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Lead User Design: Medication Management in Electronic Medical Records

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Abstract

Improvements in medication management may lead to a reduction of preventable errors. Usability and user experience issues are common and related to achieving benefits of Electronic Medical Records (EMRs). This paper reports on a novel study that combines the lead user method with a safety engineering review to discover an innovative design for the medication management module in EMRs in primary care. Eight lead users were recruited that represented prescribers and clinical pharmacists with expertise in EMR design, evidence-based medicine, medication safety and medication research. Eight separate medication management module designs were prototyped and validated, one with each lead user. A parallel safety review of medicaiton management was completed. The findings were synthesized into a single common set of goals, activities and one interactive, visual prototype. The lead user method with safety review proved to be an effective way to elicit diverse user goals and synthesize them into a common design. The resulting design ideas focus on meeting the goals of quality, efficiency, safety, reducing the cognitive load on the user, and improving communication wih the patient and the care team. Design ideas are being adapted to an existing EMR product, providing areas for further work.

Keywords:

Electronic Medical Records; Electronic Prescription; User Interface Design; Safety; Lead User Method.

Introduction

There are an estimated 380,000 to 450,000 preventable Adverse Drug Events (ADEs) occurring annually in the United States [1]. Similarly, in Canada, there are an estimated 70,000 potentially preventable Adverse Events each year, 24% of which (approximately 16,800) are related to medication errors [2]. Electronic medication management systems are considered one way to help improve these errors.

Despite the potential of eHealth systems, such as Electronic Medical Records (EMRs), evidence of benefit has been inconsistent [3]. Designing better systems requires getting aspects "right" [4], including content, workflow, and user interfaces (UI). Designing effective UI in clinical information systems is challenging [5]. There are several UI elements to consider for clinical decision support, including: consistency, appropriate visualization, and presenting advice at the time of decision making in a way that matches clinical goals [6].

There is ongoing usability research in the area of clinical information systems; however, there appears to be a lack of design research to uncover innovative features to improve the safety and usability of the medication management within tools in systems such as EMRs. The Common User Interface project (CUI at http://www.cui.nhs.uk) was one key exception, although it focused on acute care and is no longer active.

Lead User Method

For this study, we looked for a user-centred method that promoted *abductive reasoning* about how a medication management system in an EMR *might be* designed. Design research can support this kind of abductive reasoning [7]. The lead user method is a user-centred design research method that promotes abductive reasoning by advanced users to develop product innovations [8], [9]. It fit the scope and scale of our study and we had previous experience with the method [10]. This method has been shown to lead to breakthrough products in domains outside [11], [12] and inside healthcare [13]. The goal of this method is to design innovative products [11] by engaging users who are ahead in their field of expertise and to discover their more extreme goals, needs, and how they consider meeting those needs [8], [14]. User selection is intentional and lead users are not meant to be representative: they are meant to be cutting edge in some way. The lead user method is a method that can fit into the software development lifecycle as an early requirements engineering tool and could be complemented by a number of additional approaches.

Study Objective

The objective of this study was to develop a novel method that worked with lead users to design a user interface for a medication management module for primary care EMRs.

Methods

We adapted the lead user method to clinical information systems to create a design of a medication management module for a primary care EMR. A novel contribution was to combine a safety review with the lead user design method.

Lead User Recruitment

Lead users considered for this study were: primary care clinicians using the EMR (e.g. family physicians, pharmacists in primary care) and individuals who had experience in designing EMRs or teaching or researching in the field of medication management/prescribing. Lead users were recruited through our existing network of Canadian collaborators. Potential participants received a recruitment letter and a consent form, and had an opportunity to ask questions before agreeing and signing the consent.

Lead User Design Sessions

Each lead user was invited to attend a series of three individual design sessions (held separately for each user). A research analyst (RA) was assigned to each lead user. The first semi-structured interview explored lead user's ideas related to why and how medications could be better managed through EMRs.

An interview guide was available for the RA to ensure that common workflows were considered (e.g., prescribing a new medication, renewing a medication, discontinuing a medication). Each lead user was encouraged to discuss workflows they considered important. In scope for the sessions was the use of EMRs in primary care for acute and chronic/ongoing medication management. Out of scope were other information systems such as hospital systems and personal health records. Sessions were recorded and transcribed for analysis. Goals, activities and visual design ideas were extracted from the interviews. Each lead user's requirements were translated into an interactive visual prototype using Axure RP Pro 7.0 (one prototype per lead user). The multidisciplinary research team reviewed interview findings as part of the analysis and the lead RA prototyped their user's requirements.

Follow up interviews with each lead user then focused on walking through their prototype to validate and refine their requirements. These sessions were recorded and the goals, activities, and prototype were revised between each session.

Safety Review

Safety is an important quality attribute of EMR systems. We integrated a safety review into our adaptation of the lead user method, combining two complementary hazard analysis methods: an adaptation of Failure Modes and Effects Analysis (FMEA) [15] and Hazop [16]. The methods are complementary since they provide opposite perspectives on hazard analysis. FMEA starts by enumerating accidental situations and successively identifies hazards, failure modes, and contributing events that may lead to these accidents. We used EMR/CPOE-related accident reports in the FDA's adverse event reporting system MAUDE [17] as well as input from lead users as the primary data source for defining an evidence-based set of prescribing-related accidents. Hazop analysis is performed in the opposite way; it starts with a given system design (or set of designs) and uses a systematic technique based on guidewords to identify potential workflow deviations that may lead to unsafe situations. In order to apply Hazop, we needed to define process model abstractions for the visual prototypes created as a result of the lead user design sessions. We used Keystroke Level Modeling (KLM) as the method for attaining this process abstraction [18]. The findings of both hazard analysis techniques were ranked with respect to severity, likelihood and detectability, and mitigations for the top-ranked hazards were incorporated into the final design of the medication management system.

Synthesis

The multidisciplinary research team (consisting of a physician, software engineer, computer science and health information science analysts) reviewed each lead user's design requirements and prototypes. In these synthesis sessions the analyst who worked with the lead user would act as their proxy, providing rationale for the specific design decisions. Using a combination of UI/Ux best practice and safety analysis feedback, preferred approaches were selected for the set of common goals. The synthesized requirements were captured in four ways: a goal model, an information model, an activity model, and an interactive visualization (in Axure RP Pro 7.0).

Ethics approval was received from the University of British Columbia's behavioural research ethics board (H13-01059).

Results

The full study took five months. Eight lead users were recruited for this study (nine were invited, one declined due to scheduling conflicts), none were lost to follow up during the study, and each contributed 3-5 hours of interviews. Collectively, the lead users had considerable relevant experience (Table 1) at regional, jurisdictional, national, and international levels. Each user was interviewed on average 3 times with additional email follow up with some for final validation. For each lead user, the analysis of the interviews included a list of goals and medication activities that should be supported in the EMR as well as a visual prototype validated by the lead user (analysis took two person weeks of effort per lead user).

Table 1 – Lead User Participant Characteristics

Average Age	50.5 years
Gender	4 Male / 4 Female
Family Physicians	6
Pharmacists	2
Average Years in Practice	22.5 years
Average Years using EMR	14.6 years
Involved in EMR Design	6
Involved in EMR / Rx research	6
Teaching or Academic Role	8

Safety Review

The safety review was approximately two person weeks of effort. FMEA-based hazard analysis identified 22 prescribing-related hazards, each of them associated with a list of potential failure modes and contributing factors. For example, the hazard "*no alert on harmful drug interaction*" was associated with "*alerting function expects data encoded in different coding system*" as one (of several) failure modes, and with "*hospital discharge medication encoded in different coding system*" as one (of many) contributing factors. Several assumptions were made to limit the scope of the analysis, e.g., hazards related to failed, lost or delayed communication of information over the network was declared out of scope for the analysis.

The Hazop-based analysis identified additional hazards that emerged from the specific UI design choices made in the visual prototypes. For example, one lead user design incorporated a patient-specific "news feed" that would alert the provider about any change in the patient's health process since her last visit with the provider (e.g., a patient had seen another provider who changed her medications). The source of the feed may be external, such as a health information exchange. The initial design did not differentiate between the state of "no news" and the state of the "news feed" (temporarily) being unavailable (an empty news display was used for both states). This design choice created a hazard associated with a provider confusing the state of "no news" with "no available news". Other hazards identified during Hazop analysis were related to the structure and timing of user processes (e.g., race conditions between the user entering and submitting her prescription and the decision support processing and raising alerts).

Synthesized Design:

Goals

Developing the synthesized design took four person weeks of effort. There were four main goals for an effective medication management system. The system should:

1. **Improve Quality of Medication Management**. This included reducing potential harm caused by medications through software and workflow design solutions.
2. **Improve Efficiency when Managing Medications**. This included supporting common workflows with elegant solutions that are quick for the users.
3. **Reduce Cognitive Load of the User.** This included ensuring that appropriate information is accessible when

making decisions throughout the encounter, and having the EMR data help when making choices.

4. **Improve Communication with the Patient and the Care Team.** This included providing features that help the user communicate about medications and changes clearly with the patient and the rest of the care team, even in EMRs that are not electronically connected.

Activities

Lead users described several activities that needed to be supported by the software. Through the research team's synthesis and review, the following activities were considered key (others were also prototyped).

Document and See Current Medications: users needed the ability to document a complete, single set of *current* medications for the patient. This included medications that were prescribed in the EMR as well as medications/supplements not prescribed or prescribed elsewhere (e.g., over the counter or prescribed by other providers). This included documenting instructions, indications, targets, expected end date, and current prescriber. The current medication list needed to show several pieces of additional information related to each medication, including: current instructions, current prescriber, prescription information, and presence of alerts related to that medication. Further, the list needed to be sorted/grouped by: alphabetical order, indications, prescriber, regular vs. PRN medications, and long-term vs. short-term medications.

Prescribe New Medications: Users wanted to ensure the system enabled them to prescribe new medications quickly and safely. When prescribing, users needed evidence-based guidance including support of medication choice and alerts for contraindications. Tools to support quick prescribing included leveraging recent medications (recent for the user) and user / clinic level medication favourites that would quickly populate all instructions and prescription information.

Represcribe Existing Medication(s): Many medications for chronic diseases are represcribed with their instructions unchanged. The system should support quick review of medications that need represcribing. For example, review: alerts, instructions, who the most recent prescriber is and when the prescription is expected to run out. The workflow should also allow for medications to be represcribed all at once or in batches (e.g. all antihypertensive medications, then all COPD medications), allowing for encounters to flow naturally.

Modify Medication Instructions: Over time, medication instructions may change for a patient. Medications may be titrated up or down. Modifying includes several options including: changing instructions (e.g., dose), stopping, discontinuing (with reason), and restarting a previously expired medication.

Receive and Review Decision Support (DS): Users simultaneously considered decision support to be important and often too intrusive. Lead users had several ideas where DS was needed and could be effective, including: selecting new medications, seeing the medication list, and reviewing or changing medications. There were several types of decision support that were desirable, including: medication selection support, drug alerts (e.g., interactions), and financial decision support (cost).

Lead users considered the issues related to dismissing alerts and how they may impact the patient in the future. An approach that was supported through the safety review was to allow alerts to be acknowledged but still be present/visible to the user (or another user) in the future.

Users also needed to seek information, such as requesting concise and trusted information about a medication (e.g., dose, indications, side effects) and suggesting medications or alternates in case of a contraindication.

Detailed Review of Current Medication(s): Several lead users were interested in a two-step process of review. A core set of information would always be available when seeing the current medication list (see above). A more detailed set of information would be available when the user wanted to review one or more medications. Details included the history of the instructions, specific prescriptions for the medication, and estimations of compliance. Reviewing a medication would provide information such as indicators/targets and would relate dosing history to effect; it would also provide details on alerts.

There were additional activities that were considered but not illustrated such as managing favorites.

Information Model

Figure 1 highlights the synthesized conceptual information model that is "medication centric". It includes core elements related to the medications, prescriptions, and related knowledge bases required to support medication activities. A medication can have multiple *instructions* over time and a medication can have zero to many *prescriptions*; this supports the need to review a medication's history effectively. Prescriptions can be collected in a *prescription order set* to allow for prescribing multiple medications for a patient within an encounter. Knowledge bases provide DS. To support efficiency, reusable medication *favourites* are available.

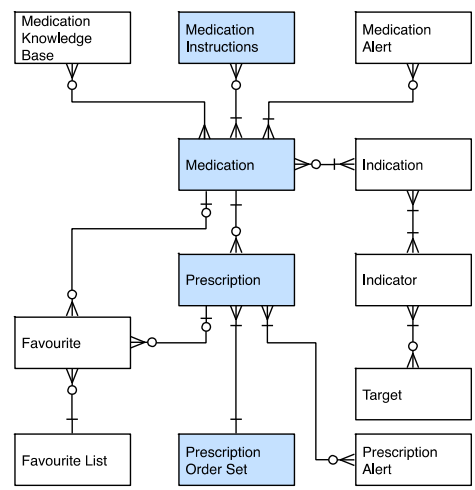

Figure 1 – The conceptual medication information model, based on the design requirements from lead users.

Synthesized Design: Visualization

The synthesized EMR UI prototype developed in this study captured the goals and activities of the lead users. The medication module UI design consists of four main panels: *current medication list*, *prescription panel, prescription order set*, and the *side panel* (Figure 2). The *EMR and patient banner* is included as misidentification is a significant safety hazard.

To enable many of the lead users' requirements, a *Medication Widget* was developed (Figure 3 and Figure 4). The widget has two states: closed and open. Each closed widget shows the medication, its current instructions, alerts (if present), and most recent prescribing information. A set of closed widgets forms the current medication list panel. The closed widget can be clicked to select the medication (Figure 5). The widget can be opened to allow the user to perform several actions on that medication: update instructions, review details (including alerts), review history, or discontinue the medication.

An *Add Medication Panel* is available when a new medication is being added. It provides the ability to add any medication (without needing to prescribe it) and provides decision support such as indications and interaction alerts. When searching for medications (by brand name or active ingredient), only active ingredient would be displayed to reduce cognitive load. Along with the formulary medications, favorite medications/prescriptions would be displayed for the user.

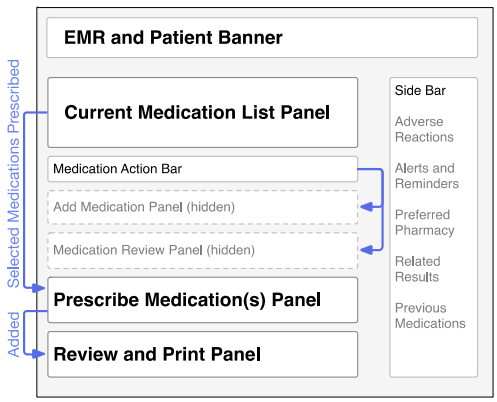

Figure 2 – Medication Management Module consists of the list of current medications, a prescribing panel, and a review and print panel.

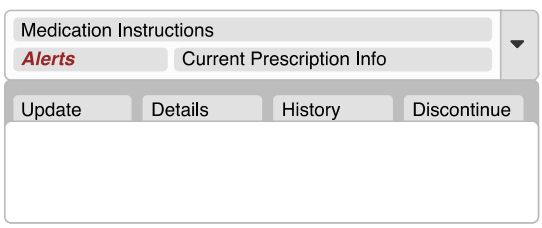

Figure 3 – The Medication Widget framework. Each widget has editing and review functionality embedded within.

Figure 4 – Example medication widet with ramipril as the current medication having one outstanding alert.

Design Comparison

The synthesized design generated through the lead user method was compared to two existing, open electronic medical records: OSCAR (www.oscarmcmaster.org) and openEMR (www.open-emr.org). We compared our design concepts to available online demo sites and user manual documentation for the equivalent core medication management functions. The new design appears to address several gaps that we saw in these products, for example: (1) a medication-centric information module (instead of a prescription module) with more coded content, (2) more robust decision support features such as suggesting alternatives, linking to indications, and having alerts visually available both when prescribing and when reviewing medications, (3) a detailed view of a medication that includes estimated adherence information and dose adjustments. However, the lead user synthesized design is currently more complex, which may prove to be challenging to new or typical users. This complexity needs to be considered and balanced when working with more typical users in busy clinics.

Discussion

This study was established to explore methods to develop innovative design solutions for medication management modules in primary care EMRs. The lead user method was adapted and applied to clinical information systems as further innovations in this area could result in significant improvements in care quality [19]. Our synthesis included the integration of a safety analysis and incorporated concepts from the literature, such as findings from the NHS' CUI project.

The lead user method was an effective way of developing the medication management module design relatively quickly. The lead user method was well received by expert clinicians. The visual validation allowed for refinement and a deeper discussion of each lead user's ideas. The synthesis by an interdisciplinary team reduced the risk of idiosyncratic design ideas from single, vocal users defining requirements in a committee or focus group. The users recommended features that were consistent with recommendations on CDSS design such as: consistency of design, appropriate visual presentation of data, use of coded data, and presenting advice at the time of decision making in a manner that matches to clinical goals [6]. Lead users have become unsolicited champions of the design, with at least half of the participants advocating for the design ideas in other EMRs or arranging opportunities to share the findings.

A challenge with this method was user selection. We found it important for lead users to have exposure to more than one EMR as well as been actively involved in the use of the EMR for research/teaching. This helped users to think outside of their own "EMR box".

Lead users thought of the EMR not just as an electronic version of the paper record, as can sometimes happen [20]. Rather, lead users considered the EMR as an interactive tool that could help with several goals: 1. Improved quality of care, 2. Improved efficiency of common workflows, 3. Reduced cognitive load, and 4. Improved communication. Decision support was an important aspect that was discussed in many areas of the medication management module and various activities. Users consistently agreed that decision support was important and they wanted it with minimal disruption. The strength of alerts was varied, depending on the workflow. Alerts would rarely stop the user from proceeding but display close to where they were active on screen (e.g., right below where they added a medication). Additional decision support such as access to knowledge bases with information on medication indications, side effects, and costs was important.

The synthesis activity allowed for integration of multiple perspectives, including the safety review and the literature. The early safety review allowed the analysis to consider lead user design ideas and potential impacts on safety and to incorporate safety elements into the design.

Limitations and Future Work

As a first phase in a design research project, further empirical evidence is needed to confirm that the design will lead to improvements in medication management. Future work is being considered along two paths: refining the methods and testing and refining the design. Three activities are proposed related to refinement and testing the design: (A) Usability testing of the prototypes with novel users. Usability testing would provide insight into the ease of use and intention to use. It was decided that the lead users would not be preferred for usability testing as (i) they were involved in the design and (ii) they were intentionally not representative of typical users. Comparative testing between multiple designs could be considered that could also show medication management errors that were

more or less likely to occur. (B) Expansion of the UI design to cover additional features. (C) Implementation of the design in an EMR. Feasibility of an implementation has been explored with the OSCAR EMR.

This study presents the results of adapting and applying the lead user method to designing aspects of clinical information systems. In this presented example, it was successful in developing a synthesized design for a medication management module for primary care EMRs. Safety was considered explicitly through the process to reduce risks to common medication errors. The resulting design included features to support quality, improve efficiency, reduce cognitive load, and improve communication. The synthesized design has been shared with OSCAR EMR and they are considering incorporating it into a future release. Future work will focus on incorporating user testing and integration into an EMR product.

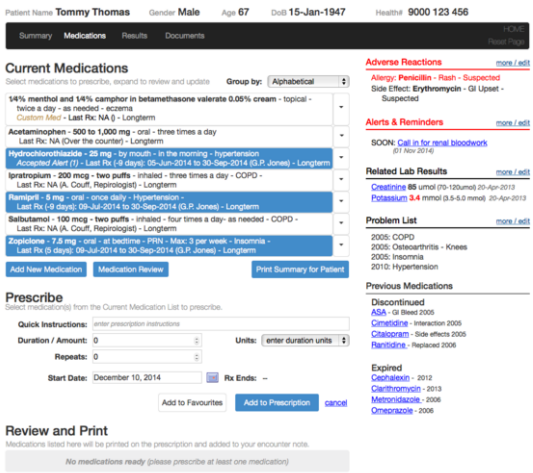

Figure 5 – The UI prototype of a medication module showing a fictitious patient with seven medications, three of which are ready to represcribed (clicked to toggle, in blue).

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