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

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Abstract

**Purpose/Specific Aims.** National sources describe the need for patient-centered approaches to improve medication management systems. We propose to design, test, and validate a novel medication management mobile application using optical character recognition (OCR) software that scans and auto-populates drug name, dosing instructions, and dosing reminders. Upon development, the following specific aims will be tested: 1) to assess accuracy of data entry via OCR; 2) to test acceptability of the software by patients, providers, and pharmacists; 3) to determine patient: a) adherence to medications and b) acceptance of software-generated reminders to update medication lists; and 4) to evaluate fixed and variable costs of the system.

**Rationale/Significance of Study.** Sparrow Health Systems and Michigan State University have the opportunity to pioneer the development of a patient-centered approach to managing complex medication regimens using mobile technology. Such technology shows promise for improving health outcomes for vulnerable patients and simultaneously empowers them to play an active role in their own healthcare. Our approach addresses the Joint Commission’s National Patient Safety Goals for medication reconciliation, which have been difficult for many facilities, including Sparrow, to achieve.

**Approaches, Design, Setting, Sample, Methods.** Our proposal is a two-phase study: Phase 1) to develop, modify, and pretest software to assess its reliability and to establish benchmark accuracy of OCR data entry, and Phase 2) a pilot study of 20 patients from a Sparrow-affiliated primary care clinic and insured by Sparrow Physicians Health Network. Once consented, patients will undergo a comprehensive medication reconciliation performed by Sparrow-employed physicians-in-training (to engage young physicians in research opportunities). Medication labels for each prescription drug will be generated at study onset by Sparrow Pharmacies. Patients will scan the labels with their smart phones for incorporation into the mobile application via OCR technology. Patients will confirm the accuracy of medication entries and retain the ability to modify information and customize dosing reminders, which will alert according to the dosing instructions specified on the medication labels. Patient responses to dosing reminders will be tracked by the software for assessment of adherence rates. Patients will be prompted to update their lists on a weekly basis – new medications can be entered via OCR (prescription drugs) or barcode scanning (over-the-counter medications) and existing medications can be modified as necessary. Patients’ medication lists will become a “single source of truth” that they maintain – both on their own smart phones and within a remote, secure database – and can share with providers at point-of-care.

**Main Research Variable(s).** We will collect demographic and health data (independent variables) and assess accuracy of OCR data entry, patient/provider/pharmacist satisfaction with the application, and adherence to medication regimens and update reminders (dependent variables). We will also measure costs of the system for various stakeholders.

**Future Funding.** The prototype generated from the proposed study offers opportunity for several enhancements that could be tested among a broader population. We have identified several options for future funding: the National Patient Safety Foundation, NIH-sponsored Small Business Technology Transfer, Michigan Pharmacists Association, and the Agency for Healthcare Research and Quality.
Purpose and Specific Aims

**Purpose.** Medication safety and management are essential to high quality patient care, yet evidence from national sources document need for improved processes that focus on a patient-centered, integrated medication management system\(^1\). In response, we propose to develop a novel approach to medication management by integrating existing health information technologies in a manner that empowers patients to play an active role in their health. We will transform a medication management smart phone application by merging it with optical character recognition (OCR) technology. Patients can then scan individual medication labels to generate and modify their medication lists, rather than by manually entering drug and dosing information. Once constructed, a feasibility/acceptability study of this patient-centered smart phone application will be conducted to determine feasibility of this approach to script entry and physician and patient acceptability of this single source document to coordinate and prompt adherence to all medications. In essence, this list will become a “single source of truth\(^2\),” which will be patient-owned and maintained on the patient’s personal smart phone and simultaneously in a remote, secure database that could ultimately be accessed and reviewed by health professionals – upon patient permission – at any point of care.

To achieve these inter-related goals we will design, test and validate OCR software that scans and auto-populates drug name and dosing instructions into a mobile application that stores this information and generates dosing reminders. Using this system, the following **specific aims** will be tested: 1) to assess accuracy of data entry via OCR (patient, software developer, and research physician/pharmacist will each confirm accuracy of data input); 2) to test acceptability of the software by patients, providers, and pharmacists; 3) to determine patient: a) adherence to medications and b) acceptance of software-generated reminders to update medication lists; and 4) to evaluate the fixed and variable costs of the system.

**Innovation: How will this transform care?**

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\(^3\). Medication reconciliation is a complex and error prone process, particularly for patients taking multiple medications, which are often prescribed by multiple providers and dispensed at different pharmacies. Medication reconciliation is typically performed by nurses and modified by physicians, often relying on patient recall and review of outdated medication lists to generate an “updated” medication list, which is manually entered into an electronic medical record (EMR). This process often leads to inaccurate information, which can be perpetuated in the EMR. Presently there is no coordinated system to track medication changes among different systems of care or among multiple providers, which puts vulnerable patients at risk for developing adverse events. Furthermore, patients with complex medication regimens have few tools to actively assist them in managing their own medication lists. The use of prescription reminder applications (“apps”) holds promise for empowering patients to maintain updated medication lists; however, entering medication information into such applications is done manually, which is both cumbersome and prone to inaccuracies. Many retail pharmacies have their own prescription reminder “apps” and patients can scan barcodes to automate prescription refill requests using a mobile device. Unfortunately, the barcodes affixed to dispensed medications contain proprietary information specific to the dispensing pharmacy, a process that is not regulated by the Food and Drug Administration (FDA)\(^4\). Given that there is no mandate to standardize medication information on medication labels dispensed to patients, we propose a system using OCR to read labels and transpose the medication information into a medication reminder application, obviating the need for a standardized barcode system. This approach is innovative in its simplicity – using existing technologies (OCR and medication reminder apps) as a means to integrate a currently disjointed system, while simultaneously empowering patients to manage their own medication lists and improve adherence by way of app-generated dosing reminders.
Background, Significance, and Rationale

**Background.** The Joint Commission requires that all health systems "accurately and completely reconcile medications across the continuum of care," and this mandate is part of National Patient Safety Goal 03.06.01. The process of medication reconciliation is becoming more complex due to the aging United States population; patients are taking multiple medications, which are often prescribed by multiple providers and dispensed at multiple pharmacies. Currently there is no coordinated system to track medication changes among different systems of care or among multiple providers, putting vulnerable patients at risk of adverse events. A recent study found that most emergency hospitalizations in elderly patients are related to a few commonly prescribed medications, including blood thinners, insulin, and oral hypoglycemic agents. The authors posited that improved management of these medications has the potential to significantly reduce hospitalizations for adverse drug events in older adults.

Currently, medication reconciliation is a time-consuming task completed by nurses who interview patients or review with them each medication they bring to the visit. Not surprisingly, this often leads to inaccurate information that is perpetuated in EMRs. Furthermore, one of the biggest challenges in healthcare today is sharing information electronically. Information entered into one EMR is not easily shared, which creates significant barriers to medication management. Vulnerable patients take multiple medications and often lack an updated medication list. Even after comprehensive medication reconciliation, patients’ medication lists seldom follow them across care settings. Thus, new drugs may be prescribed that are therapeutic duplications or potentiate the risk of drug-drug interactions.

Bar-code technology improves the safety of medication administration. As noted above, barcodes affixed to prescription medication labels at time of dispensing include proprietary information specific to the dispensing pharmacy, a process that is not regulated by the FDA. Further, information contained on medication labels are regulated by State Boards of Pharmacy, creating heterogeneity among the type of information required on medication labels to patients and its layout. Therefore we propose using optical character recognition (OCR) technology to electronically capture drug and dosing information from medication labels and impute the data into the respective fields within a medication reminder mobile application that will empower patients to play a more active role in maintaining their own medication lists. In addition, the software application will have the ability to scan universal product codes (UPC) from over-the-counter (OTC) medications and incorporate this information into patient medication lists. The ability to simultaneously track prescription and OTC medications makes this application comprehensive, particularly given the need for patients and providers to monitor drug-drug interactions. Furthermore, the medication reminder application will be programmed to send patients weekly alerts to update their medication lists, as well as to monitor their adherence to drug regimens by means of a dosing reminder system. In the end, patients will have a portable – and updated – medication list to share with their medical providers, regardless of their location of practice.

**Significance.** This application addresses an issue of critical importance for both patient safety and transitions of care, particularly given the lack of inter-operability among EMR systems within our local community. This work is significant because it initiates and tests a patient-centered approach to medication management that prompts patients to adhere to their medication regimen and to routinely update their personal medication list. This list will become a patient’s “single source of truth,” which can be shared with their medical providers upon granting permission. This work begins to solve a critical problem in medication management. For example, a patient admitted to Sparrow Hospital may receive care from multiple providers in the community (primary care physician, cardiologist, or neurologist), each with unique “updated” medication lists maintained within different EMR systems (Epic, Centricity, others). These medication lists may or may not reflect what medications the patient actually uses, and unfortunately there is no “clearinghouse” for medication lists to be merged and updated by the patient. Furthermore, health information exchange (HIE) in the Lansing community is in its infancy. While the Great Lakes Health Information Exchange (GLHIE) aims to improve coordination of care among different institutions and sites
of care, the technology to meaningfully exchange data is limited and access is cumbersome, leaving vulnerable patients with complex medication regimens at risk for adverse events.

Our application shifts the responsibility from a disjointed, inefficient system to the patient (or proxy) by empowering them to manage their own medication lists with a simple tool that can be updated in real-time (when medications are dispensed at the pharmacy), travels with them (housed within their smartphone), and is also maintained remotely in a HIPAA-secured remote database (with potential to transfer “patient-reported medication lists” electronically using Health Language Seven [HL-7] interfaces to promote healthcare informatics interoperability). This would be a step towards developing a patient-centric community health record bank (HRB), which some propose as a viable option for improving the current trajectory of health information technology (HIT).

The impact of our patient-centric medication management program would be two-fold. First, medication safety would be improved because patients would maintain their own “truly” updated, real-time medication list, which could be shared with any of their providers at point-of-care. This patient-centric medication list would empower patients to discuss their medication regimens with their providers, and alert providers to potential therapeutic duplications or drug-drug interactions. Furthermore, it would provide knowledge of medications prescribed by other physicians and identify use of over-the-counter (OTC) medications, which are often overlooked. Second, transitions of care would be improved, since patients would control their own medication lists and could share this information with their providers, regardless of care location (office, hospital, or nursing home) or which EMR was in use. This process has the potential to be further streamlined when inter-operability of EMRs comes to fruition via data transmission (possibly via HL-7) to-and-from remote, secured databases. Future expansion of this application (e.g. recognition of medication labels from other pharmacies) would broaden its generalizability, as medication information could be uploaded via OCR regardless of the dispensing pharmacy.

Mobile technology is an emerging method for monitoring patients’ adherence to prescription drug regimens. A recent pilot study evaluated the use of a smart phone medication reminder application in an underserved urban population and found high rates of user acceptability, increased rates of self-reported adherence to drug regimens, and a trend toward increase in medication refill rates. Sterns et al. reported similar improvements in adherence rates using a smart phone based medication management program (iRxReminder) for elderly patients recovering from stroke. This pilot demonstrated compliance with 83% of medication events and that real-time data collection was more accurate than patient-recall of medication dosing using personal diaries.

Rationale. Sparrow and MSU have the opportunity to pioneer the development of a patient-centered approach to managing complex medication regimens using mobile technology, which simultaneously empowers patients to play an active role in their own healthcare. Ultimately this approach conforms to National Patient Safety Goals, which have been difficult for many facilities, including Sparrow, to achieve.

Preliminary work. In a recent study conducted at Sparrow Senior Health Center, Sarzynski et al. studied the accuracy of provider-documented medication lists for elderly patients depending on whether or not they “brown bag” their medications for outpatient appointments. Among the cohort of 46 patients, average age was 79.8 and average medication use was 9.9 per patient per day, of which 5.7 were prescription drugs. Of patients who “brown bag” their medications for outpatient primary care visits, only 39% brought all of the medications that they reported taking. Furthermore, medication lists for these elderly patients contained many inaccuracies, including dosing errors, as well as errors of inclusion (chart list included medications that patient was no longer taking) and omission (chart list did not include medications that the patient reported taking). These results mirror other studies in younger populations that report frequent inaccuracies in physician-maintained medications lists.

Dr. Sarzynski has recently partnered with Electronic Medical Office Logistics (EMOL) Health LLC, a Michigan-based small business that maintains a portfolio of web applications that work to search, group, and organize medical information to streamline and improve processes for a wide range of healthcare
professionals. The primary focus of EMOL is data aggregation, which is valuable to many parties in the healthcare industry, including: patients, providers, pharmacists, and Government and Non-Governmental Third Party payors, because streamlined information is vital to determine compliance with treatments, cost/benefit analyses, and clinical trials. The EMOL system of data aggregation is continuously and extensively tested (>95% accuracy) in a private oncology practice and utilizes up to three OCR programs to correctly identify target information. Furthermore, EMOL has ongoing partnerships with investigators at MSU, including a Small Business Technology Transfer (STTR) grant focusing on technological approaches to improve symptom management for patients enrolled in cancer treatment studies. In addition, EMOL has developed custom interfaces using Apple® mobile devices.

Dr. Sarzynski is partnering with Ronald Melaragni (RM), RPh, Director of Sparrow Pharmacy Plus and David Weismantel (DW), MD, MS, Director of the Sparrow-MSU Family Medicine Residency Program. As collaborators, RM will assist in pharmacy data management and DW will assist in patient recruitment and data analysis.

Dr. Sarzynski has elicited ongoing support for this proposal from key personnel at Sparrow and MSU, including Michael Zaroukian, MD, PhD, Vice President & Chief Medical Information Officer, Sparrow Health System; William Wadland, MD, MS, Chair, Department of Family Medicine, Michigan State University; and Kevin Foley, MD, Chief, Geriatrics Division, Department of Family Medicine, Michigan State University. In addition, Dr. Sarzynski has elicited the expertise of Wayne Seiler, Director of Business Development, SRS Pharmacy Systems – the hardware and software vendor for medication labels generated by Sparrow Pharmacies – in order to develop and refine this proposal. Please see letters of support from these key personnel (pages 15-24).

**MSU Technologies & Spartan Innovations.** A version of this proposal was submitted to MSU Technologies in 2012 and underwent an initial screening report. We will engage in further discussions with MSU Technologies and Spartan Innovations pending further development of the software.

**Approach**

**Design.** The proposed project will be a two-part study. The studies will be conducted over 1 year according to the timeline provided (page 14).

**Phase 1.** Once the software is designed and adapted to the smartphone (iPhone), tests will begin using “dummy” data to preview the system. Accuracy will be defined as the percentage of 10 unique data field entries entered correctly (patient name, pharmacy name, prescription number, medication name, dose, route, frequency, National Drug Code [NDC], prescribing provider, and refills remaining) by OCR extraction from pictures of medication labels. A preview of 20 prescription labels will be generated for this phase. These “dummy” prescription labels will be photographed for incorporation into the application by OCR technology. Accuracy percentages will be reported per prescription. In addition, we will preview data entry for 10 OTC medications by scanning their UPC codes; accuracy will be calculated similarly using drug name and dose as unique data fields.

**Phase 2.** Using a longitudinal descriptive design, we will conduct a pilot study of selected patients within a “controlled” medical system to test the four aims of the study as detailed below.

**Phase 2 – Pilot Study – Specific Approach**

**Sample.** For Phase 2, twenty patients will be recruited from the Sparrow Family Medicine Residency clinics who are insured by Sparrow Physician Health Network (SPHN), which incentivizes patients to use Sparrow Pharmacies to fill their prescriptions and to use Sparrow-affiliated hospital services for emergency and/or inpatient care.

**Inclusion criteria.** Patients must be >18 years old, take ≥3 medications, and have an Apple® iPhone (4th generation or beyond) with ongoing service or iPod Touch (5th generation).

**Exclusion criteria.** Minor children and incapacitated adults.
Setting. Patients receiving primary care at a Sparrow-affiliated outpatient clinic. Specifically, we will target a single teaching clinic, the Sparrow Family Medicine Residency Program to enroll patients and to engage Family Medicine Residents and Geriatric fellows to collaborate on this project.

Recruitment. Using Epic EMR, we have identified more than 300 patients that meet the inclusion criteria above. We will ask patients’ primary care providers (PCPs) to recruit patients from this pool on behalf of the investigators. Specifically, we will generate standardized explanations of the study and ask PCPs to invite patients to participate by any number of strategies: 1) sending a secure message via Sparrow MyChart (Epic EMR’s patient portal for communicating with medical staff); 2) sending a letter by mail; 3) personal invitation during an upcoming scheduled appointment; and 4) by personal phone call (Figure 1, page 37). In addition, we will also post advertisements for the study in the clinic waiting room, which will briefly explain the study and have a quick response (QR) code that directs potential patients to a website where they can learn more and pre-register. The rationale for choosing this setting and patient population is to focus on developing the proposed technology in patients that use a single pharmacy system. Therefore, adapting the OCR technology to read medication labels will begin by using medication information presented in the same format for imputing drug information into the mobile app database. Further studies will be needed in order to adapt this technology to medications dispensed at other pharmacies.

Variables

Independent variables: 1) demographic data (e.g. age, sex, socioeconomic status); 2) healthcare variables (e.g. co-morbidities, number of medications at index appointment, number of prescribing providers).

Dependent variables: 1) accuracy of data entry – percentage of medication data (patient name, pharmacy name, prescription number, medication name, dose, route, frequency, NDC, prescribing provider, and refills remaining) imputed correctly into the mobile application using OCR technology to read medication labels; 2) acceptance of the mobile medication management application (patients, providers, and pharmacy personnel); 3) patients adherence rates to a) medication regimen (by patient-self report, whereupon patients can attest to [or not] taking a dose of a medication via the alert/prompt dosing reminder function of the mobile app) and b) weekly software-generated reminders to update medication lists; and 4) fixed and variable system costs.

Outcome Measures

1. Accuracy of data entry via OCR – Accuracy will be assessed by multiple means during the study. Accuracy will be defined as the percentage of unique data field entries (patient name, pharmacy name, prescription number, medication name, dose, route, frequency, NDC, prescribing provider, and refills remaining) entered correctly by OCR extraction from pictures of medication labels. Accuracy percentages will be reported per prescription.

Accuracy will be assessed for each imputed medication, beginning at study onset (index appointment) and for all medications entered for the duration of the study (6-9 months). Accuracy will be ascertained by 3 methods (Figure 1, page 37):

a. Patient confirmation – when medications are entered into smart phone via app, patients will be prompted to confirm the accuracy of each medication entry

b. Software developer – by tracking patient responses to attestations of accuracy via the software prompts (above) and by comparing each medication label picture with entries made into EMOL’s secure, remote database

c. Physician/pharmacist confirmation – a researcher will compare each medication label picture with entries made into EMOL’s secure, remote database
Accuracy of data entry for OTC medications will be calculated similarly using drug name and dose as unique data fields (patients will be prompted to specify route and frequency).

2. **Acceptability/Use**
   a. **Patient acceptability/use.** We will ascertain acceptability of the system using surveys embedded into the mobile application. This approach improves response rates and stores data on the secure EMOL server for longitudinal analyses and mobile application surveys. These surveys will be generated at weeks 1 & 2, month 1, and monthly thereafter.
   b. **Provider acceptability/use.** We will distribute surveys to providers within the Family Medicine Residency Clinic who have provided care to enrolled patients at the end of our study.
   c. **Pharmacist acceptability/use.** We will distribute surveys to pharmacists within the Sparrow Pharmacy Plus network at the end of our study.

3. **Adherence.** Two rates of adherence will be measured:
   a. **Patient adherence to drug regimen.** 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.” Adherence will be measured as the proportion of drug events (each unique dose of each medication on the regimen) taken per patient per month, as reported by patient attestations using the mobile application and compiled by the software developer.
   b. **Patient adherence to weekly software-generated reminders to update medication lists.** Adherence will be measured as the percentage of reminders that were acknowledged and performed (if necessary) per patient per month, as reported by patient utilization of software-generated reminders and compiled by the software developer. At the conclusion of the study, we will attempt to validate patient attestations of adherence to reminders by comparing Sparrow Pharmacy medication lists with patient-updated medication lists on the remote database.

4. **System Costs.**
   a. **Fixed.** Cost to build the technology, prepare software, and maintain server space.
   b. **Variable.** Incremental costs required for increased bandwidth to service additional patients, and per patient cost for storing/retrieving information from servers.

**Instruments** – see appendix for specific instruments (pages 33-34)
   - **Patient acceptability/use.** Software-generated surveys at weeks 1 and 2, month 1, and monthly thereafter for duration of study.
   - **Provider acceptability/use.** Survey distributed by researchers at conclusion of study.
   - **Pharmacist acceptability/use.** Survey distributed by researchers at conclusion of study.
   - **Best Possible Medication History.** As defined by the High 5s Action on Patient Safety, will be used at index appointment (described below) to reconcile medications at study onset.

**Data Collection Schedule and Procedures.** All data – with the exception of provider and pharmacist surveys – will be collected using the EMOL Health remote, secure database. Researchers will have access to the database via EMOL’s website using a password-protected login. The data collection schedule will follow the format detailed in the timeline (page 14). Briefly, accuracy will be assessed at study onset (index visit, see description below) and for the duration of the study as new medications are added to patient’s regimens. Patient acceptability will be assessed at weeks 1 and 2, month 1, and monthly thereafter. Provider and pharmacist acceptability will be assessed at the completion of the study. Adherence to drug
regimens and software-generated reminders to update medication lists will be assessed on an ongoing fashion and reported monthly.

**Index Appointment.** The index appointment for initial medication reconciliation will be performed by HIPAA and IRB-trained physicians-in-training (Geriatrics Fellows or senior Family Medicine Residents, MD or DO) and will serve as an opportunity to engage in scholarly activity. The appointment will be made at a mutually agreed upon time and take place within the Family Medicine Residency site at no cost to the patient. Resident(s)/fellow(s) will be supervised by an attending physician, which will be arranged by the co-investigator Residency Program Director (DW). At the appointment the physician investigator will describe the study, answer questions, and obtain consent (Figure 1, page 37). Next, the physician investigator will obtain a Best Possible Medication History (BPMH) using the protocol defined by the High 5’s Project: Action on Patient Safety, a collaborative safety initiative developed by the WHO, The Joint Commission, and the US Agency on Healthcare Research and Quality (AHRQ)\(^22\).

Briefly, the patient will be asked to bring in their updated medication list (if they presently maintain one), as well as all medication containers for all prescription (oral, intravenous, inhaled, injected, etc.) and non-prescription medications (over-the-counter and supplements). The investigators will also have access to patients’ medication lists as documented in the Sparrow Epic EMR. During the appointment, medications will be reconciled, and the EMR will be updated to reflect each patient’s medication list. Next, physician investigators will inquire where each of the prescription medications is presently being filled. For medications not filled by Sparrow Pharmacy, investigators will request that these prescriptions be transferred or refilled at a Sparrow Pharmacy with a price-match guarantee.

Next, the researcher will assist the patient in downloading the mobile application to their smartphone and provide a tutorial and written brochure highlighting use of the application. The researcher will assist the patient to the pharmacy where duplicate medication labels will be printed (Figure 1, page 37). Finally, the researcher will demonstrate how to photograph the medication label with the patient conducting a return demonstration. Patients will be shown how to use the application, assess accuracy of the information auto-populated into the fields of the medication management application, and modify incorrect entries. The patient and researcher will jointly confirm the accuracy of the data entry (by prompt of the mobile application) for each entry that is made by taking a picture of the medication for incorporation into the program by OCR technology. The patient will then customize the application for dosing reminders (e.g. what time at “night” to alert for dosing evening medications). In the end, each patient will be given a brochure with key points and reference for technical assistance.

**Data Analysis and Interpretation.** We will generate descriptive statistics for the following outcomes: 1) accuracy of data entry (imputing drug info using OCR); 2) satisfaction with the application (patients, providers, and pharmacists); and 3) patients’ adherence rates to: a) drug regimens and b) weekly reminders to update medication lists. Given the small number of patients we will produce graphic displays that identify the number and percent of patients by salient characteristics adhering to medications over time and responding to surveys over time. Moreover we will describe both the attrition of patients who cease use of the app, and the patterns of missing data with respect to entering new scripts and OTC medications, replying to adherence prompts and to the surveys. These data will be critical to making summary assessments of accuracy and patient acceptability. The potential influence of baseline demographic characteristic will be assessed through the application of appropriate nonparametric univariate statistical procedures. All analyses will be conducted using SAS 9.1 (SAS Institute Inc, Cary, North Carolina).

Finally, costs of the system will be evaluated by separating into fixed costs (cost to build the technology, prepare the software, and maintain server space) 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). In addition, variable costs will be paired against levels of patient adherence to 1) medication regimens and 2) weekly reminders to update medication lists.
Research Priorities and Implications for Practice and Research

Information generated from the proposed pilot – accuracy of medication information entry, patient satisfaction with the program, and adherence rates using the technology – will direct future refinements to the application. The over-arching goal for developing the medication management application is to empower patients to play an active role in their healthcare. Patients can use the tool to share their updated medication list with any of their healthcare providers, which will be of particular importance for vulnerable patients who have multiple prescribing providers and who have frequent encounters with the healthcare system. The updated list can serve as a starting point for medication reconciliation, discussing appropriateness of medications, possible side effects, and drug-drug interactions. Addressing these issues is central to improving patient safety, and our proposal arms patients with a tool that will aid them in actively participating in such conversations with their healthcare providers.

Furthermore, we anticipate additional upgrades to our application in the future. First, it is feasible to extend the application to medications dispensed at other pharmacies by refining the OCR technology to accept medication data presented in different formats. Second, the application could be enhanced to read medication labels on non-flat surfaces (e.g. round pill bottle), which could be accomplished using the “panorama” feature of newer-generation smart phones. Third, the application could be expanded to other smart phone operating systems (e.g. Android). Fourth, the application could be upgraded to include a national drug database (e.g. Lexicomp or Medispan), which would allow real-time assessments of drug-drug interactions, regardless of which pharmacies a patient used. In addition, such databases contain pictures of medications, which could be included in the application as a useful adjunct to dosing reminders, especially when generic substitutions are made (changing the appearance of the pill). Lastly, with advancement of inter-operability in the future, it is feasible that patients’ medication lists housed in the “cloud” could be shared electronically with EMRs by request (and with permission) of the patient. This would improve transmission of information during transitions of care, particularly among patients who seek care from multiple providers and/or in multiple settings.

Future Funding Sources

We anticipate that start-up funding for this project will be used to develop the application and identify areas for improvement and enhancement. Thus the pilot will serve as a starting point for a larger project that would test enhancements to the application among a broader population. We have identified several options to apply for future funding:

1. National Patient Safety Foundation – Research Grants Program, which seeks to fund new, innovative projects directed toward enhancing patient safety in the US. The NPSF has consistently funded research related to improving medication management. Access to the Research Grants Program is located at: http://www.npsf.org/for-healthcare-professionals/programs/research-grants-program/
3. Michigan Pharmacists Association (MPA) – Foundation Grants, which has previously funded a Medication Assessment Program in collaboration with Wayne State University. Access to the Foundation Grants program is located at: http://www.michiganpharmacists.org/mpa/whoWeAre/foundation/grants/
Research on Human Subjects

If funded, the PI will obtain approval for the study from the MSU and Sparrow IRBs. Patients will be recruited by physicians-in-training under the supervision of DW (co-investigator), all of whom have the requisite HIPAA and IRB-training. The recruitment and consent process will follow as previously described (Figure 1, page 37). Any potential errors in the medication history (e.g. serious drug-drug interactions) will be immediately reported to the patient’s primary care physician (PCP).

Medical data, including patient names and medication lists will be 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. A remote, secure database will store updated medication entries as auto-populated by OCR interpretation of medication labels. All research personnel will have access to this database in a password-protected environment.

Patients will be identified numerically by sequential accession into the study. A master list indicating patient assignments will be secured on a single password-protected computer and housed separately from the master database used for data analysis. A master database that includes reference to de-identified patient data, including dependent and independent variables, will be housed in an electronic format on a password-protected computer. All data will retain minimal demographic information (age and sex), but will not contain names or medical record numbers. The electronic format will be utilized for statistical analysis.

With the development of any new medical information technology there are risks of breach of confidentiality, including unintended sharing of medication lists, which will be clearly explained in the consent process. The above procedures are intended to protect patients’ rights and prevent unintentional breaches of confidentiality.

Women, Children, and Minority Inclusion in Clinical Research

The study population is meant to be representative of a typical adult primary care population, without preference to gender or racial/ethnic group. Patients who are unable to legally consent themselves for inclusion in the study (e.g. children and incapacitated persons) and who do not have the requisite mobile technology (iPhone generation 4 or higher or iPod Touch 5th generation) will be excluded from the study. The purpose supporting the composition of this study is described above.

Facilities and Resources

Clinical Setting. Patients will be recruited from the Sparrow-MSU Family Medicine Residency Clinics located at:

1. Sparrow Family Health Center-Central (located adjacent to Sparrow Hospital in the Sparrow Professional Building). Central provides care for 20,000 patients annually. There are 5-6 full-time equivalent faculty and 10 upper level residents assigned to this site.

2. Sparrow Family Health Center-Mason (located 16 miles southeast of Lansing in the Mason Community Health Center). SFHC-Mason provides care for 9,000 patients annually. Two full-time equivalent faculty and six upper level residents are assigned to this more rural training site.

The index appointments for medication reconciliation will occur in a private patient room within the designated clinical sites under the supervision of an attending physician as arranged by the co-investigator Residency Program Director (DW).

Pharmacies. Sparrow Pharmacy Plus is an affiliate of Sparrow Health Systems offering full pharmacy services at 9 locations within the Greater Lansing Area. Each pharmacy location uses the same, coordinated software system – supported by SRS Pharmacy Systems. Medication labels produced at these pharmacies follow the same format and include the requisite information for OCR interpretation.
Technical Support. EMOL Health operates its data center from inside the Waveform facility. By using Waveform, EMOL Health is able to focus on security and server operations knowing that an independent team of experts is handling connectivity, energy management and availability. The technical staff at EMOL Health manages security and backups with a multi-layered approach. The first layer of security is the information technology (IT) policies EMOL Health follows, ensuring proper adherence to standards and documentation. The second layer of security is the network firewalls with intrusion detection. A third layer of security is a server backup system with point-in-time recovery. The fourth level is host-based intrusion detection systems (IDS) and active response, first blocking out and then alerting EMOL Health technical staff to any suspicious system activity. The technical team at EMOL Health understands that security is an ever-evolving process that requires constant adjustment to facilitate the appropriate balance of data availability and security. EMOL Health uses state-of-the-art facilities and processes to make sure a data is safe and available to the right person at the right time.
APPENDICES

1. Reference List (pages 12-13)

2. Timetable for Accomplishing the Work (page 14)

3. Letters of Support (pages 15-23)
   a. Kevin Foley, MD, Chief, Geriatrics Division, Department of Family Medicine, Michigan State University (page 15)
   b. Michael Zaroukian, MD, PhD, Vice President & Chief Medical Information Officer, Sparrow Health System (pages 16-17)
   c. Wayne Seiler, Director of Business Development, SRS Pharmacy Systems (page 18)
   d. Electronic Medical Office Logistics (EMOL) Health LLC – price quote for software and application development and description of work (page 19-23)

4. Mandatory Letters of Support (page 24)
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5. Biographical Sketches of All Key Personnel (pages 25-32)
   a. Erin Sarzynski, MD, MS, Assistant Professor, Geriatrics Division, Department of Family Medicine, College of Human Medicine, Michigan State University (pages 25-27)
   b. Ronald Melaragni, RPh, Director of Sparrow Pharmacy Plus (pages 28-29)
   c. David Weismantel, MD, MS, Associate Professor, Department of Family Medicine, College of Human Medicine, Michigan State University, and Director of the Sparrow-MSU Family Medicine Residency Program (pages 30-32)

6. Instruments (pages 33-34)
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8. Budget Justification (pages 35-36)

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11. Statement Regarding Intellectual Property (page 38)
Reference List

The proposed study will be completed in 1 year. The first 3-6 months will be spent developing the software and performing initial tests to assess accuracy of data entry (feasibility). Identification of potential patients will occur simultaneously with software development. The remaining 6-9 months will be used for the pilot study, with the goal of enrolling all patients within the first 6 months to allow for a 6 month pilot.

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<th>Q4</th>
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<tr>
<td><strong>Software development</strong></td>
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<td><strong>Phase 1: Preliminary test of accuracy</strong></td>
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<td>Obtain IRB approval</td>
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<td><strong>Phase 2: Test aims in pilot study</strong></td>
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<td><strong>Aim 1: Assess accuracy of data entry via OCR</strong></td>
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<td>Patient Confirmation</td>
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<td>Software Developer</td>
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<td>Physician/Pharmacist</td>
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<tr>
<td><strong>Aim 2: Assess acceptability</strong></td>
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<tr>
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<td>Providers (end of study)</td>
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<td><strong>Aim 3: Assess patient adherence</strong></td>
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<tr>
<td>Medication Regimen</td>
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<td>Weekly Reminders to Update Med List</td>
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<tr>
<td><strong>Aim 4: Analysis of cost</strong></td>
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April 11, 2013

Barbara Given, PhD, RN, FAAN
Interim Director for the Center for Innovation and Research
Michigan State University / Sparrow Hospital

Dear Dr. Given and Selection Committee,

It is my pleasure to provide this letter expressing strong support for the research proposal submitted by Erin Sarzynski, MD titled, “Integrating Health IT to Develop a Patient-Centered Approach to Medication Management.”

As the Director of the Michigan State University College of Human Medicine’s Geriatric Division and the Program Director of the MSU-Sparrow Geriatrics Fellowship Program, I have worked extensively with Dr. Sarzynski as a trainee and more recently as a faculty colleague. She has assumed a lead role as a clinical researcher in our Division and distinguished herself among her peers through her scholarly accomplishments to date.

I have reviewed Dr. Sarzynski’s proposal and recognize that her idea is innovative in that it offers an easily disseminated, patient-centered approach to empower vulnerable patients to assume an active role in their health care by improving the process of medication reconciliation and their adherence to treatment recommendations. Moreover, I believe that long-term plans for this research can lead to changes in clinical practices that may significantly improve patient safety and reduce health care costs. She is well qualified to conduct the proposed research and has access to all required resources.

Funding of Dr. Sarzynski’s proposal will provide a unique opportunity for our incoming geriatric medicine fellows to collaborate with her and gain valuable research experience while under her supervision. As an endorsement of Dr. Sarzynski’s proposal, I have committed protected time to allow our fellows to participate in her pilot study.

I enthusiastically support Dr. Sarzynski’s proposal and hope that you will give it your full consideration. If you need additional information in support of Dr. Sarzynski’s grant application, please do not hesitate to contact me.

Sincerely,

Kevin T. Foley, MD, FACP
Associate Professor, Division of Geriatrics and Gerontology
Director of Education and Clinical Operation
Improving the health of the people in our communities by providing quality, compassionate care to everyone, every time

April 12, 2013

Barbara Given, PhD, RN, FAAN
Interim Director for the Center for Innovation and Research
Michigan State University / Sparrow Health System

Dear Dr. Given,

I am pleased to provide this letter of support on behalf of Erin Sarzynski, MD for her proposal, “Integrating Health IT to Develop a Patient-Centered Approach to Medication Management.” As Vice President & Chief Medical Information Officer at Sparrow Health System, I have had the privilege of discussing this proposal with Dr. Sarzynski and have provided her with feedback and suggestions regarding the project.

I find the proposed study innovative because it leverages increasingly common use of smartphone technology by consumers and combining it with optical character recognition (OCR) technology to engage patients in medication management. Patients would use their smartphones and the proposed software solution to capture and record medication names and dosing instructions directly from the labels on their medication bottles. This would allow patients to more easily develop an accurate, complete and up-to-date list of prescribed and dispensed medications. Such a list is an important prerequisite to medication reconciliation in the office or hospital. If successful, this technology can be adapted to nonprescription medications, vitamins and nutritional supplements, which Caregivers tend to omit from EHR medication lists due to incomplete information, time constraints or sheer volume. The software could then be configured to encourage patients to review and update the status of all medications, including those they are no longer taking, along with the reason why. This too will help ensure an accurate medication list and facilitate medication reconciliation by health professionals.

This patient-friendly and patient-centered approach to developing and maintaining a list of current medications puts patients at the center of their own medication management and helps identify discrepancies between what is prescribed and what the patient is actually taking. The application will have the ability to track patient adherence to medications, a function of mobile health technology that shows promise for improving the health of all and, especially, vulnerable patients.

While I have not had a chance to complete a full review of the methodology contained in the proposal, I am enthusiastic about the potential of a consumer-facing, smartphone-enabled strategy for patients to record and manage their medications, and am happy to lend my strong support for this MSU-Sparrow Center for Innovation and Research grant proposal. I admire Dr. Sarzynski’s steadfast commitment to improving quality and safety by combining information technology solutions and patient engagement to increase the accuracy and completeness of medication lists. I also admire her creativity, persistence and openness to
feedback in searching for more feasible and potentially successful ways of achieving these desired results.

I hope this information is useful. Please do not hesitate to contact me if I can provide any additional information in support of Erin’s grant application.

Best regards,

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS
Vice President & Chief Medical Information Officer
Sparrow Health System
825 E. Michigan Ave., P.O. Box 30480
Lansing, MI 48909-7890
Phone: (517) 802-2611; Assistant (Amy): (517) 802-2655
Fax: (517) 802-2700; Pager: (517) 228-9078
Email: michael.zaroukian@sparrow.org
April 8, 2013

Barbara Given, PhD, RN, FAAN
Interim Director for the Center for Innovation and Research
Michigan State University / Sparrow Hospital

Dear Dr. Given,

I am delighted to provide this letter of support on behalf of Erin Sarzynski, MD for her proposal, "Integrating Health IT to Develop a Patient-Centered Approach to Medication Management."

Presently, I am Director of Business Development at SRS Pharmacy Systems, a Michigan-based company that manages pharmacy software and prescription labeling for community pharmacies, including Sparrow Health System.

In this role, I have had several meetings with Dr. Sarzynski regarding her proposal, including joint meetings with Ronald Melanagni, RPh, Director of Sparrow Pharmacy Plus. I have provided insight regarding the process of maintaining pharmacy databases and labeling practices. Further, we have discussed the benefits of using optical character recognition (OCR) for use in reading our labels to auto-populate medication information into the proposed software. I believe this technology holds promise for streamlining medication management and empowering patients to maintain updated medication lists.

In summary, I recommend Dr. Sarzynski’s proposal for the MSU-Sparrow Center for Innovation and Research grant. I look forward to working with her in the future. Please contact me if I can provide any additional information in support of Dr. Sarzynski's grant application.

Regards,

Wayne Sellek
Director of Business Development
SRS Pharmacy Systems
1. Introduction

EMOL Health is submitting this proposal at the request of Dr. Erin Sarzynski. The purpose of this project is to develop an iPhone application that reminds patients to take their medications by simply taking a photograph of that medication and its prescription pill bottle. EMOL Health would be developing the client application and all required back end infrastructure to facilitate the collecting, storing, warehousing, and backing-up of all data for this project.

2. Proposed Work

EMOL Health proposes that an iPhone application be developed for the end user. EMOL Health also proposes that backend system be developed to facilitate the intricate components of this project that cannot be performed on the phone due to its limited processing capacity. In this project the mobile device will capture a picture of the prescription pill bottle that will be sent to EMOL Health servers for image processing. This processing will include optical character recognition (OCR) and then heuristic pattern matching to attempt to identify the following attributes:

- Prescribing Physician
- Route
- Dosage
- Refills
- Drug Name
- Dose Schedule and Frequency

Using the information above the servers will then inform the mobile phone application to configure itself for patient adherence reminders. In addition the application on the mobile phone will ask the study subjects survey questions to assess satisfaction.
3. **Statement of Work**

The following major tasks will be accomplished by the proposed work:

**Development and Deployment Tasks**

- Develop an iPhone Mobile Application
  - Event-Based Accounting
  - Adherence Tracking
  - Photo Capture
  - Secure API Communication
  - API Communication Exception Handling
  - API Response Processing
  - Patient Surveys
  - Patient Medication Dosage Changes
  - Patient Medication Changes
- Develop API
  - Secure Messaging Protocol
  - Image Compression and Meta Data (send)
  - Structured Data Response (receive)
  - Structured Fields Prompts
  - Backup/Restore Data to Phone
- Image to Structured Data System
  - Store Images for Later Validation
  - Decode UPC for Over Counter Drugs
  - Determine and Verify Fields
  - Prompt for Any Unknown Required Fields
- Configure System for 25 Subjects
- Develop System for Data Export
- Deploy and Test a Multiple Host PiTR (Point in Time Recovery) System to Ensure Zero Data Loss
- Remote Site Backup of All Collected Data

**Possible Additional Tasks**

- Custom reporting/queries
- Direct SQL access to warehouse
- Create a web-based query and reporting tool
- Supporting and fielding any technical support phone calls
4. Facilities and Resources

EMOL Health operates its data center from inside the Waveform facility. By using Waveform, EMOL Health is able to focus on security and server operations knowing that an independent team of experts is handling connectivity, energy management and availability. The technical staff at EMOL Health manages security and backups with a multi-layered approach. The first layer of security is the information technology (IT) policies EMOL Health follows, ensuring proper adherence to standards and documentation. The second layer of security is the network firewalls with intrusion detection. A third layer of security is a server backup system with point-in-time recovery. The fourth level is host-based intrusion detection systems (IDS) and active response, first blocking out and then alerting EMOL Health technical staff to any suspicious system activity. The technical team at EMOL Health understands that security is an ever-evolving process that requires constant adjustment to facilitate the appropriate balance of data availability and security. EMOL Health uses state-of-the-art facilities and processes to make sure a data is safe and available to the right person at the right time.
5. **Project Schedule and Cost**

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<td>Deployment Tasks</td>
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<td>Ongoing Data Collection</td>
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<td>Data preparation and Export</td>
<td>$3,600</td>
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<tr>
<td>Server Operational Costs</td>
<td>$3,000</td>
</tr>
<tr>
<td><strong>Project Total</strong></td>
<td><strong>$51,750</strong></td>
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EMOL Health would be able to have the system operationally ready for study subjects in three calendar months.

6. **Assumptions**

Data collection will not last longer than 9 months and the entire project will not last longer than 1 year.

There will be no more than 25 study subjects.

All study subjects will be on one health insurance plan.

All study subjects will go to the same pharmacy network.

Subjects will have no more than 10 medications.

Medication labels with be flat on the medication bottles, or a secondary flat label will be provided.

Everyone using the system has an iPhone 4 or newer with iOS 6.0.0 or newer.

The 25 subjects will not change once the project has started.

The designated individual receiving any data during the project is able to open a CSV, ZIP and/or JPG file.
7. **Background on EMOL Health**

EMOL Health has an industry-unique capability to parse data from physician dictation records, providing unmatched depth to our aggregated patient data. Additionally, EMOL Health has the capability to interact directly with patients via our Patient Reporting and Educational Systems (PRES) over the Internet, phone, SMS txt, or other mobile device.

Our unique, proprietary software also instantly and effortlessly finds, mines and aggregates all digital data from physician practices, whether from IT systems in labs, pharmacies, patient management systems, imaging centers or EMRs. Our software mines not only data in fixed fields but also less structured data found in the physician dictations, nursing notes, faxes and other scanned documents. This is done via a combination of Natural Language Processing (NLP) and Optical Character Recognition (OCR) technologies.

Further our PRES products enable us to collect patient-reported outcomes, improve symptom management and patient education, and increase adherence and compliance to national treatment guidelines; both in the office and at home. Our PRES systems are clinically proven and have been developed to be user-friendly, self-care oriented, and intuitive. The PRES applications utilize a centralized database that is accessible from anywhere in the world and on most mobile devices.

In addition to EMOL Health’s unique technological solutions, our staff has a thorough understanding of oncology practices and patients. When developing products, our staff is continually advised by an experienced oncologic physician and oncology practice manager. Our products are beta-tested in large oncology practices.

8. **Contact Information**

Contact information for EMOL Health is provided below:
Contact Brian Decker
E-Mail: Brian.Decker@EMOLHealth.com
Phone: 248.434.1670 x201
Fax: 248.928.7036
Address: 5158 Elmhurst Ave, Royal Oak, MI 48073
URL: http://www.EMOLHealth.com
April 2, 2013

Michigan State University/Sparrow Health System
Center for Innovation and Research
Attn: Barbara Given, PhD, RN, FAAN and the
Advisory Board of the Center for Innovation and Research
Sparrow Professional Building
1200 E. Michigan Ave, Suite 305
Lansing, MI 48912

Dear Selection Committee:

I am pleased to write in support of the project entitled, “Integrating Health IT to Develop a Patient-Centered Approach to Medication Management”, for which Dr. Erin Sarzynski is the principal investigator. The project is very important in that it addresses a major topic related to patient-centered care concerning accurate and safe medication management as an information technology in the care of aging persons. The proposal is highly innovative by transforming existing medication management for the use of cell phone technology and optical care recognition (OCR) so that patients can generate and modify the medication list by scanning their own individual medication labels rather than entering drug dose and dosing information manually. The major goal of this research is to conduct a feasibility study using this new technology to enable patients to manage their own medications, thereby improving medication safety and compliance.

As her Department Chair, I am fully in support of Dr. Erin Sarzynski’s role as the principal investigator for the proposed project. The Department of Family Medicine will provide at least 3% in-kind effort of Dr. Sarzynski to the project. In addition, the Department is fully in support of the effort that Dr. David Weismantel, Sparrow-MSU FM Residency Program Director, will provide to the success of the project. Dr. Weismantel is an MSU paid faculty member within the Department of Family Medicine, but leased to Sparrow Health System to be the overall program director. Dr. Weismantel has advanced training in epidemiology and research. He can serve as an on-site champion for the success of this project. Under his directorship is the direct management of all clinical care in the proposed clinical sites for this project. An additional advantage of this project is that it will mentor senior residents in scholarship. It is also anticipated that the fellows in the Geriatric Fellowship program, sponsored both by Michigan State University and Sparrow Health System, will be active participants.

I feel that this project is both feasible and achievable because of the mutual support of both Michigan State University and Sparrow Health System. The proposed practice sites are ideal settings for implementation and application of this project. It is anticipated that this project will result in further extramural funding and expanded studies.

Sincerely yours,

William C. Wadland, MD, MS
Professor and Chair
Department of Family Medicine

MSU is an affirmative-action, equal-opportunity employer.
A. Personal Statement

I am an energetic, young clinician researcher hoping to develop a career path in medication management. My interest in research stems from my Master’s Degree program where I was a co-author on a grant that funded projects leading to several peer-reviewed publications. Thereafter I pursued research interests in medical school and residency, including a study highlighting iron-deficiency as a complication of proton pump inhibitor use, the first such report to appear in the medical literature. My interest in medication management expanded during my geriatrics fellowship training when I conducted a pilot study to test the effects of the “brown bag” intervention as a method to accurately reconcile elder patients’ medications. Results of this project have been presented at two national geriatrics meetings, including acceptance at the Presidential Poster session for the American Geriatrics Society annual meeting. Further, I was successful in obtaining grant funding from Blue Cross Blue Shield Foundation of Michigan in order to complete the project and disseminate its results, including a pending manuscript submission. While I am early in my academic career, I have identified senior academicians who have mentored me, provided constructive feedback for improving my research proposals, and ultimately developed collaborative relationships. I see the MSU-Sparrow Center for Innovation and Research grant funds as an opportunity to foster my ambitious career plans and use as a stepping stone to obtain future funding at a national level.

B. Positions and Honors

Positions

2000-2001  Research Assistant, Department of Entomology, Michigan State University, East Lansing, MI
2001-2003  Graduate Research Assistant, Department of Entomology & Nematology, University of Florida, Gainesville, FL
2007-2010  Clinical Instructor, Department of Medicine, Michigan State University
2010-2011  Clinical Instructor, Department of Family Medicine, Geriatrics Division, Michigan State University
2011-Pres  Assistant Professor, Department of Family Medicine, Geriatrics Division, Michigan State University, College of Human Medicine, East Lansing, MI

Honors

2005  17th Annual Summer Institute in Geriatric Medicine, Boston University Medical Center
2005  Professor Leonard J. Luker Scholarship ($5,850) for research related to diseases of aging and geriatrics

2010 Outstanding Resident in Endocrinology, Michigan State University Internal Medicine Residency at Sparrow Hospital Annual Graduation and Awards Ceremony

2010 Outstanding Senior Resident – Resident-voted, Michigan State University Internal Medicine Residency at Sparrow Hospital Annual Graduation and Awards Ceremony

2010 Outstanding Senior Resident – Faculty-voted, Michigan State University Internal Medicine Residency at Sparrow Hospital Annual Graduation and Awards Ceremony

C. Selected Publications


Sarzynski E, Liburd O. Effect of trap height and within-planting location on captures of cranberry fruitworm (Lepidoptera: Pyralidae) in highbush blueberries. Forest and Agricultural Entomology, 2004;6:199-204.


Sarzynski E, Wagner D, Noel M. Expanding the observed structured clinical examination (OSCE) to teach documentation, coding, and billing. Med Teach, 2013 in press.

D. Research Support

Ongoing

Sarzynski E (PI) 5/4/12-5/3/13
Blue Cross Blue Shield Foundation of Michigan
Physician Investigator Research Award Program ($10,000)
Outpatient Medication Reconciliation: Does Accuracy Improve if Patients “Brown Bag” their Medications?

The study’s aims are: To determine the completeness and accuracy of physician-documented medication lists; to determine discrepancies (inclusion/omission and dosing errors) between medication lists documented by physicians and those reported by patients; to compare discrepancies between patients that bring their medications to outpatient appointments (“brown-baggers”) and patients who do not; to determine factors associated with medication list discrepancies
Completed

Liburd O (PI) 2002
Florida Fruit & Vegetable Research & Education Foundation, Inc. ($39,692)
Developing an IPM Program for Management of Flower Thrips in Florida Blueberry Plantings

Specialty Crop Research Grants Program.
Role: Co-Investigator

The study’s aims were: To develop and evaluate the use of environmentally sound pest management programs, including non-chemical mechanisms and novel biological insecticides, to control flower thrips in Florida blueberry plantings.
BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. DO NOT EXCEED FOUR PAGES.

NAME
Ronald J. Melaragni, RPh

POSITION TITLE
Administrative Director – Sparrow Pharmacy Plus

eRA COMMONS USER NAME (credential, e.g., agency login)

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

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A. Personal Statement

I am a Registered Pharmacist with more than 40 years’ experience in both clinical and retail settings. The latter part of my career has been in pharmacy leadership capacities, but I have never strayed far from a pharmacist’s primary purpose—meeting the needs of customers, providing excellent customer service, and improving the health-related outcomes of my patients.

Throughout my career I have been integrally involved in strategic planning, policy development, and advancing public health at the employer and state levels. To that end, my present and past professional affiliations include: Michigan Pharmacists Association -- President (2008); -- Political Action Committee; - - Board liaison to several local chapters; -- Year 2000 Advisory Board; Michigan Pharmacy Foundation Board of Trustees; Michigan Society of Community Pharmacists Board of Directors; Michigan Medicaid Pharmacy Provider Liaison committee; Capital Area Pharmacists Association; Sparrow Health System Pharmacy & Therapeutics committee.

As a leader, I have been involved in developing special projects to enhance the work of pharmacy staff and their value to the health system and its customers. For example, I played an ancillary role in preparing for and implementing a new EMR program as part of system-wide adoption. Also, shortly after being hired by Sparrow Health System, I streamlined a dysfunctional multiple-pharmacy group and grew it into a well-organized retail pharmacy business. I have always embraced new technology as it presented itself, championing systems that better served customers and improved pharmacy operations, and resulted in improved patient health care outcomes.

By nature, I am a collaborator. I frequently partner with other health system units to address needs, resolve issues, implement systems, and work to enhance the organization.

As Administrative Director of a 5-pharmacy retail chain affiliated with a well-respected mid-Michigan health system, I am confident that I bring an operational perspective to devising solutions for potential issues during project implementation. I am excited about this opportunity to share my expertise toward a change that will affect people’s lives in such a positive way.

B. Positions and Honors

Positions
1965 – 1977    Franklin Pharmacy – Flint, Michigan - Pharmacist – Pharmacy Manager – Co-Owner/Manager
1997 – 2000  Kessel Pharmacy (acquired by Kroger) – Flint, Michigan - Pharmacist – Pharmacy Manager – Pharmacy Administrator (9 stores)
2000-Present  Sparrow Pharmacy Plus [affiliated with Sparrow Health System] – Lansing, Michigan Administrative Director (5 locations)

Honors

2012  Michigan Pharmacist of the Year (2012)
BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. DO NOT EXCEED FOUR PAGES.

NAME
David Weismantel

POSITION TITLE
Associate Professor

MSU WEISMANTEL

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

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<td>University of Michigan Medical School, Ann Arbor, MI</td>
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<td>Mayo Graduate School of Medicine, Rochester, MN</td>
<td>Residency</td>
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<tr>
<td>University of Arizona College of Medicine, Tucson, AZ</td>
<td>Fellowship</td>
<td>1998</td>
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<td>Michigan State University, Department of Epidemiology, East Lansing, MI</td>
<td>Masters</td>
<td>2003</td>
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<tr>
<td>Harvard School of Public Health</td>
<td>Leadership Dev</td>
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A. Personal Statement

My role as co-investigator is to assist with the research design, data collection, and analysis. I am an Associate Professor of Family Medicine with degrees in Medicine and Epidemiology. I have extensive experience in assisting colleagues, resident physicians, and students in the design and execution of both prospective and retrospective studies. In addition to my research and informatics activities, I am actively involved in clinical practice and educational administration. My combination of clinical and informatics skills will ensure that all data collection, analyses, and presentations are clear and appropriate.

B. Positions and Honors

Positions

1993-1996 Senior Associate Consultant, Mayo Clinic, Department of Family Medicine, Rochester, MN
1996-1999 Instructor in Family Medicine, Mayo Medical School, Rochester, MN
1997-1999 Assistant Director, Scottsdale Healthcare Family Practice Residency Program, Scottsdale, AZ
1999-1999 Clinical Assistant Professor of Family & Community Medicine, University of Arizona, College of Human Medicine, Tucson, AZ
1999-2006 Assistant Professor, Michigan State University, Department of Family Medicine, East Lansing, MI
2000-2001 Family Practice Clerkship Coordinator (Lansing), MSU, Department of Family Medicine
2001-Pres Peer Review, Journal of Family Medicine
2003-2004 Assistant Editor, Family Practice Inquiries Network (FPIN)
2008-2012 Assistant to the University Physician, MSU
2009-2012 Associate Chair, Clinical Affairs, MSU, College of Human Medicine, Department of Family Medicine
2006-Pres Associate Professor, MSU, Department of Family Medicine, East Lansing, MI
2012-Pres Associate Chair for Graduate Medicine Education, MSU, Department of Family Medicine
2012-Pres Director, Sparrow/MSU Family Medicine Residency Program, Lansing, MI
Honors

1997-1998 Outstanding Teacher of the Year, Scottsdale Healthcare Family Practice Residency
2009-2012 Named one of the “Best Doctors” in America, Best Doctors, Inc.
2010 Alpha Omega Alpha Honors Medical Society – Faculty Inductee
2011 College of Human Medicine Outstanding Clinician Award

C. Publications


D. Research Support

Ongoing
U01/DD000498
Reed (PI) 6/1/12-5/31/16
Centers for Disease Control and Prevention
Data Coordinating Center for Autism and Other Disabilities
The purpose of this cooperative agreement, with CDC, is for the Michigan State University Biomedical Research & Informatics Center to serve as the data coordinating center (DCC) for a multicenter study to support the collection of clinical data and research data management related to developmental disabilities, such as Autism Spectrum Disorders (ASD) and other Developmental Disabilities (DD). The project involves the creation of a comprehensive, web-based clinical research management system application to manage work flow, enroll and track subjects, capture and house clinical and biological data, track the chain of custody of samples, capture the product of a substantial medical records abstraction operation, and provide medical coding services for all text field in both interview and medical records data.
Role: Co-Investigator

Completed
1R01HS020046-01
Malouin (PI) 9/30/10 – 6/30/12
Comparative Effectiveness of Primary Care Practice Transformation by Two Insurers
The proposed research will examine the comparative effectiveness of two different PCMH strategies, including different payment and facilitated support interventions, utilized by two different regional health plans, on improvement in outcomes - cost, quality and experience in pilot practices.
Role: Co-Investigator

D56HP05217
Ferenchick, Gary S (PI) 6/01/09-7/31/11
HRSA
Predoctoral Training in Primary Care
This grant is focused on the specific objectives aimed at integrating key educational competencies with an EHR system: 1) To develop an exportable educational program to train students in the use of EHR systems; 2) To expand and transform our successful projects linking the Clerkship Directors in Internal Medicine (CDIM) curriculum to mobile technology by linking key CDIM curricular objectives to an electronic health record (EHR) system in a manner that facilitates rapid, workflow-integrated access to relevant curricular objectives and content; 3) To develop data systems for specific health conditions that connect trainee behaviors (e.g., reviewing information, ordering tests, updating problem lists, drug-drug interaction queries, responding to alerts and reminders, using evidence based decision-support tools, communication and resource utilization) to the competencies underlying the behaviors and the standards for demonstrating competencies in specific health conditions.
Role: Co-Investigator/Statistician

A0418A
Hol trop JS (PI) 1/1/07 – 12/31/09
American Academy of Family Physicians Foundation.
*Depression, Anxiety and Health Risk Behaviors: What is the Real Scope of the Problem in Primary Care?*
Role: Co-Investigator
Instruments

**Patient acceptability/use.** Sample survey questions: “In the past week, did you . . .”
1. Use the application?
2. Modify your medication list? (e.g. add/delete a medication, change dose, OTCs)
3. Encounter problems with the application? (if yes, prompt for explanation)
4. Respond to dosing reminders?
5. Find the application helpful?
6. Others

**Provider acceptability/use.** Sample survey questions: “In the past 9 months, did you . . .”
1. Provide care to patients using the application?
2. Engage patients in discussing their medication regimens using the application?
3. Did patients prompt you to review their medications as a result of the application?
4. Have ideas for improvements to the application?

**Pharmacist acceptability/use.** Sample survey questions: “In the past 9 months, did you...”
1. Assist patients in using the application (e.g. take picture of medication label)?
2. Have ideas for improvements in the application?
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 medication list or pill bottle(s) with you?
- Use show and tell technique when they have brought the medication with them?
  - How do you take (medication name)?
  - How often or When do you take (medication name)?
- Collect information about dose, route, and 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?
  (Anticipate 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., multivitamin)? If yes, how do you take (vitamins name(s))? (If more than one, take them together or separately?)
- Do you take any minerals (e.g., calcium, iron)? If yes, how do you take (minerals name(s))? (If more than one, take them together or separately?)
- 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 names? How many drops do you use? How often? In which eye?
- Do you use ear drops? If yes, what are the names? How many drops do you use? How often? In which ear?
- Do you use nose drops/nose sprays? If yes, what are the names? 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 in the last few months? If yes, what are the names?

Antibiotics
- Have you used any antibiotics in the past 3 months? If so, 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 if not specifically described in the chart/file, may need to be clarified with patient.

Adapted from University Health Network

When Should the BPMH be Completed?
It is recommended that medication reconciliation teams complete the BPMH 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.
Research Grants Program
BUDGET WORKSHEET

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**Budget Justification**

**Principal Investigator:** Erin Sarzynski, MD, MS – Assistant Professor, Department of Family Medicine, Geriatrics Division, MSU, will assume primary responsibility for scientific aspects of the project, including development and oversight of overall methodology, including obtaining IRB approval, ensuring requisite HIPAA and IRB-training for all research personnel, overseeing patient recruitment performed by physicians-in-training, coordinating services between clinical and pharmacy sites, data management (supported by proposed software as able), and will lead report writing. Dr. Sarzynski will work closely with Brian Decker and David Weismantel to ensure data quality and identify missing or anomalous data, as well as prepare data for analyses to address study aims. Dr. Sarzynski will devote 10% funded time and 3% in-kind support to this project.

**Co-Investigator:** Ronald Melaragni, RPh – Administrative Director, Sparrow Pharmacy Plus, will serve as the pharmacy liaison to the study. As a Co-Investigator, he will assist with educating pharmacy staff regarding the project, flag patients in the system in order to generate duplicate medication labels, and provide support for medication reconciliation at index appointments (pharmacy fill records) and at the conclusion of the study (comparison of pharmacy database with patient-managed application database). Mr. Melaragni will devote 5% in-kind effort to this project.

**Co-Investigator:** David Weismantel, MD, MS – Associate Professor, Department of Family Medicine, MSU and Program Director of the Sparrow-MSU Family Medicine Residency Program, is a senior clinician with extensive experience in biostatistics and epidemiology, will serve as a Co-Investigator and director at the clinical sites. In this role he will direct clinical care in support of the project, including patient...
recruitment and providing oversight for Senior Residents and/or Geriatrics Fellows who will be performing initial medication reconciliations. In this capacity he will be mentoring learners in their scholarship requirements. In addition, Dr. Weismantel will participate in developing and executing the statistical analysis plan and collaborate with the PI to ensure integrity of data. Dr. Weismantel will devote 5% in-kind effort to this project in his role as Sparrow-MSU Family Medicine Residency Director.

**Research Assistant:** Estimated cost to hire a HIPAA-trained research assistant with medical training to provide technological support for the project. Specifically, the research assistant will triage phone calls from patients and direct patients to appropriate support systems following a scripted protocol. The research assistant will advise patients to contact their physician for all questions related to medication issues, including dosing queries, drug-drug interactions, and side effects. The research assistant can provide direction regarding simple technology issues, including Internet connectivity, assistance with taking pictures of medication labels, etc. All questions related to software/application issues will be immediately directed to EMOL Health LLC. Anticipate 6 hr/wk for 40 weeks at $25/hr plus fringe at 7.65%. $6,459

**Other Expenses**

**Software Developer:** Brian Decker – President and CEO, Electronic Medical Office Logistics (EMOL Health) – will develop an iPhone application for the end user. EMOL Health also proposes that a backend system be developed to facilitate the intricate components of this project that cannot be performed on the phone due to its limited processing capacity. In this project the mobile device will capture a picture of the prescription label that will be sent to EMOL Health servers for image processing. This processing will include optical character recognition (OCR) and then heuristic pattern matching to attempt to identify the following attributes: patient name, pharmacy name, prescription number, medication name, dose, route, frequency, NDC, prescribing provider, and refills remaining. Using the information above the servers will then inform the mobile phone application to configure itself for patient adherence reminders. In addition, the application on the mobile phone will ask the study patients survey questions to assess satisfaction. $51,750

**Sparrow Pharmacy Plus medication labels:** Estimated cost to produce duplicate medication labels for Phase 1 and Phase 2 studies (20 patients with average of 10 medications per list). $500

**Price matching for non-Sparrow medications:** Estimated cost to “price match” reduced-cost medications that patients have had filled at other pharmacies (e.g. $4 at Wal-Mart or free antibiotics at Meijer) and transfer to Sparrow Pharmacies. $1000

**Incentives:** Estimated cost to provide gift card incentives to patients who participate in the study – each of the 20 participants will receive a $25 gift card upon completion of the study. $500
Figure 1. Flow diagram of study to test a mobile application for medication management
Anticipated Obstacles

We anticipate the following obstacles related to the study: 1) patient(s) forget his/her smart phone and/or battery is depleted, 2) duplicate medication labels become smudged or wrinkled, making OCR interpretation less reliable, and 3) price tags may obscure UPC of OTC medications making scanning unreliable. In such circumstances, index appointments may need to be rescheduled, duplicate labels may need to be reprinted, and/or data entry can proceed manually. We will include a default for manual data entry and/or modification of incorrectly imputed data for such circumstances. Furthermore, we will elicit instances of inaccurate automated data entry from patients with each unique medication entry by means of software generated, automated prompts. In addition, we will elicit periodic feedback from patients regarding issues that they have encountered while using the application (see instruments, patient surveys) and utilize the research assistant to triage application-related technological issues immediately to EMOL Health.

Statement Regarding Intellectual Property

We anticipate that if funded, the proposed study will lead to intellectual property rights. As such, issues regarding ownership of intellectual property will need to be resolved to the satisfaction of all parties prior to the use of any grant-awarded funds.