like that I can track my glucose level and I can see what I’ve been doing, and if food was what was causing me to have highs or lows.”

Theme 4: PHR users do not proactively share the information with their providers.

PHR users were already oriented to self-care. While some reported that an advantage of PHR use was maintenance of information in a central location, users did not associate this idea with sharing information with their providers. Additionally, some users had the perception that, “The doctor already has all of my information.”

Theme 5: Providers who knew patients were trained in PHR use did not ask for the information.

Providers continued to only ask participants for traditional sources of information, such as glucometer readings, diaries and log books, and recall of information despite knowing that the PHR was introduced to patients.

Quantitative Findings – Social Cognitive Outcomes

Qualitative findings were corroborated by the quantitative results. No significant changes were observed in the control group for any social cognitive outcomes: modifying factors (3.78±0.53 to 3.70±0.48, p=.204); self-efficacy (3.77±0.39 to 3.80±0.43, p=.317); and diabetes knowledge (4.13±0.53 to 4.19±0.52, p=.254). In the intervention group, no significant changes were observed in modifying factors (3.78±0.48 to 3.84±0.48, p=.379) or self-efficacy (3.82±0.37 to 3.84±0.39, p=.657); however, there was a significant improvement in diabetes knowledge (4.11±0.49 to 4.25±0.37, p=.029).

No significant changes were observed in PHR users for any social cognitive outcomes: modifying factors (3.92±0.43 to 3.99±0.44, p=.322); self-efficacy (3.89±0.29 to 3.97±0.33, p=.105); and diabetes knowledge (4.14±0.54 to 4.35±0.31, p=.098). Similarly, no significant changes were observed in PHR non-users: modifying factors (3.69±0.50 to 3.74±0.50, p=.740); self-efficacy (3.77±0.42 to 3.75±0.40, p=.498); and diabetes knowledge (4.09±0.45 to 4.19±0.40, p=.168).

Quantitative Findings – Clinical Outcomes

At baseline, participants’ average HbA1c was 7.69 percent (control = 7.53±1.53, intervention = 7.86±1.96), with a non-significant differences between groups (p=.301). At follow-up, participants’ average HbA1c level was 7.86 percent, (control = 7.75±1.22, intervention = 7.98±2.01). There was no significant difference between groups at follow-up for HbA1c (p=.455). A paired samples t-test revealed no significant change in HbA1c from baseline to follow-up for either the control (p=.252) or
Examining just the intervention group, PHR users had an average HbA1c of 7.46±1.72, and non-users had an average of 8.14±2.10 at baseline, a non-significant difference (p=.204). At follow-up, PHR users had an average HbA1c of 7.78±1.94 and non-users had an average of 8.12±2.07, also a non-significant difference (p=.546). A paired samples t-test revealed no significant change in HbA1c from baseline to follow-up for either the PHR users (p=.338) or non-users (p=.901).

Mixed Findings

Participants did not change their health information tracking behaviors to include PHR use—evidenced by only 23 individuals in the intervention group (41 percent) using the PHR more than once after baseline, and the qualitative themes that revealed users were either already utilizing other tracking mechanisms, did not see added value for their self-management, and/or experienced technical or computer literacy problems. As many of the PHR users were already self-tracking, no greater incremental change in quantitative outcomes was reasonably expected. Indeed, this was manifested in the lack of significant change to HbA1c and nearly all social cognitive outcomes. This finding is further supported by the qualitative themes, which revealed no paradigm change in patient-provider communication about self-monitoring; no additional information sharing with their diabetes care provider; and no solicitation of information by the provider themselves.

Discussion

Implications for Patients

Most patients used the PHR infrequently, if at all. Exposing the patient to the PHR possibilities for self-care and providing technical training for use was insufficient to impact short-term HbA1c or most social cognitive outcomes, indicating that the intervention was a “failure” despite education and training to maximize use. Individuals who used the PHR most frequently were already tracking their information using other tools (e.g., paper records, Excel), and non-users were non-trackers regardless of mechanism. Even while qualitative themes revealed that participants recognized value in the PHR for self-management, this resulted in minimal use. Additionally, with an average of 12 years since initial diagnosis, many participants had likely established routines for self-care tracking. This suggests there may be benefit in offering this type of tool to newly diagnosed individuals who have not yet established behavioral habits.

Diabetes knowledge did improve in the intervention group. However, given the overall lack of PHR use, this finding may be more appropriately explained by the education and training component of the intervention. This conclusion is also supported by the fact that while both PHR users and non-users increased their diabetes knowledge score (4.14 to 4.35; and 4.09 to 4.19, respectively), neither increase was significant. Thus, robust training and education with ongoing support may be an important strategy for stimulating patient adoption of new self-management tools. Future studies
may be able to use this study’s training framework and approach during initial implementation of such tools.

Implications for Providers

Qualitative themes revealed the PHR did not stimulate interactions between patients and providers. Despite providers being aware of the study and one provider documenting that their patient was participating in the “PHR study,” the introduction of a PHR did not create a common communication framework for provider and patient. This is problematic as providers are recognized as a crucial stimulus for adoption and use of self-management tools, and may need education about the potential that PHRs hold for enhancing patients’ self-care behaviors.48-51 Future research should address effective strategies for educating providers about the benefits of these tools and identifying how use of the PHR or similar technologies might fit into provider workflow.

Implications for PHR Vendors

To produce clear value for patients with various needs, the PHR will require enhanced functionalities. There is increasing focus on patient-centered clinical decision support tools such as identification of drug-drug interactions and preventive care reminders that advance its use beyond an information repository.52-54 Similarly, patient portals often include additional features such as secure messaging with health care providers, refill requests, and appointment scheduling. Recent studies of patient portals found that sustained use of secure messaging and refill requests can lead to improvements in glycemic, blood pressure, and lipid control55,56. Combined with appropriate positioning of the PHR in patient’s self-care, these enhanced functionalities may stimulate adoption and use resulting in positive effects on health outcomes.57

Limitations

As noted in the methods, the study time frame made it unlikely that clinical change would be observed. Future research should consider longer studies (i.e., minimum of one year) to assure adequate time to demonstrate HbA1c change and facilitate more in-depth exploration of potential benefits associated with PHR use.

Detailed information about PHR use (e.g., number of logins, number of times viewing a specific section within the PHR) was not obtainable. Thus, the simple measure of whether a patient used the PHR even once after baseline was used to classify PHR users and non-users. While this resulted in limited understanding about users’ actual PHR behaviors, the overall lack of use made it unlikely that access to this data would have led to significantly different interpretations of the study findings.

Finally, given the incidence of Type 2 diabetes across various patient populations, there was an underrepresentation of males and minority study participants, which may limit generalizability to these groups.
Conclusions

PHR use in this study demonstrated no significant impact on most social cognitive outcomes (the exception being a statistically significant improvement in diabetes knowledge that was likely not explicitly tied to PHR use), and no impact on clinical outcomes. The PHR did benefit some patients in ways that did not result in clinical changes; however, there remain numerous limitations to this technology that inhibits adoption and sustained use. In their current form, there is little that makes standalone PHRs an attractive option for patients. However, much of this learning can still be applied to similar technologies such as patient portals. Future research should focus on how to optimize the design of these technologies, communicate its usefulness to patients, identify optimal ways to integrate use into provider workflow, and facilitate patient-provider communication that will lead to positive impacts on social cognitive and subsequently, clinical outcomes.

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Author Biographies

Kevin T. Fuji, Pharm.D, MA, (kfuji@creighton.edu) is an associate professor of pharmacy practice at Creighton University.

Amy A. Abbott, PhD, RN, (amyabbott@creighton.edu) is an associate professor of nursing at Creighton University.

Kimberly A. Galt, PharmD, PhD, FNAP, FASHP, (kimberlygalt@creighton.edu) is professor of pharmacy sciences at Creighton University.

Notes


3. Ibid.


57. Ibid.
There are no comments yet.