Grant Final Report

Grant ID: R18HS017034

Personal Health Records and Elder Medication Use Quality

Inclusive project dates: 09/07/07 - 08/31/11

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Abstract

Purpose: To examine the impact of a personal health record (PHR) on medication use quality among older adults.

Scope: Online PHRs have potential as tools to manage health information. We know little about how to make PHRs accessible for older adults and what effects this will have.

Methods: Laboratory sessions compared the usability of a commercial PHR among older vs. younger adults. Because all participants had difficulty in the laboratory tasks, especially managing medication information, we partnered with a group of older adults (age 65+) in 13 sessions over 4 weeks to obtain design guidelines for a new PHR (Iowa PHR). We tested prototypes of Iowa PHR in focus groups of older adults and tested the final version in a six-month randomized controlled trial. After completing mailed baseline questionnaires, eligible computer users aged 65 and over were randomized 3:1 to be given access to the PHR (n=802) or serve as a standard care control group (n=273). Follow-up questionnaires measured change from baseline medication use, behaviors, quality, and adherence.

Results: Older adults were interested in keeping track of their health and medication information. A majority (55.2%) logged into Iowa PHR and used it but only 16.1% used it frequently. Compared with low/non-users, high users reported significantly improved medication management behaviors, reported better medication reconciliation by their providers, and recognized significantly more side effects but there was no difference in quality or adherence measures. PHRs can engage older adults, however features that motivate continued use will be needed.

Key Words: personal health record; medication management

Final Report

Purpose

This study was conducted under the Agency for Healthcare Research and Quality funding opportunity, "Ambulatory Safety and Quality: Enabling Patient-Centered Care through Health IT." The purpose of this study was to examine the impact of a personal health record (PHR) system on medication use quality among older adults by focusing on supporting self-management. This study was responsive to the following interest area: *patient self-management.*

The original specific aims included testing of a commercially available PHR in the context of a physician practice based research network (PBRN):

Specific Aim 1. To develop, through patient and provider focus groups, measures of patient Medication Therapy Management (MTM) behaviors and patient self-efficacy for MTM;

Specific Aim 2. To compare, in a trial in a primary care PBRN, the 6- and 12-month patient-reported MTM behaviors, medication adherence, patient- and physician-centric medication quality indicators, patient self-efficacy for MTM, and patient beliefs about medication, among those randomized to a current, representative PHR system vs. those randomized to usual care; and

Specific Aim 3. To investigate the usability of this PHR system in a human-computer interaction laboratory compared with alternative prototypes developed through participatory design with older adults of varying ability levels, and associate PHR performance with measures of cognitive, motor, and perceptual ability.

Due to early study findings, revisions to Specific Aims 2 and 3 and associated revised ordering of study procedures were implemented in September 2009 (Specific Aim 1 was not changed). The revised aims were:

Specific Aim 2 (formerly Aim 3). To investigate the usability of the original PHR system in a human-computer interaction laboratory compared with the new, interactive PHR system developed through participatory design with older adults.

Specific Aim 3 (formerly Aim 2). To compare patient-reported MTM behaviors, medication adherence, and quality indicators among those randomized to a new, interactive PHR system vs. those randomized to usual care.

Due to early findings among physician focus groups, subject recruitment was from a population-based sampling frame of older adults rather than the PBRN.

Scope

Background and Context

Personal health records (PHRs) electronic records of "health-related information on an individual that conforms to nationally recognized interoperability standards and that can be drawn from multiple sources while being managed, shared, and controlled by the individual".[1]. This information includes health conditions, medications, health behaviors, test results, healthcare appointments, and other personal information. The data in PHRs can be populated by provider-based electronic records, health system administrative data, and by patients.[2] Proponents of the patient-centered medical home and accountable care organizations as well as the IOM report on preventing medication errors, advocate efforts to involve patients in managing their own health.[3-5] PHRs are an opportunity to increase this involvement. The thinking is that increased access to their health information will increase patient activation and consequently improve patient health behaviors and ultimately health outcomes.[5,6]

From 7 to 10% of the US population currently reports using a PHR[7,8] and this is expected to increase dramatically if PHRs and related tools are included in the 2013 and 2015 meaningful use criteria as planned.[9] However, the designs of PHRs are widely variable and evidence about the effects of PHRs is scant. In our study we chose to design a PHR in partnership with older adults - a priority population group which has a high potential to benefit from increased patient activation but for whom barriers to computer use exist. Because medication management is a complex health behavior requiring daily decisionmaking to take or not take a medication, and because most older adults take many medications, our focus was on the PHR as a means to activate older adults for a more engaged role in medication management and medication use quality. Medication management and patient self-management have been identified as priority areas for improvement in health care quality identified by the Institute of Medicine.[10]

The elderly are vulnerable to medication side effects because of their multiple chronic conditions, increased exposure to numerous medications, and the effects of aging on pharmacokinetic and pharmacodynamic properties of medications.[11] The risks for medication errors among elderly patients increase when they visit multiple physicians for their comorbidities. Use of medications by older adults living in the community is far from optimal. We know that medication errors lead to at least five percent of hospital admissions among older adults.[12,13] Further, the elderly and their prescribers misuse medications. Between 14 and 23% of the elderly receive a medication they should not have been prescribed.[14-16] Up to 40% of patients do not take their medications as prescribed.[17] Underuse of certain medications such as beta blockers or ACE inhibitors is also of concern. Increasingly there are reports of age disparities in receipt of evidence-based therapies, for example in cancer[18-21] and cardiovascular disease.[22-24] The large-scale Cooperative Cardiovascular Project found that those most in need of treatments were least likely to get them, yet the magnitude of treatment benefit did not vary by either age or functional status strata.[22,23]

PHR systems afford promise for medication management in rural states, such as Iowa, where the already existing shortage of primary care physicians is predicted to get worse. In addition, sophisticated integrated health informatics capacity is not a reality for rural areas. Engaging patients to use a PHR is an appealing method to help offset these access barriers. Situated at Iowa's flagship academic institution, this research was conducted at the University of Iowa,

Department of Epidemiology, in collaboration with researchers from the Institute for Clinical and Translational Science, the College of Pharmacy, and the Departments of Computer Science, Family Medicine, and Biostatistics.

Settings and Participants

Specific Aim 1: Medication Management Focus Groups. One caregiver and two older adult focus groups convened at a public library in a Midwestern university town. A total of fifteen older adults and four caregivers participated in these study activities. They were recruited through a convenience and purposive sample drawn from the Seniors Together in Aging Research (STAR) volunteer research registry administered by the Center on Aging at the University of Iowa. We queried the STAR registry for persons age 65 years or older who reported at least two illnesses, excluding vision problems, hearing problems, or difficulty in cognitive abilities. For the older adult caregiver focus groups, we limited participants to persons age 65 and older who identify as caregivers of a family member or friend currently or in the past six months. Four provider practice focus groups attended by 29 physicians and associated staff were held at physician practices in Iowa. These practices were affiliated with the Iowa Research Network (IRENE), a practice-based research network (PBRN).

Specific Aim 2: PHR Design and Usability Testing. Research volunteers were recruited for activities in this study aim to test the commercially available PHR system initially purchased for this study, and to design and test the PHR system developed by the University of Iowa (UIowa) for the trial. The new PHR system was called Iowa PHR. Testing took place in several steps and samples.

- Step 1. Tests of the commercially available PHR. Using passive advertising on the UIowa campus and surrounding community, we drew an age-stratified, convenience sample of participants to test the purchased PHR system. Participants were persons aged 18-25 or 65+ who (1) took at least one medication daily, (2) could read a computer screen and use a mouse and keyboard, (3) use the Internet/Web for at least 30 minutes a week on average, (4) were not currently or in the previous 5 years an information technology (IT) or health professional, and (5) were able to travel to the UI for study appointment. Testing occurred in a research laboratory on the UIowa campus. Twenty-five participants were enrolled [13 in the 18-25 age group (median age 21, range 19-25, 77% female) and 12 in the 65+ age group (median age 71, range 65-80, 67% female)].

- Step 2. Iowa PHR design sessions. Residents (n=8) at a community-based retirement facility participated in a series of 13 one-hour design sessions held at the facility conference room. Study inclusion/exclusion criteria were: (1) Age 65 or older, (2) taking at least one medicine daily, (3) able to read a computer screen, use a computer mouse and keyboard, (4) uses the Internet for at least 30 minutes during a typical week, (5) has an email account, and (6) would be able to attend most or all of the sessions. The sessions were co-facilitated by the five research team members in attendance.

- Step 3. Iowa PHR focus groups. STAR registry volunteers (n=8) tested early prototypes of the Iowa PHR in focus group sessions. Groups convened at a conference center on the

University of Iowa campus. Inclusion and exclusion criteria were identical to the PHR design sessions described above.

- Step 4. Iowa PHR usability testing. Volunteers (n=6) from the STAR registry and previous design session participants assessed the Iowa PHR system's usability. Participants met the following inclusion and exclusion criteria: (1) takes at least one medication daily, (2) able to read a computer screen, and use mouse and keyboard, (3) uses the Internet/Web for at least 30 minutes a week on average, (4) not currently or in the past five years was not an IT or health professional, and (5) able to travel to the University of Iowa for the study appointment. Testing occurred in a research laboratory on the UIowa campus.

Specific Aim 3: PHR Trial. To identify participants for the PHR trial, we mailed a brief computer use survey to a simple random sample of adults age 65+ from a 2009 list of all registered voters in Iowa. We invited respondents to that survey who reported computer use in the past month to participate in the trial. Of 2,263 eligible persons, 1,163 enrolled in the PHR trial (PHR group: 873; control group: 290) and 1,101 persons completed both the baseline and followup survey.

Methods

Study Design and Data Collection: Specific Aim 1—Medication Management Focus Groups

Research team members facilitated all focus groups and guided the sessions through pre-identified topics and prompting questions. Sessions were audiotaped and transcribed; facilitators also took notes during the sessions.

Study Design and Data Collection: Specific Aim 2—PHR Design and Usability Tests

Tests of the Commercially Available PHR. Our usability expert conducted an environmental scan of more than 50 PHRs and selected the one that had the most usable features. Considerations used to select a PHR for use by older adults included that such a system should: meet full medication use functionality; take into account declines in vision, working memory, and motor skills; have a simple user interface with large targets for clicking, larger text, and simple navigation; and comply with standard usability principles or AARP recommendations on Web site design for older adults.

All subjects completed questionnaires on computer use and preferences. Subjects completed a series of ten computer tasks using the selected commercial PHR while we recorded their voice, facial expressions, and browser navigation experiences. Participants were asked to: log on to the PHR system; add and modify medications; record doctor visits; print medication list; record health status, date of flu shot, blood pressure, and missed medications; and enter physician

contact information. For each task, an assistant tracked the actual start and stop time. Subjects reported how long they thought each task took. Following the computer tasks, subjects completed a questionnaire on their experiences and explained questionnaire scores that indicated dissatisfaction with the PHR system.

Iowa PHR Design Sessions. The purpose of these sessions was to elicit features desired by older adults for a PHR system. We began each design session with a description of what we hoped to accomplish, and by fielding questions about those activities. Thereafter, attendees would break into small groups facilitated by research team members, with the session moderator floating between groups. In small groups, subjects would generate ideas through discussion on the topic at hand. The groups recorded ideas using "sticky notes" which the facilitator collected and clustered visually on a white board. Toward the end of each session, the full group reconvened to share and explore ideas from the smaller groups. A team member recorded detailed notes on all full group discussions. Following each session, research team members met to distill concrete design parameters for developing the PHR. In between meetings, the team further explored and discussed session highlights and key themes to guide the next session's topic.

Iowa PHR Focus Groups. We obtained feedback on early Iowa PHR prototypes by convening four focus groups with a group of older adults. The process of eliciting feedback on PHR prototypes and distilling findings from the sessions mirrored the approach used in the design sessions. Discussions were more directed and less exploratory as the goal was to elicit feedback on specific prototypes presented to attendees rather than to explore PHR design features.

Iowa PHR Usability Testing. After PHR development activities were completed, we conducted basic usability testing. We identified and resolved several issues through the process.

Study Design and Data Collection: Specific Aim 3—PHR Trial

Baseline questionnaire respondents were enrolled in the trial (N=1,163) over a three-month period and randomly assigned at a 3:1 ratio to be invited to use the Iowa PHR (intervention group) or receive usual care (control group). Notification of study group assignment was sent by mail to all trial participants. Follow-up questionnaires were mailed to trial participants who did not withdraw from the study (N=1,159) between 4 and 6.5 months after study assignment; 97.3% were mailed between 6 and 6.5 months after assignment. Reminder emails were sent to baseline and followup questionnaire non-responders who had provided email address information. For the followup survey, we mailed a second copy of the questionnaire followed by telephone when necessary to non-respondents.

Trial Survey Data Processing. All survey data were collected on optical scan-formatted questionnaires and processed with Cardiff TeleForm.[25] Prior to data entry, questionnaires were edited for stray marks, and light handwriting was traced using dark ink to ensure proper capture by the TeleForm system. Questionnaires were scanned, errant or undetectable responses were manually corrected, and data were exported to a SQL (Structured Query Language) database. Study staff reviewed all medication data collected via baseline and followup surveys. Pharmacy

technicians coded prescription and over the counter (OTC) medication names using a standardized, commercially available database. Retrospectively, a 6% randomly selected sample of baseline questionnaires was drawn and survey responses were compared to database values for accuracy.

Iowa PHR System Engagement Data. PHR system use and navigation data for PHR group trial participants were logged automatically throughout the study period and linked to survey data. The system generated timestamps for logins and clicks on links within the study PHR.

Iowa PHR Intervention

Iowa PHR Description. Iowa PHR was developed (Aim 2) specifically for use by older adults for this study. Iowa PHR is a Web-based application that features a tabbed interface design. Users can enter, view, and print their current and past medicines, allergies, health conditions, and health event tracking over time. An embedded tutorial video provides assistance with the system.

Prior research suggested individualized user feedback was a key facilitator to health IT adoption by older adults.[26] In keeping with this finding and the focus on medication management behaviors, we developed a set of user-friendly medication safety messages based on the Assessing Care of Vulnerable Elders project (ACOVE-3) medication use quality indicators.[27,28] Iowa PHR displays a message when a user enters a medication with an associated ACOVE-3 safety concern. The messages display in three levels of increasing detail and complexity to facilitate tiered information take-up: a brief alert containing the basic reason for concern, a summary level that includes recommended actions, and a detailed explanation of the alert. Within a month following the first user login, we deployed a revised version of Iowa PHR. This revision attempted to address our early observation that while many subjects entered medications that generated a brief safety message, only a minority were opting to click on the message to view the more detailed alert summary. We identified a likely cause of this low click-rate as the relatively low visibility of the safety messages displayed on the "Current Medications" tab of Iowa PHR. Our goal was to increase the visibility and uptake of these messages. We revised the system to feature these safety messages on the "Home" tab of the Iowa PHR system and added visual cues on the "Current Medications" tab where these messages displayed. Concurrently, these revisions to the Web application presented an opportunity to roll out additional ACOVE messages to Iowa PHR users that we were unable to implement with the initial system deployment due to time constraints. We adapted four general medication use patient quality indicators from the ACOVE project[27] and displayed them to all users on a rotating basis upon login: (1) keeping an up-to-date medication list, (2) receiving an annual medication review, (3) knowing the indication for all current medications, and (4) receiving patient education on the indication, administration, and possible side effects of each medication.

Intervention (Iowa PHR) Group Procedures. Accompanying the notice of study group assignment, PHR group participants were sent an invitation to use the study PHR for a period of one year, a quick-start guide, and their login credentials. Upon initial login to Iowa PHR, users agreed to the terms of an online informed consent document, followed by two user-selected security questions from a pre-defined list. Participants who did not log in to Iowa PHR were sent

a reminder letter 3-4 weeks after the initial invitation. PHR group participants were also sent a letter notifying them of revisions to the Iowa PHR system.

Measures: Specific Aim 1—Medication Management Focus Groups

Transcripts and notes from patient, caregiver, and provider focus groups were analyzed to identify core themes that represented participants' perceptions of personal health records and medication management, and to guide the summary and interpretation of results. Emergent themes were reviewed by research team members against *a priori* core MTM functions and refined as appropriate. Items were constructed for the PHR trial to assess how the study PHR may support such patient-initiated medication management functions.

Measures: Specific Aim 2—PHR Design and Usability Tests

Tests of the Commercially Available PHR. We assessed the usability of the commercially available PHR system through the following specific measures: demographic information (age, gender, living arrangement, education, health); modified versions of the Computer Attitude Questionnaire[29] and Questionnaire for User Interaction Satisfaction;[30] degree of computer task completion; actual and perceived time to complete tasks; and a checklist of desirable PHR features. In addition, the following were administered to older adults: medication management support questions; Mini-Mental State Examination;[31] Drug Regimen Unassisted Grading Scale;[32] Hopkins Medication Schedule;[33] Beckman's Tasks;[34] Trail Making Tests,[35] and the Test of Functional Health Literacy in Adults – Short Version[36].

Iowa PHR Usability Testing. We tested the basic usability of the Iowa PHR system through the following measures: health status, computer use, and demographic information; experiences with and observations of computer tasks; actual and perceived time to complete tasks; modified Questionnaire for User Interaction Satisfaction; and opinions on the Iowa PHR system post-use. The aim of these tests was to assess basic system functionality to rapidly identify and troubleshoot system flaws. System issues encountered by participants were corrected before implementation in the trial.

Measures: Specific Aim 3—PHR Trial

PHR Trial Measures. Table 1 lists the measures that were administered to trial participants pre-randomization (at screening for trial inclusion and at baseline), and post-randomization. *Current computer use* was defined as use of a computer to visit Web sites, or to send or receive email in the past month.

Table 1. Data elements collected for the PHR trial

Name	Data collection event: Screening survey	Data collection event: Baseline survey	Data collection event: Follow-up survey
Computer use	X		
Disability[37]	X		
Demographic information	X	X	X
Healthcare utilization		X	X
SF-12 v2[38]		X	X
Baseline and interval chronic condition history		X	X
Prescription and over-the-counter medication inventory		X	X
Self-reported adverse drug events[39]		X	X
Self-reported medication adherence [40]		X	X
Patient-reported medication management behaviors		X	X
Medication management risk indicators		X	X
Medication changes		X	X
Medical Care Preferences			X
Internal Health Locus of Control			X
Krantz Health Opinion Survey - Behavior Involvement Subscale			X
Self-efficacy for medication management behaviors			X

Health status was measured using the full SF-12 v2 and physical and mental health scores.[38] Nineteen common health conditions were queried at baseline, and conditions diagnosed in the previous 6 months were collected at followup. Participants were asked to consult the labels for prescription medications they currently take, and to list the name, strength, date the last prescription was filled, dose, length of time taking, purpose, and side effects they watch for. When more than 10 medications were being taken, only name and strength were queried for medications 11 through a maximum of 20 prescription medications. Name and reason were queried for non-prescription medications taken in the past 2 weeks. To determine rates of potentially inappropriate medications, we compared baseline and followup medications with drug lists compiled from the ACOVE project.[27] An adapted version of Morisky's work[40] was used to measure self-reported medication adherence. Medication risk behaviors were assessed using items adapted from the Medication Use Self-Evaluation (MUSE) scale.[41] Additional medication management behavior and self-efficacy items were developed for Specific Aim 1 and included on the baseline and followup surveys. These items aimed to assess how patients used and maintained medication lists, and the how medication lists may facilitate medication reconciliation in the context of health care visits.

We omitted several measures from the followup survey that were included in the baseline survey due to low response variability, and we added new measures to support exploratory analyses of other domains of medication management behaviors. The prescription drug subscale and the global preference item of the Medical Care Preference Measure (MCP) were used to assess care-seeking preferences.[42] The Internal Health Locus of Control,[43] and the Behavior Involvement subscale of the Krantz Health Opinion Survey[44] were also included at followup.

Subject gender, age, ethnicity, race, education, marital status, and living situation were collected at baseline. Age was calculated based on when the initial sample was selected.

PHR system use data for PHR group trial participants were linked to subject survey data. Event timestamps were logged when users: visited any major interface tab or sub tab; added, edited, or deleted any information; printed a report; or clicked on the Iowa PHR tutorial.

Statistical Methods

Analyses were undertaken using SAS/STAT software Version 9.2 SAS Institute Inc., Cary, NC, USA.

Iowa PHR Usability Testing. To test the commercially available PHR, groups of older and younger participants were described and compared by demographics, and computer use/ availability/ attitudes. Ten PHR related tasks were assessed for completeness, accuracy and time required for completion and compared between age groups. Because of small sample size (13 subjects in group $\leq$25 years old, and 12 in group $\geq$65 years old), Fisher's Exact test was used to compare categorical variables, and non-parametric Exact Wilcoxon rank-sum test was used to compare continuous variables. To assess differences in perceived and actual time to complete computer tasks, we used the Wilcoxon Signed rank test to test if difference in time is equal to 0. We described subject experiences with task completion in narrative form.

Main Trial Analyses. At the first stage of analysis, groups for subjects randomized for PHR use and controls were compared pre- and post- intervention. Independent sample t-tests were used to compare group means for continuous variables. Group proportions for categorical variables were compared using Chi-square tests.

User Subgroup Analyses. Because of low PHR use rates among the intervention group, we then performed subgroup analyses comparing users and non-users within the intervention group. PHR (intervention) group participants were classified by level of system engagement. *High use* was defined as multiple user logins over the duration of the trial with health information entered or edited during the session. *Low use* was defined as one or more logins but where health information was entered or edited during only one session. *Non-users* were examined in two groups: those who logged into the system but did not enter any health-related information and those who never logged in. After observing consistently comparable findings for low users and non-users, we proceeded to dichotomize high use vs. all others (referred to as user/non-user respectively). Similar to main trial analysis, unadjusted comparisons were performed using independent sample t-tests for continuous variables and Chi-square tests for categorical variables. Logistic regression and linear regression models were applied to compare post-intervention characteristics for high and non-users adjusting for corresponding pre-intervention values and total number of medications.

Results

Commercially Available PHR

We reviewed 58 PHRs listed in myphr.org. Most were geared toward young families and were family rather than individual-oriented. Few provided easy to access online demonstrations. A majority were poorly designed. We only found 12 out of 58 that could be potentially used in our study. Problems included poorly designed forms (e.g., left-justified labels, limited medication use functionality), difficult navigation (e.g., too many clicks to access a function),

and complex user interfaces (e.g., too many options, most of which would be rarely used). The commercially available PHR we selected had a simple user interface and simple navigation and was designed for a low literacy population. However, we noted several limitations even prior to testing including ambiguous and limited medication functionality.

In testing this PHR, there was only modest overall satisfaction with the system as measured by the Questionnaire of User Interaction Satisfaction (QUIS). The median value was 5.1 for older participants and 5.3 younger participants for average response to 16 survey questions [on the scale from 1 (the worst) to 9 (the best)]. On average, only six of 16 responses were above 5 (median possible response) for older participants. The lowest scores for older participants were for the questions: "Ease of operation depends on your level of experience" [Always(1) to Never(9)] median score=3; "Tasks can be performed in straight forward manner" [Never(1) to Always(9)] median score 4.5; "Learning to operate the system" [Difficult(1) to Easy(9)] median score= 4.5.

Subject attempts to complete mock tasks in the commercial PHR yielded a variety of data entry strategies and mixed success. Both young and older participants had difficulty entering medications and widely varied in how and where they recorded the information. Participants continued to uniformly have difficulty adding medications to the system and expressed considerable frustration. The majority of participants could not find the functionality for printing the medication list and those who succeeded in printing anything used the "file: print" option in their browser. Only one participant optimally recorded the date they received a flu shot. Most participants could record a blood pressure reading and note that they missed a medication dose in the correct location (health diary for both), but often expressed being dissatisfied because "health diary" is too general. Twenty of 25 participants could successfully enter physician contact information. Only 10 did so without difficulty. Only eight participants indicated that they stopped taking a medication correctly without difficulty. Three completed it with difficulty and the remainder failed to use the "medications" tab to indicate medication discontinuation. Finally, participants chose a wide array of approaches to indicate a medication strength change due to test results as there was no clear way to perform it. Most of the approaches selected did something to the "medications" list but often the old dose remained as current and a new record with a new dose was added to their record. This would show on report as currently taking two different doses.

Subjects' time estimates for task completion were close to actual time for older adults and somewhat higher than actual time for younger adults. Older adults took more time to complete most of the tasks and less than 50% of older adults accurately completed some of the tasks.

Iowa PHR Participatory Design Sessions

Principal Findings. Over the course of 13 design sessions in four weeks with a group of older adults, we learned:

1. Older adults want to keep track of a lot of information but are willing to enter very little. Participants listed over 20 separate items they wanted to track for each medication but were only willing to keep track of about five. The top items were: name, dose, how to take it, what is the reason for taking it, and information on precautions and interactions.

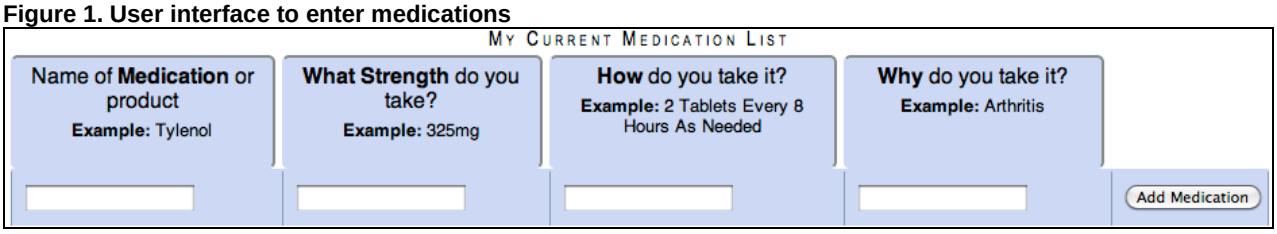
2. Medication warnings developed for health care providers do not translate readily into information for older adults. Many such warnings to prescribers are about medications that should not be prescribed to older adults. However, for the older adult who is already taking such a medication, how should they be told they should not be taking it? Participants could not understand why their doctor would prescribe it or their pharmacist dispense it if it was not safe. In spite of these concerns, there was strong agreement that patients should receive these warnings. Suggestions included using short sentences, less technical vocabulary, and three levels of information. Participants agreed that the first level should always be visible and should clearly explain what the safety concern is. They uniformly disliked the idea of seeing a generic alert that they would have to click to reveal. Older adults differed in the amount of information that they wanted to see about a warning.

3. Perceived privacy and security are crucial for adoption. Concerns about the privacy of the data were exacerbated by a lack of understanding of how the Internet works. Many participants had difficulty understanding how the data would be stored and secured. There were many mentions of "big brother" looking over their data and of employers or pharmaceutical companies taking advantage of the data to the detriment of patients.

Translating Findings into the User Interface. Because we identified problems with the medication components of available PHR products, we concentrated particularly on the module to help older adults keep track of their medications and obtain warnings. We extended many of these lessons to the other components of the PHR.

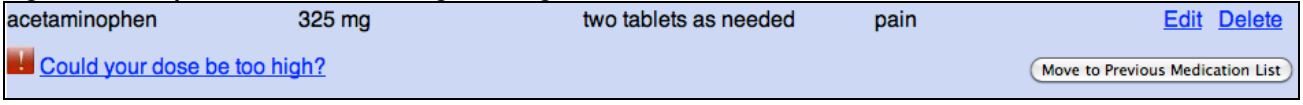
1. Keeping track of medications. Users enter the name of the medication, which they can enter in free text or select from an auto-complete list that includes thousands of prescription and over-the-counter medications. A screenshot is in Figure 1.

Figure 1. User interface to enter medications



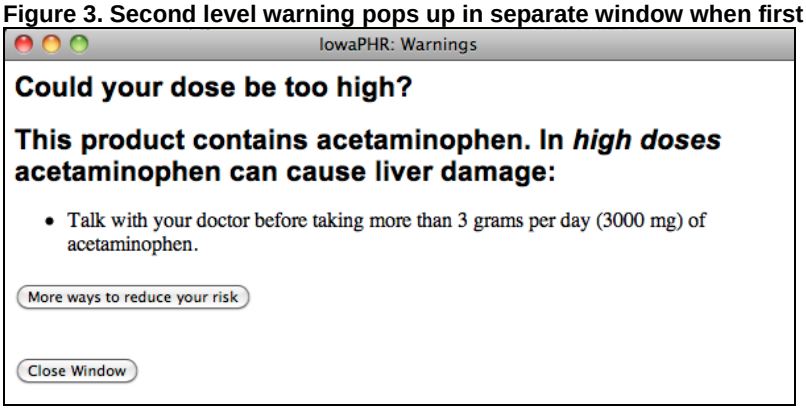
2. Warnings. The system provides users with three different levels of detail. The first level uses just a few words and shows the warning under the name of the medication. It is meant to provide essential information and to catch user attention, using easy to understand vocabulary.

Figure 2. Example of first level warning showing under medication



Clicking on the first level warning pops up a window showing the second level warning. This level provides more details about why the warning was triggered and providing advice to the patient. In Figure 3, basic advice is provided on how to avoid overdosing on acetaminophen.

Figure 3. Second level warning pops up in separate window when first level warning is clicked



Clicking on the "more ways to reduce your risk" button shows additional information on the pop up window. In additional feedback we obtained in the three meetings with another group of older adults, our three-level warning approach has been well received, providing the right level of information at each point. It does not overwhelm users with all details at once, provides useful information at all levels, and enables older adults to obtain further information in case they are interested in learning more.

3. Use of video for expectations and training. We inserted a video to describe and present how to use our system. In our focus groups, we noticed that being able to see a very quick demonstration of how to use the system made it significantly easier for older adults to navigate and use the PHR.

Iowa PHR Trial Results

Of the 1,163 people randomized, trial analyses were conducted with 1,075 persons (92.4% of initially enrolled trial participants). We excluded 62 cases who did not complete the followup survey, 23 who did not receive their mailed study group assignment, and 3 for whom followup survey discrepancies suggested someone other than the subject completed the survey. Mean age was 72 years and 56.8% of participants were women. The study groups were well-balanced (Tables 2 and 3). At baseline, control group subjects were more likely to have changed the strength or dose of a prescription medication in the past 3 months ($p=0.0228$) (Table 3).

At followup, intervention group participants were less likely to have started an over-the-counter medication in the previous three months (8.9% vs. 13.2%, $p=0.039$) and to be taking two or more NSAIDs (14.1% vs 19.4%, $p=0.0355$) (Table 3). All other followup comparisons between study groups post-intervention were statistically insignificant at $p < 0.05$.

Table 2. Description of subjects

Baseline Characteristic	Randomized to PHR use N=802	Control N=273	PHR vs control p-value*
Gender			0.4649
Gender: Male	341 (42.5%)	123 (45.1%)	
Gender: Female	461 (57.5%)	150 (54.9%)	
Age	72.5 (6.0)	72.0 (6.3)	0.2662
Non-Hispanic white**	782 (99.0%)	267 (98.2%)	0.2855
Race: White	782	269	
Race: American Indian	1	1	
Race: Asian	0	0	
Race: Black/African-American	4	0	
Race: Native Hawaiian	0	0	
Race: Other Race	3	2	
Race: Unknown	12	1	
Hispanic/Latino ethnicity	1	2	
Highest education completed			0.1862
Highest education completed: Some High School or less	14 (1.8%)	1 (0.4%)	
Highest education completed: High School diploma or GED	183 (23.2%)	77 (28.3%)	
Highest education completed: Technical or trade school/some college	273 (34.6%)	88 (32.4%)	
Highest education completed: Bachelor's degree	181 (23.0%)	55 (20.2%)	
Highest education completed: Master's degree or higher	137 (17.4%)	51 (18.8%)	
Computer use at screening			
Computer use at screening: Days of computer use in past 7 days	6.1 (1.7)	6.0 (1.6)	0.5879
Computer use at screening: Health IT use score	1.9 (1.3)	1.9 (1.4)	0.6796
Computer use at screening: Comfortable with switch from paper to electronic med records	621 (77.4%)	213 (78.0%)	0.8398
Computer use at screening: Use computer at home	785 (97.9%)	269 (98.5%)	0.4997
Disabled	162 (20.2%)	60 (22.0%)	0.5306

* P-values from Chi-square tests for categorical variables and t-tests for continuous variables comparing group of subjects randomized to use PHR with control group.

** In all trial analyses, we operationalized race and ethnicity as non-Hispanic white vs. other racial/ethnic categories.

Table 3. Pre- and post-intervention characteristics of trial participants (N=1075)

Table 3a. Section: health and well-being

Characteristic	Baseline: Randomized to PHR use N=802	Baseline: Control N=273	Baseline: PHR vs control p-value*	Follow-up: Randomized to PHR use N=802	Follow-up: Control N=273	Follow-up: PHR vs control p-value*
Mental Health T-score-SF12	55.5 (7.4)	54.9 (7.9)	0.3334	55.2 (7.5)	54.7 (8.0)	0.4107
Physical Health T-score-SF12	45.9 (10.6)	46.1 (10.3)	0.7427	45.1 (10.8)	45.0 (11.0)	0.9523

Table 3a. Section: medications

Characteristic	Baseline: Randomized to PHR use N=802	Baseline: Control N=273	Baseline: PHR vs control p-value*	Follow-up: Randomized to PHR use N=802	Follow-up: Control N=273	Follow-up: PHR vs control p-value*
Number of prescription drugs	4.1 (3.2)	4.2 (3.2)	0.8444	4.0 (3.1)	4.1 (3.2)	0.6757
Number of over-the-counter drugs	4.1 (2.8)	4.3 (3.1)	0.4084	3.6 (2.5)	3.9 (2.7)	0.0530
Total number of drugs (prescription and OTC)	8.2 (4.6)	8.4 (4.8)	0.5116	7.6 (4.4)	8.1 (4.7)	0.1604
Use of potentially inappropriate medications (ACOVE)	207 (25.8%)	66 (24.2%)	0.5920	164 (20.4%)	53 (19.4%)	0.7129
Taking 2 or more NSAIDS (including aspirin)	155 (19.3%)	63 (23.1%)	0.1832	113 (14.1%)	53 (19.4%)	0.0355*

Table 3b. Section: attitudes about health and health care

Characteristic	Baseline: Randomized to PHR use N=802	Baseline: Control N=273	Baseline: PHR vs control p-value*	Follow-up: Randomized to PHR use N=802	Follow-up: Control N=273	Follow-up: PHR vs control p-value*
Medical Care Preferences Score (4 items)				12.8 (3.2)	13.0 (3.3)	0.4739
Medical Care Global Preferences (1 item)				2.6 (1.1)	2.7 (1.1)	0.2697
Internal Health Locus of Control				24.1 (5.5)	24.2 (4.9)	0.9182
Krantz Behavioral Involvement Scale				29.3 (6.5)	29.8 (6.4)	0.2897

Table 3c. Section: health care/healthcare providers

Characteristic	Baseline: Randomized to PHR use N=802	Baseline: Control N=273	Baseline: PHR vs control p-value*	Follow-up: Randomized to PHR use N=802	Follow-up: Control N=273	Follow-up: PHR vs control p-value*
In past 3 months: Saw primary care provider	549 (69.3%)	186 (68.9%)	0.8950	544 (68.4%)	189 (69.5%)	0.7454
In past 3 months: Saw specialist doctor	416 (52.8%)	140 (52.2%)	0.8755	412 (51.8%)	151 (55.5%)	0.2926
In past 3 months: Treated in ER	86 (10.8%)	21 (7.9%)	0.1621	68 (8.5%)	20 (7.3%)	0.5347
Number of doctor visits 3 Months	2.5 (3.2)	2.3 (2.8)	0.3462	2.1 (2.5)	2.3 (2.3)	0.3196
Any change in Med Use -3 months:	286 (35.7%)	94 (34.4%)	0.7138	349 (43.5%)	124 (45.4%)	0.5839
Any change in Med Use -3 months: Start Rx med	155 (19.3%)	48 (17.6%)	0.5248	190 (23.7%)	56 (20.5%)	0.2803
Any change in Med Use -3 months: Stopped Rx med	93 (11.6%)	30 (11.0%)	0.7855	123 (15.3%)	39 (14.3%)	0.6750
Any change in Med Use -3 months: Change strength/dose of Rx med	80 (10.0%)	41 (15.0%)	0.0228*	110 (13.7%)	38 (13.9%)	0.9328
Any change in Med Use -3 months: Start OTC med	49 (6.1%)	16 (5.9%)	0.8815	71 (8.9%)	36 (13.2%)	0.0388*
Any change in Med Use -3 months: Stopped OTC med	12 (1.5%)	9 (3.3%)	0.0634	37 (4.6%)	12 (4.4%)	0.8815
Any change in Med Use -3 months: Change strength/dose of non-Rx med	18 (2.2%)	6 (2.2%)	0.9641	19 (2.4%)	12 (4.4%)	0.0840

Table 3d. Section: medication reconciliation

Characteristic	Baseline: Randomized to PHR use N=802	Baseline: Control N=273	Baseline: PHR vs control p-value*	Follow-up: Randomized to PHR use N=802	Follow-up: Control N=273	Follow-up: PHR vs control p-value*
Keep list of current medications:	508 (63.9%)	175 (64.6%)	0.8412	559 (70.6%)	196 (72.1%)	0.6432
Keep list of current medications: Reason for medications on list	133 (26.5%)	33 (19.8%)	0.0788	210 (37.8%)	59 (30.4%)	0.0635
Keep list of current medications: Usually shows medication list to doctor	404 (80.8%)	131 (78.4%)	0.5080	435 (78.2%)	154 (78.6%)	0.9223
Keep list of current medications: Put non-Rx drugs on med list	391 (77.7%)	128 (75.7%)	0.5928	435 (78.1%)	155 (79.1%)	0.7734
Keep list of current medications: Updated med list in past 3 months	264 (53.1%)	81 (48.5%)	0.3017	293 (52.9%)	105 (54.4%)	0.7162
At last doc visit: Provider asked whether keep med list	313 (40.1%)	89 (34.4%)	0.1017	342 (44.7%)	112 (42.6%)	0.5503
At last doc visit: Had med list	453 (59.3%)	152 (59.4%)	0.9816	504 (66.4%)	173 (66.3%)	0.9718
At last doc visit: Had med list—Showed med list	333 (74.3%)	111 (73.5%)	0.8422	378 (75.4%)	127 (73.8%)	0.6734
At last doc visit: Someone asked about med strength at last doc visit			0.6899			0.6687
At last doc visit: Someone asked about med strength at last doc visit—Yes, for all meds	251 (32.3%)	91 (35.0%)		301 (39.6%)	112 (42.4%)	
At last doc visit: Someone asked about med strength at last doc visit—Yes, for some meds	75 (9.7%)	26 (10.0%)		110 (14.5%)	34 (12.9%)	
At last doc visit: Doctor compared records with what patient said they were taking	514 (66.7%)	180 (70.0%)	0.3175	523 (69.0%)	176 (66.9%)	0.5322
At last doc visit: Doctor compared records with what patient said they were taking—Differences between doctor and patient medication records	63 (8.2%)	21 (8.1%)	0.9445	77 (10.1%)	21 (8.0%)	0.3003

Table 3e. Section: managing medications

Characteristic	Baseline: Randomized to PHR use N=802	Baseline: Control N=273	Baseline: PHR vs control p-value*	Follow-up: Randomized to PHR use N=802	Follow-up: Control N=273	Follow-up: PHR vs control p-value*
Number of medication management problems	1.4 (1.4)	1.5 (1.5)	0.1823	1.4 (1.4)	1.6 (1.5)	0.1514
Knows how to recognize side effects				566 (73.7%)	201 (75.3%)	0.6110
Medication side effects in past 3 months	86 (11.0%)	22 (8.2%)	0.1944	100 (12.9%)	33 (12.2%)	0.7883
Morisky adherence scale	14.2 (1.8)	14.1 (1.9)	0.4762	13.8 (1.9)	13.9 (1.9)	0.9821

* P-values from Chi-square tests for categorical variables and t-tests for continuous variables comparing group of subjects randomized to use PHR with control group.

**In all trial analyses, we operationalized race and ethnicity as non-Hispanic white vs. other racial/ethnic categories.

Iowa PHR Trial Results: Sub-Analyses of Intervention Group— I. Description of System Engagement

By the end of the study period, 311 people (38.8%) had never attempted to log on to the system. Of the 491 (61.2%) who attempted, only 28 (5.7%) did not complete the login process, and 20 (4.1%) completed login but performed no activity with the PHR. The remainder (443; 55.2% of 802 intervention group subjects) performed some type of activity with the PHR; 341 of these (77% of those using the system, 42.5% of intervention group subjects) entered health information. More than 40% of all intervention group participants entered at least one medication, and the system displayed at least one medication warning message for nearly one-third (Table 4). The most frequent Iowa PHR-generated medication warnings were for nonsteroidal anti-inflammatory drugs (NSAIDs) (23%), angiotensin converting enzyme (ACE) inhibitors (11%), and acetaminophen (6%).

Table 4. Description of Iowa PHR system engagement

Action	N	Percent of PHR participants to whom action applied (N=802)	Percent of PHR users who entered ≥1 medication (N=331)
Login	491	61.2%	
Visited at least one feature past login process	443	55.2%	
Viewed tutorial video	374	46.6%	
Edited allergy	159	19.8%	
Entered health condition	170	21.2%	
Entered tracking information	113	14.1%	
Entered demographic or emergency contact information	274	34.2%	
Printed report: Current medication or wallet card	284	35.4%	
Printed report: Medication warnings	26	3.2%	
Printed report: Other report	71	8.9%	
Entered medication	331	41.3%	100.0%
Any warning generated	255	31.8%	77.0%
Specific warning generated: NSAIDs	186	23.2%	56.2%
Specific warning generated: ACE Inhibitors	91	11.3%	27.5%
Specific warning generated: Acetaminophen	50	6.2%	15.1%
Specific warning generated: Anticholinergics	39	4.9%	11.8%
Specific warning generated: Warfarin	19	2.4%	5.7%
Specific warning generated: Loop diuretics	22	2.7%	6.6%
Specific warning generated: Benzodiazepines	16	2.0%	4.8%
Specific warning generated: Iron	10	1.2%	3.0%
Specific warning generated: Skeletal muscle relaxants	6	0.7%	1.8%
Specific warning generated: Barbiturates	1	0.1%	0.3%
Specific warning generated: Ketorolac	1	0.1%	0.3%

Measures of PHR use frequency did not differ by gender or age group. Neither frequency of medication or health information entries, medication warning messages nor user warning clicks varied by gender. Significant age group differences were observed for entry of any health information; with increasing age, frequency of entering medication information, any health information, medication warnings, and warning clicks decreased (Table 5).

We classified 129 people (29.1% of those using the system, 16.1% of intervention group subjects) as “high users” because they logged in multiple times and had multiple interactions in

which they manipulated health information. In sub-analyses in the intervention group comparing high users vs low/non-users, high users were more likely than low/non-users to be men (51.2% vs 40.9%, p=0.03), were younger (mean age 71.5 vs 72.7, p=0.025), and were heavier computer users (6.5 days per week vs 6 days per week, p=0.0002). There were no significant differences between high and low/non-users in education, marital status, or whether living alone (p's > 0.27).

Table 5. Usage characteristics by age group

Action	65-69 N=311	70-74 N=227	75-79 N=153	80+ N=111	p_value*
Login	194 (62.4%)	132 (58.1%)	103 (67.3%)	62 (55.9%)	0.1854
Among participants with login: More than one login	104 (53.6%)	61 (46.2%)	54 (52.4%)	34 (54.8%)	0.5449
Among participants with login: Mean days between logins, among return users	26.9 (18.7)	21.1 (13.9)	23.0 (14.0)	25.1 (16.0)	0.1471
Among participants with login: Entered medication	147 (75.8%)	87 (65.9%)	63 (61.2%)	34 (54.8%)	0.0056*
Among participants with login: Entered any health information	151 (77.8%)	89 (67.4%)	64 (62.1%)	37 (59.7%)	0.0071*
Among participants with login: Any warning generated	117 (60.3%)	62 (47.0%)	52 (50.5%)	24 (38.7%)	0.0108*
Clicked on any medication warning for expanded view	48 (24.7%)	24 (18.2%)	24 (23.3%)	5 (8.1%)	0.0302*

* Group comparisons test- p-value from Chi-square test for categorical variables and from ANOVA for continuous variables.

Iowa PHR Trial Results: Sub-Analyses of Intervention Group— II. Associations of PHR Use with Change in Medication Management Behaviors and Quality

There were numerous differences in baseline health and medication use characteristics between high users and low/non-users (Table 6). High users reported significantly more prescription and nonprescription medications at baseline and significantly more medications associated with PHR medication warning messages. They were significantly more likely to be keeping a medication list and showing it to their doctor. They reported significantly more medication management problems.

High use of the PHR was associated with numerous changes in medication use and management at followup (Table 6). All comparisons between high users and low/non-users at followup adjusted for baseline differences in the characteristic (if baseline was available) as well as for total number of baseline medications (Table 6, column 6).

Table 6. Comparison of high vs. low/non-user intervention subgroups on pre-intervention (baseline) and post-intervention (followup) characteristics (N=802)

Table 6a. Section: health and well-being

Characteristic	Baseline: High Users N=129	Baseline: Low/ Non-Users N=683	Follow up: High Users N=129	Follow up: Low/ Non-Users N=683	Follow up: Adjusted† mean difference (SE) or OR (95% CI) for High vs Low/ Non-Users
Mental Health T-score-SF12	55.3 (7.1)	55.5 (7.4)	54.9 (7.7)	55.2 (7.5)	0.04 (0.59)
Physical Health T-score-SF12	46.0 (10.0)	45.8 (10.7)	45.8 (10.5)	44.9 (10.9)	0.80 (0.62)

Table 6b. Section: medications

Characteristic	Baseline: High Users N=129	Baseline: Low/ Non-Users N=683	Follow up: High Users N=129	Follow up: Low/ Non-Users N=683	Follow up: Adjusted† mean difference (SE) or OR (95% CI) for High vs Low/ Non-Users
Number of prescription drugs	4.7 (3.0)*	4.0 (3.2)	4.6 ((3.1)*	3.9 ((3.1)	0.04 ((0.15)
Number of over-the-counter drugs	4.7 (2.9)*	4.0 (2.8)	4.3 (2.9)**	3.4 (2.4)	0.48 (0.17)**
Total number of drugs (prescription and OTC)	9.3 (4.6)**	8.0 (4.6)	8.9 (4.7)***	7.4 (4.3)	0.48 (0.24)*
Use of potentially inappropriate medications (ACOVE)	43 (33.3%)*	164 (24.4%)	35 (27.1%)*	129 (19.2%)	1.24 (0.69 , 2.24)
Taking 2 or more NSAIDs (including aspirin)	30 (23.3%)	125 (18.6%)	25 (19.4%)	88 (13.1%)	1.52 (0.85 , 2.71)

Table 6c. Section: attitudes about your health and healthcare

Characteristic	Baseline: High Users N=129	Baseline: Low/ Non-Users N=683	Follow up: High Users N=129	Follow up: Low/ Non-Users N=683	Follow up: Adjusted† mean difference (SE) or OR (95% CI) for High vs Low/ Non-Users
Medical Care Preferences Score (4 items)‡			13.2 (3.3)	12.8 (3.2)	0.54 (0.31)
Medical Care Global Preferences (1 item)‡			2.7 (1.1)	2.6 (1.1)	0.11 (0.11)
Internal Health Locus of Control‡			24.5 (4.9)	24.1 (5.6)	0.71 (0.53)
Krantz Behavioral Involvement Scale‡			29.7 (6.7)	29.3 (6.4)	0.67 (0.63)

Table 6d. Section: healthcare/healthcare providers

Characteristic	Baseline: High Users N=129	Baseline: Low/ Non-Users N=683	Follow up: High Users N=129	Follow up: Low/ Non-Users N=683	Follow up: Adjusted† mean difference (SE) or OR (95% CI) for High vs Low/ Non-Users
In past 3 months: Saw primary care provider	95 (73.6%)	454 (68.5%)	90 (69.8%)	454 (68.2%)	0.88 (0.57 , 1.36)
In past 3 months: Saw specialist doctor	75 (58.6%)	341 (51.7%)	74 (57.4%)	338 (50.8%)	1.07 (0.70 , 1.62)
In past 3 months: Treated in ER	11 (8.5%)	75 (11.3%)	15 (11.7%)	53 (7.9%)	1.40 (0.75 , 2.60)
Number of doctor visits 3 Months	2.4 (2.1)	2.5 (3.4)	2.3 (2.6)	2.1 (2.5)	0.10 (0.23)
Any change in Med Use -3 months:	48 (37.2%)	238 (35.4%)	72 (55.8%)**	277 (41.2%)	1.62 (1.09 , 2.40)*
Any change in Med Use -3 months: Start Rx med	27 (20.9%)	128 (19.0%)	45 (34.9%)**	145 (21.5%)	1.79 (1.18 , 2.72)**

Table 6d. Section: healthcare/healthcare providers (continued)

Characteristic	Baseline: High Users N=129	Baseline: Low/ Non-Users N=683	Follow up: High Users N=129	Follow up: Low/ Non-Users N=683	Follow up: Adjusted† mean difference (SE) or OR (95% CI) for High vs Low/ Non-Users
Any change in Med Use -3 months: Stopped Rx med	17 (13.2%)	76 (11.3%)	35 (27.1%)****	88 (13.1%)	2.23 (1.40 , 3.56)***
Any change in Med Use -3 months: Change strength/dose of Rx med	13 (10.1%)	67 (10.0%)	21 (16.3%)	89 (13.2%)	1.13 (0.66 , 1.93)
Any change in Med Use -3 months: Start OTC med	9 (7.0%)	40 (5.9%)	17 (13.2%)	54 (8.0%)	1.62 (0.90 , 2.91)
Any change in Med Use -3 months: Stopped OTC med	3 (2.3%)	9 (1.3%)	10 (7.8%)	27 (4.0%)	1.81 (0.84 , 3.87)
Any change in Med Use -3 months: Change strength/dose of non-Rx med	4 (3.1%)	14 (2.1%)	7 (5.4%)*	12 (1.8%)	2.96 (1.13 , 7.75)*

Table 6e. Section: medication reconciliation

Characteristic	Baseline: High Users N=129	Baseline: Low/ Non-Users N=683	Follow up: High Users N=129	Follow up: Low/ Non-Users N=683	Follow up: Adjusted† mean difference (SE) or OR (95% CI) for High vs Low/ Non-Users
Keep list of current medications:	98 (76.0%)**	410 (61.6%)	113 (88.3%)****	446 (67.2%)	3.68 (1.83 , 7.37)***
Keep list of current medications: Reason for medications on list	28 (28.6%)	105 (26.1%)	57 (50.4%)**	153 (34.6%)	2.14 (1.26 , 3.64)**
Keep list of current medications: Usually shows med list to doctor	71 (72.4%)*	333 (82.8%)	87 (77.0%)	348 (78.6%)	1.20 (0.62 , 2.34)
Keep list of current medications: Put non-Rx drugs on med list	77 (78.6%)	314 (77.5%)	89 (78.8%)	346 (77.9%)	1.09 (0.58 , 2.05)
Keep list of current medications: Updated med list in past 3 months	59 (60.8%)	205 (51.3%)	62 (55.4%)	231 (52.3%)	1.15 (0.70 , 1.89)
At last doc visit: Had med list	83 (65.4%)	370 (58.1%)	100 (80.0%)***	404 (63.7%)	2.48 (1.36 , 4.54)**
At last doc visit: Had med list—Showed med list	61 (74.4%)	272 (74.3%)	75 (75.0%)	303 (75.6%)	0.90 (0.47 , 1.71)
At last doc visit: Someone asked about med strength at last doc visit (Yes for all/some vs No)			*		1.61 (1.05, 2.45)*
At last doc visit: Someone asked about med strength at last doc visit (Yes for all/some vs No)—Yes, for all meds	51 (40.2%)	200 (30.8%)	58 (46.4%)	243 (38.3%)	
At last doc visit: Someone asked about med strength at last doc visit (Yes for all/some vs No)—Yes, for some meds	13 (10.2%)	62 (9.6%)	24 (19.2%)	86 (13.5%)	
At last doc visit: Doc compared records with what patient said they were taking	89 (70.1%)	425 (66.0%)	95 (76.0%)	428 (67.6%)	1.50 (0.93 , 2.42)
At last doc visit: Doc compared records with what patient said they were taking—Differences between doc and patient med records	15 (11.8%)	48 (7.5%)	24 (19.0%)***	53 (8.4%)	2.21 (1.27 , 3.85)**

Table 6f. Section: managing medications

Characteristic	Baseline: High Users N=129	Baseline: Low/ Non-Users N=683	Follow up: High Users N=129	Follow up: Low/ Non-Users N=683	Follow up: Adjusted† mean difference (SE) or OR (95% CI) for High vs Low/Non-Users
Number of med management problems	1.6 (1.6)*	1.3 (1.3)	1.8 (1.5)***	1.4 (1.4)	0.15 (0.09)
Knows how to recognize side effects‡			104 (81.9%)*	462 (72.1%)	1.76 (1.08 , 2.86)*
Totally confident asking questions about medications (score=10)‡			110 (85.3%)	548 (81.4%)	1.34 (0.79 , 2.27)
Totally confident talking to a doctor about possible side effects (score=10)‡			109 (84.5%)	548 (81.4%)	1.23 (0.73 , 2.06)
Med side effects in past 3 months	17 (13.4%)	69 (10.6%)	29 (22.8%)***	71 (10.9%)	2.24 (1.35 , 3.70)**
Morisky adherence scale	14.2 (1.5)	14.2 (1.8)	14.0 (1.6)	13.8 (2.0)	0.22 (0.16)

Significantly different from Low/Non-users at * p<0.05 ** p<0.01 *** p<0.001 **** p<0.0001

P-values from Chi-square tests for categorical variables and t-tests for continuous variables comparing group of subjects with high PHR use with low users/non-users within data collection point (baseline or followup).

† Linear regression models were used for continuous characteristics and logistic regression models for categorical characteristics (PROC GENMOD procedure was used for both models), models included corresponding characteristic and total number of drugs at baseline.

‡ Assessed post-intervention only (no baseline); comparisons between high users and low/non-users are adjusted for total number of drugs at baseline.

Medication Taking. After adjusting for baseline differences, at followup high users reported significantly higher over-the-counter medication use compared with low/non-users. They were also significantly more likely to report a change in medication use, in particular to have started a new prescription medication, to have stopped a prescription medication, and to have changed the strength or dose of an over-the-counter medication. Self-reported adherence to medications did not differ between high and low/non-users, either at baseline or followup.

Medication Lists and Medication Reconciliation. The percent reporting they keep a current medication list was significantly higher among high users compared with low/non-users, adjusted for baseline values. They were also significantly more likely to report including the reasons for taking each medication on their list. When reporting about medication discussions during their last doctor's visit, high users were significantly more likely to report they had their medication list with them, that someone asked them about the strength of their medications and that differences were detected between their list and the doctor's records.

Medication Management Problems and Quality. High users were significantly more likely to report having a side effect in the past 3 months compared with low/non-users, but they also were more likely to report that they know how to recognize side effects. The crude difference between high and low/non-users in number of medication management problems at followup was explained by adjusting for pre-existing differences in medication problems and number of medications. Similarly, the crude difference between high and low/non-users in medication quality indicators (number of potentially inappropriate medications and number using multiple NSAIDS) at followup was explained by adjusting for pre-existing differences in these measures. No significant differences in medication self-efficacy were observed.

Interaction Term Modeling. Interaction terms were examined for characteristics that showed statistically significant or marginally significant associations ($p<0.1$) with both assessment time (referent: baseline) and study groups (referent: high users). We found a significant overall group X assessment interaction effect as a predictor of keeping a medication list ($p=0.0029$) and for medication side effects ($p=0.0436$). In both cases, differences between high users and other users increased from baseline to followup.

Health Status. Physical health declined from baseline to followup in all user groups ($p=0.001$). High users and low/non-users did not differ in either physical or mental health. Similarly, there were no differences observed in healthcare utilization.

Discussion and Conclusions

As a result of extensive focus group, participatory design, and usability testing we learned that older adults are interested in keeping track of their health and medication information and are able to do so when a system is designed with their needs in mind. Working intensively with a small group of older adults provided valuable insights on the design of a PHR targeted to them that would have been very difficult to obtain otherwise. We have developed a Web-based PHR system based on the lessons learned in these sessions. Our PHR follows a minimalist approach, tracking as little information as possible while enabling meaningful use in order to increase adoption. Our medication warnings emphasize specific recommended actions that patients can take. In a randomized controlled trial of this PHR among older adults, a majority (55.2%) logged in and used it.

In intention-to-treat comparisons of 802 participants randomized to PHR access vs 273 usual care controls, PHR access alone had minimal effect on medication behaviors and quality: there was improvement in one quality measure (using multiple NSAIDs). However, only a minority (29.1% of users, 16.1% of intervention group subjects) used the PHR more than once. In sub-analyses of the PHR intervention group, many self-reported medication management behaviors improved for patients who engaged with the system by using it two or more times, compared with those who never used it or visited only once. Improvements included keeping a medication list, including reasons for each medication on the list, having their list with them at a doctor visit, having providers query them more extensively about their medications (i.e. their strength), and reporting that differences were detected between their record and their doctor's record. These improvements among high users did not translate into improvements in medication use quality as measured by the number of potentially inappropriate medications or taking multiple NSAIDs. Self-reported adherence was also no different between high users and low/non-users. Increments in medication behaviors may have been too small and duration of followup too short to observe an impact on these outcome variables. Alternatively, it may be that these improvements in behaviors require further delivery system, provider education, and health information technology supports to translate them into effective changes in medication use quality.

Older adults who engaged with the PHR system tended to have indicators of higher computer self-efficacy and greater health needs: more engaged users were younger, male, used computers more frequently, took more medications, had more medication problems, and were already more likely to be keeping a medication list prior to the study. These findings are consistent with theories of self-management behaviors and trials of interventions to encourage them, which

consistently find that perceived need and perceived self-efficacy are facilitators for behavior adoption.

There was a doubling in self-reported adverse drug effects from baseline to followup for the high users but no change for low/non-users. Upon first consideration, this is counterintuitive. However, because medication safety warnings were triggered for 77% of users who entered medications in the PHR, the likely explanation is that the study intervention increased participant awareness about side effects. Consistent with this interpretation was that they also were significantly more likely to report they knew how to recognize side effects. Recognition of an adverse effect is a necessary first step toward resolving it. PHRs should develop features that encourage and support interaction with healthcare providers about resolving medication side effects.

Although the sampling frame for the trial was population-based, study participants were likely to be more motivated than average, limiting the sample representativeness. For example, participants in both study groups had a high rate of keeping a medication list at baseline. A less health and computer-literate population may have more room for improvement, which could translate into larger effect sizes. In contrast, lower self-efficacy could be a greater barrier to achieving improvements in such populations. In order to participate in the trial, older adults had to first respond to a brief mailed screening questionnaire about computer use (response rate 23.5%), indicate eligibility by using computers in the past month (67.5% of screening questionnaire respondents), and complete a baseline mailed questionnaire (48.9% response rate among eligibles).

Another potential limitation is that the PHR did not have interoperability with medical record or insurance systems. This reflects the reality of health information systems in a rural state at present, but likely underestimates the features and opportunities available elsewhere and in the future for rural communities. Finally, the findings of the sub analyses of the PHR intervention group were exploratory. It is possible that the observed differences over time between high users and low/non-users were due to some unmeasured characteristics predictive of changing medication management motivation over time rather than to use of the PHR.

We found increasing age to be associated with less engagement with the study PHR. In part this may result from the cognitive, physical, perceptual, visual and motor, changes older adults experience. However, we took great care to reduce interface barriers in designing the PHRs suggesting that some of these differences may represent a generational difference in computer experience among subgroups of elders: the younger-old (age 65-69) were mid-career age when computers emerged in the workplace. However, in the next decades, an increasingly smaller proportion of older adults will report inexperience with personal computer interfaces and health IT. If true, these differences may be mitigated in the coming decades with increasing workplace and personal computer experience.

The minimal PHR effects in the main intention-to-treat trial analyses suggest that implementation of the PHR elements in the next stages of meaningful use criteria in 2013 and 2015 is unlikely to result in substantial improvement in medication use behaviors or outcomes at the population level. Whether lack of an overall effect was due to low frequency of use or limited effect when used remains an important question. Our analyses of more frequent users suggest that PHRs can engage older adults to try to avoid medication misuse. However, whether those who choose not to use a PHR would also have benefited remains unanswered. Assuming that such individuals could attain benefits from a PHR if they used one, system design features that reinforce repeated interaction with the system are needed. These may include customizing PHRs

to the specific needs of users, providing them with fresh, relevant content, as well as community interaction features, and more options for entering and viewing information, including the use of mobile devices.

The purpose of this Funding Opportunity Announcement (FOA), "Ambulatory Safety and Quality: Enabling Patient-Centered Care through Health IT," was to investigate novel methods or evaluate existing strategies for using health IT to create or enhance patient-centered models of care in the ambulatory setting. We were able to demonstrate in a priority population (rural elders) how a Web-based PHR can engage patients in medication management and potentially stimulate more complete medication reconciliation discussions with providers and increase patient awareness of medication safety issues. These results support the long-term goal of the FOA which is "to improve the delivery of patient-centered care in ambulatory settings, with a particular focus on transitions of care, personal health records, and improved patient-clinician communication and decision making."

Future Exploratory Analyses

In the coming months we intend to conduct other exploratory analyses of the study data. Examples of questions we are interested in investigating include:

- What experiences do users of the study PHR report? What barriers to use did they experience? What aspects of the PHR were most/least useful?

- Is use of the study PHR for medication therapy management tasks (e.g., to create a medication list) associated with specific medication use outcomes (e.g., discussing medications with physicians, etc.)?

- Is use of the study PHR associated with accuracy of respondent knowledge of medication purpose/reason?

- How do patient-reported survey and PHR-entered medication records compare in terms of completeness? Which factors predict PHR-entered medication record completeness? Is medication record completeness related to other outcomes (e.g., medication changes, detection of adverse events, NSAID taking)? The answers could help refine our understanding of how PHRs affects patient behaviors: general "activation" vs. specific knowledge gained and applied.

- Does receipt of specific Iowa PHR-generated warnings for specific medications predict changes in the cited medication?

- What is the relationship between PHR use and health locus of control?

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