Integrating Health Information Technology to Develop a Patient-Centered Approach to Medication Management

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EXECUTIVE SUMMARY

Among patients with chronic illness, approximately 50% do not take their medications as prescribed. Non-adherence to medications costs the United States more than $100 billion annually in avoidable hospitalizations. Yet patients with multiple chronic conditions who are highly adherent to their medications have lower disease-specific and all-cause medical costs, as well as lower hospitalization rates. Unfortunately, non-adherence to medication regimens is complex with multiple contributing factors, including patient, provider, and systems concerns. Medication adherence applications ("apps") available on smart phones offer potential to engage patients in their own healthcare by providing a tool that addresses patient-related factors that contribute to non-adherence. Specifically, these apps allow patients to develop and maintain a personalized, updated medication list that they can share with their healthcare providers. Patients can use these tools to ask their providers questions about their medication regimens, while simultaneously receiving automated dosing reminders, which offers promise for improving adherence. Unfortunately, none of the commercially available apps are clinically tested, so their impact on improving adherence to medication regimens remains unclear. Furthermore, these apps require manual entry of drug and dosing information, which is both time consuming and prone to errors.

We developed a medication management system – PresRx OCR, an iPhone app – that addresses key barriers to improving medication adherence. Together with a Michigan-based small business, we designed, tested, and validated a mobile app that auto-populates drug name and dosing instructions directly from patients’ medication labels. Specifically, patients used their iPhones to take pictures of their medication labels within the app. Next, the app uploads images to a remote database server that uses optical character recognition (OCR) technology to automate data entry for drug name and dosing information. Using a client-server model, the app then receives drug and dosing information back from the server, which schedules dosing alerts in patients’ phones according to their dosing time preferences. Ultimately, patients used the app to maintain updated medication lists and respond to dosing alerts. The app also prompted patients to take surveys to assess their satisfaction with the user interface.
Researchers had access to the secure server, which tracked responses to dosing reminders and survey responses. Researchers used the real-time data maintained in the server to assess patients’ adherence to drug regimens (pre-test, post-test; i.e. pre-app, during-app), satisfaction with the application, and elicit feedback through review of survey responses.

Optical character recognition automated data entry for key elements of medication labels, including drug name, dosing instructions, and National Drug Code (NDC) numbers. Accuracy of auto-populated information exceeded 95% for drug name and dosing frequency. Overall, eight patients piloted the system for an average of six months. At baseline, patients used an average of 3.4 chronic prescription medications. Their pre-test adherence scores were moderate to high. Patients liked the app’s design, rating the system nearly 70% on usability scales, indicating that the app was marginally acceptable for consumer use. Additional feedback included issues with sync speed and system logouts, both of which occurred due to interrupted internet connectivity (iPhones navigating between various internet connection options). We addressed these issues in an app upgrade that was available mid-way during the pilot study. Three patients had the upgrade installed on their iPhones and reported improved sync speed and retained login information.

Post-test adherence – as measured by the app’s dose tracking system – was high during the first month of app use (>90%), but waned mid-way during the 6-month pilot study. Adherence improved during the fifth and sixth months, possibly related to re-engagement by installing the app upgrade and because patients with poor adherence dropped out. Among drug classes, patients were more adherent to cardiovascular and psychiatric medications than oral hypoglycemic or respiratory drugs. Compared with pre-test measures of adherence, post-test adherence rates were marginally lower. This trend may reflect limitations of adherence measures, or that patients who used the app became more aware of their non-adherence and responded more honestly in post-test surveys.

Overall, our pilot study demonstrated the feasibility of using a mobile health (mHealth) application to address unintentional non-adherence (due to forgetfulness). Ultimately, we need to conduct larger studies among patients at risk for non-adherence in order to see the impact on adherence. The key strengths of our system include: patient-centered design, incorporating
patient feedback into system updates, real-time adherence tracking, integration with a remote database server, and survey deployment. Many of the limitations we identified are important areas for further research, especially because they will affect interoperability of patient-centered (mHealth apps) and provider-centered (Electronic Health Records) systems. Specifically, our major limitations were due to interruptions in internet connectivity: slow synchronization speed and random system logouts. Once we resolved these issues, we uncovered another limitation: failed partial synchronization, a problem that caused patients’ medications to “fall off” their lists at random. While we have since resolved this issue, it is worth exploring on a larger scale, particularly as Electronic Health Records (EHRs) improve their patient portals. As patient portals advance beyond “read only” health data, we anticipate more patient-centered features, including interactive medication dosing reminders. Such features demand a reliable solution to “real-time” data synchronization.

We believe our system uncovered a major [ongoing] barrier to effective health information exchange (HIE): sub-optimal data synchronization. Ultimately, the vision of effective HIE is to allow patients and healthcare providers to electronically access medical information maintained by multiple organizations securely and efficiency. Our pilot study highlighted barriers to data synchronization using a client-server model for smartphone applications. Yet despite our system’s limitations, our patients valued its impact on their medication taking behavior. Furthermore, our system was cost-effective – $15 per patient per month, approximately the same cost as a generic monthly medication. Such cost may be reasonable for stakeholders to invest, particularly if it leads to improved adherence, lower 30-day hospital readmission rates, and patient-centered outcomes.

Moving forward, we see opportunities for Sparrow Health Systems and Michigan State University to influence the development and evaluation of evidence-based mHealth tools. Presently, medication management applications are “stand-alone” systems that do not integrate with clinician-centered EHRs. While patient-centered, these systems must eventually integrate with EHRs in order to engage patients and clinicians in making optimal treatment plans. We believe this goal is the intent of many patient portals – for patients to interact with clinicians regarding their care. Yet presently most patient portals are “read only” and do not
optimally engage patients in their own care. Through discussions with Epic, a commercial EHR vendor, we believe they are actively developing enhancements to their mobile patient portal, which would replicate the dosing alert system we assessed in the current study. In the future, we hope to test interactive extensions of EHR patient portals (e.g. MySparrow) in order to clarify the clinical effectiveness of mHealth medication adherence tools. These next steps are critical to advancing the Center for Innovation and Research, and put Sparrow Health Systems and Michigan State University at the forefront of Health IT and interoperability research.

ACKNOWLEDGEMENTS

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BACKGROUND

Medication Cost and Medication Management

Fifty percent of patients with chronic illnesses do not take their medications as prescribed.\textsuperscript{1,2,3} In the United States, the annual cost of non-adherence to medications is $100 billion, while overall drug related problems – including non-adherence – costs nearly $290 billion annually.\textsuperscript{4,5} Non-adherence is associated with poor patient outcomes, including increased risk of morbidity and mortality.\textsuperscript{6} Conversely, patients with chronic diseases who are highly adherent to their medications have lower disease-specific and all-cause medical costs, as well as lower hospitalization rates.\textsuperscript{7}

Safe medication management – assessing patients’ medications for appropriateness, safety, and optimal use – is essential to high quality patient care.\textsuperscript{8} Yet evidence from national sources document need for improved processes that focus on patient-centered, integrated medication management systems.\textsuperscript{9,10} Furthermore, the Joint Commission requires that all health systems "accurately and completely reconcile medications across the continuum of care," which is a current National Patient Safety Goal.\textsuperscript{11} These tasks are complex and error prone processes, particularly for patients taking multiple medications, as evidenced by the frequency of reconciliation errors during care transitions.\textsuperscript{12,13} Worse, inaccurate medication lists are often perpetuated in electronic health records (EHRs), which puts vulnerable patients at risk for adverse drug events.\textsuperscript{14,15} Presently, there is no coordinated system to track medication changes among different systems of care or among multiple providers. Furthermore, patients with complex and changing medication regimens have few evidence-based tools to assist them in managing their own medication lists.

The International Society for Pharmacoeconomics and Outcome Research (ISPOR) defines optimal adherence as, “the degree or extent of conformity to the recommendations about day-to-day treatment by the provider with respect to the timing, dosage, and frequency.”\textsuperscript{16} Mobile technology is an emerging method for improving patients’ adherence to prescription drug regimens. A 2012 Cochrane Review found strong evidence that weekly text-messaging systems can improve adherence to highly-active antiretroviral treatment (HAART) in patients infected with HIV.\textsuperscript{17} Among low-income patients with poorly controlled diabetes, a text
message–based mobile health intervention (TExT-MED) improved medication adherence. Fewer studies have assessed the impact of smartphone applications for improving medication management. In one Spanish study, elderly patients without previous smartphone experience easily used a medication management application, which improved adherence rates and increased perceived independence in medication management.

The use of prescription reminder applications (“apps”) holds promise for empowering patients to maintain updated medication lists. However, entering medication information manually is both cumbersome and prone to inaccuracies. Furthermore, none of the commercially available apps have been clinically tested, so their effect on adherence remains uncertain. Despite these barriers, even older adults are interested in using mHealth apps to augment medication management, particularly if they are involved in the development of the user interface.

Unfortunately, medication labels (including barcodes) affixed to medications dispensed by pharmacies are not regulated by the Food and Drug Administration (FDA), leading to variations in label appearance for identical medications across the 50 states and across dispensing pharmacies. Furthermore, there is no mandate to standardize medication label information. Therefore, there is no efficient and accurate way to automate the process of imputing drug and dosing information into patients’ medication management apps.

**Medication Management through a Smartphone**

We developed a novel approach to medication management by integrating smartphone camera features with existing health information technology in order to automate drug information imputation and assess adherence to chronic medications. Specifically, our medication management system – PresRx OCR – uses optical character recognition (OCR) to “read” pictures of medication labels and transpose the relevant information into the app, obviating the need for manual data entry by the patient. We incorporated a similar process for imputing over the counter (OTC) drug information by scanning universal product (UPC) barcodes. This approach is innovative in its simplicity – using existing technologies (OCR and medication reminder apps) as a means to simplify data entry, while simultaneously
empowering patients to manage their own medication lists and improve adherence by way of app-generated dosing reminders.

To test feasibility and usability of our system, we: 1) assessed the accuracy of data entry via OCR; 2) tested patients’ acceptability of the software; 3) determined patient adherence to chronic medications; and 4) calculated the fixed and variable costs of the system.

Our application – PresRx OCR – is a tool that patients keep with them (via their smartphone) and update in real-time. Furthermore, patients’ medication lists are maintained remotely in a HIPAA-secure remote server database. This feature is essential because it allows for future health information exchange (HIE). For example, in the future patients could share their medication lists with clinicians (“patient-reported medication lists”) electronically using Health Language Seven [HL-7] interfaces, a language used to promote healthcare informatics interoperability. This is a first step towards developing a patient-centered community health record bank (HRB) and is important for shaping the trajectory of HIE.25
METHODS

Design
We conducted a two-phase feasibility and acceptability study of our app, PresRx OCR. Our overarching goal was to develop and test a patient-centered medication management application for iPhone users (Figure 1).

**Phase 1. Software Development and Initial Testing.** Electronic Medical Office Logistics (EMOL Health) developed software by merging two existing technologies: 1) a medication scheduling system (PresRx); and 2) optical character recognition (OCR) software. We used OCR of medication labels to automate data entry into key fields in the medication management application: medication name, dose, route, frequency, and National Drug Code [NDC].

![Figure 1. Schematic of PresRx OCR features, including information exchange between remote, secure database server.](image-url)
We utilized a remote, secure database server to transmit medication data back-and-forth between patients’ phones, as opposed to maintaining information exclusively within patients’ phones (Figure 1). This afforded each patient a backup system in case of lost or damaged phone or software.

Researchers worked with software programmers to generate a list of design requirements:

1. Simple design – intuitive layout, including five sections: 1) daily calendar for responding to dosing alerts (patient-centered list arranged by time of day: morning, afternoon, evening, and bedtime); 2) condensed medication list (clinician-centered, appears in same format as most EHR medication lists); 3) real-time adherence tracker, 4) profile (patients can tailor their reminder times up front); and 5) help screen (including contact information and links to recruitment brochure and consent form).

2. Simple data entry – offers patients the ability to enter drug and dosing information in any of three ways: 1) utilize OCR’s ability to automate data entry of key information from pictures of medication labels, including drug and dosing information (e.g. a medication label such as “metformin 500mg tabs, take 1 tablet twice daily” auto-populates metformin into the drug name section, 500 into the dose section, mg into the units section, and schedules doses according to patient’s preferred morning and evening dosing times); This feature required sophisticated camera present in iPhone 4S generation or higher; 2) scan UPC barcode on OTC medications; or 3) free-text medication name and dosing information (i.e. type in, similar to other medication management applications).

3. Patient-centered organization – medications grouped according to time of day, with dosing specified by patients’ preferred reminder times (see screen shot of calendar tab, Figure 2).
4. Each medication dose correlates with a unique dosing alert (e.g., twice-daily medications have morning and evening alerts). Patients’ responses to dosing alerts become a proxy for their medication taking behavior.

5. Quality dosing alerts – dosing alerts (audio and visual) displayed on patients’ “lock screen” and patients able to “swipe into” the application, which opens to the schedule screen, where patients then respond to dosing alerts.

6. Patients respond to dosing alerts by specifying one of three options:
   - “take” = indicates patient took that specific medication dose
   - “remind” = requests a reminder within four hours
   - “skip” = indicates patient did not take that specific medication dose
   - Dosing alerts with no response in 24-hours are coded to “ignore” and equated to “skip”

7. Adherence “tracker” – calculates patients’ adherence in real time.
   - **Adherence** calculated by summing “take” responses and dividing by the total number of dosing alerts (for all chronic prescription medications).

8. Help screen – ability to easily contact researchers for technical support, and link to consent form and recruitment brochure.

9. Integrated surveys – patients can complete adherence (Morisky Medication Adherence Scale, MMAS-8) and user interface (System Usability Scale, SUS) surveys within the application (patients prompted to take SUS every two weeks for longitudinal data).

10. Single operating system – iOS – developers refined existing iOS technology as a platform to develop our medication management application; we chose to limit our app development/testing to a single platform (iOS) before expanding to other platforms.

11. National Drug Code (NDC) database – we integrated the Food and Drug Administration’s (FDA) open-source NDC database to cross-reference information auto-populated by OCR (e.g. drug name and dosage) in order to ensure accuracy of information.

12. Universal Product Code (UPC) database – we integrated an open-source UPC database in order to auto-populate drug and dosage information of over-the-counter (OTC) medications by barcode scanning.
13. Data housed in a remote, secure database so that researchers have real-time access to adherence data (#taken/#alerts) and pictures of medication labels (used to confirm accuracy of automated OCR data entry). By relaying information via a remote database server, patients’ data could not be lost if their phone was stolen, lost, or destroyed (Figure 1).

**Initial Testing.** Once designed, we previewed the software by testing accuracy of auto-populating medication entries by taking pictures of medication labels. We defined accuracy as the percentage of unique data field entries entered correctly (medication name, dose, route, frequency, and National Drug Code [NDC]) by the OCR technology integrated [remotely] into the application (i.e. OCR was performed via the remote server, not within patients’ phones). We chose these five data elements among several medication label components because they were critical prescription elements and necessary in order to populate the requisite fields of the medication management application. We generated thirty “dummy” prescription labels, including oral and non-oral medications, and combination medications (Figure 3, left). In addition, we previewed data entry for OTC medications by scanning their UPC codes (Figure 3, right).

![Figure 3. Novel options for entering drug and dosing information into the PresRx OCR app. In addition to manually entering data, patients can take pictures of medication labels (left) or scan UPC barcodes (right) to automate data entry.](image-url)
Phase 2. Prospective Pre- and Post-Test Longitudinal Cohort Study. We conducted a pilot study of selected patients within a “controlled” medical system to test the four aims of the study:

1. assess the accuracy of data entry via OCR
2. test patients’ acceptability of the software
3. determine patient adherence to prescription medications for chronic conditions
4. calculate the fixed and variable costs of the system

Study Population. Eligible patients were employed by Sparrow Health Systems (SHS), received primary care services at SHS, and insured by Sparrow Physician Health Network (SPHN), which incentivizes patients to use a single pharmacy system, Sparrow Pharmacy Plus. Sparrow Health Systems employs approximately 7500 people in the greater-Lansing area.

Inclusion Criteria. Age at least 18 years old and taking three or more chronic medications, defined as prescription medications taken for chronic conditions.

Exclusion Criteria. Minor children, incapacitated adults, and not using an Apple® iPhone (4S generation or beyond) with ongoing service, not willing to have all prescriptions filled at any one of several Sparrow Pharmacy Plus locations.

Recruitment. We used two strategies to accrue patients into the study (Figure 4). Initially, we recruited patients from a single Sparrow Primary Care Clinic (Sparrow-MSU Family Medicine Residency) using Epic Electronic Health Record’s “research” module. We queried the EHR for patients that met inclusion criteria. We alerted providers when their patients met inclusion criteria using an electronic “flag” in the EHR. We incorporated the e-flag into providers’ workflow, prompting them to ask patients to meet with a study coordinator after their appointment to learn more about the study. After six weeks, we had enrolled only two patients (both withdrew due to medical issues unrelated to study participation), so we modified our recruitment strategy based on office staff recommendations (Figure 4). Key issues in failing to accrue were: target audience too small, patients not using an iPhone 4S generation or beyond, and taking fewer than three chronic medications.
Figure 4. Flow diagram of recruitment, enrollment, and participation in the PresRx OCR (iPhone app) medication management study.
Our second recruitment strategy involved a mass email to all SHS employees (approximately 7500 people) that described our study and included an electronic recruitment brochure (Appendix 1). The email was addressed to: everyone@sparrow.org, which goes to a clearinghouse for review prior to dissemination. Interested employees contacted research personnel via email or phone call to learn more about the study. Next, patients who wanted to participate in the study met with our study coordinator who screened for inclusion/exclusion criteria and obtained informed consent. Using this strategy, 12 patients responded to the email and nine patients enrolled (Figure 4). Overall, we enrolled 11 patients in our study; three withdrew prior to installing the app on their phones. We downloaded the app onto eight patients’ phones.

**Index Appointment.** Index appointments for initial medication reconciliation were performed by HIPAA and IRB-trained physicians (Figure 5). These physician-investigators described the study, answered questions, and confirmed informed consent. The physician-investigator then obtained a Best Possible Medication History (BPMH) using the protocol defined by the High 5’s Project (Appendix 2). Once medications were reconciled and the EMR updated, all prescriptions were e-prescribed (if needed) to a Sparrow Pharmacy Plus location in order to obtain [flat] medication labels from which patients could take pictures.

Next, physician-investigators assisted the patient in downloading the mobile application to their iPhone and provided a demonstration. During this face-to-face meeting, patients customized the application for dosing reminders (e.g. what time at “night” to alert for dosing evening medications). Next, physicians

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<td>1. Review study, answer questions</td>
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<tr>
<td>2. Perform medication history (BPMH)</td>
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<tr>
<td>3. Transfer prescriptions to participating pharmacy</td>
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<tr>
<td>4. Assist patient downloading application</td>
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<td>5. Demonstrate how to use the application</td>
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<td>- Help screen</td>
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<td>- Profile page – preferred dosing times</td>
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<td>6. Administer surveys (MMAS-8)</td>
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<td>7. Obtain medication labels [duplicates, flat]</td>
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<td>8. Assist patient taking pictures of medication labels to incorporate drug name and dosing information into the application (via OCR)</td>
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<tr>
<td>9. Assist patient scanning UPC codes of OTC medications</td>
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<tr>
<td>10. Clarify accuracy of medication regimen and alerts</td>
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<td>11. Reminder about SUS surveys every 2 weeks</td>
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**Figure 5. Procedures for index appointments.**
obtained medication labels from the participating pharmacy and demonstrated how to photograph medication labels for incorporation into the app. Physician-investigators showed patients how to use the application, assess accuracy of auto-populated information, and modify incorrect entries. All patients conducted return demonstrations. Patients and investigators jointly confirmed the accuracy of each automated medication entry, both by medication label picture taking (prescription medications) and UPC barcode scanning (OTC medications). Physician-investigators answered questions, and every patient received a brochure with key points and reference for technical assistance (Appendix 1).

Patients began the six-month observation period of the trial upon completing their index appointment. Researchers tracked patients’ responses to their dosing alerts for the duration of the study, up to December 31, 2014. Patients received a $25 iTunes gift card for participating in the study (regardless of study duration or participation in exit interviews).

Measures

**Patient Characteristics.** We assessed: 1) demographic data (e.g. age and sex); and 2) healthcare variables (e.g. co-morbidities, number of chronic medications at index appointment). We ascertained patient characteristics by abstracting information from their electronic health records. We defined chronic medications as prescription medication(s) for a chronic condition (lasting at least 3 months).

**Accuracy of Auto-Populated Medication Dosing Information.** To confirm reliability of the software (validation), we calculated the percentage of auto-populated medication data (medication name, dose, route, frequency, and NDC) imputed correctly into the mobile application using OCR technology for: 1) initial testing (“dummy” medication labels); and 2) patients’ medication labels.

**Patient Acceptance.** We assessed patients’ acceptance of our mobile medication management application quantitatively using a validated satisfaction survey, the System Usability Scale (SUS) and qualitatively using semi-structured exit interviews (Appendices 3 and 4). The SUS, developed in 1986, includes ten items (statements) that responders rate on a five-item Likert scale. Scores range from 10-100, with higher scores indicating greater satisfaction.
with the user interface. The SUS is highly reliable (alpha = 0.91) and useful over a wide range of interface types; scores ≥70 indicate acceptable user interfaces, 60-70 marginal, and ≤60 unacceptable.\textsuperscript{27} We prompted patients to complete SUS surveys every 2 weeks while using the system (surveys integrated into the mobile application). In addition, we added a final “free text” comment section after the 10 SUS items so that patients could provide specific feedback. We calculated each patient’s survey response rate and used their average SUS score.

We conducted exit interviews among four of the five patients who completed at least six months of the study and agreed to have their interviews audio-recorded. We conducted interviews in order to determine: 1) how patients’ medication taking behavior was affected by using the app (if at all); 2) what they liked and disliked about the app; and 3) ideas for improvement. See Appendix 4 for interview questions and probes.

\textbf{Adherence.} We calculated adherence to medication regimens using both objective and subjective measures in order to balance their respective strengths and weaknesses.\textsuperscript{28,29} We compared adherence rates over two time periods: six months before app use (pre-test) and the six months associated with app use (post-test). The International Society for Pharmacoeconomics and Outcome Research (ISPOR) defines optimal adherence as “the degree or extent of conformity to the recommendations about day-to-day treatment by the provider with respect to the timing, dosage, and frequency.”\textsuperscript{16}

\textbf{Objective Adherence Measure.} We assessed pharmacy fill histories to calculate proportion of days covered [PDC]\textsuperscript{30} over two six-month time periods (pre- and post-app) to obtain objective adherence rates. The PDC assesses how many days in a given time period patients had access to their medications.\textsuperscript{30} A PDC is calculated by dividing the number of days in a period “covered” by a medication by the number of days in the period.

\textit{For example, there are 184 days for the 6-month study period (July 1, 2014 through December 31, 2014). A patient that had an “index” prescription filled on August 1, 2014 would have 153 days in her period (184-31=153). If the refill contained a 90-day supply, that would “cover” the patient through October 30, 2014. If the patient filled another 90-day supply on November 19, 2014, that would cover the remaining days in the period (12 days of November and 31 days of December = 43 remaining days in the period). This patient’s PDC is:} \( (90+43)/153 = 133/153 = 86.9\% \) - considered “highly adherent.”
**Subjective Adherence Measures.** We assessed patient-reported (subjective) adherence by two methods: 1) pre- and post-app validated adherence surveys: Morisky Medication Adherence Scale (MMAS-8,\(^\text{31}\) Appendix 5), which has an alpha reliability of 0.83; and 2) patients’ responses to the mobile medication application dosing alerts.

While using the app, patients could respond to dosing alerts within 24-hours of the reminder (patients could select “take” or “skip” or ask for a reminder of up to four hours in the future). App adherence was calculated as the proportion of drug events (each unique dose of each medication in the regimen) taken, as reported by patient attestations using the mobile app and compiled by the software (i.e. \#taken/\#alerts). We calculated adherence rates by patient per month, and by medication class per month.

**System Costs.** We evaluated costs of the system by separating into fixed costs (software development and operational costs) and variable costs (incremental costs related to need for increased bandwidth to service additional patients, and cost of storing and retrieving information from the servers per patient).

**Data Transmission and Protection of Identifiable Health Information**

Pictures of patients’ medication labels included identifiable health information, which were transmitted via secure API communication, including a Secure Messaging Protocol with Image Compression and Meta Data (send) and Structured Data Response (receive) as detailed by EMOL Health. We deployed a Representational State Transfer (REST) service in order to communicate between the mobile application and the database. A REST API consists of actions taken on objects, represented by the HTTPS method used and the URL of that object. We used Secure Socket Layer (SSL) communication with the API to ensure data security. A remote, secure SQL server stored updated medication entries as auto-populated by OCR interpretation of medication labels. All research personnel had access to this database in a password-protected environment. Similarly, patients’ responses to dosing alerts (e.g. taken or skip) were maintained in the remote, secure database in order to calculate real-time adherence rates. We also maintained patients’ responses to SUS and MMAS-8 surveys in the database.
Data Analysis

We generated descriptive statistics for the following outcomes: 1) accuracy of auto-populated data entry (Phases 1 and 2); 2) satisfaction with the application; and 3) patients’ adherence rates to medication regimens. Given the small number of patients, we produced graphic displays that identified patients by salient characteristics of adhering to medications and responding to surveys over time. Moreover, we compared patients who used the app for at least six months to those who ceased using the app before the study ended. We also compared patients who used the upgrade with those who did not receive the upgrade. We accounted for missing data by listwise deletion. We assessed the influence of baseline demographic characteristics and comparison of subgroups through the application of appropriate nonparametric univariate statistical procedures. We conducted all quantitative analyses using SAS 9.3 (SAS Institute Inc., Cary, North Carolina).

An expert in qualitative methods (AK, see Acknowledgements, p. 6) analyzed transcripts of exit interviews by identifying patterns across participants and key themes using a directed content analysis approach. This qualitative method utilizes structured questions and a predetermined coding strategy, both based on prior research; the goal of the data analysis is to identify and categorize every instance of a particular phenomenon, including both supporting and non-supporting instances.

The protocol was approved by the Michigan State University and Sparrow Health Systems Institutional Review Boards.
RESULTS

Phase 1. Software Development and Initial Testing

We developed an easy-to-use medication reminder application for iPhone users, PresRx OCR. We included five key sections – daily calendar, condensed medication list, adherence tracker, patient profile, and help screen – separated as tabs on the screen (Figure 6):

Figure 6. Screen shots of PresRx OCR iPhone application. Circles indicate tab selection, which specifies screen. Top panel left to right: app icon with 2 pending dosing alerts; daily calendar screen for responding to dosing alerts; condensed medication list. Bottom panel left to right: real-time adherence tracker; patient profile screen (specify preferred dosing times); help screen.
Patients could enter their medication regimens via any one of three options (Figure 7):

1) Free-text (manual entry)
2) Picture of medication label (OCR automates entry of drug and dosing information)
3) Scan a UPC barcode for OTC medications

Figure 7. Novel options for entering drug and dosing information into the PresRx OCR app. In addition to manual data entry, patients can take pictures of medication labels (left) or scan UPC barcodes (right) to automate data entry.

We programmed the app to avoid auto-populating data fields unless the information was accurate, as cross-referenced with the NDC database. We used this cross-reference feature to avoid displaying incorrect drug and dosing information.

Initial Testing. Overall, medication information was auto-populated frequently (range 67% for NDC to 100% for Drug Name, Figure 8). Importantly, auto-populated information was accurate (Average 95%, Figure 8). We then cross-referenced medication labels that auto-populated National Drug Code (NDC) numbers with a NDC database to ensure accurate dose information.
Figure 8. Phase 1 – Accuracy of auto-populated medication label information. Results indicate whether medication information from 30 "dummy labels" was auto-populated; shading indicates accuracy of auto-populated fields.

Phase 2. Prospective Pre- and Post-Test Longitudinal Cohort Study

We screened 78 patients using our combined recruitment strategies (Figure 4). Among patients flagged in the EHR, 60 were excluded (did not use an iPhone 4S or beyond or taking fewer than three chronic medications), four declined to participate, and two withdrew (ill health unrelated to study enrollment). We recruited the remaining 12 patients from our mass email. Researchers could not contact two patients after several attempts, one withdrew (time constraints), and one was excluded (used an Android OS). Overall, we had eight patients using the system. Average patient age was 43 (range 28–54, Table 1). Patients had a range of comorbidities: 50% cardiovascular diagnoses (n=4), 25% diabetes mellitus (n=2), 25%
respiratory diagnoses (n=2), and 38% psychiatric diagnoses (n=3). Patients took an average of 3.4 chronic medications. All patients were employees of Sparrow Health System. Overall, patients used the app for nearly six months (range 2.6-7.9 months, Table 1).

### Table 1. Baseline characteristics of study participants, including pre-app adherence rates.

<table>
<thead>
<tr>
<th>ID</th>
<th>Age</th>
<th>Sex</th>
<th>Meds</th>
<th>Chronic Medications</th>
<th>Duration (mo)</th>
<th>MMAS-8*</th>
<th>PDC**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>44</td>
<td>F</td>
<td>3</td>
<td>Carvedilol, lisinopril-HCTZ, omeprazole</td>
<td>7.9</td>
<td>3.5</td>
<td>100</td>
</tr>
<tr>
<td>2</td>
<td>28</td>
<td>F</td>
<td>3</td>
<td>Sertraline, methylphenidate, fluticasone-salmeterol</td>
<td>4.9</td>
<td>4</td>
<td>42.7</td>
</tr>
<tr>
<td>3</td>
<td>50</td>
<td>M</td>
<td>3</td>
<td>Metformin, enalapril, simvastatin</td>
<td>6.9</td>
<td>5.5</td>
<td>71.1</td>
</tr>
<tr>
<td>4</td>
<td>48</td>
<td>F</td>
<td>4</td>
<td>Triamterene-HCTZ, citalopram, esomeprazole, topiramate</td>
<td>6.9</td>
<td>8</td>
<td>89.4</td>
</tr>
<tr>
<td>5</td>
<td>36</td>
<td>F</td>
<td>4</td>
<td>Metformin, saxagliptin, lisinopril, desogestrel-ethinyl estradiol</td>
<td>5.9</td>
<td>4.75</td>
<td>87.8</td>
</tr>
<tr>
<td>6</td>
<td>39</td>
<td>F</td>
<td>2</td>
<td>Fluticasone-salmeterol, montelukast</td>
<td>4.1</td>
<td>6.5</td>
<td>-----</td>
</tr>
<tr>
<td>7</td>
<td>54</td>
<td>F</td>
<td>3</td>
<td>Venlafaxine, amitriptyline, meloxicam</td>
<td>6.0</td>
<td>8</td>
<td>89.4</td>
</tr>
<tr>
<td>8</td>
<td>43</td>
<td>F</td>
<td>5</td>
<td>Nadolol, celecoxib, sulfasalazine, pantoprazole, amiloride-HCTZ</td>
<td>2.6</td>
<td>2.5</td>
<td>83.6</td>
</tr>
<tr>
<td>AVG</td>
<td>43</td>
<td>3.4</td>
<td></td>
<td></td>
<td>5.7</td>
<td>5.3</td>
<td>84.0</td>
</tr>
</tbody>
</table>

*MMAS-8 scores range 0-8; high=8, medium=6-8, low=<6

**PDC is proportion of days covered (patient has access to medications); >80% indicates high adherence

During pilot testing, researchers compiled a list of patients’ feedback (phone calls, emails, text messages, and free-text SUS survey responses) in order to identify areas for improvement. We triaged key elements of the list based on patient feedback, which developers incorporated into a software upgrade (Table 2). The software upgrade was available in September 2014 and installed on patient’s iPhones shortly thereafter.
Table 2. Prioritized list of upgrades for PresRx OCR medication management app.

<table>
<thead>
<tr>
<th>Upgrade Item</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermittent internet connectivity – randomly logging patients out of the system</td>
<td>v1.1</td>
</tr>
<tr>
<td>Sync speed – app is slow when it first launches and when patients respond to dosing alerts</td>
<td>v1.1</td>
</tr>
<tr>
<td>Activate flash/torch when taking pictures (to improve image contrast → improve OCR accuracy)</td>
<td>v1.1</td>
</tr>
<tr>
<td>Watermark past responses to dosing alerts (so patients can see responses to past dosing alerts)</td>
<td>v1.1</td>
</tr>
<tr>
<td>Improve tracker page so that adherence percentages are not obscured</td>
<td>v1.1</td>
</tr>
<tr>
<td>Modify lock screen alerts such that the app launches into the appropriate screen (e.g. to respond to dosing alerts or take a survey)</td>
<td>v1.1</td>
</tr>
<tr>
<td>Time zone troubleshooting</td>
<td>v1.1</td>
</tr>
<tr>
<td>Add medication pictures via NDC look-up</td>
<td>v1.1</td>
</tr>
<tr>
<td>Ensure that OCR works regardless of picture orientation (portrait/landscape)</td>
<td>v1.1</td>
</tr>
<tr>
<td>Ensure that data collection will be seamless, regardless of which version of the app patients use</td>
<td>v1.1</td>
</tr>
<tr>
<td>iOS 8 optimization</td>
<td>v1.1</td>
</tr>
</tbody>
</table>

**Accuracy of Auto-Populated Medication Dosing Information.** Medication name was auto-populated into the app from 97% of patient labels (Figure 9). Unfortunately, NDC was only auto-populated half of the time; we used the NDC information to cross-reference data imputed by OCR. Accuracy of auto-populated medication information fields was >90% accurate for all fields, including 95% for drug name and 98% for drug dose.
Patient Acceptance. Five of the eight patients completed at least six months of the study (Figure 4). All eight patients experienced issues with random logouts. We attributed this issue to interrupted internet connectivity (iPhone negotiating between different internet connections, e.g. Wi-Fi and LTE). The logout issue was addressed in the app upgrade (available September 2014), but only three patients had the upgrade installed on their iPhones (Patient IDs: 1, 4, and 7; Table 3). Patients responded to fewer than half of the bi-monthly SUS surveys despite app-automated reminders (31% response rate). Average SUS scores were 69.4, indicating that the application was marginally acceptable for use (range 40-90, Table 3).
Patients who rated the app poorly were more likely to complete bimonthly SUSs, suggesting that this was a reasonable mechanism to convey issues regarding the system.

Patient satisfaction measured by SUS was not correlated with study duration or completion, nor whether or not patients received the app upgrade. However, older patients rated the app more favorably than younger patients did \((P=0.02)\). Thus, we should not assume that middle-aged or older patients are resistant to using mHealth technology.

**Exit Interviews.** Four patients (50%) agreed to complete audio-recorded exit interviews. We asked open-ended questions to learn about their experiences while using the application. Specifically, we asked whether the app changed their medication taking behavior, what they liked and disliked about the app, and ideas for improvement. Overall, patients thought the app was easy to use and helpful for forgetfulness (unintentional non-adherence). Patients commented on a few limitations, including medications “falling off” their lists, but stated that the upgrade had improved sync speed and addressed the issue of random log-outs. All of the interviewees provided high overall ratings and two asked if they could continue using the application despite completing the study (see Box on pages 28-29).
EXIT INTERVIEWS

Impact on medication taking behavior

Given that complex medication regimens may contribute to unintentional non-adherence, medication management is a key area of focus. Participants reported that the app had helped them manage their medications via its automated dosing alert function. When asked if the app helped, P5 stated:

I think so because I had to keep remembering to track it and say I took it, so it kind of helped me remember to take them.

Similarly, P4 reported:

[The app] helped me remember to take medicines at night ... [newly prescribed twice-daily medication], so it helped me remember to take them at night.

Two participants reported that the app had helped them gain insight into their medication management routine. P4 felt that she had learned “consistency,” while P5 reported:

I learned that I don’t take my medication every day [laughter]...more than I thought I didn’t.

Gaining insight into previously unexamined behaviors related to medication management can constitute the first step in improved self-efficacy and modifying one’s health. From this perspective, the app proved beneficial.

Forgetfulness is a critical contributor to unintentional non-adherence, so the app was designed to improve date and time dose adherence through its use of specific preferred dosing times and dosing alerts that participants could tailor to their individual needs. P1 reported that the app improved how she took her medications:

Yeah, I think it helped me to take them more consistently around the same time because it’s almost like you don’t even know...It just kept me on track, it really did...This almost keeps me accountable because it would remind me every time they were due, and I’d have to comply in order to move on to the next day, so it kept me on track that way. It was almost a way that it was ingraining it in my mind that it’s 8 o’clock, I’ve got to do this, so there’s time when I’d remember, and I didn’t even need the app because the app was getting my mind used to doing it that way...

Aspects of the App Participants Liked and Disliked

All four participants reported that the app was easy to use and included multiple positive features:

I liked that it showed...you were able to look back to see, you know, how compliant or non-compliant you are with your medications [P5].

[I liked] the ease of its use...It was very, to me it was very eye pleasing. It wasn’t like an eyesore. It wasn’t complicated...[Specifying preferred dosing times] was absolutely fabulous...[Taking pictures of medication labels and having that picture then be converted into the information] was really, really useful too. That was super easy [P1].
As this was a feasibility study of an app prototype, we asked participants to first describe what they did not like about the app, and then offer suggestions for improvements. Three out of four participants mentioned that they experienced medications “falling off” or dropping off their list:

Yeah, that one happened quite often. Probably I’d say at least more than a half a dozen times that that would keep occurring and I’d have to put it [medication] back in there. That would get really frustrating [P1].

Other issues included the screen freezing and random log-outs, both reported by two participants:

The only negative thing is sometimes when I would try to chart it, it would freeze, and I would say take, and it would go away and come right back. I’d hit take, and it’d go away and come right back, so a lot of times I just got frustrated, and I just went out of it. Most times when I came back it was gone. I don’t know why it just kept doing that, like a lot [P5].

Two participants, P4 and P5, limited their recommendations to addressing the medication drop-off problem described above. P7 mentioned being able to respond to dosing alert beyond the 24-hour time limit, as well as a larger font to improve readability. Both P7 and P1 said that there should be a way to differentiate between choosing to skip a medication (e.g., stopping an antihistamine because the season changed and it was no longer indicated) vs. forgetting to take a medication, speaking to intentional versus unintentional non-adherence.

Finally, P1 addressed the issue of habituation, described in the context of smartphone apps as the potential for a patient’s response to decline with repeated smartphone reminders:

I’m sure there’s always little things, little quirky things you can put in [to improve the app] because I think what happens when you get on the routine is that it almost doesn’t seem like a trigger anymore, so if like every quarter or every six months or something it does a little something different like now I’ve got this little dude that’s doing a happy dance to take his pills... I don’t know if would be literally just something as simple as changing the color...Okay, so what’s the new color of the quarter, or what’s the new color of the six months, or you know, just something to keep people engaged with it.

Overall Impressions of the App

Despite the problems already described, all four participants reported that their overall impression of the app was positive and they would recommend it to a friend:

I liked it. I really liked it, and I’d actually love to continue to keep using it, and I wish that they had something like that out there because even with the little bit of quirks here and there I find that I was more consistent with taking my medication...[P1].

Even the one already-highly-adherent participant, P7, endorsed the app for general use:

If I wanted it, and I was going to get it from the app store, I would say it was a five [five out of five stars], but I probably wouldn’t want it, but if I wanted it and I thought well this would really help remind me to take my birth control pill every day like let’s say an 18 year old...so you know to get back to would I recommend this to somebody: Maybe I would to whenever my teenagers were teenagers [laughter]. That probably would have been a good thing on their phone to take the pill every day, now that I think about it.
Table 3. Summary of participants’ app use, including alerts, software updates, acceptance, and adherence rates during app use.

<table>
<thead>
<tr>
<th>ID</th>
<th>MMAS-8*</th>
<th>MMAS-8*</th>
<th>PDC**</th>
<th>PDC**</th>
<th>#Alerts</th>
<th>#Taken</th>
<th>App Adherence</th>
<th>SUS***</th>
<th>RR****</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-Test</td>
<td>Post-Test</td>
<td>Pre</td>
<td>Post</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>3.5</td>
<td>3.8</td>
<td>100%</td>
<td>95.7%</td>
<td>738</td>
<td>643</td>
<td>87.1%</td>
<td>70.6</td>
<td>27%</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>-----</td>
<td>42.7%</td>
<td>22.8%</td>
<td>361</td>
<td>248</td>
<td>68.7%</td>
<td>52.5</td>
<td>67%</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>5.5</td>
<td>-----</td>
<td>71.1%</td>
<td>50.0%</td>
<td>755</td>
<td>644</td>
<td>85.3%</td>
<td>-----</td>
<td>-----</td>
<td>No</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>6.8</td>
<td>89.4%</td>
<td>53.9%</td>
<td>660</td>
<td>654</td>
<td>99.1%</td>
<td>80.6</td>
<td>31%</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>4.8</td>
<td>2.5</td>
<td>87.8%</td>
<td>90.2%</td>
<td>707</td>
<td>347</td>
<td>49.1%</td>
<td>68.0</td>
<td>46%</td>
<td>No</td>
</tr>
<tr>
<td>6</td>
<td>6.5</td>
<td>-----</td>
<td>-----</td>
<td>100%</td>
<td>337</td>
<td>238</td>
<td>70.6%</td>
<td>75.0</td>
<td>38%</td>
<td>No</td>
</tr>
<tr>
<td>7</td>
<td>8</td>
<td>7</td>
<td>89.4%</td>
<td>100%</td>
<td>440</td>
<td>406</td>
<td>92.3%</td>
<td>78.0</td>
<td>42%</td>
<td>Yes</td>
</tr>
<tr>
<td>8</td>
<td>2.5</td>
<td>-----</td>
<td>-----</td>
<td>83.6%</td>
<td>331</td>
<td>246</td>
<td>74.3%</td>
<td>-----</td>
<td>-----</td>
<td>No</td>
</tr>
<tr>
<td>AVG</td>
<td>5.3</td>
<td>5.0</td>
<td>84.0%</td>
<td>73.5%</td>
<td>4329</td>
<td>3426</td>
<td>79.1%</td>
<td>69.4</td>
<td>31%</td>
<td>37.5%</td>
</tr>
</tbody>
</table>

*MMAS-8 scores range 0-8; high=8, medium=6-8, low=<6
**PDC is proportion of days covered (patient has access to medications); >80% indicates high adherence
***SUS scores range 0-100; higher scores indicate greater satisfaction; ≥70 is acceptable
****RR is response rate for SUS surveys (app sent automated reminders every 2 weeks)

Adherence. We assessed adherence to chronic prescription medications using objective (PDC) and subjective (MMAS-8 and responses to app’s dosing alerts) measures both before patients used the app (pre-test) and during the time period that patients used the app (post-test).

Pre-Test. Patients’ average pre-app adherence rates as measured by PDC (objective measure) was 84%, indicating highly adherent medication taking behavior at baseline (range 43-100%, Table 3). There was poor correlation between PDC and MMAS-8 results. Overall, patients’ average MMAS-8 scores were 5.3 at baseline, indicating low adherence (range 2.5-8, Table 3).

Post-Test. Again, we noted poor correlation between objective and subjective adherence rates during the time patients used the app (post-test). PDC rates decreased marginally from pre-test to post-test (84% and 74%, respectively), but this was not a significant decline in adherence ($P=0.35$; Table 3). Similarly, MMAS-8 scores decreased non-significantly from pre-test to post-test (5.3 to 5.0, respectively, Table 3).
**Adherence based on patients’ responses to dosing alerts.** During the six-month pilot study, patients received 4,329 dosing alerts and responded “take” to 3,426 alerts. Overall, this indicates a 79% adherence rate, which approaches the 80% threshold for highly adherent medication taking behavior. Furthermore, the overall 79% adherence rate (subjective measure from responses to app dosing alerts) is exactly between the range of calculated PDC scores (84% pre-test and 74% post-test). This result suggests that adherence rates calculated based on responses to app dosing alerts correlates well with objective measures of adherence (specifically PDC). Reported adherence rates were higher during initial app use (>90%, Figure 10) than during the middle of the study. Mid-way through the study (3-5 months), reported adherence rates averaged 70%, and improved again towards the end of the study (Figure 10). Notably, patients began reporting issues with random logouts at two months, which limited our data collection.

*Figure 10. Adherence to chronic medications per patient per month.*
during the time leading up to the upgrade. We were unable to track each logout event.
Therefore, we cleaned the raw data by removing “ignored” responses that spanned more than five days, since this likely indicated that the patient was logged out of the system for that duration of time. Still, it is unknown whether “ignored” reflected intentional non-adherence or merely those patients who were logged out of the system. Unfortunately, our five-day cut-off was arbitrary, and we classified patients with “blank” responses for up to four days as “skip” (non-adherent), which may have negatively affected adherence rates.

We cleaned our raw data similarly for patients whose medications “fell off” their lists, i.e. we deleted entries with responses where the medication name field was blank.

Adherence rates were highest for cardiovascular and psychiatric drugs (86% and 87%, respectively; Figure 11). Overall adherence was <70% for oral hypoglycemic and

![Figure 11. Adherence to different classes of chronic medications per month.](image)
respiratory medications. Regardless of medication class, patients reported lower adherence rates during the middle of the study, compared with when they started using the app (overall 22% decrease in adherence between months 1 and 3, P=0.02). These results may indicate a need for patient re-engagement.

**Subset Analysis.** We assessed patients’ average app-adherence rates for the first three months of the study, which allowed a fair comparison of all participants. Overall adherence was no different among patients who completed the entire study compared with those who used the app for less than six months (P=0.23). However, the three patients who received the app upgrade had higher adherence rates in the first three months of the study than the remaining five patients who did not receive the upgrade (93.3% v. 71.2%, P=0.04). We observed this difference despite the fact that the upgrade was available after the third month of the study. These results may indicate that patients who received the app upgrade were more “engaged” in their health at baseline – and thus more adherent to their chronic medications – than patients who did not pursue the invitation to upgrade their app. Regardless, identifying baseline characteristics that predict patient engagement at baseline are necessary in order to identify patients most likely to benefit from an intervention.

**System Costs.** Fixed costs included application development and monthly operational costs (Table 4). Operational costs included system maintenance, licensing, data retention, tracking adherence, and technical support (including personnel costs). Variable costs included $100/patient for maintaining medication lists (managing changes) and uploading pictures of medication labels. Overall, per-patient cost will decrease significantly as more patients use the system (e.g. $9/patient/month with 10,000 patients using the system, Table 4).
Table 4. Summary of fixed and variable costs for using medication management mobile application.

<table>
<thead>
<tr>
<th># Pts</th>
<th>Fixed Costs</th>
<th>Variable Costs</th>
<th>Overall Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Development</td>
<td>Operational/month</td>
<td>$100/patient</td>
</tr>
<tr>
<td>100</td>
<td>$49,000</td>
<td>$2,859</td>
<td>$10,000</td>
</tr>
<tr>
<td>1,000</td>
<td>$49,000</td>
<td>$2,859</td>
<td>$100,000</td>
</tr>
<tr>
<td>10,000</td>
<td>$49,000</td>
<td>$2,859</td>
<td>$1,000,000</td>
</tr>
</tbody>
</table>

At the conclusion of our study, we organized patients’ feedback to generate a second prioritized list for future upgrades (Table 5).

Table 5. Prioritized list of proposed upgrades for PresRx OCR medication management app v1.2

<table>
<thead>
<tr>
<th>Upgrade Item</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine why medications randomly fall off patients’ lists (major patient safety issue)</td>
<td>v1.2</td>
</tr>
<tr>
<td>Streamline app installation/update process (e.g. offer via App Store)</td>
<td>v1.2</td>
</tr>
<tr>
<td>Increase size of buttons and/or space between buttons for patients with large fingers</td>
<td>v1.2</td>
</tr>
<tr>
<td>For pictures, develop an auto-focus feature</td>
<td>v1.2</td>
</tr>
<tr>
<td>Improve differentiation between &quot;dose&quot; and &quot;strength&quot;</td>
<td>v1.2</td>
</tr>
<tr>
<td>Make advance scheduling feature more intuitive (linear navigation)</td>
<td>v1.2</td>
</tr>
<tr>
<td>Allow patients to “modify” responses (e.g. if they erroneously pushed “skip” instead of “take”)</td>
<td>v1.2</td>
</tr>
<tr>
<td>Add a section on Help page for “anytime feedback”</td>
<td>v1.2</td>
</tr>
<tr>
<td>Improve organization and tracking for “as needed” medications</td>
<td>v1.2</td>
</tr>
<tr>
<td>Improve scrolling for patients with long medication lists</td>
<td>v1.2</td>
</tr>
<tr>
<td>Clarify whether we need a “window period” for patients to respond to dosing alerts</td>
<td>v1.2</td>
</tr>
<tr>
<td>Combination drugs – dose field must allow “/” symbol (e.g. Lisinopril-HCTZ &quot;20/25&quot;)</td>
<td>v1.2</td>
</tr>
</tbody>
</table>
DISCUSSION

Proof of Concept (Feasibility)

We developed and tested a medication management application for iPhone users. Our application has several features that are unique compared with those available in the App Store. Specifically, we tested novel methods for auto-populating drug and dosing information: 1) by taking a picture of one’s medication label; or 2) scanning a UPC code of an OTC medication. In addition, our application integrates the FDA’s National Drug Code database to ensure patients’ drug and dosing information is accurate in their scheduling system. Our feasibility test is one of few studies to test the impact of mHealth applications on adherence to chronic medications. For instance, one small randomized study reported increased adherence to antiretroviral therapy among patients with HIV using a smartphone app. A second larger multi-site study is evaluating smartphone adherence tools among patients with Parkinson’s disease. Unfortunately, these studies assessed patients with a single chronic disease and evaluated multiple interventions, not just the medication reminder system.

Our study adds to the emerging data about effectiveness of mHealth applications. Specifically, we evaluated novel strategies for tailoring medication management for individual patients with multiple chronic conditions. First, it evaluated patients taking several chronic medications (not a single drug for a single chronic condition), and we obtained adherence data for six months. In addition, we assessed adherence rates before and during application use (pre/post study) via objective and subjective measures, features common among similar feasibility studies.

Second, we offered patients several ways to impute their medication lists (free text, pictures of medication labels, and scanning barcodes). We chose these strategies in an attempt to address key issues of medication management: patients take prescription and non-prescription medications, with varying dosing schedules. Our goal was to enter patients’ medication information accurately and efficiently into a streamlined, accurate list with real-time update capabilities. Ultimately, our system could evaluate drug-drug interactions and adherence protocols by way of National Drug Code (NDC) look-up. This critical step – using OCR
to convert images of NDC numbers on medication labels into machine-encoded text – is essential to offering additional app enhancements (e.g. common side effects). Unfortunately, there is no FDA mandate to standardize information presented on prescription drug labels, including whether or not to include NDC numbers, making OCR challenging. Furthermore, most medication labels are applied to cylindrical medication vials, which is a further barrier to accurate OCR data analysis. Despite these barriers, we are hopeful that lessons learned from our pilot study will influence other mHealth product development and refinements.

We elicited feedback about our application frequently, which we used to identify opportunities for enhancements. Patients could easily contact researchers to report software problems and provide constructive criticism. Researchers worked jointly with app developers to produce a second version of the application that provided “bug fixes” based on patient feedback. We were able to track adherence for patients using either version of the application. Specifically, we used a remote/secure database server to track real-time responses to dosing alerts, record responses to surveys, and review pictures of medication labels (used for OCR to auto-populate information into the app). These data relayed information to/from the patients’ phones via internet connections, which allowed researchers to monitor behavior.

In addition to administering SUS surveys, we also conducted exit interviews at the end of the study in order to obtain unstructured feedback about our application and to inquire about specific issues in software design. We believe that proactively eliciting patient feedback is essential to developing effective patient-centered mHealth tools.

**Patient Population**

Our cohort represented a middle-aged patient population that took an average of three chronic medications (not including OTC medications). We recruited our patients from a list of all Sparrow Health System employees, specifically those incentivized to use a single pharmacy, which enabled us to test novel aspects of data entry (i.e. we needed consistent medication labels to test OCR technology to automate data entry for drug name and dosing information).

While our cohort was appropriate for a feasibility study, it does introduce limitations, including small sample size and single site design. Our patients were relatively healthy and took
few chronic medications. Furthermore, because our patients were all health system employees, they likely had higher-than-average health literacy. However, we believe that limiting the scope of our study – both in size and baseline demographics – was essential during the early stages of app development in order to elicit meaningful feedback and address issues in a timely fashion.

Adherence

Interestingly, objective (PDC) and subjective (MMAS-8) scores produced divergent estimates of our study patients’ pre- or post-app adherence rates. Since PDC reflects patients’ access to medications, rather than actual medication taking behavior, the PDC may have over-estimated adherence rates. In addition, some studies indicate that the Morisky has high false-positive rates, meaning that patients score in the non-adherent range when objective measures suggest that patients are adherent. Specifically, in order to be considered highly adherent, patients must report positive responses to all eight MMAS-8 questions; a negative response to a single question indicates moderate adherence. Alternatively, since MMAS-8 is a subjective measure of adherence, patients may have been reluctant to over-estimate their adherence for researchers. As one patient commented during her exit interview, she had not realized how often she missed doses of her medications until she started using the app. Therefore, perceived behavior may be very different from actual behavior, although it is difficult to extrapolate our findings to a broader population given our small sample size. Regardless, when we measured adherence based on responses to dosing alerts (app adherence rates), and our estimates were consistently between pre-test and post-test PDC scores, indicating it was a reliable proxy for patients’ actual medication-taking behavior.

Overall, both objective and subjective measures of adherence decreased non-significantly during app use, which may reflect patients’ recognition of their medication-taking behavior. Given our select patient population with high pre-app PDC values, it may have been difficult to measure the app’s ability to improve adherence, since highly adherent patients have little room to improve their medication-taking behavior above baseline, regardless of the intervention.
Our study highlighted several areas for improvement, both unique to our application and to medication management applications in general. First, we offer some general advice about whether to recommend mHealth medication management applications: these apps may only be useful to a select group of patients, specifically those with unintentional non-adherence (often due to forgetfulness). Yet even among patients with high rates of unintentional non-adherence, mHealth apps may only be useful to patients who keep their smartphone on their body throughout the day and who can seamlessly integrate the system into their daily routines. Beyond optimal patient selection, app design and navigation is important. For instance, large button design is important for patients with limited vision and those with large fingers.

Of greater concern, applications that rely heavily on internet connectivity (as ours did) introduce opportunities for errors, including problems associated with poor or intermittent internet connectivity. In our study, this led to unintentional logouts (e.g. when patients moved from a Wi-Fi environment to a 4G connection) and slow synchronization speed (e.g. medication updates were slow to “refresh”). While we were able to resolve these issues in our upgrade, we subsequently identified a new “bug,” medications randomly “fell off” patients’ lists. While we were unable to reproduce this bug reliably, we believe it is due to failed partial synchronization between the remote server database and the iPhone application. Specifically, we could reproduce the error by launching and closing the app in rapid succession while medications were synchronizing, but only when internet connectivity was poor. Thus, we believe problems arose in settings where complex interactions among factors caused interrupted internet connectivity. This dilemma is an issue that will face any application that synchronizes data between server databases and personal devices in real time. While one could overcome many of these problems by building the system to work locally within the smartphone, it would be challenging for researchers (or clinicians) to review real-time adherence rates. For example, if patients’ adherence data were stored only within their own device, clinicians would have to rely on patients to upload their data to a server (rather than vice-versa) or program periodic uploads, which may compromise the benefits of “real time” functionality. We believe resolving these issues are necessary prior to expanding the system to another operating system (e.g. Android). We suspect many of our limitations were related to patients’ iPhones navigating
internet connectivity (intermittent), working with a small research-oriented technology developer (fewer resources for troubleshooting issues), and limited funding.

While this research did not examine these issues directly, patients and clinicians should have real-time access to updated medication lists maintained by patients (mHealth apps) and integrated with EHRs, perhaps via enhanced patient portals (Figure 12). Ideally, clinicians would have access to patients’ updated medication lists and adherence data in order to make

![Diagram of mHealth 'personal health record' application that synchronizes with Electronic Health Records (EHRs). System interoperability - including real-time synchronization - is a key element.](image)

Figure 12. Conceptualization of mHealth ‘personal health record’ application that synchronizes with Electronic Health Records (EHRs). System interoperability - including real-time synchronization - is a key element.
educated dosing decisions. Presently this is difficult to achieve because patients’ medication lists are maintained in several EHR systems (e.g. primary care, various specialists) and often independently by patients, which may not use the same EHR vendor. Furthermore, most patient portals are “read only,” such that they provide access to information, but do not allow patients to modify incorrect information. This redundancy and limited patient accessibility leads to discrepancies among various medication lists. We believe that patients should ultimately play a larger role in maintaining their own medication lists, which will likely require greater interoperability between EHR vendors and enhanced patient portals. However, clinicians play an important role, including their responsibility to inform patients about their medications, especially providing tailored information about new medications (e.g. common side effects). Regardless, we believe that medication management applications will be most useful to patients and clinicians when they integrate with EHRs, including interactive patient portals (e.g. MySparrow – Sparrow Health System’s version of Epic MyChart). Unfortunately, many patient portals serve as “read-only” resources that do not engage patients in their healthcare. Furthermore, mHealth applications that integrate reliable health information (e.g. medication side effects) into the other patient-centered features will further improve care. Such patient education features may be particularly useful for older adults who have established personal routines for medication management.\textsuperscript{38}

Improving the novel aspects of our application requires several conditions: improved camera ability (e.g. image stabilization, auto-focus/auto-snap) and flat medication labels. Unfortunately, only one large pharmacy produces medication labels on flat surfaces.\textsuperscript{24,39} Furthermore, there are no FDA mandates regarding standardized medication labels. In fact, not all medication labels contain National Drug Code (NDC) numbers, which was a key feature in our ability to confirm accuracy of auto-populated medication information. Worse, the barcodes on many medication labels are pharmacy-specific and unrelated to NDC number, such that tracing back to NDC number is not feasible. Given these barriers, it seems prudent to focus future research efforts on testing adherence features associated with commercially available EHRs’ patient portals (e.g. features currently under development at Epic).
System costs vary depending on the number of patients using the system. Yet even in a small-scale system – e.g. only 1,000 patients using the application – cost is similar to that of a single monthly generic medication ($15/patient/month). This cost may be a reasonable investment for an insurer, especially given the potential cost savings of greater medication adherence for chronic conditions.

Ultimately, our study highlights the need for additional research to assess the effectiveness of mHealth applications for improving medication adherence. In order to clarify their utility, we need to test such applications among a larger, more diverse patient population. Specifically, we need to assess older adult patients, those with multiple chronic conditions, those with complex medication regimens, and those with additional barriers to self-care (e.g. visual impairment, cognitive deficits, functional impairments, etc.). Ideally, we would test the system among patients with multiple providers that use multiple EHR vendors, challenging the concept of patient-centered care in a time when system inter-operability is of supreme importance.
CONCLUSIONS

We developed a medication management application for iPhone users – PresRx OCR – that empowers patients to maintain updated medication lists and adhere to their chronic medications. Our system automated data entry by extracting key drug and dosing information from patients’ medication labels using optical character recognition (OCR) technology. Middle-aged patients rated the app more favorably than did younger patients, indicating that benefits of mHealth may extend beyond young patients populations to include older patient populations. The app tracked patients’ responses to dosing alerts, acting as a subjective measure for assessing adherence to chronic medications. Overall, app-measured adherence rates correlated well with objective measures of adherence, indicating that it is a reliable measure for assessing adherence. Overall, patients’ adherence to chronic medications was highest within the first month of using the application, but waned until we re-engaged them by offering an app upgrade. Moving forward, it is essential that future mHealth studies carefully select patients who are most likely to benefit from particular mHealth interventions – those with select patient engagement characteristics. Ultimately, we need to conduct additional research in order to assess the role of mHealth medication management apps among diverse patient populations. Ideally, we will test interactive extensions of EHR patient portals (e.g. MySparrow), which are currently being developed. These next steps are critical to advancing the Center for Innovation and Research, and put Sparrow Health Systems and Michigan State University at the forefront of Health IT and interoperability research.
REFERENCES


APPENDICES

Appendix 1. Recruitment Brochure.

Potential Benefits to Patients
- Improved adherence to routine medications using dosing reminders.
- A tool to manage medications, including an "updated" list to share with healthcare providers.
- Receive a $25 gift card upon completing study.

Contact Information
MSU-Sparrow Center for Innovation and Research
517-384-3279
sparrowสวม innovations.msu.edu

Call to:
- Email
- Ask questions
- Receive technical support
- Contact the researchers
- Report a problem

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Funded by:
MSU-Sparrow Center for Innovation and Research

Integrating Health IT to Develop a Patient-Centered Approach to Medication Management

Fifty percent of patients with chronic illnesses do not take their medications as prescribed.
Non-adherence to medications costs the United States more than $100 billion annually in avoidable hospitalizations.
Non-adherence to medication regimens leads to poor patient outcomes, including disease progression, poor quality of life, and even death.

Eligibility Criteria
- Receive primary care services at a Sparrow practice
- Age 18 or older
- Take at least 3 chronic medications
- Fill your prescriptions at any Sparrow Pharmacy Plus location
- Or willing to transfer all prescription medications to a Sparrow Pharmacy Plus location (price matching available)
- Use an iPhone 4S generation or beyond
- Speak English fluently

Study Objectives
A research study to:
- Determine patients' adherence to medication regimens using a medication adherence iPhone application ("app")
- Test a novel method for data entry of drug and dosing information into adherence apps using iPhone camera
- Elicit patient feedback regarding satisfaction with the medication management app

What Participants Will Receive
- A survey about their understanding of and adherence to their medication regimens.
- A free iPhone app – a tool that:
  - Streamlines medication management
  - Assists patients in maintaining an up-to-date medication list to share with their healthcare providers
  - A comprehensive medication evaluation that will be used to generate their updated medication list on their iPhone medication management application.
  - A demonstration of the app on their iPhone and assistance with the novel aspects of data entry. Patients will be prompted to confirm the accuracy of medication entries and gain the ability to modify information and customize dosing reminders. This feature will allow patients to schedule dosing reminders when they are most likely to take their medications.

What participants will do
- Meet with researchers for an in-depth medication review at the start of the study
- Agree to have their prescription medications filled at any Sparrow Pharmacy Plus location
- Track adherence to their medication regimen using iPhone app dosing reminders
- Respond to weekly reminders to update their medication list
- Respond to periodic surveys about their satisfaction with the application
- Participate in a post-study interview
- Anticipate 10-20 hours of time commitment over 6 months
Appendix 2. Best Possible Medication History.

Figure 6 – Best Possible Medication History Interview Guide* Used with Permission

Introduction
- Introduce self and profession.
- I would like to take some time to review the medications you take at home.
- I have a list of medications from your chart/file and want to make sure it is accurate and up to date.
- Would it be possible to discuss your medications with you (or a family member) at this time?
  - Is this a convenient time for you? Do you have a family member who knows your medications that you think should join us? How can we contact them?

Medication Allergies
- Are you allergic to any medications? If yes, what happens when you take [allergy medication name]?

Information Gathering
- Do you have your [prescription list or pill bottles] with you?
  - Use dose and all techniques when they have brought the medications into the home.
    - How do you take [medication name]?
  - How often or When do you take [medication name]?
- Collect information about dose, quantity, frequency for each drug. If the patient is taking a medication differently than prescribed, record what the patient is actually taking and note the discrepancy.
- Are there any prescription medications you (or your physician) have recently stopped or changed?
  - What was the reason for this change?

Community Pharmacy
- What is the name and location of the pharmacy you normally go to?
  - [Enter name of pharmacy] (Enter more than one).
  - May we call your pharmacy to clarify your medications if needed?

Over the Counter (OTC) Medications
- Do you take any medications that you buy without a doctor’s prescription? (Give examples, i.e., Aspirin). If yes, how do you take [OTC medication name]?

Vitamins/Minerals/Supplements
- Do you take any vitamins (e.g., multivitamins)? If yes, how do you take [vitamin name(s)]?
- Do you take any minerals (e.g., calcium, iron)? If yes, how do you take [mineral name(s)]?
- Do you use any supplements (e.g., glucosamine, St. John’s Wort)? If yes, how do you take [supplements name(s)]?

Eye/Ear/Nose Drops
- Do you use any eye drops? If yes, what are the name(s)? How many drops do you use? How often? In which eye?
  - Do you use ear drops? If yes, what are the name(s)? How many drops do you use? How often? In which ear?
  - Do you use nose drops/nose sprays? If yes, what are the name(s)? How do you use them? How often?

Inhalers/Patches/Creams/Ointments/Injectables/Samples
- Do you use inhalers, medicated patches, medicated creams or ointments, injectable medications (e.g., insulin)? For each, if yes, how do you take [medication name]? Include name, strength, how often.
- Did your doctor give you any medication samples to try for the last few months? If yes, what are the name(s)?

Antibiotics
- Have you used any antibiotics in the past 3 months? If yes, what are they?

Closing
This concludes our interview. Thank you for your time. Do you have any questions?
If you remember anything after our discussion please contact me to update the information.

Notes: Medical and Social History of the specific medications discussed, could be obtained with patient.

Adapted from University Health Network

When Should the BPHS be Completed?

It is recommended that medication reconciliation teams complete the BPHS early in the patient’s admission (once the decision to admit the patient has been made), and identify and reconcile discrepancies within the first 24 hours of admission. Each team will need to determine what best practice is for them.
Appendix 3. System Usability Scale.

**System Usability Scale**


1. I think that I would like to use this system frequently
   - Strongly disagree
   - Strongly agree
   1 2 3 4 5

2. I found the system unnecessarily complex
   - Strongly disagree
   - Strongly agree
   1 2 3 4 5

3. I thought the system was easy to use
   - Strongly disagree
   - Strongly agree
   1 2 3 4 5

4. I think that I would need the support of a technical person to be able to use this system
   - Strongly disagree
   - Strongly agree
   1 2 3 4 5

5. I found the various functions in this system were well integrated
   - Strongly disagree
   - Strongly agree
   1 2 3 4 5

6. I thought there was too much inconsistency in this system
   - Strongly disagree
   - Strongly agree
   1 2 3 4 5

7. I would imagine that most people would learn to use this system very quickly
   - Strongly disagree
   - Strongly agree
   1 2 3 4 5

8. I found the system very cumbersome to use
   - Strongly disagree
   - Strongly agree
   1 2 3 4 5

9. I felt very confident using the system
   - Strongly disagree
   - Strongly agree
   1 2 3 4 5

10. I needed to learn a lot of things before I could get going with this system
    - Strongly disagree
    - Strongly agree
    1 2 3 4 5
Appendix 4. Script for Exit Interviews.

Exit Interview – Patient Questionnaire

“Thank you for participating in the medication management study. I would like to ask you some questions to get your feedback about the iPhone app. Rather than taking notes, I’d like to audio-record your responses so that I capture all of your comments. Your responses will remain confidential and we will not use your name in any presentation or publication. Before we start our interview, I’d like you to complete a brief survey, which I hope will trigger your memories about using the app. Our session will last about 20 minutes, after which you’ll receive your $25 iTunes gift card incentive. Thank you!”

1. Did the app help you to manage your medications? (patient empowerment)
   If “yes” probes:
   - What made it successful?
   - What did you learn from the app?
   - How did using the app alter your interactions with your doctors in the clinic?
   - How did the app alter your interactions with your pharmacist?
   If “no” probes:
   - Can you tell me more about why it did not?

2. Did the app change how you take your medications? (adherence)
   If “yes” Probes:
   - How did the app change your medication taking behavior?
   - What was successful?
   - Can you tell me about any problems you encountered?
   If “no” probes:
   - Can you tell me more about why it did not?

3. What did you like about the app?
   Probes:
   - Can you talk a little bit about the app’s design and layout?
   - What is your opinion of specifying “preferred dosing times” up front?
   - What did you think about the dosing alerts?
   - Can you tell me about taking pictures of labels to add medications to your list?
   - How about how you navigated the app?
   - How easy was it to contact the researchers for questions/concerns?
4. **What did you dislike about the app?**
   **Probes:**
   - Can you tell me about any problems you encountered while using the app? **For example:**
     o Speed – syncing or uploading medication label pictures
     o Random logouts
     o App installation
     o App upgrade
     o Medications “falling off” the list

5. **What would you do to improve the app?**
   **Probes:**
   - How can we make it easier to **add new medications**?
   - How can we **simplify navigation**?
   - How can we make the **scheduling more intuitive**?

6. **What was your overall impression of this medication management app?**
   **Probes:**
   - Would you **recommend this app to a friend**?
   - If this app were available on the **“App Store,” how would you rate it (0-5 stars)**

Appendix 5. Morisky Medication Adherence Scale (MMAS-8).

©Morisky Medication Adherence Scale (MMAS-8-Item). This is a generic adherence scale and the name of the health concern can be substituted in each question item.

You indicated that you are taking medication for your (identify health concern, such as “high blood pressure”). Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your [health concern] medication.

(Please check your response below)

<table>
<thead>
<tr>
<th>Question</th>
<th>No=1</th>
<th>Yes=0</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you sometimes forget to take your [health concern] pills?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your [health concern] medicine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. When you travel or leave home, do you sometimes forget to bring along your [health concern] medication?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Did you take your [health concern] medicine yesterday?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. When you feel like your [health concern] is under control, do you sometimes stop taking your medicine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your [health concern] treatment plan?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. How often do you have difficulty remembering to take all your medications?

(Please circle your response below)

Never/Rarely............................................4
Once in a while.......................................3
Sometimes.............................................2
Usually..................................................1
All the time.............................................0