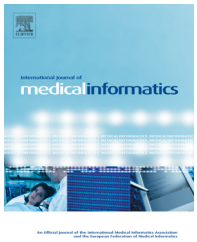
INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS 83 (2014) 473–483



journal homepage: www.ijmijournal.com

Usability evaluation of pharmacogenomics clinical decision support aids and clinical knowledge resources in a computerized provider order entry system: A mixed methods approach

Emily Beth Devine[a,b,c,*], *Chia-Ju Lee*[a], *Casey L. Overby*[a,d], *Neil Abernethy*[a,b], *Jeannine McCune*[b], *Joe W. Smith*[e], *Peter Tarczy-Hornoch*[a,f,g]

[a] *Department of Biomedical Informatics and Medical Education, University of Washington, Seattle, WA, United States*
[b] *Pharmaceutical Outcomes Research and Policy Program, University of Washington, Seattle, WA, United States*
[c] *Department of Health Services, University of Washington, Seattle, WA, United States*
[d] *Department of Medicine, Program in Personalized and Genomic Medicine, University of Maryland, Baltimore, MD, United States (formerly Department of Biomedical Informatics and Medical Education, University of Washington, Seattle, WA United States)*
[e] *UW Medicine Pharmacy Informatics, University of Washington, Seattle, WA, United States*
[f] *Department of Pediatrics, Division of Neonatology, University of Washington, Seattle, WA, United States*
[g] *Department of Computer Science and Engineering, University of Washington, Seattle, WA, United States*

ARTICLE INFO

Article history:
Received in revised form
16 March 2014
Accepted 15 April 2014

Keywords:
Clinical decision support systems
Clinical knowledge resources (not a MeSH term)
Medical order entry systems
Pharmacogenetics
User-computer interface

ABSTRACT

Background: Pharmacogenomics (PGx) is positioned to have a widespread impact on the practice of medicine, yet physician acceptance is low. The presentation of context-specific PGx information, in the form of clinical decision support (CDS) alerts embedded in a computerized provider order entry (CPOE) system, can aid uptake. Usability evaluations can inform optimal design, which, in turn, can spur adoption.

Objectives: The study objectives were to: (1) evaluate an early prototype, commercial CPOE system with PGx-CDS alerts in a simulated environment, (2) identify potential improvements to the system user interface, and (3) understand the contexts under which PGx knowledge embedded in an electronic health record is useful to prescribers.

Methods: Using a mixed methods approach, we presented seven cardiologists and three oncologists with five hypothetical clinical case scenarios. Each scenario featured a drug for which a gene encoding drug metabolizing enzyme required consideration of dosage adjustment. We used Morae® to capture comments and on-screen movements as participants prescribed each drug. In addition to PGx-CDS alerts, 'Infobutton®' and 'Evidence' icons provided participants with clinical knowledge resources to aid decision-making.

Results: Nine themes emerged. Five suggested minor improvements to the CPOE user interface; two suggested presenting PGx information through PGx-CDS alerts using an

* *Corresponding author at*: Pharmaceutical Outcomes Research & Policy Program, University of Washington, Box 357630, Seattle, WA 98195-7630, United States. Tel.: +1 206 221 5760; fax: +1 206 543 3835.
E-mail address: bdevine@uw.edu (E.B. Devine).
http://dx.doi.org/10.1016/j.ijmedinf.2014.04.008

'Infobutton' or 'Evidence' icon. The remaining themes were strong recommendations to provide succinct, relevant guidelines and dosing recommendations of phenotypic information from credible and trustworthy sources; any more information was overwhelming. Participants' median rating of PGx-CDS system usability was 2 on a Likert scale ranging from 1 (strongly agree) to 7 (strongly disagree).

Conclusions: Usability evaluation results suggest that participants considered PGx information important for improving prescribing decisions; and that they would incorporate PGx-CDS when information is presented in relevant and useful ways.

1. Introduction

Mapping of the human genome in 2003 opened new avenues for research [1]. Pharmacogenomics (PGx), the study of how genetic variations affect differences in drug response, is positioned to be the first genomic advance to have a widespread impact on the practice of medicine [2]. Already, the FDA includes information about 43 PGx biomarkers in the labels of 155 drugs [3].

Although surveys of US physicians indicate wide acceptance of the concept of PGx, these surveys also suggest the adoption rate remains low [4–6]. Given the growing number of biomarkers and the complexity of combinatory relationships of disease, gene, PGx test, drug, and dose, clinical decision support (CDS) will be needed to facilitate diffusion of PGx information to inform clinical practice [7]. Presentation of PGx context-specific information, such as alerts embedded in computerized provider order entry (CPOE) systems, can aid uptake of PGx knowledge.

CPOE with PGx-CDS alerts will be useful to classify drug responders, tailor drug therapy, optimize drug response, and reduce adverse drug events [8]. Yet, poorly designed alerts could introduce errors, cause alert fatigue, or hinder adoption of CPOE systems [9]. Usability evaluations inform proper design of clinical information systems, and can facilitate adoption [10,11]. To date, usability studies focus on CDS alerts in the context of CPOE systems [10], however the usability of PGx-CDS alerts has not yet been studied. The objectives of this study were to: (1) Evaluate the usability of an early prototype, commercial CPOE system with PGx-CDS alerts in a simulated work environment (from the prescriber perspective). (2) Identify improvements to the CPOE user interface, and (3) Understand the contexts under which PGx knowledge embedded in an EHR could be useful to clinicians.

2. Methods

2.1. Study design

Ours was a usability study of a CPOE system with PGx-CDS alerts that was comprised of a heuristic evaluation, supplemented by a participant satisfaction survey. We employed two sets of heuristics. The first set used fourteen principles customized by Zhang for the health domain [11], and is based on usability heuristics and rules from Nielsen [12] and Shneiderman [13]. The second set used seven clinical knowledge heuristics designed to measure knowledge utilization in healthcare [14–16] (Supplementary Appendix A). Our data collection method centered on a concurrent 'think-aloud' process, by which our aim was to identify possible improvements that could be made to the prototype CPOE system, and understand under what circumstances prescribers accessed knowledge to aid prescribing decisions.

2.2. Study set-up

The study was conducted using a prototype version of PowerChart® (Cerner Millennium®), the University of Washington's (UW) inpatient EHR application. The CPOE system provides auto-fill selection of generic drugs, and standard doses, routes and frequencies. We employed Cerner's Discern Expert® rules engine to provide real-time CDS alerts. The CPOE and Discern Expert modules of PowerChart had not been implemented at UW when our study began. From within PowerChart, participants could access both the UW Health Sciences Library ('Links and Reports') and the internet, and therefore were accustomed to certain available clinical knowledge resources. However, none provided focused genomic or PGx recommendations. To address this, each scenario was comprised of two parts. First, each participant read a short clinical case including the indicated drug and patient-specific PGx allelic variants with corresponding phenotype. Participants could then click an 'InfoButton' linking to curated genomic knowledge resources that further described the relevant gene and laboratory value (Fig. 1a; Supplementary Appendix B).

Once satisfied, participants were directed to the second part of the exercise, using the CPOE system to prescribe the drug for the hypothetical patient. In this context, when the PGx-CDS alert popped up, the participant was provided an opportunity to view additional evidence – curated PGx knowledge resources specific to the drug-gene pair. Participants accessed these resources by clicking on an 'Evidence' button in the alert (Fig. 1b; Supplementary Appendix B).

2.3. Drugs selected for study

In previous work Overby designed 565 decision rules for CDS, specific to the 71 drugs for which biomarkers were codified in the FDA label as of May 2011 [17]. Fifty-five percent of these drugs involved genes encoding cytochrome P-450 (CYP-450) drug metabolism; 42% of these defined cardiology or oncology drugs. Thus, for the usability study, we created CDS alerts around the five cardiology (carvedilol,